

# TOBACCO OR HEALTH IN THE EUROPEAN UNION

PAST, PRESENT AND FUTURE



## THE ASPECT CONSORTIUM



European Commission

# **TOBACCO OR HEALTH IN THE EUROPEAN UNION**

**PAST, PRESENT AND FUTURE**

Prepared by the ASPECT Consortium with financing from  
the Directorate-General for Health and Consumer Protection

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## Foreword

At a conservative estimate, tobacco kills over 650,000 people each year in the European Union.

Fighting tobacco use has been a public health priority for the European Community since 1985 and the launch of the “Europe Against Cancer” Programme. Since those early days, Community tobacco control has developed into three broad areas - legislation; mobilising European and International action and programme actions.

With the Products Directive in 2001, the Community has introduced strict regulation around the sale and marketing of tobacco products, becoming the first region in the world to ban the use of misleading descriptors on cigarette packets, such as “mild” or “light”. The European Community and its Member States can also boast the most comprehensive advertising legislation for tobacco in the world. On an international stage, the European Community has been instrumental in designing and achieving consensus on the World Health Organization's Framework Convention on Tobacco Control, the world's first global health treaty.

As this Report shows, there is evidence that these and other measures by the Community and within the Member States have had a positive impact on smoking rates. Nearly two decades ago smoking prevalence for males was often around 50%. Although results vary from country to country, many Member States have reduced their prevalence of male smokers - some by as much as 15-20%. This translates into thousands of lives saved and sends out the important message: tobacco control works.

However, while we have won many individual battles, it is clear that we have yet to win the war. Smoking remains the largest single cause of preventable death and disease in Europe. Smoking rates for females are increasing in some Member States and the average age to start smoking is now 11 years in some European countries. The tobacco industry is increasingly aware of the need to target children and young adults to assure its future market.

Therefore, despite our many achievements, it is clear that we cannot afford to rest on our laurels. We must keep up the momentum.

This Report fills an important gap in tobacco-control policy for Europe. It represents the first attempt to draw together in one comprehensive book an analysis of tobacco-control policy (past, present and future) in the European Union. The Report presents the extent of the public health and economic cost of smoking and tobacco to European society. It provides a review of the effectiveness of previous tobacco policies and an analysis of the extent to which the tobacco industry has sought to undermine and influence political decision making at all levels.

The evidence presented is built up from a review of the currently available science, expert analysis and from the findings of a number of expert workshops and international conferences, such as the Limerick Tobacco Control Conference “Change is in the Air” that took place in June 2004 under the Irish Presidency of the European Union.

Most importantly, the Report presents a set of recommendations. I hope that these will feed into and inform policy discussions, at European level or within Member States, and help to define a European tobacco-control policy for the future.



**David Byrne**

European Commissioner for Health and Consumer Protection

## Consultation process for the ASPECT (Analysis of the Science and Policy for European Control of Tobacco) report

The preparation and drafting of the ASPECT (Analysis of the Science and Policy for European Control of Tobacco) report has involved one of the most extensive consultations and peer reviews ever undertaken in European tobacco control.

A consortium created for the purpose of writing the report and consisting of GOPA-Cartermill (GC), the European Heart Network (EHN), the European Network for Smoking Prevention (ENSP) and the European Respiratory Society (ERS) convened an Expert Panel drawn from a wide range of relevant disciplines to provide expertise and peer review of the report. Tobacco control experts from the 28 countries covered in this report were appointed as National Counterparts to advise on matters of fact and accuracy relating to their countries. Additionally, a panel of International Experts was appointed to provide a global perspective and advice on the latest developments in other leading tobacco-control jurisdictions. A list of the Expert Panel and National Counterparts, as well as a list of International Experts can be found in Annexes 1, 2 and 3, respectively.

The report was written and circulated for comment between March and September 2004. Five workshops were organised to identify state-of-the-art policy and research and to facilitate discussion and consensus building: one on tobacco product regulation in Brussels in March 2004 and a second on smoking in the workplace in Krakow in May 2004. The three final workshops on tobacco-control research, civil society, and product regulation and harm reduction were organised jointly with the Office of Tobacco Control, the Irish Department of Health and the European Commission and took place during the High Level conference on tobacco control held under the Irish Presidency in Limerick in June 2004. The timing of all five enabled extensive consultation on and discussion of the recommendations of the report to take place. A list of speakers and topics covered in these workshops can be found in Annexes 4, 5 and 6.

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## EXECUTIVE SUMMARY

The effects of tobacco use on individual and population health across Europe are described in Chapter 1 of this report. Smoking continues to be the largest single cause of death and disease in the European Union (EU), despite the progress that has been made in tobacco control. Over 650,000 Europeans are killed every year because they smoke, one in seven of all deaths across the EU, and over 13 million more are suffering from a serious, chronic disease as a result of their smoking. It is also now established, beyond doubt, that tobacco smoke is a serious environmental health hazard, killing some tens of thousands of non-smoking Europeans, with many millions more having illnesses exacerbated by inhaling other people's smoke.

Smoking harms nearly every organ of the human body, causing a broad range of diseases, but the full extent of the damage is still unknown, as even today, over 50 years after the first links between smoking and lung cancer were established, more diseases are being found to be caused by smoking. However, it is known that about half of all continuing regular smokers will be killed by their smoking and those that die in middle age as a result of their smoking lose on average 22 years of life, with a larger proportion of that shortened life span being spent in ill health.

Although the tobacco epidemic is at different stages in different countries across Europe, it is clear that millions more Europeans will die and suffer ill health as a result of their smoking over the decades to come. Smoking attributable deaths among females are still increasing and the full extent of the epidemic among females has not yet been realised. Even among males, lung cancer mortality rates are still rising in four countries within the EU. Smoking is also becoming increasingly associated with poverty, making a significant contribution to the widening gap in health inequalities across the EU. To illustrate the impact of tobacco use in the EU, brief descriptions of mortality patterns are given for five European countries.

Given that all of these deaths and diseases are completely preventable, Chapter 1 also explores the important role that nicotine plays in keeping people smoking and the dramatic benefits to health that result when people stop.

Chapter 2 describes how all Member States in the EU are also touched by the production, manufacturing, distribution and sale of tobacco products. Tobacco growing represents only a small portion of EU agricultural activity with only 1.3% of EU farms producing tobacco, using 0.1% of the agricultural land. In addition, Europe's share of world tobacco growing has been declining since the mid-1980s.

Nevertheless, tobacco is the most heavily subsidised crop per hectare in Europe. The EU spends nearly €1,000 million annually on these subsidies: 2.3% of the Common Agricultural Policy budget, and 1.1% of the total Commission budget. The EU has wisely determined to phase out these subsidies by 2010.

Tobacco manufacturing in the EU/European Free Trade Association region keeps steady at an estimated 25% of global cigarette production. The EU is a net importer of raw tobacco and a net exporter of manufactured tobacco products, providing 20% of the world's supply. Tobacco farming and manufacturing jobs represent a mere 0.13% of EU employment, and this figure is declining. The impact of tobacco-control efforts on employment would be

negligible, because money currently spent on tobacco and related medical care will be spent on other goods and services, or saved for investment in other activities.

The EU bears a substantial economic burden due to smoking. A conservative estimate of these costs falls between €98-130 billion a year, or between 1.04-1.39% of the region's Gross Domestic Product for 2000. The true costs are undoubtedly higher, and will continue to escalate if appropriate measures are not taken. This increase in costs will result from higher smoking rates in the new EU10 Member States, healthcare improvements and increasing demand for healthcare services. Smokers, but also non-smokers, governments and employees have to cover these costs. Empirical evidence shows that tobacco consumption represents a net burden for state budgets even after accounting for collected tobacco tax and savings in social security payments due to premature mortality among smokers.

EU Member States impose both ad valorem and specific excise taxes on tobacco products, in addition to Value Added Tax. The choice of the type of excise tax has profound implications for the amount of tax paid per cigarette pack, and is one of the reasons why cigarette prices vary substantially among Member States. Specific excise taxes are more efficient; they are easier to administer and better support the EU's public health goals because they discourage the smoking of all cigarette brands equally, rather than encouraging substitution of less expensive brands.

Chapter 2 describes how the current level of tobacco taxation in EU Member States is below the optimal level with respect to potential revenue generation. Higher tobacco taxes are by far the most cost-effective tobacco-control measure, and will generate increased tax revenue, even in the presence of smuggling. They will also increase the costs of cigarettes, which are still quite affordable for the majority of the EU population. Non-price-based tobacco-control policies are most effective as part of a comprehensive tobacco-control program. Even though cigarette smuggling will not prevent the desired impact of higher cigarette taxes on tobacco consumption and government revenue, it can diminish the effect of this measure.

Chapter 3 describes how, since the 1980s, tobacco-control policy in the EU has developed and evolved against a background of continuous development of the EU itself, including community enlargement from six countries in 1957, to nine in 1973, 10 in 1981, 12 in 1986, 15 in 1995 and 25 in 2004. It is also a story of dynamic interactions, between community institutions, between these institutions and Member States, between Member States, and between the European Community (EC) and external countries and organisations, such as the World Health Organization (WHO).

Every piece of legislation enacted by the EU, whether in the form of directives, regulations, resolutions or recommendations, requires a legal basis in the treaties that created the EU. To date, all of the legislation on labelling, advertising and product regulation has been based on the internal market legislation, Article 95 EC (previously Article 100a EC), rather than the public health legal base (Article 152), which does not permit this type of legislation. Partly as a result, four out of the six pieces of legislation on labelling, marketing and regulation of tobacco products enacted since 1989, have been the subject of legal challenges, and other actions have been brought against the Commission by the tobacco industry challenging other aspects of the legislative process. Considerable progress has been made in spite of this, although European tobacco control would have been even more advanced had a dedicated public health legal base been available.

Since 1987, tobacco control has been at the heart of the Public Health policy of the EC and has fallen into four broad areas: public health, taxation, health and safety in the workplace, and agriculture. Much of the Community's policy on tobacco control has been initiated and developed by the Health and Consumer Protection Directorate-General of the European Commission (formerly DGV, the Directorate for Employment and Social Affairs). To date, the policy has produced, inter alia, directives on tobacco advertising, labelling and tar yields, a tobacco products directive, tobacco taxation legislation, health and safety at work directives restricting smoking in the workplace, two conferences organised jointly with the WHO, three EU Presidency conferences and support for other European tobacco-control conferences. The EC has also signed the WHO Framework Convention on Tobacco Control (FCTC) and acted effectively against tobacco smuggling in some Member States.

Chapter 3 goes on to describe how the Europe Against Cancer (EAC) programme provided the basis for this successful EC policy on smoking prevention. Key factors driving its success were: high level political support, the committee of cancer experts, a dedicated team within the European Commission, partnership with key stakeholders, a high profile media strategy, a pro-active legislative approach and the provision of policy-oriented research from an expert office to support legislative initiatives.

The Council was very active on health from 1985 onwards and tobacco control has been one of its top priorities. From 1988-2003, the Health Council met 35 times with tobacco control on the agenda 31 times.

The debate on tobacco advertising in the EU has so far lasted for 15 years and is ongoing, although at the moment a tobacco advertising ban in 18 EU countries is in force. The EC's first directive on tobacco labelling had an enormous impact. As directives are binding on Member States, even countries with almost no tobacco-control legislation had to strengthen their health warnings, and EC legislation was becoming an example for many countries who wanted to join the EU.

EC policy on tobacco also had an impact outside the EU. In Sweden, for instance, tobacco-control policy had reached a plateau in the 1980s. The EAC programme (in which Sweden participated) contained several proposals which, from a Swedish perspective, appeared radical and controversial at the time. EAC reinvigorated tobacco control in Sweden during the 1990s. EC legislation also strengthened the WHO Framework Convention.

Hence, Chapter 3 shows that in spite of its reliance on the internal market legal base for public health legislation, the EC has undertaken an extensive range of tobacco-control measures in the last 20 years that have had an enormous influence within and outside the EU. Ratification of the FCTC by all 25 EU Member States will ensure that comprehensive tobacco advertising bans are enacted nationally within 5 years of ratification, making up for the annulment of the 1998 Tobacco Advertising Directive. This will leave tobacco product regulation and workplace smoking restrictions as the two most urgent tobacco-control tasks facing the EC and the Member States over the next decade.

Chapter 4 of this report shows how funding for tobacco-control programmes is related to tobacco use. In general, the more that is spent on tobacco control, the greater the reduction in smoking prevalence. Analysis of data from the USA indicates a consistent pattern that tobacco-control expenditure reduces cigarette sales. The effectiveness of mass media



campaigns depends on their scale and duration. Expenditures have to be high enough to reach smokers a sufficient number of times with sufficient duration. Largely as a result of such expenditure, smoking prevalence in Massachusetts fell from 23.5% in 1990 to 19% in 1999, a decline about four times greater than in other states in the USA. By contrast, although the fall in smoking prevalence in the UK between 1970 and the 1990s was the largest in the world over that period, it has now slowed considerably and, on current trends, will not reach Massachusetts levels for another 20 years.

The Centers for Disease Control and Prevention (CDC) in the USA estimate that states need to spend between \$1-3 per capita per year on tobacco-control programmes, over a sufficient period of time to be fully effective. They also recommended high and low desirable spending levels. For California they recommended a high expenditure of \$17 per capita per year and a low of \$6. The actual spend is \$4 per capita. For Massachusetts the actual spend was \$7. The current figure in the UK is just under \$2 per year, still three times less than the recommended California minimum, yet within the EU the UK is the top spender. In the EU, the actual Massachusetts figure would mean €5.7 per capita or €2,600 million a year, and even the UK actual figure would translate at EU level to €740 million being spent per year on tobacco control. Thus, EU Member States are seriously underspending on tobacco control.

There is some evidence from European countries of the impact of various specific policy elements, including emerging evidence from Belgium, the Netherlands, Poland and the UK that larger more prominent health warnings have measurably, and considerably greater impact. On advertising bans, the World Bank concluded that the most comprehensive restrictions would reduce consumption by >6% in high income countries. This estimate suggests that the EU's (annulled) ban on advertising would reduce cigarette consumption by nearly 7%. EU action against smuggling has reduced smuggling at Member State level, as has been shown dramatically in Spain, one of the few countries in the world to have tackled smuggling successfully. From 1995-2002 the proportion of smuggled cigarettes in the market fell from 16% to 2%. Finally, evidence is reviewed of the impact of the new treatment services in the UK, which shows that they are successfully reaching smokers in deprived areas, and thus have the potential to help reduce health inequalities.

Spending on research to underpin EU tobacco-control policy needs to be increased. In particular, Europe-wide measurement of smoking prevalence, using standard methodology is needed as a matter of the greatest urgency. These surveys should be done annually if possible and their results should be published so that European citizens can see the effect of tobacco-control policies.

As smoking is increasingly concentrated among lower socioeconomic groups, reaching these groups is essential if tobacco consumption is to be reduced across Europe. To meet this challenge, comprehensive tobacco-control policies should fully implement measures tailored to the needs of lower socioeconomic groups and smoking prevalence surveys should include data broken down by socioeconomic status.

Chapter 4 identifies the following interventions as core tobacco-control policies that should be prioritised in all tobacco-control programmes: price increases through higher taxation; comprehensive advertising and promotion bans of all tobacco products, logos and brand names; bans/restrictions on smoking in workplaces; better consumer information including counter advertising (public information campaigns), media coverage, and publicising research

findings; large, direct health warning labels on cigarette boxes and other tobacco products; and lastly treatment to help dependent smokers stop, including increased access to medications.

Chapter 5 identifies that government regulation is also needed for tobacco products themselves, although it is critically important that this does not detract attention from the other essential components of tobacco control outlined above. The focus of regulations to date has been mainly on machine-based measurements of tar, nicotine and carbon monoxide (CO) yields, and ingredients. However, the complexity of cigarettes and other tobacco products requires a new, more comprehensive, regulatory framework that aims to reduce their harmfulness by focusing on a number of dimensions, including product characteristics and emissions, exposure, injury, disease risk, claims and research, and surveillance. In addition, recognising both that tobacco products are highly engineered sophisticated nicotine delivery devices, and the potential proliferation of novel tobacco and nicotine products in the near future, it will be important for regulations to take into account the fundamental role that nicotine plays in tobacco use, and provide a framework within which different products can be meaningfully assessed.

The comprehensive regulatory framework set out in Chapter 5 will require a much wider range of technical skills and expertise than is currently the case. Increased regulatory capacity is therefore required.

Chapter 6 describes how tobacco industry efforts to influence tobacco-control policy in Europe have been extensive, wide-ranging and systematic. It is clear that there has been a coherent marketing strategy to target stakeholders, which mirrors the one targeting consumers. In both cases the objective is the same, i.e. to influence behaviour: in the case of consumers their smoking behaviour; in the case of stakeholders their regulatory, lobbying and professional behaviours. The combined aim of these activities is the greater profitability and longevity of the corporation. In the process, this inflicts unprecedented harm on Europe's public health.

The strategies used in the tobacco industry's "stakeholder marketing" include the identification of threats and opportunities so as to minimise the former and exploit the latter. For example, the 1998 tobacco advertising ban was a threat, but it could be attacked using sympathetic Member States, the principle of subsidiarity and the EU's relatively weak public health provisions. The industry also went to great lengths to identify potential allies, recruit them to the cause and provide them with suitable quid pro quos. These allies ranged from grassroots smokers' rights groups right up to Heads of State. Conversely, adversaries were also identified and then attacked rather than courted. The industry's systematic attempts to undermine the WHO are the most high profile example here, but smaller organisations, including the International Agency for Research on Cancer (IARC) and the European Bureau for Action on Smoking Prevention have also been the focus of their efforts.

The report illustrates that the tobacco industry's stakeholder marketing has been effective, and the implications of this success could not be more serious. In one vital policy area for example, i.e. the control of marketing communications, the industry succeeded in delaying and overturning a key European directive. When a similar advertising ban was introduced in the UK in 2003, the Government calculated it would save some 3,000 lives a year. By this logic, the tobacco industry's success in fighting the European advertising ban cost tens of thousands of lives.

In one sense, this stakeholder marketing is to be expected; it is standard business practice to try and influence the regulatory environment. However, tobacco is not a standard business. Cigarettes are uniquely harmful, and the sheer scale of illness and premature death caused by tobacco is unprecedented. It is this public health threat that has led to increasingly severe limitations on tobacco's consumer marketing. By contrast, however, its stakeholder marketing remains entirely unfettered and, arguably, from the tobacco industry's perspective, all the more important.

There is, therefore, an urgent need to stop the industry's attempts to influence tobacco-control policy in Europe. One option for doing this is full regulation of the tobacco market; a method that removes all forms of stakeholder and consumer marketing.

Chapter 7 of this report makes a number of recommendations for the future of tobacco-control in the EU as follows.

### **I. ORGANISATIONAL AND STRUCTURAL RECOMMENDATIONS: INVESTMENT AND REGULATORY CAPACITY**

- Member States and the EC need to affirm their commitment to tobacco control and to reducing tobacco-related morbidity and mortality by ratifying and implementing the FCTC at the earliest possible opportunity. In order to meet their FCTC obligations, all Member States will need to develop and implement comprehensive tobacco-control strategies encompassing prevention, protection, cessation and harm reduction. Implementation of the FCTC should be according to the strictest standards possible within national constitutional limitations.
- Implementing comprehensive tobacco-control strategies will require much greater levels of investment in tobacco control across the EC. Economic evidence indicates that tobacco-control interventions are the second most cost-effective way to spend health funds, after childhood immunisation. The CDC in the USA have set recommended levels at between €4.8-12.73 per capita for spending in the USA and these levels should be adopted in the EU. In recognition of the current low levels of funding for smoking prevention in the Member States, it is recommended that Member States immediately increase per capita spending by €1-3.
- Implementing comprehensive tobacco-control strategies will also require much greater regulatory capacity and expertise. A preferred option is for Member States to create national dedicated agencies to coordinate the tobacco-control strategy. Such organisations could be situated within the ministry responsible for smoking prevention policy, a public health institute, or be set up as an independent body. An appropriate mix of regulatory skills would be necessary to reflect the diverse nature of tobacco regulation.
- The EC has a clear role to play in coordinating and supporting strategies at national level and facilitating cooperation between Member State governments. Resources available for tobacco-control actions at European level fall far short of the levels available in other jurisdictions, such as the USA and Canada. Activity at the European level is critically important because of the transnational nature of the tobacco industry and the need to facilitate an exchange of information and dissemination of best

practice. There are a number of cost-effective actions that can be taken at supranational level. Therefore, the report recommends that resources at European level are secured and sustained in the future. Existing European sources of funding, such as those available from the Tobacco Fund, should be targeted at the most effective smoking prevention measures and used to complement Member State actions. Levels of resources set for tobacco control should continue at the level foreseen for the Tobacco Fund between 2006 and 2008.

- There is a need for greater capacity dedicated to tobacco control at EC level to support this work. In particular, capacity to assess and regulate nicotine and tobacco products in the Commission and Member States needs to be greatly increased and include the range of technical skills needed. At Member States level such staff could be housed in the dedicated tobacco-control agencies described above. At European level this could be provided by an extension of existing capacity within the European Commission and/or the establishment of a European tobacco and nicotine products regulatory agency. The consensus of the expert contributors to this report is that a European agency would be the best and most proportionate response within the framework of existing EU regulation of other products such as pharmaceuticals, food and cosmetics.
- The remit of such an agency would include all aspects of tobacco and nicotine product design and marketing, as well as risk analysis and risk assessment. Ultimately, it could have powers to commission and carry out research into all aspects of tobacco and nicotine products, tobacco-control policy and interventions and approve market authorisations for products.
- Until regulatory capacity can be increased, a multidisciplinary tobacco product regulation advisory committee should be set up urgently at European level to advise on tobacco regulation.
- It is essential that all regulatory, scientific and advisory capacity at Member State and European level be independent of all tobacco industry influence.
- Increased capacity is needed at civil society level for tobacco control. Partnerships are needed with a wider range of stakeholders in society to ensure the success of smoking prevention strategies. Non-governmental organisations, professional organisations and other stakeholders working in fields affected by the tobacco epidemic should endeavour to ensure that their response is appropriate to the scale of the problem, to the extent that financial resources permit.

### 1.1. The need for greater research capacity

- Whilst historical experiences of the European region, and activities in countries around the world provide considerable material to analyse what works in relation to tobacco-control policy at population level, the report uncovers a major lack of European research on which to base tobacco-control policies and test interventions. A strong science base for tobacco-control policy and interventions is, therefore, essential to improve societal understanding of the effects of tobacco on health and to best direct resources towards its control.

- A research seminar should be convened at European level to assess EU and international tobacco research capacity, coordination and funding, and develop a coordinated EU tobacco research strategy.
- In the short term, until such a strategy can be developed and implemented, a number of immediate research priorities have been identified to clarify the true scale of the tobacco epidemic: improved surveillance data, harmonised methodologies for research (e.g. the collection of prevalence and mortality data using standardised methodology), regular measurement of individual smoke exposure across populations, and measurement of the impact of tobacco-control policies and interventions (including on gender and inequalities). In order to finance these research priorities, funding needs to be identified within the EC or remaining sums of the Tobacco Fund should be used.
- An increase in tobacco research funding will be required. At EU level tobacco research should be given its own budget line in the next Research Framework Programme (2006-2010). Funding should match that given by the National Institutes of Health in the USA (currently €450 million per year or, pro rata per capita, €680 million). European budget lines, such as the sixth framework programme, should be applied to tobacco research.
- A better organisational structure for research targeted at tobacco use would comprise the following: the creation of tobacco-control research networks and research training networks across Europe. Strengthened national capacity is needed to develop tobacco-control research strategies, coordinate national programmes and oversee implementation, in coordination with national tobacco-control bodies (see above) and national research organisations. This will require increased funding at Member State level.

## **2. RECOMMENDATIONS ON SPECIFIC SMOKING PREVENTION INTERVENTIONS**

### **2.1. Taxation**

- Regular increases in tobacco taxes should be an implicit part of government efforts at EU and Member State level as these underpin other tobacco-control measures.
- Differences in tax rates should be harmonised on the basis of specific rates as opposed to ad valorem.
- The tax on “roll your own” tobacco should be raised to prevent substitution towards this form of tobacco products.
- Tobacco should be removed from the Consumer Price Index.
- Increased international cooperation to coordinate taxation policies and combat smuggling is needed. The EC should develop European legislation building on the agreement between the European Commission, ten Member States and Philip Morris International (PMI) to combat smuggling and counterfeiting.
- Early negotiation of an FCTC protocol on illicit trade, taking as a minimum the

provisions of the EU-PMI agreement and any subsequent directive based upon it, should be a priority for the EU to stem the huge losses to the Member States and Community from international tobacco smuggling.

## 2.2. Advertising and sales promotions

- All Member States that have not done so should enact comprehensive tobacco advertising bans, including bans on point of sale displays, in line with the conditions of FCTC ratification.
- All types of tobacco sales promotions should be banned. The proposed EU Regulation on Sales Promotions currently under discussion in the European Parliament and the Council provides a suitable mechanism for doing so.

## 2.3. Tobacco outlets

- Internet sales of tobacco products should be prohibited as well as the sale of tobacco products in vending machines.

## 2.4. Smoke-free work and public places

- The EU and Member States should follow the Environmental Protection Agency, IARC and the Finnish and German governments and classify secondhand smoke as an occupational carcinogen.
- Legislation prohibiting smoking in all workplaces would have most impact if enacted at European level. The legislation developed in Ireland and Norway should serve as the model for a European directive.
- EC legislation should be supplemented by Member State legislation to include public places that are not workplaces.

## 2.5. Cessation strategies

- All Member States that have not done so should develop national smoking cessation and treatment strategies. These should include training of health professionals, development of a national network of smoking cessation treatment services, increasing the accessibility of nicotine replacement therapies and removing inequalities in the provision of these services.

## 2.6. Tobacco product regulation

- A new comprehensive regulatory framework for all tobacco and nicotine products needs to be implemented.
- Comprehensive disclosure of the physical, chemical and design characteristics of all tobacco products should be required and made public. This should include, inter alia, the type of tobacco used, the way the tobacco is processed, ingredients added, product engineering, physical and chemical characteristics of the emissions of all

tobacco products, the availability of nicotine and other psychoactive constituents, the mode of use and the behaviour of the user.

- Directive 2001/37/EC should be improved by adopting the WHO's Study Group on Tobacco Product Regulation definition for ingredients.
- The tobacco industry is required to fully disclose additives used in their products according to the letter and spirit of the directive. In view of the high risk potential of tobacco products, such detailed information should take precedence over trade secrecy.
- Member States and the EC should agree a harmonised system for receiving the required information on ingredients and emissions from tobacco. This system should specify the exact form and content of the information to be transmitted, which methods for measurement should be used, and that the data should also take into account synergistic effects of the ingredients. The information provided should allow comparability between different tobacco companies. A harmonised system should also be established for Member States to analyse, verify and then report this information to the European Commission.
- A common list of ingredients cannot be produced until scientifically agreed criteria have been drawn up to assess the toxicity and addictiveness of ingredients and their public health impact.
- Any future regulation of ingredients should be based on the principles that the substance is not toxic, does not enhance the addictive properties of tobacco products and does not make the product more attractive. Further research and analysis is needed to create scientifically sound criteria for any approval or prohibition of ingredients.
- In view of the fact that it is technologically and economically feasible for cigarettes to meet fire safety standards, tobacco manufacturers should be required to produce and market only "fire-safe" (or "reduced-ignition propensity") cigarettes in the EU.
- Harmful constituents of tobacco and tobacco smoke should be reduced and ultimately removed where feasible. As a first step the immediate reduction of tobacco-specific nitrosamines (TSNAs) in tobacco products, without increasing the overall harm caused by these products, should be made mandatory.
- Member States and the European Commission need to begin to assess injury risk from tobacco products. A stepwise procedure should be used, starting with established tests e.g. for cytotoxicity and genotoxicity, and then continuing with tests for other adverse effects, including enhancement of addiction.
- Communication relating to health aspects of different tobacco and nicotine products and any changes in their characteristics should be strictly regulated. The mandatory phasing out of toxic constituents recommended in this chapter should not be accompanied by any health claims.

- Any new tobacco product of any kind, including new brands of cigarettes, must be given prior approval by regulators before entry to the market.

## 2.7. Labelling and packaging

- Effective pictorial health warnings should be made mandatory on both sides of all tobacco products. These warnings should cover at least 50% of each of the two largest surfaces. New warnings should be introduced on a regular basis. In the long term (within 10 years) the whole cigarette pack should become a platform for mandatory health promotion messages.
- The requirement for tobacco manufacturers and importers to print tar, nicotine and CO yields on packs should be rescinded. The remaining space on packs should be reserved for health and consumer information messages to be agreed upon by the European Commission and Member States.

## 2.8. Tobacco industry surveillance

- There is a need for ongoing, comprehensive surveillance of tobacco industry activity across the European region.
- Member States and the Community must ensure the fullest possible levels of transparency in all dealings with the tobacco industry.





# TOBACCO USE AND EFFECTS ON HEALTH

Ann McNeill

## 1. INTRODUCTION

This chapter discusses the effects of tobacco use on the health of individuals, as well as the effects on public health, in other words the overall impact on populations across Europe. Although the focus of this chapter is the effect of smoking cigarettes, which are by far the dominant form of tobacco use across Europe, the effects of other forms of tobacco used in Europe are also briefly examined, including pipe and cigar smoking, hand-rolled tobacco smoking, water-pipe smoking, bidi smoking and use of smokeless tobacco.

As smoking is the most researched topic in biomedical history, this opening chapter can only provide the briefest overview of current knowledge. Furthermore, scientists are continuing to discover the precise mechanisms by which tobacco causes disease in the human body, refining our understanding of the overall impact of smoking and causing us to recalculate the scale of the epidemic.

This chapter draws on leading authoritative reviews of the literature published in this field, in particular those of the World Health Organization International Agency for Research on Cancer (IARC), the UK Royal College of Physician reports and the US Surgeon General reports. On the whole, the evidence from these different reviews is very consistent, but this chapter highlights where there are still uncertainties. Due to constraints on space, this chapter does not offer explanations of why and how cigarette smoking causes specific diseases.

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## 2. THE EFFECTS OF TOBACCO ON INDIVIDUAL HEALTH

### 2.1. Cigarette smoking

Cigarette smoking harms nearly every organ of the human body, thereby causing a broad range of diseases<sup>1</sup>, at least 24 of which are fatal, as well as a massive burden of chronic illness.

The long-term risks of smoking have been quantified in a cohort study of British doctors that compared the overall survival of smokers and non-smokers over time. This study attempted to recruit all the doctors registered in Britain in 1951. Over 34,000 male doctors were enrolled and the 50-year follow-up, which included over 25,000 deaths, was published in 2004<sup>2</sup>.

The proportions who died in middle age (defined as aged 35-69 years) varied from 24% of never-smokers (defined as those who have never reported having smoked as much as one cigarette or 1 g of tobacco per day for as long as 1 year)<sup>a</sup> to 42% of cigarette smokers for those born in 1900-1909, but were 15% versus 43%, respectively, for those born in the 1920s. The risks to heavy smokers (defined as smokers of 25 or more cigarettes a day)<sup>a</sup> were more marked, with ~50% of those born in the first three decades of the 20th century dying in middle age. The absolute differences in the probability of survival of smokers and non-smokers were less extreme in old age, because almost all people die by age 100. Nevertheless, even

<sup>a</sup> These definitions of never-smoker and heavy smoker are used consistently throughout this chapter unless otherwise specified.

after middle age, the difference in mortality rates between smokers and non-smokers remained significant. For males born around the 1870s, only 10% of smokers aged 70 survived to 90 years compared with 12% of never-smokers; and for those born during the 1910s, 7% of smokers aged 70 survived until they were 90 years compared with 33% of never-smokers.

These survival data are for British male physicians observed in a particular historical period, and the pattern of survival will differ somewhat in different countries, for different classes and at different times. This study showed that, for continuing cigarette smokers, the eventual risk of dying as a result of their smoking varied from about one-half to about two-thirds; however, for the purposes of generalisability, the authors concluded that smoking killed about one-half of those who regularly smoked. The important message is the relative survival rather than the absolute percentages. The findings have been supported by studies in other countries. For example, a study relating life expectancy to smoking in 31,000 Danish people found similar survival curves for smokers versus never-smokers, among both males and females<sup>3, 4</sup>.

Estimates have also been made from the Danish data for health expectancy, i.e. the average lifetime in good health<sup>5</sup>. This study found that, in addition to the years lost from dying earlier from smoking, a greater number of years survived are marred by poor health. Males who continued to smoke heavily (defined here as at least 15 g tobacco per day) had 8 more years in poor health than never-smokers. Females who continued to smoke heavily had an average of 12 more years spent in poor health, in addition to the loss of life. A study from the Netherlands found similar results<sup>6</sup>.

The largest similar study is the American Cancer Society's second Cancer Prevention Study involving more than one million adults from the USA aged 30 years or over at the start of the study in 1982. This study found that, among males in the USA, smoking is associated with about two-thirds of all the deaths in middle age among those who smoke cigarettes regularly<sup>7</sup>.

In general, there is a strong dose-response relationship between smoking and the diseases caused by smoking, such that heavier smoking and longer duration of smoking are related to a higher risk of disease.

Whilst the composition of the cigarette smoke inhaled varies depending on the type of tobacco used, the design of the cigarette (including the presence or absence of filters and use of additives) and the way cigarettes are smoked, the overall health risks to smokers do not differ greatly for cigarettes with different design features.

Peto *et al.*<sup>8</sup> have recently estimated mortality from smoking in the European Union (EU) (updating a similar study published in 1994<sup>9</sup>). They estimate that, in EU25<sup>b</sup> countries, smokers who die in middle age as a result of their smoking lose an average of 22 years of life. Even those dying as a result of their smoking at age 70 or older lose 8 years. On average, smokers who die as a result of their smoking die 14 years earlier than never-smokers. These new data allow a comparison between the risks of dying from tobacco use compared with other factors. In the year 2000, for every 1,000 individuals across all EU25 countries who smoke regularly, one will be murdered and seven will be killed in road crashes, but 500 will be killed by their smoking.

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<sup>b</sup> EU25 are the 25 Member States of the newly enlarged EU

### 2.1.1. Diseases caused by cigarette smoking

Table I lists the diseases and other adverse health effects caused by cigarette smoking. It is important to note that, overall, males and females who smoke face similar risks for these major causes of death, although there are unique risks faced by females, as indicated in the table. The following sections focus on the major causes of death: cancers, respiratory diseases and cardiovascular diseases. Reproductive diseases are also included because of the important cross-generational effects of smoking.

#### 2.1.1.1. Cancers

In 2004, the IARC published a Monograph<sup>10</sup> concerning the carcinogenicity of tobacco smoking, which updated their earlier review of these issues, the Monograph published in 1986<sup>11</sup>. The 2004 report indicated that there is now sufficient evidence for a causal association between cigarette smoking and 16 different cancers. This indicates a doubling over the last 18 years in the number of cancers found to be caused by cigarette smoking, showing that, even today, 54 years after the first links between smoking and lung cancer were established, yet more diseases are being found to be caused by smoking.

Table I lists the cancers which are identified in the revised IARC Monograph<sup>10</sup> as being caused by smoking. In these cancers, the observed relative risks range from ~2 for stomach cancer to more than 20 for lung cancer. In addition, there is suggestive evidence (not yet sufficient to infer a causal relationship) that smoking causes other cancers, such as colorectal cancer. There appears to be a small decreased risk of endometrial cancer among smokers.

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From the British doctors study<sup>2</sup>, current cigarette smokers have over twice the risk<sup>c</sup> of dying from all cancers combined than never-smokers. For heavy smokers the risk is three-fold compared with never-smokers.

Lung cancer is by far the most common cause of death from cancer in Europe when both sexes are considered, and tobacco smoking increases the risk of all major histological types of lung cancer<sup>10</sup> for both males and females. Cigarette smoking is the major cause of lung cancer: "In populations with prolonged cigarette use, the proportion of lung cancer cases attributable to cigarette smoking has reached 90%."<sup>10</sup>

Duration of smoking is the strongest determinant of risk of lung cancer<sup>10</sup>. Risk also increases in proportion to the number of cigarettes smoked, so that mortality from lung cancer is 25 times higher in heavy smokers than in never-smokers<sup>2</sup>.

Further details of the relationship between smoking and the various different forms of cancer can be found in the recent IARC report<sup>10</sup>.

<sup>c</sup> Relative risks are a function of the age, time and smoking characteristics of the population studied, and are not absolute values. Therefore, they vary from study to study. This report gives relative risks taken from the British doctors study<sup>2</sup> unless otherwise stated. These risks are, therefore, illustrative.



### 2.1.1.2. Respiratory diseases

Smoking is the most important cause of emphysema and chronic bronchitis, collectively known as chronic obstructive pulmonary disease (COPD). Smoking causes nearly 90% of all cases of emphysema<sup>2</sup>. Mortality from COPD is 14-times higher in cigarette smokers than in never-smokers<sup>8</sup>. Again, dose is important, with mortality from COPD being nearly 24-times higher among heavy smokers than never-smokers. There has been a suggestion that females may have more symptoms of COPD than males even if they have smoked the same amount over the same number of years<sup>13, 14</sup>.

A causal relationship exists between smoking and contracting acute respiratory illnesses, including pneumonia<sup>1, 15</sup>, in people without underlying smoking-related COPD. Smoking is also linked to an increased risk of contracting infectious diseases, such as tuberculosis, influenza and the common cold. In addition, smoking exacerbates asthma. A causal relationship has also been identified between smoking and a premature onset of and an accelerated age-related decline in, lung function, as well as all common respiratory symptoms among adults, including cough, phlegm, wheeze and dyspnoea.

The risk of dying from any respiratory disease is three times higher for smokers than never-smokers and nearly five times higher for heavy smokers as compared with never-smokers<sup>2</sup>. However, death rates from respiratory diseases will vary according to other country-specific factors (see also Mortality from smoking across Europe section).

Children and adolescents who smoke are also damaging their lungs. A causal relationship has been identified between smoking in adolescence and impaired lung growth, early onset of lung function decline, respiratory symptoms including cough, phlegm, wheeze and dyspnoea, and asthma<sup>1</sup>.

### 2.1.1.3. Cardiovascular diseases

Smoking increases a person's risk of cardiovascular disease, which is an umbrella term for coronary heart disease (CHD), cerebrovascular disease (ischaemic and haemorrhagic stroke), aortic aneurysm and peripheral arterial disease. The risk of mortality from any cardiovascular disease in all cigarette smokers is greater than 1.6 times that of never-smokers, with the figure rising to 1.9 times in heavy smokers<sup>2</sup>.

The relative risk of cardiovascular disease associated with smoking is low in comparison to lung cancer and COPD. Unlike lung cancer and COPD, cardiovascular disease has multiple causes. Smoking acts synergistically with these other risk factors, such as diet and lack of physical exercise, to increase the risk of cardiovascular disease. Thus, the high rate of cardiovascular disease in European populations means that there are similar numbers of deaths from cardiovascular disease and lung cancer attributable to smoking in the population (see Mortality from smoking across Europe section).

Over the age of 60 years, the relative risk of heart attack doubles, but under the age of 50 years smoking is associated with a more than five-fold increase in risk<sup>16</sup>. There is a synergistic action in females who smoke and use the contraceptive pill, resulting in a substantial increase in the risk of myocardial infarction<sup>17</sup>.

The relative risks of stroke are also very dependent on the age of the population in which they are measured<sup>18</sup>. The risk of stroke increases dramatically at older ages, but the relative risk from smoking declines with age. The reasons for this are not fully understood, but may relate to very early onset of illness in individuals who are particularly susceptible to some of the adverse effects of smoking.

### 2.1.1.4 Reproductive diseases

Maternal smoking during pregnancy is an important cause of ill health for both mother and foetus<sup>19</sup>.

Smoking causes “cot death” or sudden infant death syndrome (SIDS)<sup>20, 21</sup>, the commonest cause of death between the ages of 1 month and 1 year (fig. 1).

Fig. 1. - Risk of cot death from maternal smoking in pregnancy

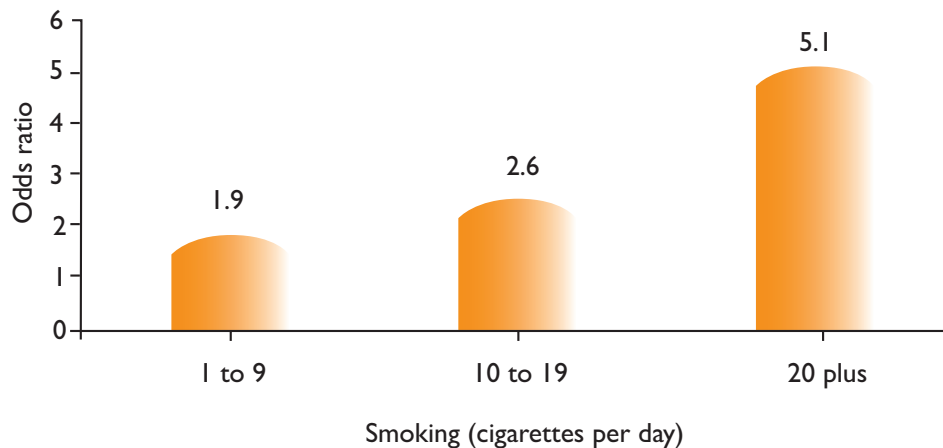


Figure reproduced with permission from Mitchell *et al.*<sup>21</sup>.

Maternal smoking is also a cause of low birth weight<sup>22</sup>, and the greater the exposure the greater the risk of having a low birth weight baby<sup>23</sup>. Full-term infants born to females who smoke during pregnancy weigh ~200 g less than those born to females who do not smoke<sup>10</sup>. Maternal smoking during pregnancy also increases the risk of miscarriage and of premature birth<sup>19</sup>, and is a cause of several complications in pregnancy, including premature rupture of the membranes, placenta praevia and placental abruption<sup>1</sup>. There is also a causal relationship between maternal smoking during pregnancy and a reduction in lung function in infants<sup>1</sup>. In addition, smoking has a causal relationship with reduced fertility in females<sup>1, 19</sup>. Some experts have stated that there is a causal relationship between smoking and sperm damage<sup>19</sup>, but not all agree that the evidence is yet sufficient to say that this is more than a statistical association<sup>1</sup>. Similarly, smoking is linked to erectile dysfunction<sup>1</sup>.

#### 2.1.1.5. Other diseases and adverse health effects

In addition to those diseases and adverse health effects known to be caused by smoking, smoking aggravates a wide variety of illnesses, such as chronic rhinitis<sup>24</sup>, multiple sclerosis<sup>25</sup> and goitre<sup>26</sup>, and has been identified as a risk factor in a range of other diseases and adverse health effects, such as rheumatoid arthritis<sup>27</sup> and skin aging<sup>28</sup>. An enhanced risk for premature mortality has also been found from the combination of smoking and diabetes<sup>29</sup>.

There is evidence that smoking is associated with increased absenteeism from work and increased use of medical care services.

#### 2.1.1.6. Interactions with other causes of disease

There is evidence of synergy between smoking and other causes of disease. For example, the combination of heavy alcohol and heavy tobacco consumption has a synergistic effect on the risk of some cancers, including oral cavity, pharynx and larynx<sup>10</sup>.

### 2.1.2. Diseases inversely associated with smoking

Smoking is associated with a reduced incidence of some diseases, including Parkinson's disease, ulcerative colitis, aphthous ulcers, allergic alveolitis, cancer of the body of the uterus, fibroids, nausea, and vomiting in pregnancy and pre-eclampsia. Most of these diseases are uncommon or seldom fatal. Any smoking-attributable decrease in mortality from these diseases amounts to <1% of the overall mortality increase caused by smoking<sup>12</sup>.

## 2.2. Other forms of tobacco use

The health consequences of smoking all forms of tobacco are broadly similar, as all deliver substantial amounts of carcinogens and other harmful combustion products<sup>10</sup>; however, the small variations worth noting are described below.

### 2.2.1. Hand-rolling tobacco

In some countries in Europe, hand-rolled cigarettes are becoming increasingly popular. For example, in the UK, over one-fifth of smokers (22%) now smoke hand-rolled cigarettes, compared with 10% in 1984<sup>30</sup>. Hand-rolled cigarettes do not need to comply with the tar, nicotine and carbon monoxide machine-based maximum yields required by the EU (see also Chapter 5). A UK study found that, even with standardised-sized tubes and amounts of tobacco, there is still considerably more variation of these yields within brands of hand-rolling tobacco in the UK than within brands of machine-manufactured cigarettes<sup>31</sup>. There are fewer studies on the health impact of hand-rolled than on manufactured cigarettes, but the available evidence indicates that risks are as great or even greater<sup>32, 33, 34</sup>.

### 2.2.2. Cigar and pipe smoking

The IARC report<sup>10</sup> identified a causal relationship between cancer of the oral cavity, oropharynx, hypopharynx, larynx and oesophagus, and cigar and pipe smoking, with the magnitude of risk similar to that from cigarette smoking and there is a comparable dose-response profile. A causal relationship has been identified between cigar and/or pipe smoking



with cancer of the lung, as well as cancer of the pancreas, stomach and urinary bladder.

The extent to which cigar and pipe smoking increases an individual's risk of some cancers, cardiovascular disease and COPD depends on whether a smoker inhales<sup>35</sup>. The risk of smoking cigars or pipes for individuals who have never been regular smokers of cigarettes, so-called primary cigar or pipe smokers, is considerably lower than in former cigarette smokers, principally because members of the primary group tend not to inhale the smoke but rely on nicotine absorption from the buccal mucosa, the lining of the mouth. Cigarette smokers who switch to cigars or pipes tend to continue to inhale the smoke and suffer similar rates of smoking-related disease to cigarette smokers.

### **2.2.3. Bidi smoking**

Bidis are manufactured in India and exported worldwide. They consist of tobacco rolled in a dried tree leaf and are usually unfiltered. Bidis are available in a variety of flavours. They are not currently popular in Europe.

Bidi smoke is carcinogenic<sup>10</sup>. The new IARC report summarises case-controlled studies, demonstrating a strong association between bidi smoking and cancers in the oral cavity, pharynx, larynx, oesophagus, lung and stomach, and almost all of these studies showed significant trends with duration of bidi smoking and number of bidis smoked.

### **2.2.4. Water-pipe smoking (also known as hubble-bubble smoking)**

This is becoming increasingly popular in some parts of Europe, e.g. Denmark. Although there is little research on this type of smoking, it has been established that it involves the inhalation of nicotine similar to other forms of tobacco use<sup>36</sup>, and also the inhalation of carcinogens and toxins<sup>37</sup>. There is emerging evidence of risks to health from this behaviour<sup>38</sup>.

### **2.2.5. Smokeless tobacco**

There are various different types of smokeless tobacco products in use around the world and the health risks of these vary considerably. Smokeless tobacco comes in two main forms: snuff (finely ground or cut tobacco leaves that can be dry or moist, loose or portion packed in sachets, and administered to the mouth, or the dry products to the nose or mouth) and chewing tobacco (loose leaf, in pouches of tobacco leaves, “plug” or “twist” form). When administered orally, the tobacco can also be mixed with other psychoactive ingredients.

In the EU, one form of smokeless tobacco, oral snuff, is banned (see also Chapter 3). A derogation was granted for Sweden, where a form of moist snuff, known as snus, is popular, with some 20% of males using it. A derogation was also granted for the European Economic Area Member State Norway, where about 7% of males use snus daily.

In India, use of their domestic types of chewing tobacco is a major cause of oral cancer<sup>39</sup> and is also harmful in pregnancy<sup>40</sup>. Given these types of tobacco are allowed in Europe, this is also a cause of concern here. The use of chewing tobacco is largely restricted to members of the Indian, Pakistani and especially Bangladeshi communities, which, for example, in the UK, make up 4.5% of the population, just over two million people.

The health risks associated with the use of smokeless tobacco in individuals are considerably less than those associated with cigarettes. The reason for this is that smokeless tobacco products do not contain the toxic pyrolysis or combustion products responsible for the great majority of the health effects from cigarettes. Several reviews of the health effects of smokeless tobacco products have been published (e.g. <sup>41, 42, 43</sup>), but relatively less research has been carried out in comparison with cigarette smoking. Concerns focus mainly on oral cancers<sup>44</sup> and cardiovascular disease<sup>45</sup>.

In Sweden, snus is manufactured and stored in a manner that causes it to deliver lower yields of some of the more harmful chemicals, in particular tobacco-specific nitrosamines, than other smokeless tobacco products<sup>43</sup>. Snus does not appear to cause cancer, respiratory diseases or stroke<sup>43, 46</sup>. Snus may cause an increase in the risk of cardiovascular disease, although a much lower risk than caused by smoking<sup>47, 48</sup> and it may be a risk factor for diabetes for heavy snus users<sup>49</sup>, although this relationship has not been found in other studies<sup>50</sup>. Snus is dependence forming and can deliver high doses of nicotine<sup>51</sup>, but the maximum serum levels are similar among all nicotine users. Snus is harmful to the developing foetus<sup>52</sup>.

### 2.3. Impact of tobacco use on others

Tobacco smoke is a serious environmental hazard and a significant cause of ill health. A review commissioned by the “Europe Against Cancer” Programme of the European Commission in 1997 concluded that: “Tobacco smoke is the most important source of indoor contaminants in environments where smoking occurs.”<sup>53</sup>

Tobacco smoke consists of side-stream smoke emanating from the burning tip of a cigarette or other smoking device (~85%), and main-stream smoke that has been inhaled and exhaled by a smoker (~15%). Other terms to describe tobacco smoke pollution include second-hand smoke, environmental tobacco smoke or air pollution caused by tobacco smoke. The exposure of non-smokers to tobacco smoke is referred to as passive smoking or involuntary smoking.

The composition of tobacco smoke will vary depending on the way the tobacco is smoked, as well as the design and composition of the delivery device. Cigarette smoke has been the most extensively studied. Main-stream and side-stream smoke consist of a gas phase and a particulate phase. As many of the gases are odourless, it is not always easy to sense when the air is not safe<sup>54, 55</sup>. Tobacco smoke contains over 4,000 chemicals, including many regulated hazardous air pollutants and hazardous wastes, more than 50 known carcinogens and more than 100 chemical poisons<sup>53</sup>. When tobacco is burned to create side-stream smoke, larger amounts of some toxic constituents are generated than when tobacco is burned to generate main-stream smoke, resulting in the tobacco smoke containing substantial amounts of these carcinogens even when extensively diluted<sup>56</sup>. It is generally believed that for many of the carcinogenic constituents that are genotoxic (i.e. cause damage to cellular DNA, resulting in mutations or cancer) there is no safe level of exposure.

Since 1986, there has been a series of authoritative reports analysing the evidence, and concluding, beyond doubt, that there are significant risks to health caused by passive smoking (table 2).

Table 2. - Reports on the health effects of passive smoking

1986	US Dept of Health and Human Services: the Health Consequences of Involuntary Smoking <sup>57</sup>
1986	Australian National Health and Medical Research Council: Effects of Passive Smoking on Health <sup>58</sup>
1986	German MAK-Commission: Passive Smoking at the Workplace <sup>59</sup>
1986	US National Research Council: Environmental Tobacco Smoke <sup>60</sup>
1987	World Health Organization IARC Monograph <sup>11</sup>
1992	US Environmental Protection Agency: Respiratory Health Effects of Passive Smoking <sup>61</sup>
1994	US Occupational Safety and Health Administration: Indoor Air Quality <sup>62</sup>
1997	Australian National Health and Medical Research Council: Health Effects of Passive Smoking <sup>63</sup>
1997	California Environmental Protection Agency: Health Effects of Exposure to Environmental Tobacco Smoke <sup>64</sup>
1997	Europe Against Cancer: Passive Smoking. The Health Impact <sup>53</sup>
1998	UK Scientific Committee on Tobacco and Health: Environmental Tobacco Smoke <sup>65</sup>
1999	US Institute for Global Tobacco Control: Environmental Tobacco Smoke <sup>66</sup>
1999	German MAK-Commission: Passive Smoking <sup>67</sup>
1999	WHO Expert Consultation: Environmental Tobacco Smoke (ETS) and Child Health <sup>68</sup>
2000	WHO: Air Quality Guidelines for Europe <sup>69</sup>
2000	American College of Occupational & Environmental Medicine: Epidemiological basis... <sup>70</sup>
2001	European Network for Smoking Prevention: Smoke Free Workplaces <sup>71</sup>
2001	Report to the French Director General of Health: Passive Smoking <sup>72</sup>
2001	Finnish Report on Environmental Tobacco Smoke and its Effects on Health <sup>73</sup>
2002	British Medical Association: Towards Smoke-Free Public Places <sup>74</sup>
2002	Health Council of the Netherlands: The Impact of Passive Smoking on Public Health <sup>75</sup>
2004	Irish Office of Tobacco Control and Health and Safety Authority: Report on the Health Effects of ETS in the Workplace <sup>76</sup>
2004	WHO IARC Monograph on the Evaluation of Carcinogenic Risks to Humans: Tobacco Smoke and Involuntary Smoking <sup>10</sup>

A range of conditions, including fatal illnesses, are caused by passive smoking and these are shown in table 3, which has been adapted from the recent review by the British Medical Association (BMA)<sup>74</sup>.

Table 3. - Health effects of second-hand smoke

<b>EVIDENCE THAT SECOND-HAND SMOKE CAUSES</b>	
<b>Adults</b>	
Lung cancer	
Coronary heart disease	
Onset of symptoms of heart disease	
Asthma attacks in those already affected	
Worsening of symptoms of bronchitis	
Stroke	
Reduced foetal growth (low-birth-weight baby)	
Premature birth	
<b>Children</b>	
Cot death (Sudden infant death syndrome)	
Middle-ear disease (ear infections)	
Respiratory infections	
Development of asthma in those previously unaffected	
Asthma attacks in those already affected	
<b>OTHER PROVEN HEALTH EFFECTS OF SECOND-HAND SMOKE</b>	
Shortness of breath	
Nausea	
Airway irritation	
Headache	
Coughing	
Eye irritation	

The risks to health are summarised in the following sections. Many of these adverse outcomes show a linear dose response, with risk increasing as exposure increases (but see cardiovascular risks below). The increased risks associated with passive smoking are consistent with those estimated from extrapolating the risk in smokers, using biochemical measures, and with evidence of tobacco-specific carcinogens found in the blood and urine of non-smokers exposed to tobacco smoke<sup>74</sup>.

### **2.3.1. Acute and sub-acute effects**

Many non-smokers feel immediate effects on breathing in tobacco smoke. They can suffer from coughing, headache, eye irritation, sore throat, sneezing and runny nose, nausea, breathing problems, and irregular heartbeat (particularly for people with heart disease)<sup>74</sup>.

### **2.3.2. Chronic effects**

#### *2.3.2.1. Cancers*

Extended exposure to tobacco smoke causes lung cancer in non-smokers. IARC recently determined tobacco smoke pollution to be carcinogenic to humans<sup>10</sup>: “There is sufficient evidence that involuntary smoking causes lung cancer in humans.”

IARC found that non-smokers living with a smoker have a 20-30% increase in risk of lung cancer compared with those who live in non-smoking households, controlling for some potential sources of bias and confounding. As with active smoking, there is a dose-response relationship between a non-smoker's risk of lung cancer and the number of years of exposure to the tobacco smoke<sup>77</sup>.

For non-smokers exposed in the workplace, IARC reviewed other published meta-analyses, which give an increased risk of lung cancer of 16-19%<sup>10</sup>.

Finland, Germany and the US National Toxicology Programme have listed tobacco smoke as a workplace carcinogen and, as long ago as 1992, the US Environmental Protection Agency classified tobacco smoke as a Class A (known human) carcinogen<sup>61</sup>.

#### *2.3.2.2. Respiratory diseases*

IARC reported that adverse effects of tobacco smoke on respiratory symptoms have been observed, with the strongest evidence being for a causal relationship with chronic respiratory symptoms<sup>10</sup>. In 1998, a review found a small but significant association between passive smoking and adult-onset asthma and COPD<sup>78</sup>. This review estimated that adults exposed at home or in the workplace had a 40-60% increased risk of asthma compared with adults who were not exposed in these places.

In people with asthma, exposure to tobacco smoke is associated not only with more severe symptoms, but also with lower quality of life, reduced lung function and increased use of health services for asthma, including hospital admissions<sup>79</sup>.

In 2001, the European Community Respiratory Health Survey<sup>80</sup> (involving nearly 8,000 adults aged 20-48 years from 46 centres in 16 countries) found that passive smoking was significantly

associated with nocturnal chest tightness, nocturnal breathlessness and increased bronchial responsiveness. Further analyses from this study have found that both intra-uterine (see below) and environmental exposure to parental tobacco smoking was related to children having more respiratory symptoms and poorer lung function in adulthood<sup>81</sup>.

#### 2.3.2.3. Cardiovascular diseases

People who live with smokers have a 25% increased risk of coronary heart disease<sup>10</sup>. Exposure to tobacco smoke has consistently been found to be associated with an increased relative risk of CHD in cohort studies and case-controlled studies, in males and females, and for exposure at home and in the workplace<sup>82</sup>.

It may seem odd that the relative risks for active and passive smoking on lung cancer are very different, namely, ~20 for active smoking and ~1.2 for passive smoking, while the relative risks for active and passive smoking on CHD are relatively close, namely 1.8 for active smoking and 1.25 for passive smoking. However, the dose-response relationship for CHD is non-linear<sup>83, 84</sup>, and we now understand that the mechanisms concerning smoking and cancer and smoking and cardiovascular disease are very different. Even small amounts of smoke may have immediate influences on clotting and thrombus formation, and long-term effects on the development of arteriosclerosis, all important factors in CHD and cardiovascular disease. Such a non-linear response helps make the epidemiological estimates of the cardiovascular effects of passive smoking biologically plausible<sup>85</sup>.

There is some evidence that second-hand smoke increases the risk of stroke. Bonita *et al.*<sup>86</sup> found that regular exposure to tobacco smoke pollution increased the risk of stroke in non-smokers by 82%. A recent cohort study found a 50% increased risk of first ischaemic stroke among females exposed to environmental tobacco smoke at home<sup>87</sup>.

#### 2.3.2.4. Effects of tobacco smoke on the health of children

Exposure to tobacco smoke is especially dangerous to young children and infants. It increases the risk of lower respiratory tract infections, such as pneumonia and bronchitis, causes coughing and wheezing, and is associated with reduced lung growth and with middle-ear disease, including recurrent ear infections in children<sup>68, 88</sup>. It is also a risk factor for new cases of asthma and increases the severity of symptoms in children with asthma<sup>89</sup>. A Dutch review of the evidence recently estimated that the increase in risk of respiratory infections in children with or without asthma varied from 20-50%<sup>75</sup>. In the UK, it has been estimated that, each year, more than 17,000 children aged under 5 years are admitted to hospitals because of respiratory illness caused by exposure to other peoples' cigarette smoke<sup>90</sup>.

#### 2.3.2.5. Exposure to tobacco smoke during pregnancy and infancy

As with maternal smoking in pregnancy, passive smoking (i.e. when non-smoking females are exposed to other peoples' smoke during pregnancy) also reduces birth weight in the offspring of non-smoking mothers<sup>10</sup>. There is also evidence that exposure to tobacco smoke pollution after birth is a risk factor for SIDS in babies of non-smoking mothers<sup>91, 92</sup>.

Exposure to tobacco smoke in pregnancy and infancy adversely affects certain cognitive abilities and behavioural characteristics of children<sup>19</sup>.

## 2.3.2.6. Other effects

Second-hand tobacco smoke is especially dangerous to people with pre-existing respiratory or cardiovascular conditions. Such individuals make up a substantial proportion of the population<sup>74</sup>.

## 2.3.2.7. Summary of increased risks from passive smoking studies

The increased risks of passive smoking are summarised in table 4.

Table 4. - Risks from passive smoking

DISEASE	INCREASED RELATIVE RISKS %
Lung cancer: exposure at home	25-35
Lung cancer: exposure at work	20
CVD: exposure at home	25
Stroke: exposure at home	50
Respiratory diseases: children	20-50
Asthma onset: adults	40-60

CVD: cardiovascular disease. Data taken from <sup>10, 19, 75, 87</sup>.

## 3. THE EFFECTS OF TOBACCO ON PUBLIC HEALTH

When he examined the effects of tobacco on many different conditions, Doll<sup>12</sup> commented: “That so many diseases - major and minor - should be related to smoking is one of the most astonishing findings of medical research...less astonishing perhaps than the fact that so many people have ignored it.”

This section focuses on the impact of continuing use of tobacco on population health. In addition to mortality trends, morbidity effects and the impact of tobacco on health inequalities are briefly described.

### 3.1. Mortality from smoking across Europe

Data from the study conducted by Peto *et al.*<sup>8</sup> in 2000 are used to give a snapshot of current mortality across Europe (table 5). Mortality figures are given for the EU25 and the European Free Trade Association (EFTA) countries. These figures are likely to be underestimates for a number of reasons, including that no data were available for Cyprus and Iceland, although 0.2% of the EU25 total was added to cover these, and deaths from passive smoking have not been included (see below). The figures from the study by Peto *et al.*<sup>8</sup> use a standard method and, therefore, the totals for different countries are directly comparable. However, some countries use different estimates of deaths caused by smoking. In these cases both figures are presented.

It is important to note that these data reflect the consequences of tobacco consumed two or three decades previously. For example, currently, more males than females are dying as a

result of their tobacco use in all EU countries and it will take some time for the current high prevalence of the use of tobacco by females across Europe to show up in these figures. For comparative purposes, the prevalence figures are given in Chapter 4.

Table 5. - Absolute deaths in 2000 attributable to smoking

COUNTRY	SMOKING-ATTRIBUTABLE DEATHS PER YEAR, 2000 N	OWN COUNTRY ESTIMATES
AU	8,903	
BE	18,646	
CY <sup>#</sup>		
CZ	17,746	
DK	12,329	
EE	2,751	
FI	5,102	
FR	60,578	66,400 <sup>93</sup>
DE	108,835	143,390 <sup>94, ¶</sup>
EL	13,332	
HU	29,070	28,000 <sup>95</sup>
IE	5,653	
IT	80,061	80,000 <sup>96</sup>
LV	4,131	4,380 <sup>97</sup>
IS		390 <sup>98</sup>
LI <sup>#</sup>		
LT	4,671	7,000 <sup>99</sup>
LU	570	
MT	295	358 <sup>100</sup>
NO	5,544	
PL	68,629	
PT	8,405	
SK	8,039	
SI	2,808	
ES	45,342	
SE	8,205	6,500 <sup>101</sup>
CH	6,978	
NL	25,725	
UK	114,771	

<sup>#</sup>: no data available; <sup>¶</sup>: tobacco-smoking-attributable mortality was estimated taking the smoking prevalence in Germany into consideration. Data taken from Peto *et al.*<sup>8</sup>.



Table 6 and figure 2 give the total estimated tobacco-attributable<sup>d</sup> deaths for the EU25. There were 656,000 deaths overall caused by smoking in the year 2000, more than one in seven of all deaths across the EU25. In the 10 new Member States alone, smoking caused nearly one in five of all deaths. There were 668,000 deaths caused by smoking in the EU25 and Switzerland and Norway in the year 2000.

Table 6. - Overall mortality due to smoking as a proportion of all deaths in the EU25 (year 2000 data)<sup>#</sup>

DEATHS DUE TO SMOKING/TOTAL DEATHS N (%)			
CAUSE	MALES	FEMALES	ALL
Lung cancer	156,000/171,000 (91)	34,000/53,000 (65)	190,000/224,000 (85)
All cancer	239,000/626,000 (38)	46,000/493,000 (9)	285,000/1,119,000 (25)
Cardiovascular	136,000/846,000 (16)	48,000/1,028,000 (5)	184,000/1,873,000 (10)
Respiratory	78,000/194,000 (40)	34,000/178,000 (19)	113,000/371,000 (30)
All causes	508,000/2,214,000 (23)	148,000/2,238,000 (7)	656,000 <sup>¶</sup> /4,452,000 (15)

<sup>#</sup>: denominator of the fraction is the number of deaths due to that disease, the numerator is the number attributable to smoking; <sup>¶</sup>: the total deaths figure rises from 656,000 to 668,000 with the addition of Norway and Switzerland (the only two EFTA countries for which data is available). Data are taken from Peto *et al.*<sup>8</sup>.

Fig. 2. - Deaths caused by smoking as a per cent of total deaths in the EU, 2000

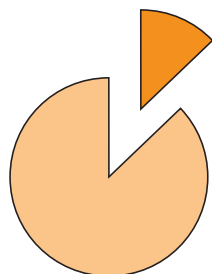


Figure modified from Peto *et al.*<sup>8</sup>.

Fig. 3. - Proportion of deaths from smoking by disease group in the EU, 2000

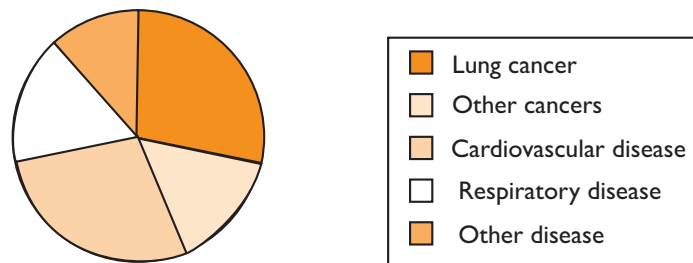


Figure modified from Peto *et al.*<sup>8</sup>.

<sup>d</sup> Attributable proportions will vary according to country characteristics, such as the prevalence of smoking in the population, but also the prevalence of other factors related to diseases caused by smoking.

### 3.1.1. Breakdown by disease group

Cancers, cardiovascular diseases and respiratory diseases together account for the great majority of the deaths caused by smoking, representing, respectively, 43, 28 and 18% of all deaths due to smoking (table 6 and figure 3). In absolute terms, smoking caused nearly as many deaths from cardiovascular disease as from lung cancer.

#### 3.1.1.1. Cancers

About one in four (26%) of all deaths from cancer in the EU is caused by smoking (table 6). Among the 10 new Member States only, this figure rises to 30%. Eighty five per cent of lung cancer deaths across the EU are caused by smoking.

Lung cancer is the leading cause of death from cancer among males. In 2000, in Denmark and the UK, lung cancer surpassed breast cancer as the most important cause of fatal cancer among females<sup>8</sup>. In these countries the epidemic of smoking among females is well established (similar to the USA where lung cancer is the leading cause of death from cancer among females<sup>102</sup>) and the same pattern is likely to occur in other countries where the prevalence of smoking among females is still rising or has recently peaked.

#### 3.1.1.2. Respiratory diseases

In the EU, three in 10 (30%) of all deaths from all respiratory disease are caused by smoking (table 6), but this rises to 40% in the new Member States. Nearly two-thirds (64%) of deaths from COPD are caused by smoking<sup>8</sup>. As with other diseases, death rates vary from country to country according to many factors. For example, the death rate from COPD and bronchial asthma is higher in Denmark<sup>103</sup> than in other western European countries, although it is not yet clear why this is the case, but differences in cigarette consumption may play a role.

Although tuberculosis was almost eradicated in Europe by 1980, rates have been increasing in eastern European countries in recent years and increased resistance to drugs commonly used to treat tuberculosis has been observed<sup>13</sup>. Smoking is only one factor in this epidemic, although a recent study from India found that smoking was a cause of half of deaths from tuberculosis in males<sup>104</sup>.

#### 3.1.1.3. Cardiovascular diseases

One in ten (10%) of all deaths from cardiovascular diseases in the EU is caused by smoking (table 6). Among the 10 new Member States only, this figure rises to 14%.

Whether smoking-attributable deaths from cancer exceed those from cardiovascular disease varies across the different EU countries, depending on the background risk of cardiovascular disease in specific nations or regions and the age of the population studied. Death rates from stroke are higher in central and eastern Europe than the other regions, and death rates from CHD are generally higher in northern, central and eastern Europe than in southern and western Europe<sup>105</sup>. This relates to the other risk factors for CHD and also to their synergistic effects with smoking. For example, data from the Seven Countries Study<sup>106</sup> have shown an interaction between smoking and cholesterol levels, smoking being more dangerous for those who also have high blood cholesterol levels. The impact of smoking on

mortality and morbidity from cardiovascular disease has been much higher in Finland when compared with southern Europe, and this interaction has also been found elsewhere<sup>107</sup>.

### 3.1.2. Trends in mortality

Mortality patterns are now indicative of the impact of smoking trends two to three decades ago. This is best illustrated in figure 4<sup>108</sup>, which shows the stages of the smoking epidemic. In general, levels of smoking have been seen as following four stages. The first is a rapid rise in smoking by males, the second a rise in smoking by females, the third a plateau in smoking among males, and the fourth a plateau and then decline in smoking in females. These trends in prevalence are followed two to three decades later by similar peaks and falls in mortality caused by smoking.

Fig. 4. - The four stages of the tobacco epidemic

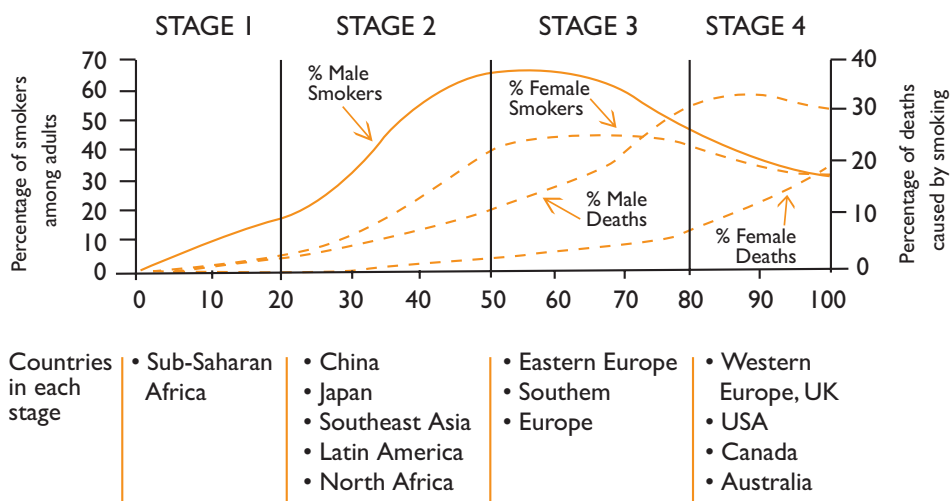


Figure adapted from Lopez *et al.*<sup>108</sup>.

The tobacco epidemic is at different stages in different European countries. In general, western European males began smoking early in the 20th century with females taking up smoking most commonly in the second half of that century. From 1950 onwards, the proportion of males smoking started to decline, but declines in females smoking only followed from the mid 1970s. Only some western European countries (most notably UK, Germany, Denmark and Finland) are in stage four of the epidemic.

The situation is different in the eastern and central European countries. The closed societies of the Soviet bloc were largely deprived of public education on the harmful effects of smoking. Reports from scientific studies of the relationship between smoking and cancer and other diseases, undertaken chiefly in the UK and the USA since the 1950s, apparently did not penetrate central and eastern European countries. Awareness of the harm to health due to smoking was very low until the 1980s<sup>109</sup>. This attitude towards tobacco, which prevailed until almost the end of the 1980s, put these countries on top of the list of world tobacco

consumption from the early 1960s until the end of the 20th century<sup>10</sup>. The prevalence of smoking by males in these countries is now peaking or only just beginning to decline, whereas smoking is still increasing amongst females. Most central, eastern and southern European countries are, therefore, in stage three of the epidemic.

Figure 5 shows the overall trends in mortality for smoking-attributable deaths over the last half of the 20th century for all the EU25 countries. The proportion of smoking-attributable deaths (fig. 5a) peaked among males in the 1980s, but the proportion of smoking-attributable deaths among females is still rising. Given that the smoking-attributable proportion of deaths could be affected by significant changes in other causes of death, figure 5b shows absolute figures for smoking-attributable deaths across the EU. This shows a similar pattern to figure 5a.

Fig 5. - Smoking-attributable deaths: a) as a proportion of all deaths and b) in thousands per year, in the EU25, 1965-2000

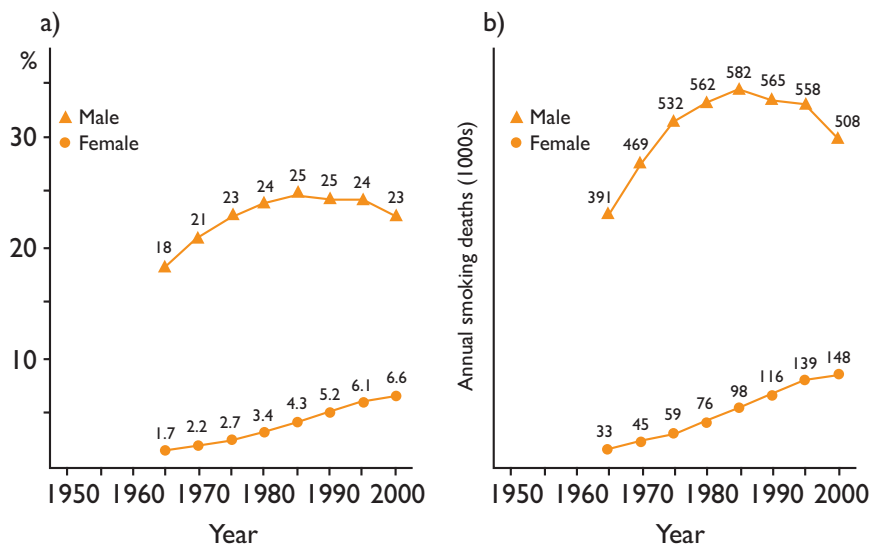


Figure reproduced with permission from Peto *et al.*<sup>8</sup>.

Figure 6 gives these trends for people aged 35-69 years, a closer approximation to the impact of smoking, as the patterns in mortality and the separation of smokers and never-smokers are more pronounced for this age group.

Figures 7 and 8 illustrate the smoking-attributable deaths as a proportion of all deaths for 35-69 year olds and in absolute numbers, in the EU15<sup>e</sup> and the 10 new Member States separately.

<sup>e</sup> EU15 are the 15 Member States of the former EU

Fig 6. - Smoking-attributable deaths a) as a proportion of all deaths and b) in thousands per year, for 35-69 year olds in the EU25, 1965-2000

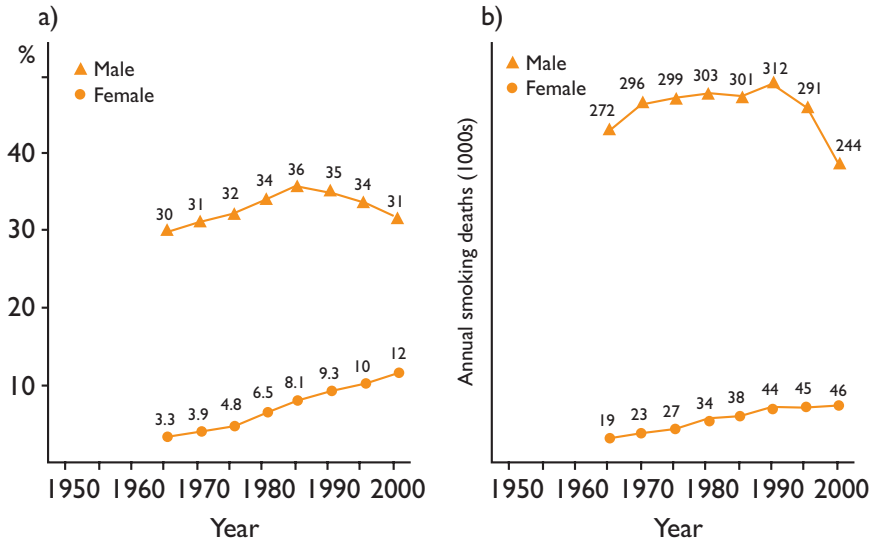


Figure reproduced with permission from Peto *et al.*<sup>8</sup>.

Fig 7. - Smoking-attributable deaths a) as a proportion of all deaths and b) in thousands per year, for 35-69 year olds in the former EU15, 1955-2000

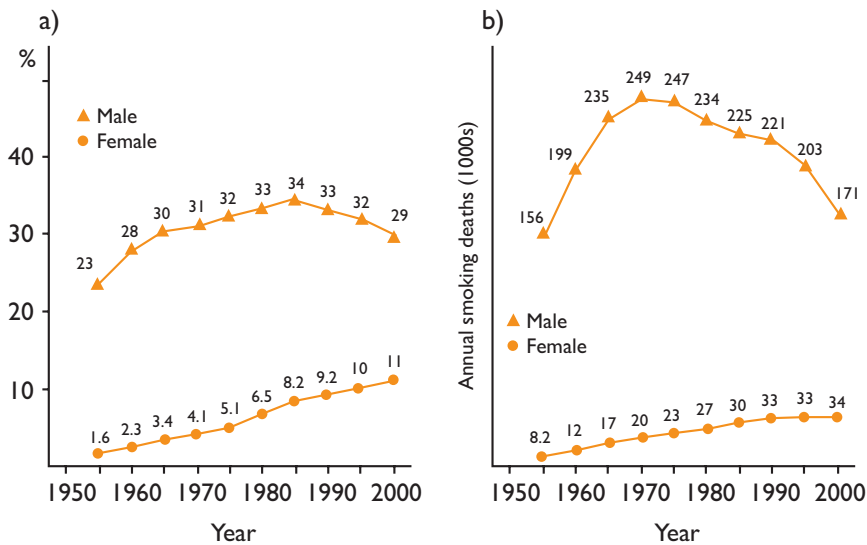


Figure reproduced with permission from Peto *et al.*<sup>8</sup>.

Fig 8. - Smoking-attributable deaths a) as a proportion of all deaths and b) in thousands per year, for 35-69 year olds in the EU10 new member states, 1965-2000

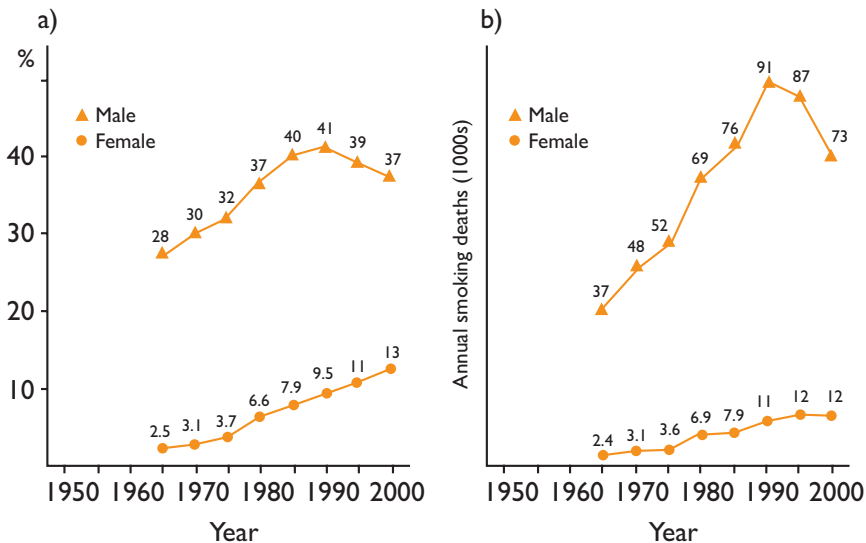


Figure reproduced with permission from Peto *et al.*<sup>8</sup>.

In the EU15, smoking-attributable mortality among males aged 35-69 years peaked at ~34% of all deaths in the mid 1980s and has been declining ever since. Absolute numbers of deaths started an earlier decline, which might indicate that smoking-related deaths were not falling as quickly as deaths from other causes of disease. Smoking-attributable mortality is still rising among females aged 35-69 years.

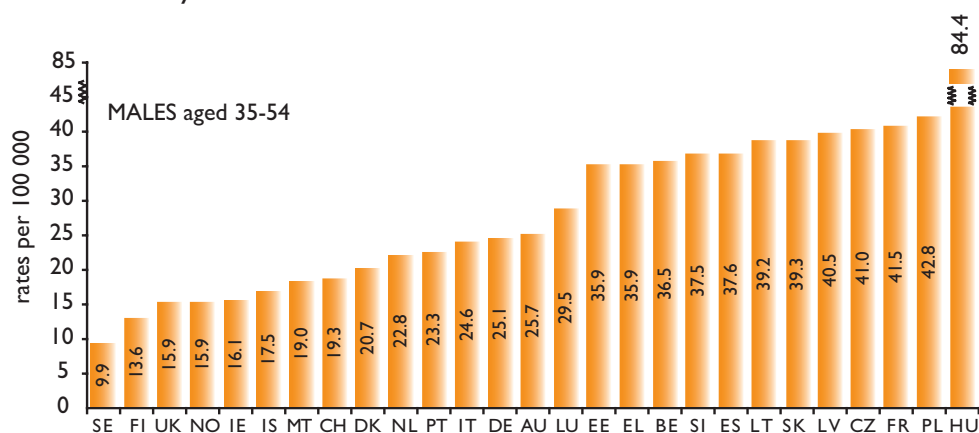
In the EU10 new Member States, smoking-attributable mortality among males aged 35-69 years peaked slightly later (~1990) and at a higher level (~41% of all deaths). Hence, in these countries, two out of every five deaths for 35-69 year olds at that time were caused by smoking. This peak is later than that observed in the EU15, reflecting different trends in prevalence in these countries, where rises in male smoking happened later than in some of the former Member States. The peak is also higher than that observed in the EU15. This could be due to a decline in deaths unrelated to smoking in the 1990s in the new Member States compared to countries of the former EU, which experienced the smoking epidemic at an earlier stage when there were many other diseases, such as infectious diseases, killing people. Females in the EU10 new Member States are now showing similar trends to the other 15 Member States, although their smoking-attributable mortality is lower but rising in a similar fashion.

In order to understand these trends better, it is important to look at country-specific data, as the nations of Europe are at different stages of the smoking epidemic. The closeness of the relationship between cigarette smoking and mortality from lung cancer is profound, and therefore is used here, as it provides a useful marker for the evolution of the smoking epidemic. Caution is needed with comparisons between countries because of possible differences in standards of diagnosis in lung cancer, methods of reporting and collecting data, as well as the reliability of lung cancer death statistics in different countries.

## 3.1.2.1. Trends in mortality from lung cancer

The following figures illustrate mortality rates at country level for cancer, and then trends in lung cancer mortality for males and females aged 35-54 years separately, as this is the age group in which the differences in mortality between smokers and never-smokers are most pronounced. Figure 9<sup>111</sup> shows the standardised mortality rates for lung cancer averaged over the three most recent years for which data are available.

Fig 9. - Standardised mortality rates from lung cancer, average value for last 3 available years<sup>#</sup>



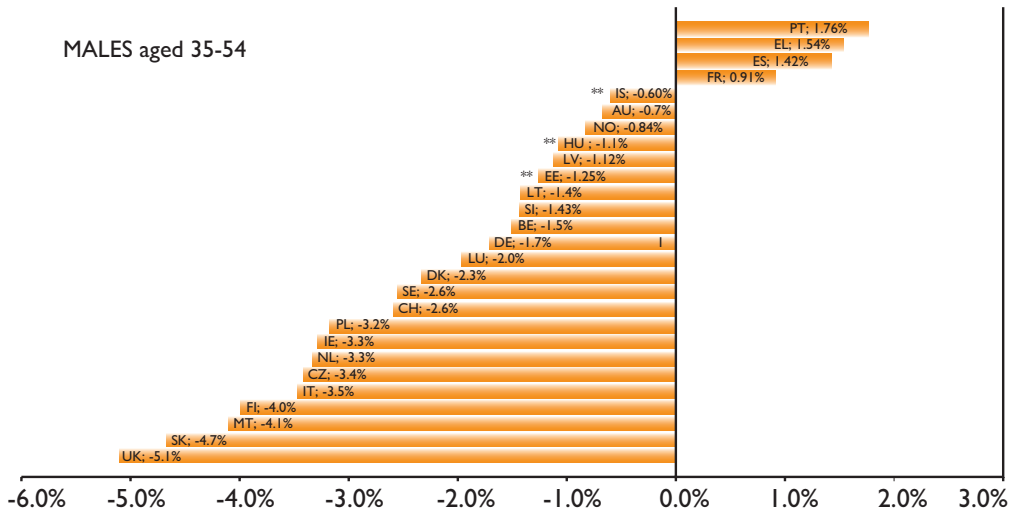
<sup>#</sup>: For most countries 1997-1999 or 1998-2000, for Belgium 1994-1996; data not available for Lichtenstein or Cyprus. Figure modified from Zatonski<sup>111</sup>.

Standardised mortality rates for lung cancer are lower in countries predominantly but not exclusively from the EU15 (most notably Sweden, Finland and the UK), whilst much higher levels are found predominantly but not exclusively among the new 10 Member States. Hungary stands out as having very high standardised mortality rates for lung cancer, twice as great as Poland, which has the second highest rate. Sweden has the lowest rate.

Figure 10 shows the year-on-year changes in lung cancer mortality rates among males over the most recent 10 years for which data are available. The greatest rate of decrease in lung cancer mortality is found in the UK. This trend began from a very high baseline level in the early 1960s and has been occurring for a few decades. In other countries the decrease began later and the change has been less dramatic. In some countries, such as Hungary and Lithuania, the decline only began in 1993/1994. In four countries, Portugal, Greece, Spain and France, where the rates have historically been low, an increase in lung cancer mortality is still observed.

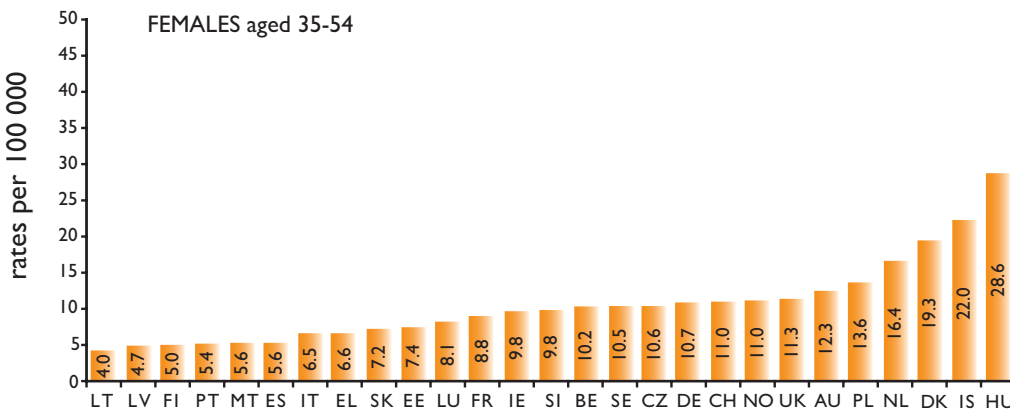
For females the picture is very different (figs 11 and 12). The current standardised mortality rates generally are lower than in males (fig. 9), but the between-country variation is again marked. Once again, females in Hungary have the highest standardised mortality rate for lung cancer, their level exceeding lung cancer mortality rates in males in more than half of the EU.

Fig 10. - Average yearly change in lung cancer mortality over 10 last available years, usually 1991-2000#



#: for Belgium 1987-1996; for Hungary, Lithuania and Romania the decline began in 1993-1994; data not available for Lichenstein or Cyprus, Norway is also excluded because only 5 years of data were available. \*\*: Statistically nonsignificant. Figure reproduced with permission from Zatonski<sup>111</sup>.

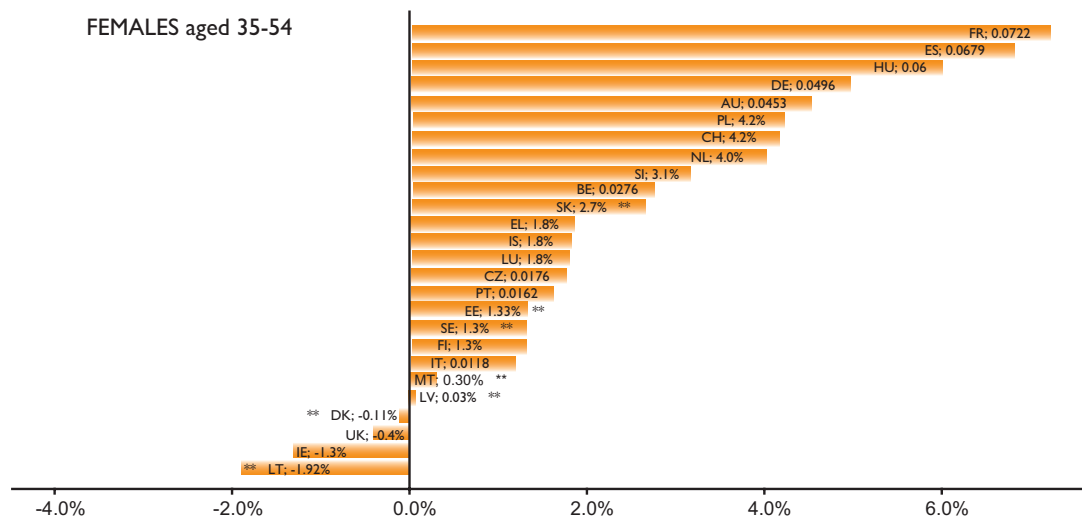
Fig 11. - Standardised mortality rates from lung cancer; average value for 3 last available years#



#: For most countries 1997-1999 or 1998-2000; for Belgium 1994-1996; data not available for Lichtenstein or Cyprus. Figure reproduced with permission from Zatonski<sup>111</sup>.



Fig 12. - Average yearly change in lung cancer mortality over 10 last available years, usually 1991-2000<sup>#</sup>



<sup>#</sup>: For Belgium 1987-1996; data not available for Lichtenstein or Cyprus, Norway is also excluded because only 5 years of data were available. \*\*: Statistically nonsignificant, very small numbers for Lithuania, Estonia and Malta. Figure reproduced with permission from Zatonski<sup>111</sup>.

Figure 12, however, shows that the vast majority of the countries in Europe are still observing increases in mortality from lung cancer among females. Only the UK and Ireland are showing systematic decreases. The greatest rates of increase in the last decade have been in France and Spain (from very low baseline levels), and Hungary. In these and other European countries, the impact of the current high prevalence of smoking among young females will not manifest itself for a few decades. Hence, female mortality from smoking is likely to rise in many European countries for many years to come.

### 3.2. Impact of other forms of tobacco

Although cigarette smoking has been very heavily researched, little is known about the public health impact of other forms of tobacco. For example, there is little evidence of the impact of smokeless tobacco use across Europe, although the widespread use of snus in Sweden over time provides some data (see Swedish case study below).

#### 3.2.1. Low tar cigarettes

As discussed in Chapter 5, following expert advice, the European Commission has followed a policy of progressively reducing machine-based maximum tar yields of cigarettes in the EU (from 1 January 2004 the maximum tar yield was 10 mg tar; Greece was granted a derogation until 1 January 2007). Many European smokers have moved to lower tar cigarettes over the last few decades in the belief that these are less dangerous than ordinary cigarettes<sup>112</sup>, a perception that was also encouraged by the tobacco industry<sup>113</sup>.

Recent reviews of the scientific literature have concluded that there is no convincing evidence of any benefit to public health from reductions in tar yields<sup>1, 114, 115</sup>.

### 3.3. Case studies

A few countries have been selected to discuss these issues in more detail:

- UK, because it is illustrative of stage four of the smoking epidemic;
- France, because the epidemic in females has not yet peaked, and mortality from lung cancer has been rising in both females and males in the last decade;
- Poland and Hungary, because tobacco-related mortality is high in these new Member States;
- Sweden, because it has the lowest mortality rates for lung cancer in males and also because the use of a form of smokeless tobacco, snus, is widespread among Swedish males.

As mortality patterns can only be fully understood in relation to changing patterns of tobacco consumption a few decades earlier, trends in use of tobacco for each of the country case studies are also briefly described. Further information on prevalence is given in Chapter 4.

#### **3.3.1. UK (see figure 13)**

The UK was the first country in the world to observe very high prevalences of smoking (~80% at the end of World War II among males) and (with Finland) high rates of smoking-attributable deaths. It is now considered to be in stage four of the smoking epidemic. Smoking-attributable mortality has been decreasing steadily since the mid-1960s and now accounts for 23% of all deaths among 35-69 year olds. As mentioned above, younger males in the UK now have one of the lowest mortality rates for lung cancer in Europe and they had the fastest rate of decline in lung cancer mortality in the 1990s (fig. 10). Among females the picture is different; figure 13 illustrates how female smoking-attributable deaths continued to increase after males peaked and only recently have begun to decline. Also notable in the UK is the fact that smoking is much more common among poorer groups in society (see also Chapter 4).

The sharper reduction in absolute numbers of deaths observed for males in figure 13b compared with that observed in male deaths as a proportion of all deaths in figure 13a suggests that deaths from causes of disease other than smoking were falling more quickly than smoking-related deaths during this time.

Fig 13. - Smoking-attributable deaths a) as a proportion of all deaths and b) in thousands per year, for 35-69 year olds in the UK, 1950-2000

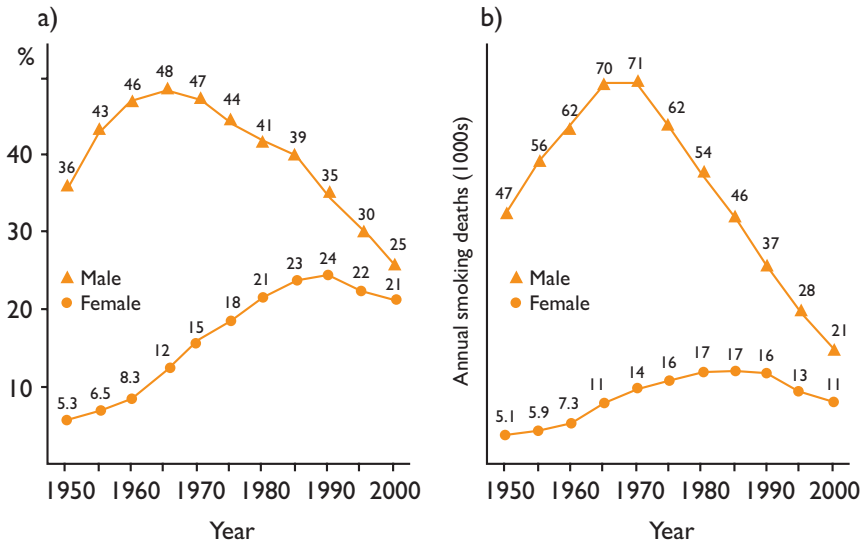


Figure reproduced with permission from Peto et al.<sup>8</sup>.

**3.3.2. France (see figure 14)**

The picture in the UK can be contrasted with that of France, where overall smoking-attributable deaths among 35-69 year old males are still very high, albeit at a lower level than that observed in the UK in the 1960s. Female smoking-attributable mortality only became measurable in the mid 1980s and is now increasing steadily.

Fig. 14. - Smoking-attributable deaths a) as a percentage of all deaths and b) in thousands per year, for 35-69 year olds in France, 1950-2000

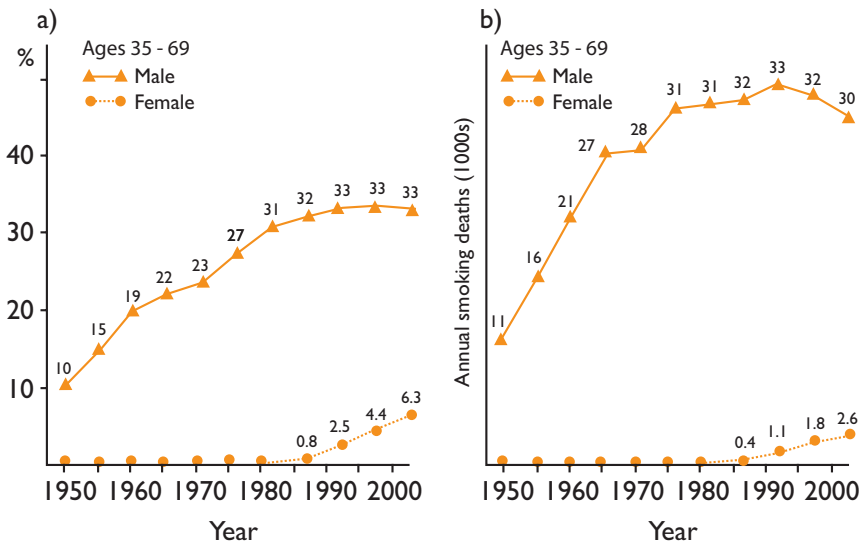


Figure reproduced with permission Peto et al.<sup>8</sup>.

Fig. 15. - Trends in mortality from lung cancer in males aged 35-54 years in the UK and France

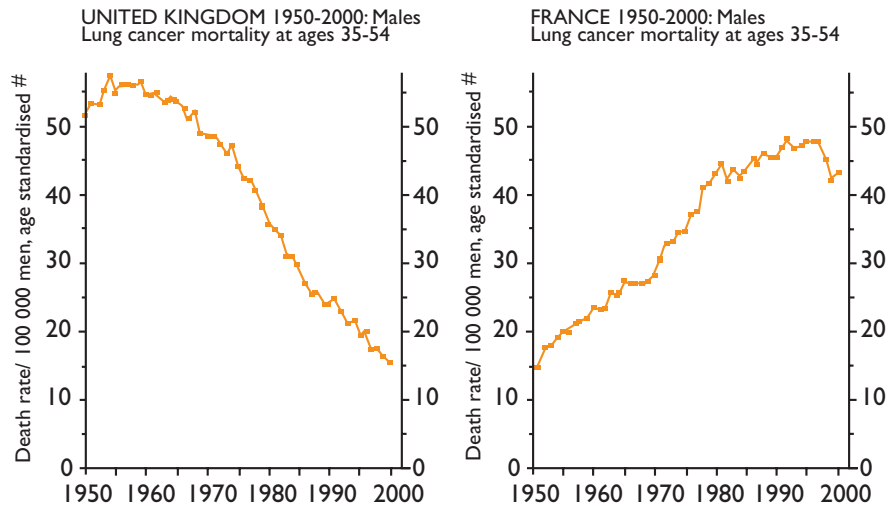


Figure modified from Zatonski<sup>111</sup>. #: Mean of annual rates in component 5-year age groups.

As mentioned earlier, mortality from lung cancer amongst middle-aged French males was still rising in the last decade (fig. 10). For males aged 35-54 years, mortality from lung cancer is showing largely the opposite pattern to males in that age group in the UK (fig. 15).

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### 3.3.3. Poland (see figures 16 and 17)

After World War II, the manufacturing of tobacco products was standardised across the entire Soviet bloc via national tobacco monopolies, and the tobacco market consisted nearly exclusively of factory-made cigarettes produced locally. The state promoted cigarettes as important basic goods and smoking was not only an acceptable behaviour but also a social norm. The prevalence of smoking among health professionals, especially females, was higher than in the general population.

This situation continued in Poland until the beginning of the 1980s, when the Solidarity movement began the transformation to democracy in Poland and the health effects of smoking were widely debated. Cigarette consumption peaked in the late 1970s and then decreased for the first time in history. Male deaths from smoking peaked in the late 1980s, but only began to decline in the 1990s. Female smoking-attributable mortality began to increase markedly in the 1970s and is still increasing.

Fig. 16. - Smoking-attributable deaths a) as a percentage of all deaths and b) in thousands per year, for 35-69 year olds in Poland, 1955-2000

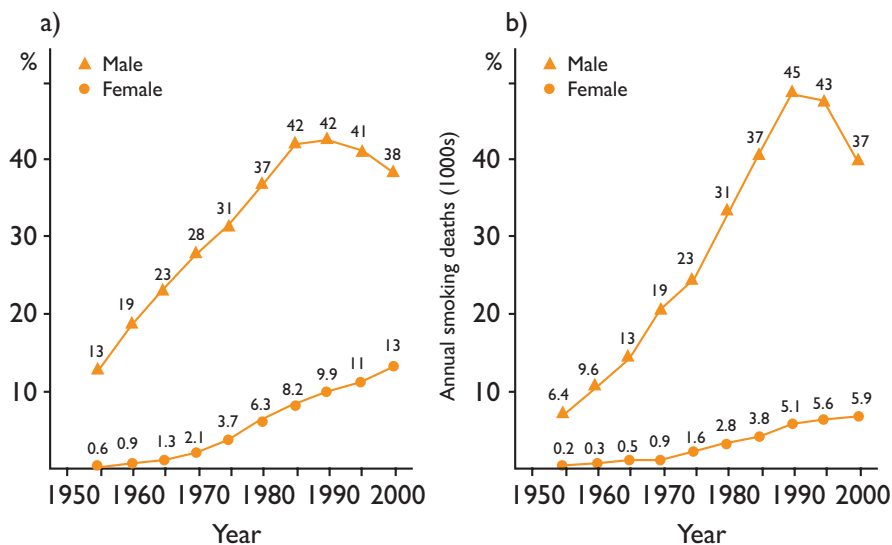


Figure reproduced with permission from Peto *et al.*<sup>8</sup>.

Fig. 17. - Trends in mortality from lung cancer in males and females aged 35-54 years in Poland

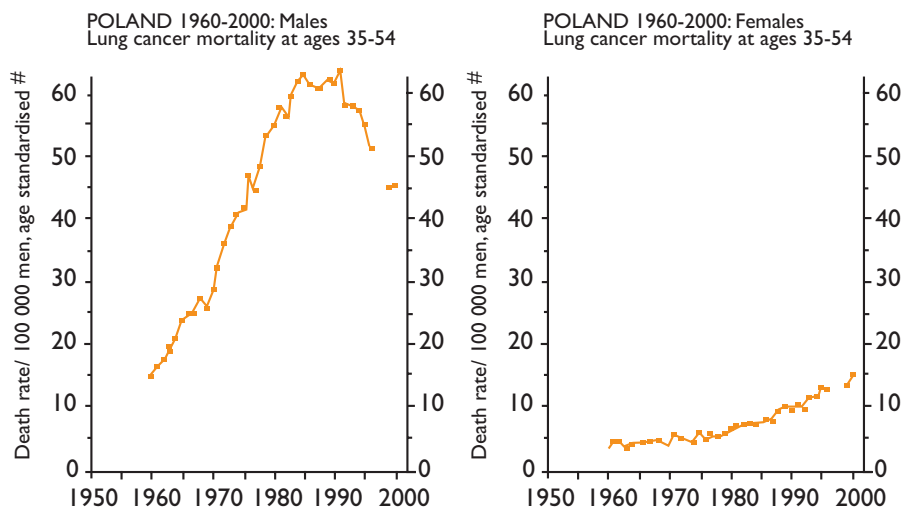


Figure modified from Zatonski<sup>11</sup>. #: Mean of annual rates in component 5-year age groups.

### 3.3.4. Hungary (see figures 18, 19 and 20)

Trends in smoking in Hungary followed a similar pattern to those in Poland. Although cigarette consumption started to decrease in the second half of the 1990s, mainly due to tobacco control measures taken by successive governments, Hungarians are still one of the heaviest smoking countries, ranking 8th in the world based on per capita cigarette consumption in adults (15+)<sup>116</sup>.

This history of very heavy cigarette consumption could help explain the very high rates of standardised mortality for lung cancer observed among males and females in Hungary (fig. 19) and as discussed above. Figure 20 shows the close relationship between cigarette consumption and cancers of the respiratory tract. Between 1948 and 2001, lung cancer mortality increased 10 fold<sup>116</sup>.

Fig. 18 - Smoking-attributable deaths a) as a percentage of all deaths and b) in thousands per year, for 35-69 year olds in Hungary, 1955-2000

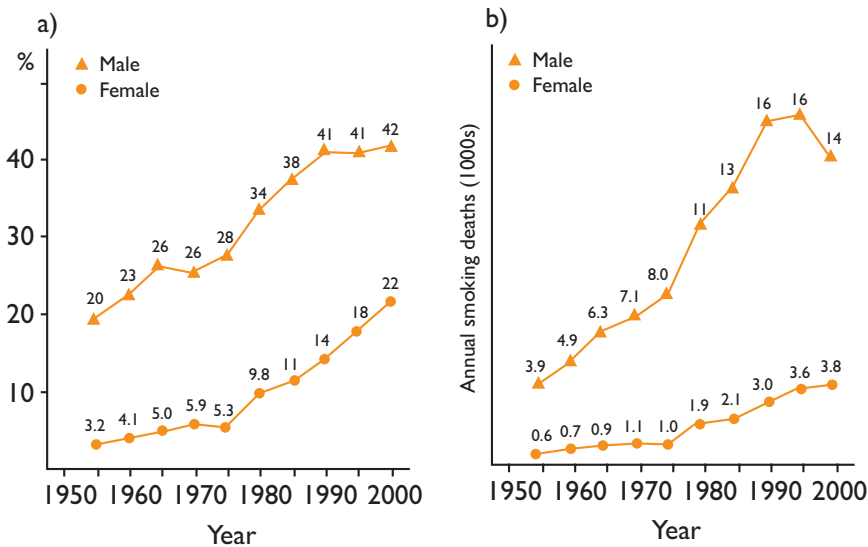


Figure reproduced with permission from Peto et al.<sup>8</sup>.

Fig. 19 - Trends in mortality from lung cancer in males and females aged 35-54 years in Poland

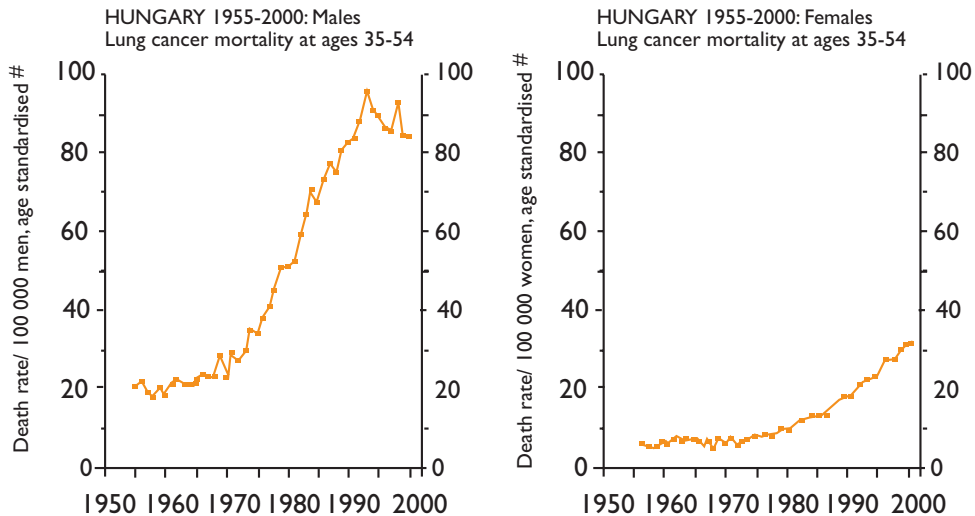


Figure modified from Zatonski<sup>111</sup>. #: Mean of annual rates in component 5-year age groups.

Fig. 20 - Cigarette consumption versus deaths from cancers of the respiratory tract in Hungary 1951-2000

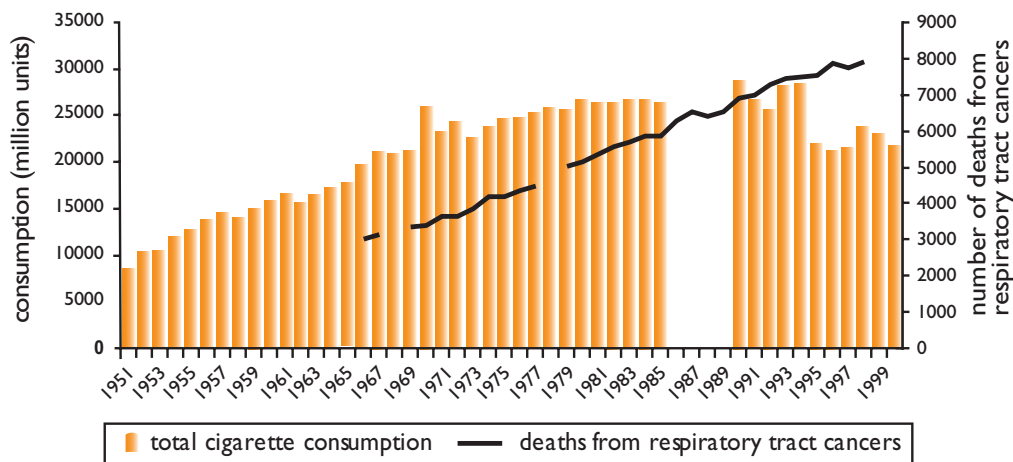


Figure reproduced with permission from Szilágyi<sup>116</sup>.

### 3.3.5. Sweden (see figures 21, 22 and 23)

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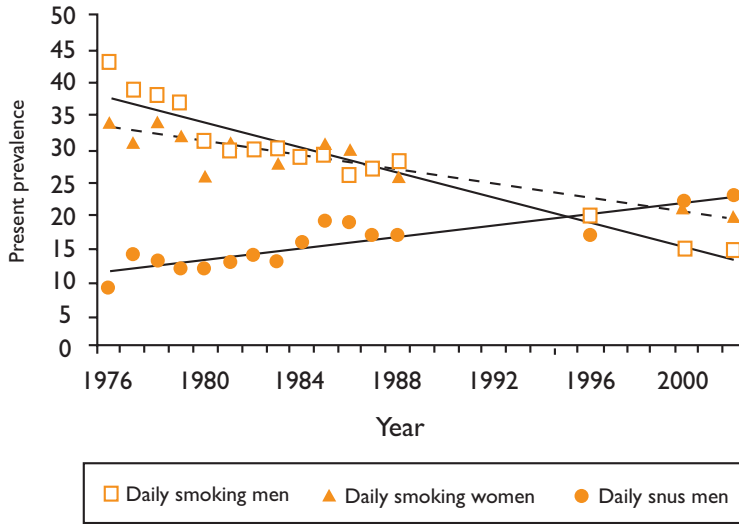
While half of the adult males (but <10% of adult females) were smokers in the mid-1940s, cigarettes accounted for less than one-third of the total tobacco consumption, with snus accounting for 40% and pipe tobacco accounting for one-fifth. Soon after the war, cigarette consumption began increasing rapidly, especially among the youth and females. In 1963, cigarettes accounted for almost 65% of total tobacco consumption and 80% of the tobacco smoked. Smoking among males reached its peak by the end of the 1960s and started to decrease during the 1970s. Among females, the increase continued and the decrease began only at the end of the 1970s. In 2002, 16% of adult males were daily smokers, compared with 19% of adult females. However, there has been an increase in the prevalence of occasional smoking. (If occasional smokers are included, the prevalences of smoking are 29% for males and females alike.)

In 2001, cigarettes accounted for almost 40% of total tobacco consumption and ~83% of the tobacco smoked. Snus accounted for ~53% of the total tobacco consumption and it is predominantly used by males.

Smoking-related mortality never reached the same high levels as in many other European countries (fig. 22). A decrease is now seen among males but still awaited among females. Indeed, figure 9 shows that Sweden had the lowest standardised mortality rate of lung cancer in males across the EU and EFTA countries.

Given the use of smokeless tobacco, rates of oral cancer in Sweden have been compared with other countries. Sweden has a low rate of oral cancer by international standards and this low rate has been falling over the past 20 years<sup>117</sup> whereas use of snus has been increasing since the late 1960s.

Fig. 21. - Prevalence of daily smoking for males and females (18-70 years) in Sweden, 1976-2002, and prevalence of daily snus use for males (18-70 years) in Sweden, 1976-2002



Data are presented as observation points and least square regression lines. Reproduced with permission from Foulds et al.<sup>43</sup>.

Fig. 22. - Smoking-attributable deaths a) as a percentage of all deaths and b) in thousands per year, for 35-69 year olds in Sweden, 1955-2000

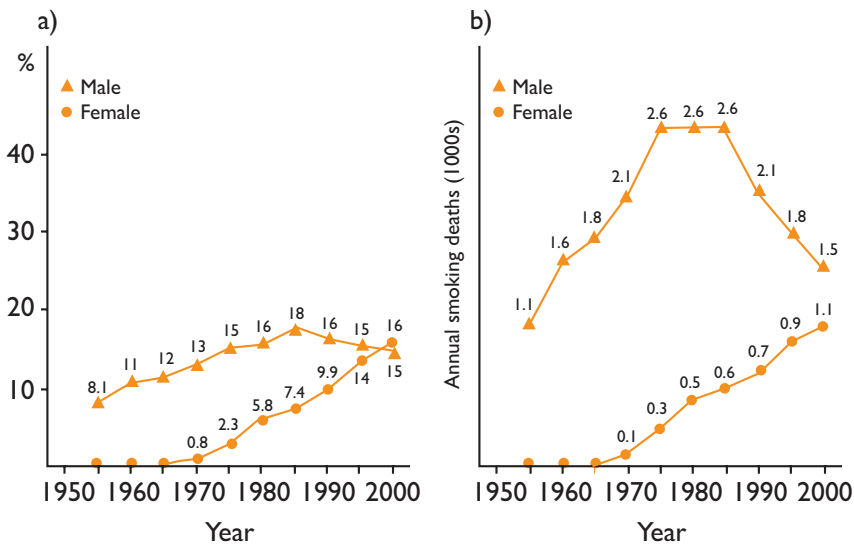


Figure reproduced with permission from Peto et al.<sup>8</sup>.



Fig. 23. - Trends in mortality from lung cancer in males and females aged 35-54 years in Sweden

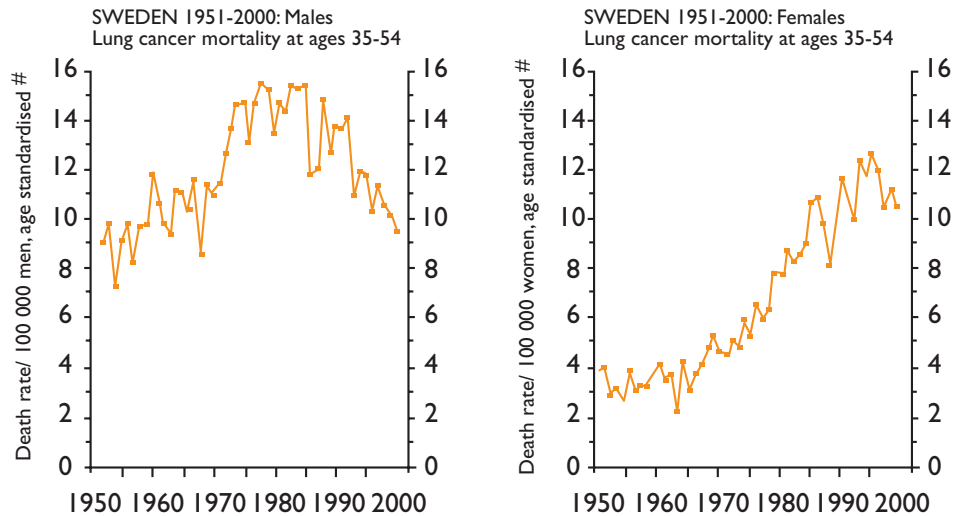


Figure modified from Zatonski<sup>111</sup>. #. Mean of annual rates in component 5-year age groups.

### 3.4. Morbidity from smoking across Europe

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As described earlier in this chapter, a wide range of illnesses and diseases are associated with or caused by smoking. Therefore, many more people are harmed by tobacco use than estimates of mortality indicate. The burden of morbidity is hard to estimate. Regarding COPD, community surveys in Europe have indicated that at least 4-6% of the adult population suffers from COPD<sup>118</sup> (for which active tobacco smoking is the single most important risk factor). A report from the USA suggested that the impact of smoking on morbidity may be 20 times greater than the mortality figures<sup>119</sup>: “For every tobacco-attributable death that occurs, there are approximately 20 people alive who are suffering from a serious, chronic disease that is attributable to cigarette smoking.”

Using this estimate would indicate that more than 13 million Europeans suffer from a serious, chronic disease as a result of cigarette smoking.

### 3.5. Smoking and health inequalities

As we will read in Chapters 2 and 4, use of tobacco and poverty are now inextricably linked. This is a reversal of the earlier picture of the smoking epidemic in European countries, where smoking was common first among males and females in the higher socio-economic groups. In general, as they gave-up, poorer groups took up smoking. In most European countries, smoking is now more prevalent in lower socio-economic groups<sup>120</sup>, which also have a higher burden of other risk factors<sup>121, 122</sup>. In addition, in the UK, cessation rates are lower in the most disadvantaged groups, which may be linked to higher nicotine dependence among these smokers, even after adjusting for cigarette consumption<sup>123</sup>.

Studies in Poland and the UK have demonstrated an association between poverty and an increase in tobacco-related mortality<sup>122, 124</sup>. For example, in Poland, researchers have estimated that tobacco use is responsible for about two-thirds of the excess risk of death in

middle age for those with only primary-level education compared with those with university education.

### 3.6. Mortality and morbidity due to passive smoking across Europe

Estimates of the number of deaths caused by passive smoking are harder to derive than those for active smoking because of the difficulties in establishing the level of exposure over a life time (both at home and in the workplace). Some estimates of exposure have been made, however, and these are summarised below.

In the UK, in 1988, it was estimated that 42% of children and 21% of non-smoking adults lived in a household where at least one person smoked<sup>74</sup>. Given that smoking prevalences among adults in many other countries are higher than they are in the UK, this could result in a potentially high prevalence of exposure to tobacco smoke among children<sup>125</sup>.

Another study estimated that in the EU15, 79% of the population aged 16 years and above were routinely exposed to tobacco smoke pollution (39% often and 40% from time to time) in 1992<sup>71</sup>. A study of seven western European countries<sup>f</sup> involving over 1,500 subjects surveyed between 1998 and 1994 about their exposure to second-hand smoke reported a similar proportion. This study found a combined estimate of passive exposure to tobacco smoke from a spouse or workplace of 79%<sup>126</sup>.

Exposure to tobacco smoke has decreased in some countries over recent years. A study in England found that exposure to passive smoking among children approximately halved from 1988 to 1998<sup>127</sup>. In addition, a study from Finland found that exposure to tobacco smoke at work decreased from ~20% in 1985 to ~6% in 2000<sup>10</sup>.

Nevertheless, exposure is still extensive across many countries in Europe and, given the high background incidence of some of the relevant conditions both in adults (cardiovascular diseases) and in children (lower respiratory tract infections), even the small relative risks described earlier in this chapter translate into substantial levels of mortality and morbidity across Europe<sup>125</sup>. One study estimated that exposure to tobacco smoke caused 50,000-100,000 deaths in the former EU15<sup>103</sup>.

Estimates of morbidity from passive smoking are even harder to make. For example, the WHO has estimated the proportion of lower respiratory tract illness in infants attributable to exposure to tobacco smoke as 15-26%, assuming that 35% of the mothers smoke at home, although the latter figure may be an overestimate<sup>125</sup>. When these estimates were applied to the population of the WHO European Region (51 countries) this resulted in between 300,000 and 555,000 episodes of lower respiratory illness in infants per year related to passive smoking<sup>125</sup>. Another recent review in England and Wales estimated that the percentage of childhood lower respiratory illness and middle-ear disease typically attributable to exposure to tobacco smoke from either parent smoking ranged from 9% for asthma prevalence and for referral for glue ear, to 25% for hospital admission for lower respiratory illness<sup>128</sup>.

As discussed earlier in this chapter, passive smoking can exacerbate underlying conditions. Given the high prevalence of some of these conditions in the population, many millions will be affected across Europe. Table 7 gives an estimate of the prevalence of conditions affected by passive smoking in the UK.

<sup>f</sup> France, Germany, Italy, Portugal Spain, Sweden and the UK.

Table 7. - Prevalence of conditions affected by passive smoking in the UK

GROUP AT RISK	PEOPLE AT RISK N
Lung disease	8,000,000
Angina	2,100,000
Previous heart attack	1,300,000
Previous stroke	400,000
Females of childbearing age	10,800,000
Pregnant females	750,000
Children with asthma	1,500,000

Table modified from the British Medical Association<sup>74</sup>.

All the risks from passive smoking are entirely preventable.

## 4. BENEFITS OF STOPPING SMOKING

No matter where you come from in Europe, or the world, stopping smoking is beneficial and has a dramatic effect. The British doctors study, using 50-year follow-up data<sup>2</sup>, compared the survival of cigarette smokers who stopped with that of those who continued to smoke. Those who stopped before 35 years of age had a survival curve that did not differ significantly from that of never-smokers. Figure 24, from the British doctors study, shows the impact of stopping before the age of 44 years.

Fig. 24. - Effects of survival for male doctors who stopped smoking aged 35-44, 1951-2001

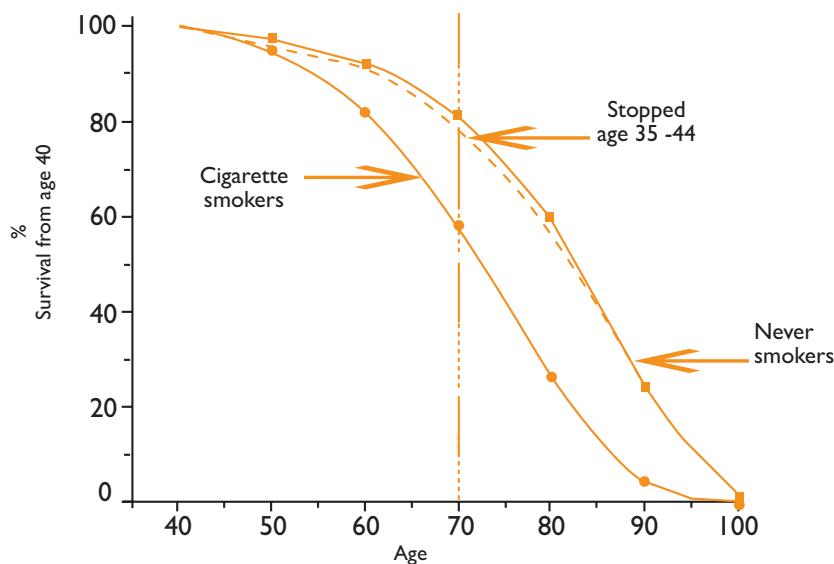


Figure modified from Doll et al.<sup>2</sup>.

The effect of stopping, shown in figure 24, can best be seen by looking at a particular age. Thus, for example, at age 70, just under 60% of current smokers in the study were still alive, compared with about 80% of those who had stopped smoking by 45 years. This is not a small difference. Even at age 90 years the difference is still marked. Only ~5% of smokers are still alive compared with ~25% of those who had stopped by age 35, almost five times as many.

For those who stopped later, this study showed that survival was intermediate between that of never-smokers and that of continuing smokers. But even those who stopped at 65-74 years of age had age-specific mortality rates beyond 75 years that were appreciably lower than those occurring among doctors who continued to smoke. Furthermore, the benefit of stopping in late middle age or old age is probably underestimated in these analyses, as some of those who stopped in later life are likely to have done so specifically because they had already developed serious diseases caused by smoking. Thus, if they were taken out of the analysis, the survival rates for healthier smokers stopping at that age would likely be better.

As Doll *et al.*<sup>129</sup> put it: “Even in middle age stopping smoking substantially increased the subsequent expectation of life.” Stopping smoking in middle age before developing cancer or some other serious disease avoids most of the later excess risk of death from tobacco use.

On the basis of this work Peto and colleagues have argued that if the goal is to reduce smoking-related disease in a population as quickly as possible, the most rapid results will be obtained by focusing on reducing the proportion of adults who continue to smoke, because this will alter patterns of disease within ~20-25 years. Encouraging and supporting adults to quit will itself help to deter children from taking up smoking.

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As with the mortality data, it is possible to see that stopping smoking delays the onset of disease and disability; these data also show that stopping even in later life brings benefits.

The following findings are drawn from the 1990 US Surgeon General's report<sup>130</sup> on the benefits of stopping. This concluded that the risk of serious disease starts going down immediately on quitting:

- in 20 hours carbon monoxide is eliminated from the body;
- in 3 days breathing becomes easier, the bronchial tubes begin to relax;
- in 3 months circulation improves;
- in 3-9 months lung function improves by ~10%;
- in 1 year the risk of heart attack falls to about half that of a continuing smoker;
- long-term stopping smoking reduces the risk of lung cancer, heart disease, strokes, chronic lung disease and other cancers.

Indeed Lightwood and Glantz<sup>131</sup> found rapid improvements in heart disease and stroke from cessation of smoking; the excess risk of an acute myocardial infarction or stroke falls by ~50% within the first 2 years of stopping smoking. They estimated that a national programme reducing the prevalence of smoking by 1% per year in the USA would, in 1 year, result in a mean of over 900 fewer hospitalisations for acute myocardial infarction and over 500 for stroke, resulting in immediate savings of between \$26 and 44 million. We recommend similar calculations be carried out for all European countries.

Even those who have survived an acute myocardial infarction benefit from stopping smoking, which can diminish their risk of a recurrent event by up to half over the first year<sup>132</sup>.

In summary, stopping smoking has substantial immediate and long-term benefits to health for smokers of all ages. The excess risk of death from smoking falls soon after cessation and continues to do so for many years.

Of course, stopping smoking or indeed use of other forms of tobacco can be difficult, largely because of dependence on nicotine.

### 5. TOBACCO USE AND NICOTINE ADDICTION

Nicotine, delivered from tobacco through smoking or oral use, is an addictive drug and tobacco use is, for the majority of smokers, essentially a form of nicotine self-administration<sup>115,133</sup>. The tobacco industry was aware of this in the early 1960s, as revealed by the following quotation from a general counsel to the tobacco company Brown & Williamson: "Moreover, nicotine is addictive. We are, then, in the business of selling nicotine, an addictive drug..."<sup>134</sup>.

The most common form of nicotine use is through cigarette smoking. Cigarette smokers have precise control of nicotine intake. The very rapid absorption of nicotine (once tobacco smoke is in the lungs, nicotine takes just 10 seconds to reach the brain) and the high blood levels that result, promote rapid and strong behavioural reinforcement from smoking. Tolerance to the toxic effects of nicotine, like nausea, develops rapidly and persists. The reinforcing effects of nicotine are renewed with each cigarette because the fall in nicotine level between cigarettes allows resensitisation of the nicotinic receptors in the brain. In summary, cigarettes are extremely efficient nicotine delivery devices which, combined with the pharmacokinetics of nicotine, promote a powerful physical and psychological addiction. How soon people smoke their first cigarette after waking is a measure of addiction. In the UK for example, just over one-third (34%) of smokers in the UK have their first cigarette within 15 minutes of waking<sup>115</sup>.

There are two well known and widely used systems for classifying diseases that address the issue of tobacco use, the WHO's International Classification of Diseases (ICD-10) and the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM-IV). Both clearly classify tobacco use as an addiction and highlight the occurrence of a withdrawal syndrome as a key characteristic of addiction. The withdrawal syndrome, which can be severe, is one of the most important factors in maintaining smoking in individuals. Tobacco withdrawal symptoms include: anxiety, restlessness, poor concentration, irritability, depression, craving, decreased heart rate and increased appetite. Craving, the urge to smoke, is the clearest predictor of relapse to smoking in ex-smokers.

Looking just at data from nicotine users who have been through a treatment programme and stopped smoking emphasises this point from a different perspective. About 75% of those stopping smoking in intensive, professional treatment programmes will be smoking again one year later<sup>115</sup>.

Finally, nicotine has been compared with other addictive drugs, according to several characteristics of addiction or causes of concern. The 1998 Report of the US Surgeon General concluded that: "the pharmacologic and behavioural processes that determine tobacco

addiction are similar to those that determine addiction to drugs such as heroin and cocaine”<sup>130</sup>, a finding endorsed by the English Royal College of Physicians in its report on nicotine<sup>115</sup>.

Since cigarette smoking causes more deaths than these other drugs and yet tobacco is the most used psychoactive drug in the world after caffeine, we can summarise all these findings by saying that nicotine is a classic drug of addiction<sup>115</sup>. However, despite this, stopping smoking is possible. Indeed, many millions of smokers in the EU have managed to give up smoking permanently.

### Acknowledgements

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- 1 US Department of Health and Human Services. The health consequences of smoking: a report of the Surgeon General. Washington, Government Printing Office, 2004.
- 2 Doll R, Peto R, Boreham J, Sutherland I. Mortality in relation to smoking: 50 years' observations on male British doctors. *BMJ* 2004; 328:1519-1528.
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# THE ECONOMICS OF TOBACCO AND TOBACCO CONTROL IN THE EUROPEAN UNION

*Hana Ross*

## I. INTRODUCTION

This chapter is about the economic aspects of tobacco consumption in the European Union (EU). It describes the impacts of smoking behaviour and tobacco-control policies on the economies of the EU/European Free Trade Association (EFTA) members<sup>a</sup>. The chapter does not cover other forms of tobacco consumption (snuff, chewing tobacco, bidis), although these forms of tobacco are also consumed in Europe (albeit on much smaller scale compared to cigarettes).

We have used the best figures available from reliable sources of macro-level data, to which we have applied the appropriate economic tools and methods in order to derive relevant estimates. Our results show that the costs of smoking are substantial, and far outweigh any "benefits" that the tobacco consumption may provide to countries.

The chapter is organised as follows: the next section provides an overview of the tobacco industry and its importance to the European economies. The third section discusses the direct and indirect costs of smoking and estimates their magnitude. The fourth section focuses on tobacco taxes and their role in tobacco control and in governments' budgets. Tobacco smuggling and its economic impact is the topic of the fifth section. In the next section the impact of the industry on social inequality is analysed. The chapter ends with recommendations as to the most effective public policy measures to reduce the costs of smoking in the enlarged EU, and suggests topics for future research to support decision-making related to tobacco controls.

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## 2. TOBACCO INDUSTRY

Tobacco production-related economic activities in Europe include farming, product manufacturing, distribution, and sales. These activities touch many economies in Europe, but the tobacco economies of individual countries vary greatly, and even a significant economic presence does not imply that these economies are dependent on the tobacco industry. The overall impact of tobacco-control policies on the economy depends on the structure of the tobacco industry in each individual country, and on the regional structure within each country. Countries and regions growing primarily tobacco will face challenges different from those in tobacco-manufacturing countries and regions. In addition, the impact will vary based on the European and country-specific trade balance in tobacco products.

A rapid decline in tobacco consumption could create transitional problems. However, the types of declines in tobacco consumption witnessed in the developed countries have been so gradual that they have created few transitional problems of any consequence.

The real issue for countries whose economies might be affected by tobacco-control measures is to reconcile the need to combat smoking for public health purposes with the need to ensure a smooth transition toward alternative economic activities.

<sup>a</sup> The European Free Trade Association includes Iceland, Liechtenstein, Norway and Switzerland.

### 2.1. Tobacco Farming

Tobacco growing represents only a small portion of agricultural activity in Europe as a whole. The EU15b countries devote about 0.1% of their total agricultural area to tobacco growing. Only 1.3% of EU15 farms grow tobacco. The primary growing countries are Greece, Italy, Spain, France and Portugal; Belgium, Germany, and Austria also grow tobacco. However, Greece and Italy together represent 75% of EU15 tobacco production<sup>1</sup>. Among the new EU10c Member States, only four grow tobacco: Poland, Hungary, the Slovak Republic and Cyprus<sup>2</sup>. The tobacco production of the EU10 countries represents together only 10% the amount of production of the EU15 countries.

The share of whole Europe in the volume of world tobacco growing has been declining steadily since 1985 when it represented 17%. The European share, toward the end of the 1990s, was 10% of global production of unmanufactured tobacco<sup>2</sup>.

Tobacco is the most heavily subsidised crop per hectare in Europe. Growers get €7,800 per hectare of land planted with tobacco, which amounts to €7,600 for every tobacco farmer per year<sup>3</sup>. Since the early 1990s, the EU has spent about €1,000 million annually on subsidies to tobacco growers. Despite the effort to reduce these subsidies, tobacco subsidies were €975 million in 2000 (about 2.3% of the Common Agricultural Policy (CAP) budget) and 1.1% of the total Commission budget<sup>4</sup>. This is by far the highest support, compared to other agricultural sectors, creating distorted incentives and high-levels of inefficiency<sup>d</sup>. All new EU Member States have obtained permission from the EU to provide tobacco subsidies from the time of their accession, but only Poland and Cyprus intend to pursue this policy option<sup>1</sup>.

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Tobacco subsidies, part of the CAP, were enacted with the following goals: to encourage farmers to grow commercially viable varieties of tobacco and reduce production of lesser quality varieties; to reduce imports of high quality tobacco; and to improve the income of tobacco farmers<sup>6</sup>. Unfortunately, subsidies have failed to accomplish any of these goals, and engender other unfortunate effects as well<sup>7</sup>:

- Farmers continue to grow low-grade varieties of little commercial value because that is all their growing conditions will support.
- Member States continue to import higher quality tobacco to use in manufacturing cigarettes.
- The scheme is economically inefficient:
  - a) it would be cheaper to give direct income support to farmers than to subsidise them, because subsidies used for means of productions would be saved;
  - b) until export subsidies were eliminated in 1992, the EU was subsidising cigarette manufacture in states that compete with manufacturing Member States;
  - c) according to the European Court of Auditors, the subsidies are poorly managed.

<sup>b</sup> 15 EU member states, includes Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the UK.

<sup>c</sup> Former 10 accession countries, includes Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia.

<sup>d</sup> The combination of production quota (reducing supply, thus increasing the market price), direct subsidies per amount of tobacco produced (reducing the market price), and the export of ~55% of the tobacco grown in the EU probably have minimum impact on the price of the final product on the market. A study found that the tobacco subsidies have almost no impact on cigarette prices<sup>5</sup>.



- The low quality tobacco is sold at very low prices and farmers' income has not been improved.

In April 2004, the Council of Ministers adopted reforms to the CAP that create a transitional scheme to phase in decoupling of payments<sup>e</sup> to farmers from their production levels. Between 2006 and 2010, member states must eliminate subsidies linked to tobacco production levels, but they will still receive money that will be distributed to current tobacco farmers in the form of Single Farm Payment unrelated to tobacco production. After 2010, 50% of all tobacco-related subsidies per holding based on the reference period 2000-2002 will be given to current tobacco farmers in the form of a single payment unrelated to tobacco production, and 50% of these subsidies will finance restructuring programmes in affected regions<sup>8</sup>. The Community Tobacco Fund established in 1998<sup>f</sup> and linked to the level of tobacco subsidies will no longer exist in 2008<sup>9</sup> (Luk Joossens, personal communication, European Cancer Leagues, Brussels, Belgium).

## 2.2. Tobacco manufacturing

Companies involved in the first processing of tobacco leaves are mainly located in the EU15 Member States where production of raw tobacco is concentrated in Italy and Greece<sup>1</sup>. Tobacco manufacturing is different. The most important producers of cigarettes are Germany, the UK, and the Netherlands, who together made 63% of EU15-manufactured cigarettes in 1999<sup>1</sup>. The Netherlands and Germany are the main producers of cigars (67% of EU15 production) and of pipe tobacco (also 67%). Unlike the situation in tobacco farming, the European share of cigarette manufacturing has not changed substantially during the 1990s and is estimated to represent 25% of global cigarette production<sup>2</sup>.

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## 2.3. Trade in tobacco

Trade in tobacco is important for the EU. In 2000-2002, the EU15 imported, in value, 34.7% of the unmanufactured tobacco traded in the world, but only 5.4% of the manufactured tobacco. At the same time, the EU15 exports represent almost 20% of manufactured and 7.6% of unmanufactured tobacco worldwide<sup>1</sup>. This is because the local production of raw tobacco is inadequate in quality and quantity to satisfy the needs of the manufacturers. Of the 350,000 t of raw tobacco produced in the EU15, 55% is exported<sup>1</sup>. The EU15 imports annually more than 500,000 t, or the equivalent of 160% of its production<sup>1</sup>. Most of the tobacco used in the EU for manufacturing cigarettes is imported; the manufactured cigarettes are either exported or consumed in the EU<sup>1</sup>.

The new EU Member States export an average of 9,470 t annually, mostly to the EU15 countries, while importing 92,060 t from the EU15 countries, Brazil, the USA, and Zimbabwe<sup>1</sup>. In summary, the EU is a net importer of raw tobacco and a net exporter of manufactured tobacco products.

Economic theory would predict that a country that is a net importer of raw tobacco or cigarettes could enjoy modest short-term economic gains from the transition to a population less dependent on tobacco<sup>10</sup>. Reduced spending on imports will permit more domestic

<sup>e</sup> Decoupling means separating the amount of subsidies from the amount of tobacco grown.

<sup>f</sup> The fund was established to inform the public of the danger of smoking, to support research to develop less harmful tobacco varieties, alternative uses for tobacco, and switching to alternative crops and activities.



spending, possibly generating more employment<sup>11</sup> and leading to an improved trade balance<sup>12</sup>. Countries that are net exporters are will not be affected by policies reducing domestic consumption. Therefore, it is possible to conclude that the overall impact of reduced smoking prevalence in the enlarged EU on both trade balance and overall employment will be positive.

### 2.4. Employment in the tobacco industry

In 2000, jobs related to the tobacco industry represented a small percentage of total EU employment. There were about 126,070 full time job equivalents (FTE) in tobacco growing, another 13,372 FTE jobs in tobacco processing, and 50,697 FTE jobs in tobacco manufacturing. The total estimated employment in tobacco-related occupations in the EU countries was 190,139 jobs<sup>1</sup>. This represents 0.13% of total EU15 employment<sup>13</sup>.

Current trends in farming and manufacturing have implications for tobacco-related employment. There has been a continuous decline in tobacco-related jobs in Europe. According to the International Labour Organization (ILO), the employment declined during the 1990s in all countries except Poland, which registered a small increase<sup>2</sup>. This is due primary to decreasing demand for low-quality tobacco grown in Europe, but also due to increased automation and rationalisation of the manufacturing process<sup>2</sup>. A UK study found that 82% of the jobs lost in the UK tobacco industry between 1963 and 1985 were due to productivity improvements (mechanisation and rationalisation)<sup>14</sup>.

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The research evidence suggests that the impact of tobacco-control policies on the overall employment in Europe will be negligible<sup>10,15</sup>. The money currently spent on tobacco will be spent on other products and services, creating different types of jobs. Depending on the spending patterns of current smokers and those who quit smoking, the shift from tobacco spending could lead to an improved trade balance (if the new spending pattern is more favourable to domestic products), to more investments (if some money not spent on tobacco translates into higher savings), or to higher employment (if the demand shifts to more labour-intensive sectors of the economy).

However, it is important to acknowledge that the sensitivity of some regions in Europe to tobacco-related employment will be greater, even if the overall level of employment in Europe will not be affected. These regions should be targeted with programmes aimed at helping tobacco farmers to switch to alternative crops/activities while phasing out tobacco subsidies. The experience from the USA shows that even if the tobacco-producing regions in the southeastern part of the USA have suffered job losses, all non-tobacco regions have collectively gained enough employment to offset the losses<sup>16</sup>.

## 3. COSTS OF SMOKING

In doing economic analysis, the policy question we seek to answer dictates which definition of the cost of smoking to employ, and the perspective from which these costs are counted. For example, the perspective could be that of a government department, the healthcare sector of the economy, or all of society. Consistency in defining costs and in perspective is particularly important to avoid both double counting and erroneous identification of transfers of funds in the economy as costs<sup>17</sup>.

### 3.1. Methods

We employed the widely used prevalence-based approach to estimating the cost of smoking. This approach is based on the estimated prevalence of smoking-related illnesses in a given year and on the costs associated with those illnesses. Because of the long time lag between smoking initiation and the onset of most smoking-related illnesses, these estimates reflect historical trends in smoking, and tend to mask the magnitude of future costs, which depend on current smoking prevalence.

### 3.2. Economic burden of smoking

The European region is disproportionately negatively affected by tobacco mortality and morbidity<sup>18</sup>. These premature deaths represent a loss of human capital, since the skills and talents of those who die prematurely are lost to society.

Apart from the loss of human capital attributable to smoking, there are also other direct and indirect costs of smoking that impose economic burdens on both smokers and non-smokers. The direct costs are usually associated with healthcare for smoking-related diseases among smokers and second-hand smoke (SHS) victims<sup>g</sup>. The indirect costs are mostly linked to productivity losses, and to foregone income taxes and contributions to social security among patient-smokers, patient-SHS victims, and the people who care for them, who would otherwise be in paid employment ("informal care").

There is very little information about the direct and indirect costs of smoking in Europe. Some estimates are available for individual countries like the Netherlands, Germany, Sweden, Iceland, and the UK, but they employ different methods, making the resulting figures incomparable. There are no peer-reviewed studies estimating the costs of smoking in the new EU10 Member States<sup>h</sup>. This lack of knowledge creates an urgent need for a comprehensive study estimating the costs of smoking. At the moment it is only possible to make provisional estimates of smoking-attributable costs. We have applied two methods to generate such provisional estimates.

The first method is based on the notion that there are two major categories of diseases associated with smoking: respiratory diseases and heart diseases. The European Respiratory Society (ERS) estimates<sup>21</sup> that the annual economic burden of respiratory diseases (including lung cancer) in all of Europe in 2000 was approximately €102 billion, or €118 per capita. The study included some indirect costs related to workday losses due to morbidity (€48.3 billion or 47.4% of the total) and due to premature mortality and rehabilitation (€20.0 billion or 19.6%), and some direct costs associated with inpatient and outpatient care (€17.8 billion or 17.5%, and €9.1 billion or 8.9%, respectively) and costs of prescription drugs including VAT (€6.7 billion or 6.6%). However, the costs of informal care, the cost of treating reproduction problems, and SHS are not included. According to the World Health Report 2002<sup>22</sup>, the smoking-attributable fraction for chronic respiratory disease among industrialised countries falls into the range of 56-80%. Therefore, it is possible to attribute between €57.12 billion and €81.6 billion of these costs to the burden of smoking in Europe. About 2/3 (67%)

<sup>g</sup> Studies have shown that passive smoking in the workplace can increase the risk of lung cancer by 17-39%, and one occupational death from cancer costs an average of €2.14 million (measured by the willingness to pay), over €70 billion per year in the EU countries<sup>19</sup>.

<sup>h</sup> A recent study commissioned by the National Institute for Health Development in Hungary in 2000 is published on the web<sup>20</sup>.

of these costs, or €38.27 billion to €54.67 billion belong to the category of indirect costs. These are conservative estimates due to the omission of some costs categories.

Each year, approximately €74 billion is spent on treating cardiovascular diseases (CVD) in the EU15. In addition, another €106 billion a year represents indirect costs due to productivity losses of premature death and disability<sup>23</sup>. Again, the costs of informal care, the cost of treating reproduction problems and costs of SHS are not included. According to the World Health Report 2002<sup>22</sup>, the smoking-attributable fraction for CVD among industrialised countries is 22%. Therefore, it is possible to attribute about €16.28 billion of the direct costs, and about €23.32 billion of the indirect costs of treatment of CVD to smoking in EU15. Extrapolating per capita costs in the EU15 to the population of EU25/EFTA will result in €48.71 billion a year of the total cost of smoking due to CVD.

Smoking-attributable costs for these two categories of diseases provide a conservative cost of smoking estimate for Europe, which ranges between €105.83 billion and €130.31 billion, or between €228 and €281 per capita. The indirect costs represent about 2/3 of the total costs of smoking, and are between €70.55 billion and €86.87 billion.

There are several reasons to expect that the true costs are larger. Only major diseases associated with smoking (respiratory diseases and CVD) are included in these estimates, and even for these diseases, not all costs are considered (e.g. the costs of informal care, the costs linked to the treatment of reproduction problems, the costs related to SHS and budgetary costs related to social services are not included). On the other hand, the costs of respiratory diseases covers all European countries, thereby overestimating the amount attributable to countries covered by this report. However, it is reasonable to expect that the majority of costs associated with smoking is disproportionately carried by EU/EFTA countries, due to their more developed healthcare and social security systems and the relative higher value of workdays lost due to smoking-related morbidity.

To verify the magnitude of the estimates of smoking-related costs calculated by applying the first method, we used a second method based on extrapolation of a 1996 estimate of costs of smoking from Germany alone. The economic burden of direct and indirect smoking-related costs in that year was €16.56 billion for selected diseases associated with smoking. These diseases included Chronic Obstructive Pulmonary Disease (COPD), lung cancer, stroke, coronary artery disease, cancer of the mouth and larynx, and atherosclerotic occlusive disease. Again, these costs did not include the costs of informal care, costs related to reproduction diseases, and costs of SHS. The direct costs represent 51% of the total, or €8.48 billion. The indirect costs accounted for 49% of the total, or €8.08 billion<sup>24</sup>. Calculating per capita costs, extrapolating them to the EU/EFTA population<sup>i</sup> and adjusting them for inflation between 1996 and 2000<sup>j</sup> will result in a 2000 estimate of costs of smoking making this figure comparable with the estimate based on the first method. On this basis, the projected estimate of direct and indirect costs of smoking for EU/EFTA countries is €97.70 billion, of which the direct costs of smoking are €49.83 billion, and the indirect costs of smoking are €47.87 billion. This estimate of smoking-related costs falls in the lower bound of estimates based on the first method.

<sup>i</sup> Given that the standard of healthcare and the per capita expenditures are lower in the new EU10 Member States, applying the estimates from Germany would lead to overestimating the healthcare costs. However, the smoking rate in many of these countries exceeds the smoking rate in Germany, which suggests proportionately larger smoking-related costs.

<sup>j</sup> Consumer price index for Germany<sup>25</sup>.

To conclude, the estimates of costs of smoking in the region of interest ranged from €97.70 billion to €130.31 billion in 2000, with the indirect costs representing at least half of the amount. This amounts to between €211 and €281 per capita (for both smokers and non-smokers), or between 1.04% to 1.39% of the region's Gross Domestic Product (GDP) in 2000<sup>k</sup>. The cost of smoking as the share of the GDP is comparable to estimates from other developed countries. A 1986 study estimated that the total social cost of smoking represented 1.4% of GDP in the USA<sup>27</sup>, and a 1999 study, also for the USA, found that the 1993 costs of smoking were 0.84% of GDP. Smoking-related costs in Canada range between 1.39%<sup>28</sup> and 2.2%<sup>29</sup> of its GDP. Two studies from Finland found that smoking cost the society 1.2-1.3% of GDP in 1987<sup>30</sup>, and 0.8% of GDP in 1995<sup>31</sup>.

A recent study from Hungary<sup>32</sup> concluded that the total cost of smoking (including the direct and indirect costs) was HUF 230 thousand million (about 1,146 million ECU<sup>l</sup>) in 1996 and HUF 270 thousand million (about €1,072 million) in 1998. This represents a loss of 2.7% and 3.2% of GDP in 1996 and 1998, respectively<sup>33</sup>. An updated estimate for 2002 indicates that the costs of smoking represent up to 4% of Hungarian GDP<sup>34</sup>. This estimate indicates that the relative economic burden of smoking may be larger among the new EU10 countries.

It is important to realise that the estimate for the European region of interest is rather conservative, because it does not take into account the costs of informal care, costs related to SHS, the costs of reproduction diseases, and the social costs of unwanted nicotine addiction, which can be quite substantial. In addition, the intangible costs such as costs of pain and suffering have not been included in these estimates. The much more comprehensive estimates of net social costs that included the social costs of unwanted nicotine addiction for Australia, range between 2.1% and 3.4% of GDP<sup>35, 36</sup>.

### 3.3. Who bears the costs?

Substantial portion of costs of smoking are borne by smokers themselves. They are true opportunity costs, because the money spent on tobacco and medical care related to smoking could be either spent on other products or be saved and invested. The economic theory calls these expenditures internal costs, because they are supposed to be offset by the utility a smoker derives from smoking. External costs are imposed by smokers on others and they constitute a rationale for government interventions. However, the addictive nature of cigarettes leads in some cases to inefficient consumers' decision, which also calls for a government intervention in these private decisions. Estimates from the USA suggest that these internal costs are more than 100 times larger than external costs<sup>37</sup>.

Non-smokers also pay for costs of smoking, primarily in the form of higher health insurance premium, medical costs related to SHS, higher taxes and higher prices for products and services.

Government incurs many smoking-related costs. The size of these costs depends on the extent to which healthcare, prevention and public health services are covered by public funds. The burden on the government appears in the form of larger disability and social benefits payments<sup>m</sup>, lost income tax and lost contributions to social benefits funds.

<sup>k</sup> Calculation by the author using GDP estimates from the United Nations<sup>26</sup>.

<sup>l</sup> The conversion to ECU and € was done using a currency converter website.

<sup>m</sup> Both victims of smoke-related diseases and the families that they leave behind are often eligible for these benefits.

The private sector of the economy is affected by higher insurance costs for smokers (including insurance for health, fire, accident, life insurance), cost related to lower productivity among smoking workers and workers exposed to SHS (time used for smoking breaks, absenteeism), hiring costs to replace labour lost due to tobacco-related morbidity and mortality, and cost related to compounding effect of smoking on workers exposed to other toxins in the workplace<sup>38</sup>. A USA study that considered most of these costs estimated that each smoker costs an employer an additional \$336-\$601 per year in 1980<sup>39</sup>. A study from Scotland<sup>40</sup> estimated that smoking in the workplace cost all Scottish employers between €380 million and €595 million due to lost productivity, €52 million due to higher rates of absenteeism, and €5 million due to fire damage in 1997 figures. This represents 0.51% to 0.77% of Scottish 1997 GDP<sup>41</sup>. A different study from Ireland showed that the costs of smoking incurred in the workplace were €819 million, or 0.7% of Irish GDP in 2002<sup>42</sup>. In the USA, the average annual loss of output arising from smoking-related mortality over the 1995-1999 period was \$81.9 billion which represented 0.98% of GDP for the relevant period<sup>43</sup>.

There are also higher cleaning costs and costs associated with providing smoking areas, and additional costs for those employers that provide sick leave benefits. Some businesses may suffer from opportunity costs due to missed opportunities to carry on business with non-smokers (e.g. restaurant, hotel and entertainment business).

Empirical evidence shows that good health has a positive, sizable, and statistically significant effect on aggregate output<sup>44</sup>. Tobacco consumption, through its negative effect on public health, has a long-term negative effect on the economic growth and prosperity of all countries.

## 4. TAXATION

### 4.1. Rationale for tobacco taxation

Tobacco, unlike most other goods, imposes social costs (called externalities) when consumed. The existence of these costs justifies government involvement in regulating tobacco consumption and constitutes an economic rationale for the excise tax on tobacco products. An economically efficient excise tax should at least cover smoking-related external costs.

In addition, recent economic literature<sup>45,46</sup> suggests that the existence of some internal (or private) costs may also justify government intervention in the personal decision on smoking behaviour. The rationale is that not all individuals correctly account for the adverse effects of smoking behaviour on their own health and/or the risk and the costs of nicotine dependency. In this case the important role of the excise tobacco taxes would be to discourage present and future smoking behaviour.

Tobacco has some advantages as a tax base: it is relatively easy to administer (collected from the highly concentrated tobacco industry), and easy to justify (based on public health arguments and the argument that tobacco has no productive value). In addition, taxing goods with low price elasticity such as tobacco results in the least market distortion, due to the relatively smaller loss in consumers' utility. The low price elasticity of cigarette demand implies that a tax increase will always secure higher revenue, and research evidence has supported that contention in a variety of contexts<sup>47</sup>.

It is important to realise that tobacco taxes are only a transfer of resources already created in the economy, they do not create any new assets. The same transfer of resources would occur if, in a tobacco-free society, taxes were levied on other goods and services. Therefore, these taxes cannot be viewed as benefits associated solely with tobacco consumption. The only adverse welfare impact from collecting taxes from a non-tobacco base would be the marginal costs associated with the switch to an alternative taxable product or service, such as alcohol, waste, fuel, fast food, etc. However, there may be some hidden political costs associated with selection of an alternative taxation base, because new taxes on alternative products/services may be difficult to sell to the public.

#### 4.2. Tobacco tax structure

Tobacco products in Europe are subject to both excise tax (which is levied either as a % of some value, "ad valorem tax", or as a specific amount per cigarette, "specific tax") and value added tax (VAT). The excise tax structure (ad valorem versus specific tax) has implications for cigarette tax revenue as well as for tobacco industry incentives and final cigarette prices.

The advantage of ad valorem tax is that it keeps pace with overall price inflation. The result is that both cigarette prices and tobacco tax revenue are automatically indexed for inflation. The disadvantage of the ad valorem tax is that it is vulnerable to industry pricing strategies. Manufacturers can lower their tax liability by decreasing prices of their products (e.g. by lowering its quality, reducing retailers' margins, or other marketing techniques), which can have negative impacts on state revenue<sup>48</sup>.

The advantage of the specific excise tax is that it is much harder to avoid compared to ad valorem tax. This makes tax collection much less dependent on industry decisions. A specific rate, applied to cheap as well as expensive tobacco, will induce consumers to upgrade their choice of cigarettes, because the relative price of high-quality cigarettes falls. A disadvantage of a specific rate is that, unlike the ad valorem rate, its revenue does not change with the price level. To avoid this effect, the specific rate can be adjusted periodically for changes in the general price index.

The primary manufacturing EU states favour the specific tax due to its higher efficiency with respect to securing budget revenue. The situation is opposite among the EU primary tobacco growing states which favour ad valorem tax due to its protection of their low quality tobacco farming<sup>49</sup>. This difference in tax structure across Europe results in large price differences. At a given tax rate, the higher the proportion of ad valorem tax, the lower the retail price. At a given volume of consumption, this implies less tax revenue.

Another important issue related to tobacco taxes and government budgets is exclusion of tobacco from the consumer price index (CPI). Given the importance of the CPI as the benchmark for inflation, raising taxes on tobacco products (which provide upward pressure on the CPI) is in conflict with low inflationary policies set by central banks and may create a disincentive to raise tobacco taxes. Also, the impact of increasing tobacco taxes in an attempt to discourage tobacco consumption would be offset, to some extent, by adjustments in income tied to CPI movements, even though this impact is relatively small. The EU has already recommended that its member countries exclude tobacco products from their respective CPIs. Luxembourg, France and Belgium have removed tobacco products from their respective CPI<sup>50</sup>.



### 4.3. Tobacco tax regulations

The European Region has a long history of regulating the production, sale, use, trade, and price of tobacco. For decades, the main objective of regulation was to generate public revenues and protect national tobacco growers and manufacturers. It is only very recently that regulation has been oriented, at least in part, towards reducing the health consequences of tobacco use.

Cigarette tax regulation at the EU level dates back to 1972<sup>51</sup>. Since the early 1980s, the EU's tobacco tax harmonisation effort has been marked by disagreements and compromises between the primarily tobacco-manufacturing and the primarily tobacco-growing member states about the appropriate tax regime.

In 1992, in view of the approaching Single European Market, the EU adopted a set of common directives to ensure a level of harmonisation of tobacco tax levels across its member states. It represented a compromise between the ad valorem and the specific taxation proponents. The directives established an overall excise incidence (specific and ad valorem combined) of at least 57% of the retail price of the most popular price category (MPPC). Taken with the minimum specified VAT rate set at 13.04%, the minimum overall level of taxation on cigarettes was 70%. Countries were free to set the balance between ad valorem and specific taxation on the condition that the latter falls in the range of 5-55% of the total tax including VAT. Although they did lead to price increases in a number of countries, these directives did not eliminate the large differences in price and tax levels that characterised the EU market. By the same token, very cheap cigarettes continued to be produced, distributed, and sold<sup>4</sup>.

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The Commission renewed its commitment to using harmonisation of minimum taxation levels as a tool to mitigate public health concerns about the impact of tobacco use<sup>52</sup>. Its 2002 directive tightened the minimum excise requirement in favour of specific taxation, which by design reduces price differentials and drives very cheap brands out of the market. The Directive, adopted in February 2002, supplemented the 57%-rule with the requirement that the total excise cannot be less than €60 per 1000 cigarettes in the most popular price category, rising to €64 per 1000 cigarettes by 1 July 2006. Alternatively, Member States can choose an "adjunct solution" which exempts them from the 57% requirement if they have a minimum total excise of €95 per 1000 cigarettes (€101 per 1000 cigarettes from 1 July 2006)<sup>53</sup>. Denmark, Finland, France, Germany, Ireland, Sweden, and the UK currently fall under that provision.

### 4.4. Member states tobacco tax and price levels

The EU policy of allowing different tax schemes contributes to the existence of a wide variety of MPPC brands, which together results in wide price differentials among the member states (table 1). This is true even for the EU15 countries where despite price differences tax rates are relatively similar<sup>49</sup>. The total cigarette tax in EU15 member states converges to about 74% of retail price and the share of excise tax in retail price is at least 57% (with the exception of Denmark, Austria and Sweden). Spain is the only EU15 state that did not comply with the minimum total excise requirement of €60 per 1000 cigarettes in 2003. Italy will have to increase its excise tax before 1 July 2006 to comply with the €64 per 1000 cigarettes limit.

Table I. - Tax rates and cigarette prices in Euros (€) for the most popular price category (MPPC) in the European Union (EU) in 2003

COUNTRY	SPECIFIC EXCISE	AD VALOREM EXCISE	TOTAL EXCISE	VAT	TOTAL EXCISE €/1000	TOTAL TAX	RETAIL PRICE €	PRICE USING PPP €
EU15 FAVOURING SPECIFIC RATES								
IE	43.59	18.32	61.91	17.36	189.44	79.27	6.12	8.50
UK	42.96	22.00	64.96	14.89	233.21	79.86	7.18	6.59
PT	38.75	23.00	61.75	15.97	64.84	77.72	2.10	3.96
DE	36.63	24.23	60.87	13.79	102.57	74.65	3.37	4.88
NL	36.49	20.51	57.00	15.97	86.64	72.97	3.04	4.22
DK	32.61	21.22	53.83	20.00	108.47	73.83	4.03	4.29
EU15 FAVOURING AD VALOREM RATES								
AU	14.25	42.00	56.25	16.67	84.38	72.92	3.00	4.55
BE	11.16	45.84	57.00	17.36	95.76	74.35	3.36	5.33
SE	10.67	39.20	49.87	20.00	102.48	69.87	4.11	4.72
LU	10.25	46.84	57.09	10.71	66.22	67.81	2.32	4.22
FI	7.56	50.00	57.56	18.03	115.12	75.60	4.00	5.19
ES	4.01	54.00	58.01	13.79	56.56	71.80	1.95	3.31
IT	3.73	54.26	58.00	16.67	60.03	74.67	2.07	3.04
EL	3.64	53.86	57.5	15.25	71.88	72.75	2.50	4.55
FR <sup>#</sup>	6.03	57.97	64.00	16.39	160	80.38	5.00	6.94
NEW EU MEMBERS								
CY	60.95	0.00	60.95	13.04	67.65	74.01	2.22	4.63
MT	6.16	53.10	59.26	13.04	89.78	72.30	3.03	6.06
CZ	18.00	22.00	40.00	18.03	26.4	58.03	1.32	3.88
HU <sup>†</sup>	28.70	23.00	51.7	16.39	40.84	71.70	1.58	4.94
PL	31.67	25.00	56.67	18.03	24.93	74.70	0.88	2.10
SK	42.22	0.00	42.22	16.70	22.80	58.89	1.08	4.00
SI	13.94	39.07	53.00	16.67	39.49	69.67	1.49	3.24
EE	25.45	24.00	49.45	15.25	25.96	64.70	1.05	2.92
LV <sup>+</sup>	37.42	0.00	37.42	15.25	9.73	52.67	0.52	1.11
LT	32.15	10.00	42.15	15.25	16.23	57.41	0.77	1.54

Data are presented as %, unless otherwise stated. VAT: value-added tax; PPP: purchasing power parity. #: Data from January 2004; <sup>†</sup>: Szilágyi *et al.*<sup>54</sup>; <sup>+</sup>: Data for filtered cigarettes. Sources: EC Directorate General Taxation and Customs Union<sup>55</sup>; and for the PPP 2003: World Travel and Tourism Council<sup>56</sup>.



Most new EU member states have been moving toward harmonisation of their tobacco tax rates with the EU15 countries since the early 1990s. On average, the share of total tax in cigarette prices is 63%, 11% point lower than in the EU15 countries (table 1). These countries either comply with or exceed the upper limit of 55% share of specific excise in total tax. However, only Malta and Cyprus meet the EU requirement of 57% of the total excise tax in retail price and the minimum total excise requirement of €60 per 1000 cigarettes.

Despite the closeness of relative cigarette taxes (particularly in EU15), the absolute taxes vary substantially. As of December 2003, EU15 states favouring specific tax levied an average tax of €3.32 per pack of cigarettes, and the EU15 states favouring ad valorem tax levied an average tax of €2.31 per cigarette pack. This is reflected in average cigarette prices in these states, which were €4.31 and €3.15 per pack at the end of 2003, respectively. The cigarette prices in the new EU10 countries vary from €0.52 per pack in Latvia to €3.03 per pack in Malta. Converting cigarette prices using the Purchasing Power Parity index (PPP) reveals a smaller price gap between the EU15 and EU10 countries; however, the difference between the average prices for these two groups is still quite large: €1.51. It is expected that this gap will narrow, because almost all new EU members (with the exception of Malta and Cyprus) will need to substantially raise their tobacco taxes to meet the EU minimum excise tax of €60 per 1000 cigarettes. Most of them have negotiated transition periods, which will last for some until December 2009<sup>51</sup>. The structure of cigarette tax will have to change in Cyprus and the Slovak Republic to introduce the ad valorem element required by the EU.

The trend in real cigarette prices in the EU between 1990 and 2000 has been quite diverse. While the real price of both local brand and Marlboro cigarettes increased by more than 5% per year in France and the UK, and it remained fairly stable e.g. in Austria, Germany and Denmark. Real Marlboro prices declined relative to local brand prices, which is not surprising considering the evidence alleging that major transnational companies conspired to fix cigarette prices<sup>57</sup>.

Despite the effort to bring the cigarette price level closer to the EU15 level, the real cigarette prices have been decreasing in most new EU member states (with the exception of Poland)<sup>58</sup>. Table 2 shows the decline in real cigarette prices in the Czech Republic and Hungary between 1990 and 2000 (the increase in the price of a local brand in Hungary has been more than offset by the decrease in price of Marlboro brand). If we compare these changes in cigarette prices with changes in real wages, we can conclude, that the affordability of cigarettes has been increasing in both the Czech Republic and Hungary, and has been kept constant in Poland during the 1990s.

Table 2. - Annual real cigarette price changes and annual changes in real wages

	LOCAL BRAND: 1990-2000	MARLBORO#: 1990-2000	REAL WAGE %: 1993-2000
CZ	-3.59	-6.45	+4.6
HU	+0.75	-6.65	+0.9
PL	+6.32	+6.48	+6.2

Sources: Economic Intelligence unit, Union Bank of Switzerland<sup>58</sup>(for cigarette prices) and author's calculation based on statistics from the UN Economic Commission for Europe (for real wage changes)<sup>59</sup>. #: Marlboro or nearest equivalent international brand.

Despite recent efforts to use cigarette taxes as a public health tool, cigarettes in Europe are still quite affordable. Converting the 2001 prices to the average minutes of labour necessary at the average wage rate to buy a pack of Marlboro cigarettes reveals that a smoker needs to work at most 30-40 minutes (Scandinavian countries, UK and Ireland) to earn a pack of Marlboro. However, in a majority of EU15 member states, only 18 to 25 minutes of labour is required to buy a pack of cigarettes, and in Switzerland and Luxembourg only 12 minutes<sup>60</sup>. The trend in affordability between 1990 and 2000 indicates a small decrease in the EU15 countries: on average, people in Europe had to work 2.6 minutes more in 2000 compared to 1990 to buy a pack of cigarettes<sup>n</sup>. Nevertheless, in three countries, namely in Denmark, Portugal and Sweden, cigarettes in 2000 were more affordable than they were at the beginning of the decade. In the UK, despite recent increases in price, cigarettes are still more affordable than they were in the 1960s<sup>61</sup>.

The opportunity costs of cigarettes are higher in the new EU member states due to lower wage rates. A pack of Marlboro required 56 and 71 minutes of labour in 2001 in Poland and Hungary<sup>60</sup>, respectively. However, the availability of cigarettes is not correctly reflected by this measure, due to an abundance of cheaper local brands. The opportunity cost of the most popular local brand in 2001 in Poland and the Czech Republic, for example, was 40 minutes<sup>60</sup> and 32 minutes<sup>62</sup>, respectively. This is comparable to the EU15 upper level of price affordability. It can be expected that the gap in the affordability of cigarettes will narrow in the future since the average wages in most new EU10 Member States are increasing faster compared to the EU15 countries<sup>o</sup>. Because general prices and wages tend to rise over time, and because even small annual changes can significantly affect price levels over a decade (a 10% annual increase would double nominal prices in less than 8 years), cigarette prices should be regularly adjusted for inflation, by means of indexing.

At present, Member States are allowed to levy a minimum excise duty on cigarettes provided that this does not raise the total tax to more than 90% of the total tax on the MPPC of cigarettes. This has sometimes proved quite inadequate to deal with circumstances such as a price war or a drastic rise in supply at the lower end of the market<sup>64</sup>. This rule will also lead to an inefficient tax policy in the new EU10 Member States where the MPPC brands are mid-range in price. Because higher taxes for tobacco products remains one of the most effective methods of curbing the consumption of tobacco products, states should be able to pursue their public health goals by setting a minimum excise tax without this limit, provided that the nominal amount does not exceed the excise duty levied on cigarettes belonging to the MPPC.

Currently fine-cut tobacco intended for the rolling of cigarettes (Roll-Your-Own (RYO)) is taxed at the minimum excise rate of either 33% of the retail selling price or €29 per kg<sup>65</sup>. This tax will be increased as of July 2004 to minimum excise of either 36% of the retail selling price or €29 per kg<sup>66,p</sup>. This still represents only about 60% of tax incidence compared to cigarettes<sup>66</sup> and leads to a substitution from cigarettes towards RYO tobacco. Sales of RYO tobacco have been recently increasing within Europe. In 2002, the sale reached 53,899 t, an 8.1% increase over the previous year<sup>67</sup>. Some governments in Europe (e.g. Germany) are

<sup>n</sup> Authors calculation based on data from the Economist Intelligence Unit<sup>58</sup>.

<sup>o</sup> Average gross annual earnings in industry and services<sup>63</sup> and author's calculation: between 1996-2002 the EU15 and the EU10 annual earning increased by 3.2% and 9.8%, respectively.

<sup>p</sup> The Czech Republic and Estonia will have to comply with this regulation by 31 December 2006 and 31 December 2009, respectively.

already taking steps to harmonise taxes between the two close substitutes. The substitution will be a particular issue for the new EU10 countries where taxes on cigarettes will be increasing in the near future.

### 4.5. Impact of tobacco taxes on consumption

Higher tobacco taxes, translated into higher real cigarette prices, will lead to a decline in smoking prevalence (by reducing smoking initiation and increasing smoking cessation), reduced cigarette consumption among those who continue to smoke even after the price increase, and to an increased tax collection from cigarette sales. Research indicates that the price elasticity of demand for cigarettes in high-income countries is, on average, -0.4% among adults<sup>68</sup>. This means that when prices increase by 10%, total consumption of cigarettes decreases by 4%. An even larger effect can be expected among countries and socioeconomic groups with lower levels of income, and among youths<sup>68</sup>. Price affects both smoking initiation and smoking cessation: 10% increase in cigarette prices can lead to a 3.4% increase in smoking cessation attempts among young adult smokers<sup>69</sup> and can decrease the probability of smoking initiation between approximately 3% and 10% depending on how initiation is defined<sup>70</sup>. Particularly for current smokers, the effect of a permanent increase in price will be greater in the long run than in the short run, because it takes longer for a person addicted to nicotine to change his/her behaviour.

The impact of a cigarette tax change will depend on how it translates into the final cigarette prices, on the cigarette prices relative to other goods, the size of the tax change relative to the initial price, the average income of the smoking population, and on the price of a close substitute (e.g. RYO tobacco). This will be a particularly important issue for new EU10 countries where the average income is expected to rise more rapidly compared to the rest of the EU. For a cigarette tax to have a sizable effect on smoking rates, it should be sufficiently large and impact final cigarette prices so it will have a significant impact on the consumer budget. However, the impact of higher cigarette taxes can be reduced if taxes on RYO tobacco do not follow the same trend, because some cigarette smokers will be motivated to switch the RYO cigarettes<sup>67</sup>. Empirical evidence shows that higher taxes will reduce cigarette consumption even under the presence of cigarette smuggling<sup>71</sup>.

### 4.6. Cost-effectiveness of tobacco taxes and other tobacco-control measures

Various economic measures reduce smoking with different levels of efficacy. A large body of international evidence suggests that price and tax increases are the most effective components of a comprehensive national tobacco-control policy.

Apart from raising cigarette prices by means of taxation, there are other ways to reduce smoking. Empirical evidence shows that a fully comprehensive advertising ban covering all media and all forms of direct and indirect advertising contributes to the reduction of tobacco consumption<sup>72</sup>. It also lessens the social desirability of smoking, in particular among young people. Along with the promotion of a smoke-free environment, regulation of advertising contributes to making non-smoking the accepted social norm. The empirical evidence from high-income countries shows that comprehensive bans can reduce the consumption of tobacco products by around 6.3%<sup>73</sup>.

Introducing smoke-free work places is another effective way to reduce smoking. Several studies focusing on this issue found reductions in quantity smoked and prevalence between

10-20%<sup>74</sup>. Following the implementation of a national smoke-free law in Finland, smoking prevalence and the number of cigarettes smoked per smoker declined by 16-17% in firms previously without bans<sup>75</sup>.

Smoking cessation is an emerging and important component of tobacco-control policies. Evidence shows that brief advice from a medical professional and behavioural support are effective in motivating smokers to quit<sup>76</sup>, and that the use of nicotine replacement therapies (NRT) increases the rate of success<sup>74</sup>. Improving access to cessation programmes would therefore reduce tobacco consumption even more.

Economists and epidemiologists use the concept of DALY (disability-adjusted life year) to compare the effectiveness of different health interventions (including tobacco-control policies), in terms of their costs per an added year of life in good health. Therefore, DALYs incorporate the combined effect of reductions in mortality and morbidity. It has been estimated that a 10% price increase could result in 600,000 to 1.8 million fewer premature deaths in the World Bank region consisting of Europe and Central Asia, at a cost as low as 3 to 78 US dollars per DALY<sup>77</sup>. As table 3 illustrates, price increases are by far the most cost efficient way to reduce smoking, both in the high-income countries of Western Europe and in Eastern Europe.

Table 3. - Cost per disability-adjusted year of life saved (DALY) for different policies and countries

POLICY OPTIONS	HIGH-INCOME COUNTRIES INCLUDING MOST WESTERN AND NORTHERN EUROPEAN COUNTRIES	EUROPEAN COUNTRIES: EASTERN EUROPE AND CENTRAL ASIA
Price increase on tobacco by 10%	83-2771	3-78
A combination of other (non-price) measures effective 2–10%	696-13924	39-784
NRT effective 0.5–2.5%	750-7206	229-794

Data are presented as US dollars. NRT: nicotine replacement therapies. Table adapted from Ranson et al.<sup>77</sup>.

The World Health Organization (WHO) has estimated the cost-effectiveness of tobacco-control measures for the European A Region (all EU and EFTA states + Czech Republic, Malta, Slovenia). Although they were obtained by applying a methodology different from the one above, they lead to a similar conclusion: the most efficient method to reduce smoking prevalence is to double the tax on tobacco products (table 4). Other tobacco-control measures when implemented in isolation are less cost effective, e.g. one DALY saved only by enforcing a smoking ban in public places would cost almost 28 times more compared to doubling the current taxes. However, combining tax increases with other tobacco-control measures is also a very cost-effective way to improve population health<sup>78</sup>.

Table 4. - World Health Organization (WHO) cost-effectiveness analyses of tobacco-control measures for European A Region

INTERVENTION	US\$ PER DALY
Doubling the current highest tax in the region, resulting in 89% tax rate <sup>q</sup>	13
Doubling the highest tax (89%) + Comprehensive advertising ban	58
Doubling the highest tax (89%) + Comprehensive advertising ban	28
Doubling the highest tax (89%) + Enforcement of smoking ban + Comprehensive advertising ban	63
Doubling the highest tax (89%) + Enforcement of smoking ban + Comprehensive advertising ban + Information dissemination	90
Doubling the highest tax (89%) + Enforcement of smoking ban + Comprehensive advertising ban+ Information dissemination + Nicotine replacement therapy	274
Enforcement of smoking ban in public places	358

The effectiveness of non-price measures is compared to the situation of no interventions being implemented. US\$ is adjusted by purchasing power parity. Source: World Health Organization<sup>78</sup>.

Overall, the cost-effectiveness of tax increases is comparable to many health interventions financed by governments, such as child immunisation (cost is about \$25 per DALY<sup>79</sup>) or to the most cost-effective primary-care intervention for reducing coronary risk factors, which cost US\$ 496-488 per year of life gained for males and US\$ 1760-5536 for females<sup>80</sup>.

#### 4.7. Fiscal implications of tobacco consumption

The government budget benefits from tobacco consumption due to tobacco taxes, which represents budget income, and due to premature deaths of smokers in a non-productive age, which represents budgetary savings in pension and healthcare payments.

The fiscal balance due to smoking depends on the extent to which services for the elderly are covered by public funds and the amount paid in social security benefits. Smokers tend to live shorter lives than non-smokers. These premature deaths result in savings in pension payments, social security payments, and health care costs for the elderly. However, the majority of the life-cycle studies indicate that the net lifetime costs of smoking are greater than zero, meaning that a smoker spends more on health care and incurs other smoke-related costs over his shorter lifetime compared to a longer living non-smoker<sup>17</sup>. The majority of these studies found that there are lifetime costs associated with smoking, but these costs are rather small<sup>30</sup>. There are also studies that concluded the opposite: there are lifetime savings

<sup>q</sup> It is assumed that the current highest rate in the region is 75% of retail price, which represent about 300% mark up. Doubling the mark up to 600% will result in 89% tax rate expressed as % of retail price. The calculation assumes that there are costs associated with tax collection and enforcement of the law.

associated with smoking, but these savings are also rather small<sup>81</sup>. These estimates include only the direct costs associated with smoking. Including indirect costs of smoking results in the net lifetime costs of smoking<sup>82</sup>. The impact of this balance on the state budget would then depend on state involvement in paying for healthcare and other social services. Evidence from Sweden, a state with a generous welfare system, shows that smokers use the social welfare system more than non-smokers, and that smoking leads to net lifetime external costs for males and females currently smoking, and for former male smokers<sup>83</sup>.

In most EU countries, cigarette taxes do not represent a significant portion of the state budget and their share of total tax collection is small (between 1-5% (fig. 1)). The only exception is Greece, where cigarette tax accounted for about 9% of total government tax revenue in 1999. The situation is similar in the new EU10 Member States (fig. 2). The exceptions are the Czech Republic and Poland, since cigarette tax represented 6-7% of government tax revenue in 1999.

Over the years, revenues from taxes on tobacco have declined in relative terms. In 1998, revenues from excise and value-added taxes on tobacco products in the EU represented on average 0.68% of GDP. The ratio was highest in Ireland (1.32% of GDP) and lowest in Greece (0.17% of GDP)<sup>49</sup>. Luxembourg is an outlier with very high tobacco tax revenue (2.08% of GDP), because it engages in considerable tax base snatching from neighbouring countries by following a low tax/high turnover sales strategy.

It is possible to predict that if a country with a price elasticity of -0.4 and 70% tobacco tax incidence increases tobacco tax by 1%, its total tax revenue would increase by 0.72%. If this increase occurred in all Member State in 1999, the combined budget increase would be €0.432 billion<sup>1</sup>. The calculation does not account for a possible increase in smuggling activities after a tax increase. However, the World Bank estimates that Germany, for example, would still increase its government revenues by at least 2.6% if it increases the tobacco tax by 10% even when increased smuggling is considered. This tax income could be raised further by a coordinated increase of 10% in tobacco tax across Europe, which would result in additional tax income in Germany of about 4.7%<sup>71</sup>. These calculations clearly show that concerted political action at the European level would be advantageous for both public health and national budgets.

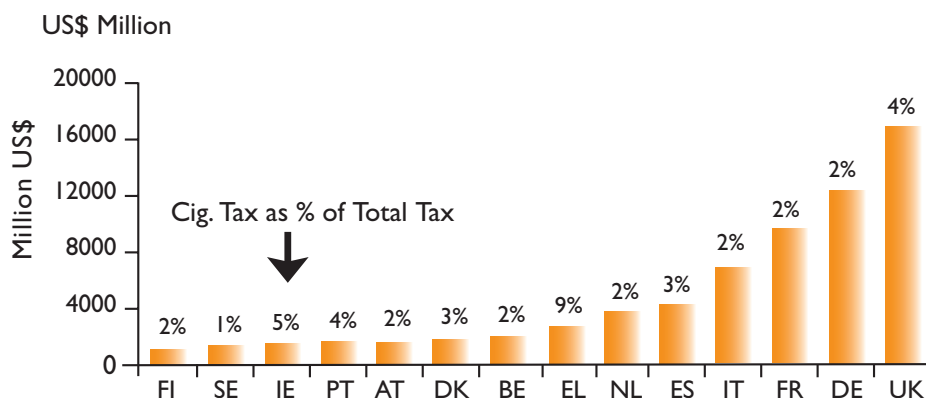
The potential to generate additional revenue from tobacco taxes will be highest in many countries of the eastern part of the Region where taxes as a percentage of prices are still relatively low.

## 5. TOBACCO SMUGGLING

Government budgets sustain opportunity costs in the form of foregone tax income due to tobacco smuggling. Apart from illegal smuggling, there is also cross-border shopping, or bootlegging. It is defined as the buying of duty-paid tobacco products in a neighbouring country for the buyer's own consumption, and is legal under the provisions of the single market. Guidelines provide quantities that an individual is permitted to buy under this regime. However, this activity is not the major source of lost revenue for state budgets<sup>84</sup>.

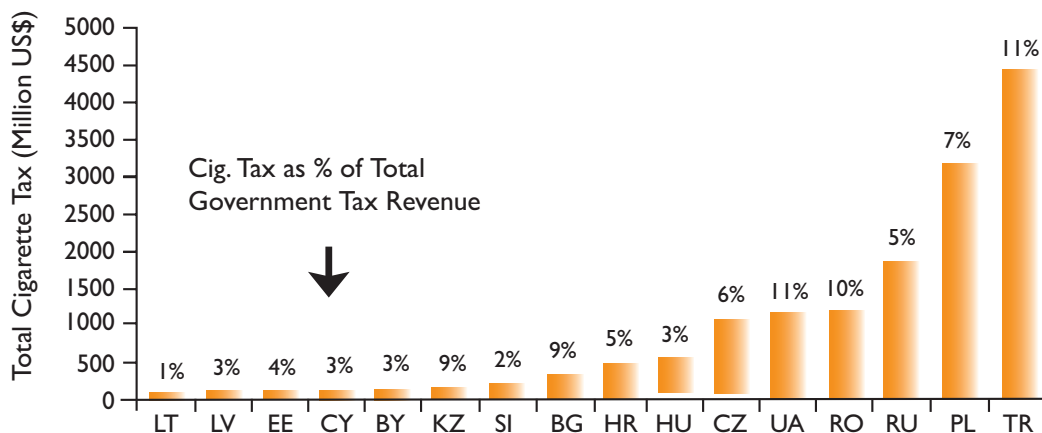
It is estimated that in a European country with the mean level of incentive, bootlegged

Fig. 1. - Cigarette tax as % of total government tax collection in European Union countries, 1999



Reproduced with permission from the World Bank, 2001. Economics of tobacco for the Europe (EU) region. Regional report: Europe (EU).

Fig. 2. - Cigarette tax as % of government tax collection in selected Eastern European and Central Asian countries, 1999



Reproduced with permission from the World Bank, 2001. Economics of tobacco for the Europe and Central Asia (ECA) region. Regional report: Europe and Central Asia (ECA).



imports account for about 3%, while smuggling accounts for about 7.7% of domestic consumption. The situation is worse in the new EU10 Member States, particularly in the Baltic countries and Poland where smuggling is estimated to exceed 15% of domestic sales<sup>71</sup>. British American Tobacco (BAT) estimates that illegal cigarette sales are largest in the eastern part of Europe where they represents about 13% of total market sales<sup>85</sup>. Cross-border shopping and bootlegging are relatively small problems compared to large-scale smuggling. However, in some countries where people travel more and the distance to the border is relatively small such as Luxemburg<sup>86</sup>, Finland<sup>87</sup> and Norway<sup>88</sup>, the scale of this problem can be larger<sup>r</sup>.

Even though the tobacco industry argues that smuggling is caused by price differences between countries that create an incentive to smuggle, there is evidence that smuggling is not due to price differences alone. If the industry argument were correct, smuggling would not exist in countries where taxes are relatively low, as in Eastern Europe. Smuggling appears to be supply-driven and is often associated with the presence of organised crime, fraud, a culture of street selling, and complicity of the industry<sup>71,89,90</sup>. Under this premise, tobacco tax increases that are scheduled in the new EU10 countries to reach the current EU tax level should not result in substantial increase in smuggling activities.

In 1998 the European Commission reported that over 50 criminal networks have been identified by investigations of large-scale smuggling of various products, including tobacco<sup>91</sup>. Among the beneficiaries of these large-scale operations are tobacco companies that use smuggling to gain market share and to market their products to those market segments which could not otherwise be penetrated due to legal barriers. The EU, in recognition of this dynamic and other conduct by tobacco companies, has filed a series of lawsuits against RJ Reynolds, Philip Morris and Japan Tobacco in the US Federal courts since August 2001 alleging fraud, racketeering, and other criminal acts<sup>92</sup>, in an attempt to recover billions of dollars of customs revenues lost through smuggling. Three lawsuits were dismissed on technical grounds, but a U.S. appeals court gave the EU a green light in January 2004 to file a new lawsuit based on money laundering laws. Philip Morris, meanwhile, countersued in a European court. The litigation between the EU and Philip Morris (Altria) was resolved in July 2004 when Philip Morris agreed to pay \$1.25 billion (€1 billion) to the EU to help combat cigarette smuggling and counterfeiting<sup>93</sup>. The payments will be made over the next 12 years, with half coming in the first 3 years, and will be shared between EU and national budgets. The agreement also requires Philip Morris to pay more if the EU authorities seize genuine Philip Morris products above defined quantities in the future. Philip Morris further agreed to fortify procedures for tracking its products, including adding indicators on certain packaging. Both sides also pledged to work together to identify the source of counterfeit cigarettes and interrupt their production<sup>93</sup>.

The industry-proposed solution to the smuggling problem (reduction of cigarette taxes) has been proven to create disastrous consequences for public health. Canada lowered cigarette taxes in 1994 to circumvent smuggling, which resulted in lost tax revenue and increasing smoking rates, particularly among young people<sup>85</sup>. The same happened in Sweden in 1998 when it lowered its cigarette taxes in the hope that it would diminish the magnitude of the contraband market. The result was a 10% decrease in government revenue from tobacco taxes in 1998<sup>94</sup> and a 19.7% increase in per capita tobacco sales between 1998 and 1999<sup>95</sup>.

<sup>r</sup> There is anecdotal evidence that cross border shopping has recently increased in France after the cigarette tax increases in 2003-2004



Smuggling can be reduced even when cigarette taxes continue to rise by adopting appropriate policies and by their active enforcement in local markets. This is confirmed by the experiences from several countries. Spain, with tobacco prices well below the EU average, was exposed to large-scale smuggling during the mid-1990s. According to estimates of the European Anti-Fraud Office, smuggled cigarettes accounted for 14.5% of the total Spanish market in 1994. A combined set of measures, including the implementation of new legislation by authorities in Andorra and tighter controls by neighbouring countries, have led to significant progress by reducing the level of smuggling to nearly 2%. At the same time tobacco prices increased twofold between 1994 and 2002 while tax revenues have risen by 155%<sup>96</sup>.

France increased cigarette taxes several times between September 1991 and December 1996 and more recently between 2002 and 2003. During the first period (1991-1996), state revenues increased twofold while tobacco consumption decreased by 14.5%. During the second period (2002-2003), when the price increased by an average of 31%, government revenues increased by some €2 billion. At the same time, consumption decreased by 13.5% without any real increase in smuggling. In order to combat smuggling, France requires a license for most companies involved in tobacco manufacturing, import/export, distribution and retailing<sup>97</sup>.

There are efforts in the new EU10 Member States to address the problem of tobacco smuggling. e.g. Lithuania, Latvia, and Estonia announced plans in early 2000 to harmonise their respective tobacco fiscal policies. This was both to qualify for EU membership that required raising cigarette tax rates, and to reduce smuggling activities in the region<sup>98</sup>.

There are also efforts on the EU level. Administrative measures implemented by the member states as of 1 January 2001 have considerably tightened the rules on transit trade in cigarettes. This should reduce the level of illegal smuggling<sup>49</sup>.

The balance between specific and ad valorem taxation is also important for the prevention of bootlegging and smuggling, because it has implications for price differentials between Member States. The most recent taxation Directive IP/02/233 of the EU favouring the specific tax and putting a floor under excise duty should lead to a decrease in price differentials and reduce the incentive for smuggling.

## 6. SOCIAL INEQUALITY AND TOBACCO CONSUMPTION

Smoking imposes private economic burdens in addition to its social costs. These private burdens are not distributed evenly along a continuum of income classes. Smoking is becoming increasingly concentrated in the lower socioeconomic groups, those least able to bear these burdens.

Among the EU15, the prevalence of smoking in 2002 was consistently higher among the unemployed (54%) and among manual workers (51%), the EU15 average being 39%<sup>99</sup>. A study from the UK revealed that only 10% of females and 12% of males in the highest socio-economic group are smokers; in the lowest socioeconomic groups the corresponding figures are three-fold greater: 35% and 40%<sup>61</sup>. Similar findings are reported for the new EU10 Member States<sup>100</sup>. Estonia reported that daily smoking in 1990 was considerably higher among males with low education, low income and among unemployed in all age groups from 16 to 64 years<sup>101</sup>. The socioeconomic gradient was even wider by 2002<sup>102</sup>.

Tobacco is responsible for much of the excess risk of premature death in lower socioeconomic groups and also for more than half the difference between adult male mortality in the highest and the lowest socioeconomic groups<sup>103</sup>. Smokers from the lower socioeconomic groups and their families not only carry a larger burden of smoking-related costs, they also spend a disproportionately larger share of their income on tobacco products and on smoking-related medical care. The combination of reduced disposable income and lower earnings has effects on their investment and consumption decisions. For example, they may eat lower quality food and spend less on preventive care<sup>100</sup>. The consequences of these decisions are often borne by the State in the form of covering medical costs for the underserved, providing social services and other support.

Tobacco control measures can help to decrease income and health disparity among the population, and this decrease can have positive effect on overall economic performance.

While tobacco taxes are regressive (the lower socioeconomic groups contribute more to the total cigarette tax collection), their increase is likely to be progressive, decreasing the relative tax incidence on the poor, vis-à-vis the rich. This is based on the premise that the poor are likely to be more sensitive to price changes, and would thus reduce their cigarette consumption by a greater percentage than the rich in response to an excise tax-induced increase in cigarette prices. Recent empirical studies confirm this hypothesis: it is found that the (absolute value of the) price elasticity of demand varies inversely with income<sup>68</sup>. Therefore, we can expect that in the long run tobacco-control measures will reduce social inequality.

Earmarking tobacco taxes is considered to be an important instrument to offset the potential regressivity of tobacco taxes and to provide funds for public health measures and tobacco control. Earmarking of tax revenues for improving medical care, particularly smoking-cessation interventions, would produce greater social and health benefits. As of the end of 2003, twelve countries in the European Region currently earmark such taxes<sup>104</sup>. Finland set a good example for other countries as it uses 0.75% of tobacco taxes for smoking prevention and health promotion. Finland's approach is similar to successful cigarette earmarking strategies in Thailand and Australia.

## 7. RECOMMENDATIONS

Research evidence shows that regular increases in tobacco taxes are the most effective tool for a sustained reduction in tobacco use. Therefore, this tobacco control measure should be made an explicit part of the government effort leading to public health improvements. Countries which have adopted such an approach have shown a significant reduction in smoking prevalence among males, a stabilisation among young people, a slight decrease among females, and a significant decrease in the male death rates due to causes attributable to tobacco use (such as cancer of the trachea, bronchus and lung)<sup>18</sup>.

The tax rate on roll-your-own tobacco should be made equal to the tax rate on one cigarette to prevent substitution towards this form of tobacco products. There is no public interest rationale for providing lower tax rates on some forms of tobacco than on others, or for providing any form of “cheap” cigarette. Availability of lower-priced tobacco products deters quitting and facilitates increased daily consumption.

Non-price economic measures such as advertising bans, introduction and enforcement of smoke-free areas, anti-tobacco mass media campaigns, and interventions by health professionals are not

fully comprehensive if they are not accompanied by higher taxation of tobacco. These non-price measures can alter society's perception of smoking behaviour and decrease smoking among irregular smokers and those most educated and sensitive to public information. However, the most vulnerable population of current and future smokers responds very little to these policies unless they are tailor-made for the particular groups (such as females, young people and lower socioeconomic groups). In addition, these measures are linked to strong public support for smoking restrictions, which can support or strengthen other tobacco-control legislation and increase voluntary compliance with these measures.

The optional future strategy for countries with comprehensive tobacco-control measures will be to sustain the progress made, in particular with regard to tax increases. Their high taxation policies need to be accompanied by flanking measures, such as smoking-cessation assistance (targeting the most vulnerable groups such as the young and those in lower socioeconomic groups), curbs on promotion of tobacco products, health education and information campaigns. The impact of tobacco tax increases should be omitted from the consumer price index in order to ensure that they do not have an inflationary effect. Even though tobacco taxes are regressive, tax increases are progressive due to their disproportionately larger impact on cigarette demand among the lower socioeconomic groups. In addition, it is possible to improve the distributional impact of tobacco taxes by earmarking and investing cigarette taxes into tobacco control, e.g. as cessation support for the low-income groups.

The process of tax harmonisation should be sustained among Member States and expanded to include other countries in Europe as well. The taxes should be set at the highest possible level and should at the same time reduce the gap in prices between countries. The only way to narrow these differences is to proceed with harmonisation mainly on the basis of specific rates. The recently set minimum of total excise of €70 per 1,000 cigarettes is a step in this direction.

The new EU10 Member States will have to choose between a predominantly specific and a predominantly ad valorem excise regime. If government wants to intervene in the cigarette market through the tax system, then the specific excise is a better instrument to raise the cost of cigarettes than an ad valorem levy. The specific excise has a price effect that cannot be avoided by the manufacturer and the consumer. By contrast, an ad valorem excise can be reduced by using lower quality and hence lower-priced tobaccos. As a result, the higher the ratio of specific to total tax, the lower the total volume of cigarettes consumed tends to be<sup>105</sup>. There is ample room to increase tobacco taxes in the new EU10 countries. Opportunities to increase government revenue and to improve public health by means of higher tobacco taxes will be particularly important for this group of countries, as will earmarking of tobacco taxes that can make tobacco-control activities more affordable in countries with lower income levels.

International cooperation is particularly important for coordinating taxation policies and for combating smuggling. The experience from countries with different levels of price clearly indicates that by adopting appropriate policies, the scale of smuggling can be reduced significantly at the same time as taxes continue to be increased. Research evidence supports the following measures controlling tobacco smuggling<sup>89</sup>:

- all cigarette packages should carry the necessary markings and product information which will allow the products to effectively be tracked and traced;
- monitoring and collecting data on cross-border trade in tobacco products, including illicit trade, and exchanging information among relevant national authorities and international bodies;

- enacting and/or strengthening the corresponding legislation and penalties.

Special emphasis should be given to strengthening cooperation between national, international and intergovernmental agencies such as the World Customs Organization to coordinate action against smuggling, including investigations, judicial prosecutions and proceedings relating to illicit trade. Effective international monitoring of transactions equivalent to that existing in international practice for trade in special and dangerous goods could be promoted throughout the European region. International action, including controls on cigarette transport, will be crucial in efforts to control smuggling<sup>89</sup>.

Narrowing price differences between countries can bring down bootlegging in the EU. Since a specific excise tax does not motivate producers to offer cheaper cigarette brands, it should be more effective in narrowing price differences than an ad valorem tax would be. Furthermore, illegal practices can be countered by levying the excise as early as possible in the production-distribution chain and by severing the link between excise and retail price. If the excise were levied at the producer level and if the member state of production were not the same as the member state of consumption, then origin states could be obliged to pay the excise and value-added tax of the destination state. This could be done by requiring the manufacturer to buy banderols from the consumer country's excise administration<sup>49</sup>.

In terms of farming policies, the strategies of the CAP should focus on promoting alternative economic activities to tobacco production during the time when the tobacco subsidies are being phased out. Tobacco farmers can be helped by stimulating rural financial, credit, insurance and savings arrangements, by improving the physical infrastructure, and by reducing entry costs to local markets (e.g. by the relaxation of burdensome licensing and regulatory requirements on microenterprises). Given the seasonal character of tobacco growing and the overall decreasing trend in tobacco-related employment in Europe, diversification from tobacco is a primary means by which many workers in the tobacco-growing industry can reduce the risk of employment volatility. The transitional scheme for tobacco farmers adopted by the Council of Ministers in April 2004 can be helpful in this process.

Unfortunately, legislation and taxation in Europe are still highly influenced by false agricultural and economic arguments, and by the threatening positions of the transnational tobacco industry. In addition, introducing new laws and regulations has not always brought tangible results, and several countries, mainly in the eastern part of Europe, are struggling with their enforcement. The lack of a strategic and comprehensive approach of national tobacco-control policies in many Member States is slowing down progress towards reduced tobacco prevalence. Insufficient coordination mechanisms, and inadequate funding and monitoring also reduce the effectiveness of policies. Finally, the lack of public support and public information is still an important constraint on the effectiveness of many national and local programmes.

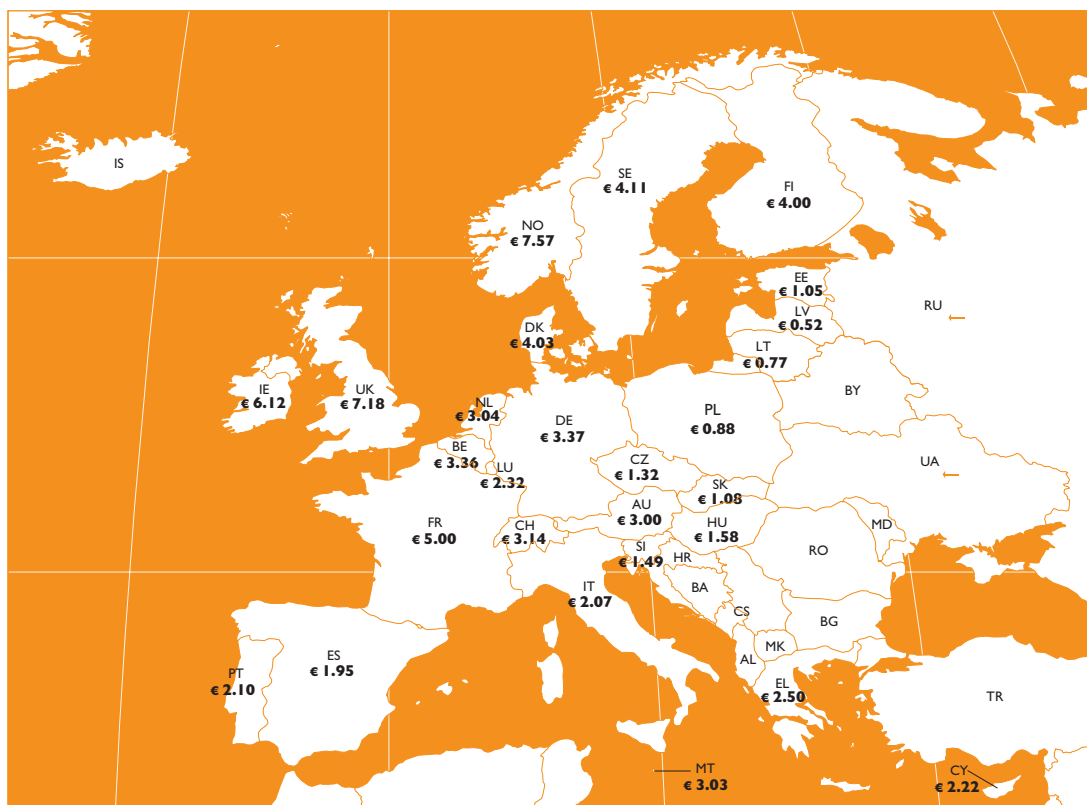
It is important to evaluate the impact of smoking behaviour and tobacco-control measures on national and regional economies. Compared to information available from other developed countries, very little is known in EU Member States about the price elasticity of cigarette demand, the costs of smoking, compensatory behaviour triggered by tobacco tax increases, etc. This knowledge gap is particularly large among the new EU10 Member States. It will be essential to monitor how adoption of various tobacco-control policies among EU/EFTA countries translates into changes in smoking behaviour in different population groups so that appropriate tobacco-control strategies can be developed. In addition, it will be important to monitor how the tobacco industry responds to the new situation in terms of price and marketing strategies. Systematic monitoring of

smoking prevalence, and tobacco-related morbidity and mortality over time would provide an important feedback to policy makers about the impact of tobacco-control interventions. EU/EFTA Member States can take advantage of existing monitoring/surveillance tools and successful research managing organisations in the area of tobacco control. For example the International Tobacco Control Policy Evaluation Project (ITC)<sup>s</sup> has designed a comprehensive survey to measure the impact of tobacco-control policies and has already tested it successfully in the UK, Ireland, Australia, Canada and the USA. Organisations such as the International Tobacco Evidence Network (ITEN) can serve as a model of how to manage international and regional tobacco-control research that is highly relevant to public policy.

### Acknowledgements

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### Appendix: Cigarette prices in € for the Most Popular Price Category in the European Union in 2003



Source: European Commission, National Governments, industry sources. Data refer to July 2003 and relate to the Most Popular Price Category. Map adapted with permission from the International Tax and Investment Center<sup>106</sup>.

<sup>s</sup> The project is a result of collaborations of top international tobacco-control researchers from Australia, Canada, the UK and USA, and led by Geoffrey T. Fong from the University of Waterloo, Waterloo, ON, Canada.

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# THE DEVELOPMENT OF EUROPEAN UNION TOBACCO-CONTROL POLICY

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## I. INTRODUCTION

While the public health competence of the European Union (EU) is limited, European Community legislation on tobacco control is based on the EU's competence to regulate the internal market. The reasons for this are historical and derive mainly from the fact that the European Community (EC), as it was originally called, was conceived and set up as an economic community. In spite of this limitation the EU has made substantial progress on tobacco control in the last 20 years. This chapter describes the development of tobacco-control policy in the EU since the 1980s and then examines some of the factors that illustrate and explain this progress. This is a story of dynamic policy development and implementation which has taken place against a background of continuous development of the EU itself, including community enlargement from six countries in 1957, to nine in 1973, 10 in 1981, 12 in 1986, 15 in 1995 and 25 in 2004. It is also a story of dynamic interactions, between community institutions, between these institutions and Member States, between Member States, and between the EC and external countries and organisations.

This chapter also examines these interactions. For example EU tobacco-control policy has had a major impact on its Member States, and has itself been influenced by Member States' national policies. Developments in the EU since 1985 have been the result of complex interactions between decisions and actions of the 15 pre-2004 Member States (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, UK), the new Member States (Cyprus, Czech Republic, Hungary, Estonia, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia joined on 1 May 2004), the European Commission, European Parliament, the Council and the World Health Organization (WHO). One of the major consequences of EU action has been that tobacco control has moved up the political agenda and influenced decision-making processes at Member State, EU and international levels.

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## 2. THE LEGAL BASIS FOR EUROPEAN UNION TOBACCO CONTROL

Every piece of legislation enacted by the EU, whether in the form of directives, regulations, resolutions or recommendations, requires a legal basis in the treaties that created the EU. Following successive treaties, actual and potential legal bases for tobacco policy include Article 32 EC (agriculture), and Articles 93 EC (taxation), 95 EC (internal market), 133 EC (common commercial policy), 137 EC (worker's protection), 152 EC (public health but see below)<sup>a</sup> and 153 EC (consumer affairs)<sup>1</sup>.

To date all of the legislation on labelling, advertising and product regulation put forward by the Commission, has been based on the internal market legislation, Article 95 EC (previously Article 100a EC). The 1989 Council resolution banning smoking in places open to the public was based on Article 235 EC, a catch all provision which was used in the absence of a

<sup>a</sup> But harmonisation of national laws (except in 3 areas which do not include tobacco control) is prohibited Article 152 (4) (c)

dedicated legal base. The 2002 Council recommendation on Tobacco Control (2002/54/EC) was based on Article 152 EC (formerly Article 129 EC), which was introduced in the Treaty of Maastricht in 1992 and amended in the Treaty of Amsterdam.

### 2.1. Why choose the internal market legal base for tobacco-control measures?

Article 152 EC places an obligation on the Community to ensure a high level of health protection in all its policies and to cooperate on health policy with international institutions. It also requires Member States to coordinate their health policies and programmes. This article also serves as a legal base for so-called “soft law”, resolutions and recommendations on public health policy which set guidelines for the Member States but which are not legally binding. However, article 152(4)(c) explicitly excludes the harmonisation of the laws and regulations of the Member States other than for blood products, organs, and in the veterinary and phytosanitary fields where the objective is the protection of public health. Thus in proposing legislation on tobacco control the Commission has used the internal market legal basis, which the Court has found to be suitable for some but not all of its tobacco-control legislation.

### 2.2. What is the effect of using the internal market legal base?

The 1986 Single European Act set out the measures to complete an internal market by 1993. The purpose of this legal basis for the internal market was to harmonise existing Member States' laws on the free movement of goods, in order to ensure the smooth functioning and completion of the internal market and overcome obstacles to competition. The internal market was defined as “an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of this Treaty”.

Measures adopted under the article establishing the internal market (Article 95 EC) must also be proportionate, meaning they must not go further than necessary in achieving these aims. When legislating on the internal market, the Community must take into account a high level of health protection (Article 95 (3) EC). Nevertheless the requirements of Article 95 can present difficulties for effective tobacco control at EU level.

The objective of tobacco-control policy is to reduce smoking-related death and disease in the EU by, inter alia, restricting the advertising and consumption of tobacco products. By implication this includes restricting the free movement and promotion of tobacco products in the EU, and measures that open up the market and promote sales are likely to conflict with this public health objective.

The use of the internal market “harmonisation” articles as a basis for public health measures has made them vulnerable to challenge from the tobacco industry. As a result, out of six pieces of legislation on the labelling, marketing and regulation of tobacco products enacted by the Community since 1989, four have been the subject of legal challenges by industry and/or a Member State, either directly by means of a call for judicial review of the measure itself, or indirectly as a challenge to the implementation of the provisions of the directive by a Member State (table 1).

Table 1. - Legal challenges to European Community legislation

DIRECTIVE	COURT CASE	OUTCOME
89/622/EEC (warning labels)	Ministero delle Finanze and Ministero della Sanità versus Philip Morris Belgium SA, case C-222/91; Queen versus Secretary of State ex parte Gallaher Ltd, case C-111/92.	Directive upheld but Italian government ordered to change national legislation to comply with directive.
98/43/EC (tobacco advertising)	Case C-376/98: Federal Republic of Germany versus European Parliament and the Council.  Salamander AG, Una Film “City Revue” GmbH, Alma Media Group Advertising SA & Co. Partnership, Panel Two and Four Advertising SA, Rythmos Outdoor Advertising SA, Media Center Advertising SA, Zino Davidoff SA and Davidoff & Cie SA versus European Parliament and Council of the European Union. Joined cases T-172/98, T-175/98 to T-177/98.	Directive annulled.  Cases dismissed on grounds of admissibility.
2001/37/EC (Tobacco Products Directive)	The Queen versus Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd, Case C-491/01.  Also, Germany versus Parliament and Council.  Japan Tobacco Inc. and JT International SA versus European Parliament and Council of the European Union, Case T-223/01.	Directive upheld.  Case dismissed for failure to lodge case within the deadline.  Case dismissed on grounds of admissibility.
2001/37/EC (Article 8, provision on sale of snus)	Case C-210/03: R versus Secretary of State for Health ex parte 1) Swedish Match AB; 2) Swedish Match UK Ltd. Case C-434/02: Arnold André GmbH & Co. KG versus Landrat of the Herford Local Authority.	Pending.
2003/33/EC (tobacco advertising and sponsorship)	Germany versus Parliament and Council, Case C-380/03.	Pending.

In addition to challenging the actual measures, other actions have also been brought against the European Commission by industry challenging other aspects of the legislative process, such as the preparatory scientific work for directives<sup>2</sup>. These cases have been brought under the access to documentation provisions introduced internally by the Council, Commission and Parliament institutions in 1993<sup>3,4</sup> and 1994 and codified in the Treaty of Amsterdam in 1997<sup>5</sup>.

The European Court of Justice has been receptive to the public health arguments in favour of smoking prevention. It has upheld most of the Community's tobacco legislation based on Articles 100a and 95 but has maintained that the primary purpose of any legislation based on this article must, logically, be to improve the functioning of the internal market<sup>b</sup>. Once this condition has been met, the Court has given Community legislators a wide discretion in the exercise of their powers to protect public health<sup>c</sup>. However, where the Court was of the opinion that a measure did not improve the functioning of the internal market, the measure has been struck down. The 1998 Tobacco Advertising Directive was annulled because the European Court of Justice (ECJ) found that its provisions banning almost all tobacco advertising in the Community introduced, rather than removed, obstacles to trade and competition<sup>d</sup>. Given the strength of the arguments in favour of comprehensive tobacco advertising bans (see Chapter 4 for more details) and the general acceptance of the Community's smoking prevention efforts by the Court, there is a strong case to be made that the 1998 Tobacco Advertising Directive would not have been annulled had Community legislators been able to rely on a dedicated public health legal base. The tobacco industry would still have challenged the measure because, as Chapter 6 points out, doing so is a key part of its lobbying strategy, but it is likely it would have met with less success. Meanwhile, but for the annulment of the 1998 directive, all 25 EU Member States would now have comprehensive tobacco advertising legislation and all the benefits for smoking prevention policy that this entails.

In spite of these limitations of the single market legislative base, use of article 100a EC/Article 95 EC has been and is a creative response to the absence of a primary public health legislative base for tobacco control, and has resulted in significant action against smoking-related morbidity and mortality on several levels.

### 2.3. Prospects for change: a new public health article

At the meeting of the Council of Ministers in June 2004 a new EU constitution was adopted<sup>6</sup>, which included a new article on public health:

Two provisions may be of assistance to tobacco control:

Article III-278 (Chapter V Areas where the union may take coordinating, complementary or supporting action Section 1, Public health)

*“By way of derogation from Article I-11(5) and Article I-16(a) and in accordance with Article I-13(2)(k), European laws or framework laws shall contribute to the achievement of the objectives referred to in this Article by establishing the following measures in order to meet common safety concerns: [...] measures concerning monitoring, early warning of and combating serious cross-border threats to health.”*

<sup>b</sup> See paragraphs 84 and 95 of Case C-376/98 and 60-61 of C-491/01.

<sup>c</sup> See paragraphs 123 of Case C-491/01.

<sup>d</sup> See paragraphs 105 and 113.

As well as Article III-278 (5):

*“European laws or framework laws may also establish incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, as well as measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the member states. They shall be adopted after consultation of the Committee of the Regions and the Economic and Social Committee.”*

The inclusion of tobacco in the EU constitution as a key determinant of human health is welcome recognition of its huge impact on the public health of the Community. However, the likely utility of Article III-278 for smoking prevention cannot be assessed until its meaning becomes clearer. In particular, the extent to which tobacco and tobacco-related disease and mortality can be considered to be a “serious cross-border threat to health” capable of justifying legislation under Article III-278 (4)(d) remains to be decided. Similarly, the meaning of “incentive measures” and the phrase “excluding any harmonisation of the laws and regulations of the member states” will have to be carefully defined. It remains to be seen what use the Community legislator will make of this revised legal base and its two potentially conflicting provisions as far as tobacco is concerned. But first the new Constitution needs to be ratified by all 25 Member States and until then Article 95 (Article III-172 under the new Constitution) will continue to be the legal base of necessity, if not of choice, for future tobacco control legislation at Community level.

### **3. A SUMMARY OF ACTION AT EUROPEAN COMMUNITY LEVEL**

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Community policy on tobacco has fallen into four broad areas: policy on agriculture, taxation, public health and, more indirectly, health and safety in the workplace. Much of the Community policy on tobacco control was initiated and developed by the Europe Against Cancer (EAC) programme of the European Commission. The story of this programme is, therefore, the cornerstone of our description of the development of EC tobacco-control policy. Wider policies, such as taxation, which are widely regarded as an essential and integral part of tobacco-control policy, are also discussed in depth in this chapter. What follows is a summary of all EC tobacco-control policy over approximately the last 20 years, followed by a description of the EAC programme (table 2).



Table 2. - Summary of European Union tobacco-control legislation 1989-2003

NAME (YEAR) OF MEASURE	NUMBER	KEY REQUIREMENTS
Labelling directives (1989, 1992)	89/622/EEC 92/41/EEC	Require rotating health warnings on tobacco products. Ban the marketing of certain tobacco products for oral use.
Advertising directives (1989, 1997, 1998, 2003)	89/552/EEC 97/36/EC 98/43/EC 2003/33/EC	Ban all forms of TV advertising for tobacco products. Ban on tobacco advertising in the press, radio and on the Internet. Ban on tobacco sponsorship of events with cross-border effects.
Tar Yield Directive (1990)	90/239/EEC	Sets a maximum tar yield of 15 mg per cigarette by December 31, 1992 and of 12 mg per cigarette from December 31, 1997.
Tax directives (1992, 1995, 2002)	92/78/EEC, 92/79/EEC, 92/80/EEC, 95/59/EC, 2002/10/EC	Set minimum levels of excise duties on cigarettes and tobacco.
Tobacco Product Regulation Directive (2001)	2001/37/EC	Larger warning labels are required on all tobacco products; descriptors suggesting that one tobacco product is less harmful than another are banned; manufacturers and importers must submit a list of all ingredients used in the manufacture of tobacco products. Maximum levels of tar, nicotine and carbon monoxide are established for cigarettes (10 mg tar per cigarette, 1 mg nicotine per cigarette, 10 mg carbon monoxide per cigarette).
Workplace Air Quality directives (1989, 1992)	89/654/EEC, 92/57/EEC, 92/91/EEC, 92/104/EEC	Require employers to ensure that workers have access to fresh air and ventilation.
Framework Directive on Health and Safety in the Workplace (1989)	89/391/EEC	Requires a health assessment to be carried out by employees which should include exposure to second-hand smoke in the workplace.
Asbestos Directive (1983)	83/477/EEC	Prohibits smoking in areas where asbestos is handled.
Resolution on smoking in public places (1989)		Invites Member States to adopt measures banning smoking in public places and on all forms of public transportation (nonbinding).
Pregnant Women Directive	92/85/EEC	Requires employers to take action to protect pregnant and breastfeeding women from exposure to an exhaustive list of substances, including carbon monoxide.
Carcinogens Directive (1990)	Directive 90/394/EEC	Restricts smoking in workplace areas where carcinogenic substances are handled.
Council resolutions (1993, 1996, 1999)		Proposals to Member States and the Commission - measures to combat smoking (nonbinding).
Council recommendation (2003)	2003/54/EC	Concerns aspects of tobacco control that are the responsibility of the Member States, including: tobacco sales to children and adolescents; tobacco advertising and promotion that has no cross-border effects; provision of information on advertising expenditure; environmental effects of tobacco smoke (nonbinding).

Since 1989 the European Community tobacco-control strategy has produced:

- three directives on tobacco taxation;
- three directives on tobacco advertising;
- two directives on labelling;
- one directive on tar yields;
- a re-casting of three earlier directives into one directive called the Tobacco Products Directive;
- eight health and safety at work directives restricting smoking in the work place;
- five non-binding resolutions and recommendations;
- two conferences organised jointly with the WHO;
- three EU Presidency conferences;
- support for three other European tobacco-control conferences;
- adoption of the WHO Framework Convention on Tobacco Control (FCTC);
- and effective action against tobacco smuggling in some Member States.

### 3.1. Directives

The advertising directives were 89/522/EEC (amended by 97/36/EC), 98/43/EC (annulled in 2000) and 2003/33/EC. The directives on labelling were 89/622/EEC and 92/41/EEC, on tar yields 90/239/EEC, and the Tobacco Products Directive was 2001/37/EC. In addition health was taken into account when taxation policy on tobacco products was elaborated through directives 92/78/EEC, 92/79/EEC, 92/80/EEC, 95/59/EC and 2002/10/EC. The health and safety at work directives were 89/654/EEC, 92/57/EEC, 92/91/EEC and 92/104/EEC, 89/391/EEC, 92/85/EEC, 83/477/EEC, 92/85/EEC and 90/394/EEC.

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### 3.2. Resolutions and recommendations

The resolutions were: “Resolution of the Council and the Ministers for Health of the Member States, meeting within the Council of 18 July 1989 on banning smoking in places open to the public”<sup>7</sup>, “Conclusions of the Council and the Ministers for Health, meeting within the Council of 27 May 1993 on the response to the Resolution on banning smoking in places open to the public”<sup>8</sup>, “Council Resolution of 26 November 1996 on the reduction of smoking in the European Community”<sup>9</sup>, “Council conclusions of 18 November 1999 on combating tobacco consumption”<sup>10</sup>, “Council Recommendation 203/54/EC of 2 December 2002 on the prevention of smoking and on initiatives to improve tobacco control”<sup>11</sup>.

### 3.3. Conferences

There was a WHO-European Community conference in Madrid in November 1988 and a second in Warsaw in February 2002, three EU Presidency conferences in November 1992 in London “Reducing smoking through price and other means”, November 2003 in Rome “Tobacco youth prevention and communication” and June 2004 in Limerick “Tobacco control policy in the European Union”. There have also been three European conferences on tobacco or health which were supported by the Community in Helsinki in October 1996, Gran Canaria in February 1999 and Warsaw in June 2002.

### 3.4. WHO Framework Convention on Tobacco Control

In 2003 the EC signed the WHO Framework Convention on Tobacco Control (FCTC).

### 3.5. Smuggling

The anti-fraud office of the European Community (OLAF) has been very active against smuggling and achieved landmark legal actions against international tobacco companies in 2000. In July 2004 Philip Morris International agreed that it will pay a billion dollars in compensation in a deal on tobacco smuggling. The agreement (see Chapter 2 for details) sets out how the company will control future smuggling of its cigarettes in the EC.

## 4. THE EUROPE AGAINST CANCER PROGRAMME

In the 1980s leaders such as President Mitterrand of France and Prime Minister Craxi of Italy felt strongly that the EC should become involved in areas other than purely economic ones. They wanted to develop a “Europe of the Citizens” rather than just a “Europe of Merchants”<sup>12</sup>. At the 1984 European Council meeting in Fontainebleau, the Council commissioned a report designed to identify areas where the EC could develop a new dimension closer to the concerns of ordinary citizens. This report was considered at the next European Council meeting and mentioned the fight against cancer as one possible area for Community action. Cancer experts made the European Council aware of the cancer challenge, informing them of their estimate that one in four Europeans living in 1985 had or would be confronted with cancer during their lifetime<sup>13</sup>.

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At their 1985 meetings in Milan and Luxembourg the European Council called on the European Commission to launch a programme against cancer. A committee of cancer experts was set up, which met for the first time in Brussels in January 1986. Each cancer expert was appointed by his or her head of state, Prime Minister, or health minister. At Commission level, a task force was created in 1986, which prepared an action plan in close collaboration with the committee of cancer experts. The objective of the programme was to reduce the number of deaths from cancer by 15% by the year 2000 (150,000 lives a year).

In order to reach this objective the Commission developed the first action plan covering prevention, information and health education, training of health personnel, and cancer research. The action plan had 75 measures and was submitted by the Commission to the Council in December 1986. This was a comprehensive and ambitious programme, owing much to the input of the committee of cancer experts. Of the 75 proposed actions the first 14 concerned tobacco (box 1)<sup>14</sup>.

## Box 1. - Tobacco proposals in the first Europe Against Cancer action plan, 1987-1989

1. Upwards alignment of taxation on tobacco manufactured in the European Community.
2. Financing of preventive actions at national level by the use of increased fiscal measures on tobacco.
3. Publication of indices excluding tobacco by the Statistical Office of the European Communities.
4. Harmonisation of cigarette labelling in the European Community.
5. Prohibition of cigarettes with a high tar content.
6. Harmonisation of the standards for the components of tobacco smoke.
7. Prohibition of tax-free sales of tobacco in the European Community.
8. Protection of children from tobacco sales.
9. Re-orientation of tobacco production to less toxic varieties and study of the possibilities of reconversion.
10. Information and public awareness campaign in the struggle against cancer.
11. Study of national provisions, and development of proposed Community regulations on tobacco smoking in public places.
12. Study of national provisions, and development of proposed Community regulations on the limitation of tobacco publicity.
13. Comparative analysis of anti-smoking campaigns.
14. Information exchange in the struggle against smoking.

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Source: European Commission, Europe Against Cancer Programme<sup>14</sup>.

The budget for the first action plan 1987-1989 was €18 million. Table 3 shows the dates and budgets of EACs three action plans, from 1987 to 2002.

Table 3. - The Europe Against Cancer action plans

ACTION PLAN	DATE	BUDGET ( € MILLIONS)
First action plan	1987-1989	18
Second action plan	1990-1994	55
Third action plan	1996-2000	64
Third action plan extension	2001-2002	27

The EAC programme was innovative and dynamic, and seven elements appear to be key to its success:

- High-level political support from the Commissioner;
- the committee of cancer experts;
- a dedicated unit within the Commission but with a considerable degree of flexibility and latitude;
- partnership with key stakeholders;
- a high profile media strategy;
- a legislative approach;
- provision of research and evidence from an expert office to support legislative initiatives.

### 4.1. High-level political support

Effective tobacco control can only be achieved with high levels of political support. From its inception, the EAC Programme enjoyed this support. Successive Health Commissioners - Manuel Marin, Vasso Papandreou, Pdraig Flynn and David Byrne - have all appreciated the benefits that good smoking prevention strategies can bring for Europe's citizens and the need to tackle the smoking epidemic. Commissioner Manuel Marin initiated the EAC programme, Vasso Papandreou proposed the ban on advertising and Pdraig Flynn encouraged its ultimate adoption. Most recently, Health Commissioner David Byrne has emphasised the crucial importance of tobacco control for Europe by placing it at the centre of his public health strategy and highlighting the enormous human and economic costs of smoking. The Commission proposal for a new products directive was adopted in November 1999 only a few months after he took office in July 1999. His support proved essential as the Commission piloted two tobacco directives and a recommendation through the Council and Parliament, and defended four separate legal challenges to Community legislation (see above). Byrne strongly supported the abolition of tobacco subsidies and the introduction of workplace smoking bans. Internationally, he strengthened links with the WHO, providing the basis for the Community's close involvement in the development of the FCTC. A striking example of Commissioner Byrne's support for tobacco control has been his refusal to meet with representatives of the tobacco industry. Towards the end of his mandate he called upon his successor to continue the fight against tobacco and keep smoking prevention efforts at the heart of Community health policy<sup>15</sup>.

### 4.2. The committee of cancer experts

The committee of cancer experts played an initial role in persuading the European Council of the need for action against cancer and assisted the Commission to develop the first action plan. Thus they had a central and key impact on policy development. They also advised the Commission on all scientific aspects of the EAC programme. During the second action plan 19 scientific reports and 22 recommendations, resolutions or statements on cancer-related issues were approved by the cancer expert committee and were disseminated by the EAC programme. During the Third action plan the committee adopted recommendations at a 1996 European conference in Helsinki, which formed the basis of the 2001 directive on tobacco product regulation<sup>12</sup>. Key persons were Professor Maurice Tubiana (France), its first chairman (1986-1994), and Professor Umberto Veronesi (Italy), the second chairman. It was an influential, independent body, invited to gatherings at the highest level before Council

meetings. Before the Commission adopted a proposed directive it was common for the chairman of the committee to explain the content of the proposed directive to the Commissioners, including the Commission President, then Jacques Delors.

#### 4.3. A dedicated unit within the European Commission

In January 1987, the EAC administrative team was established. The EAC team was not located with the majority of Directorate General V (DG) staff in Luxembourg but separately in Brussels. In December 1987, the team was attached directly to the European Commission's Director General's Office, the DG for employment, industrial relations and social affairs. This implied a shortened line of command and thus a shorter and quicker decision-making process than usual. The evaluation report of the first action plan suggested that this privileged position was crucial for EAC's effectiveness<sup>16</sup>.

#### 4.4. A partnership approach

Proposal 14 of the first EAC action plan was "Information exchange in the struggle against smoking" and so the Commission adopted a partnership approach in the fight against cancer, aimed at involving everyone concerned with the fight against cancer at national level. The partners were:

- the committee of cancer experts;
- the cancer associations and leagues, and the anti-smoking organisations (the spearhead of the programme);
- producers of television medical programmes who helped spread the message of cancer prevention;
- representatives of general practitioners, who play a central role in early detection and screening for cancer;
- senior officials in the health, education and research ministries.

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Whilst the committee of cancer experts "set the scene", it was the partnership with voluntary organisations that offered the delivery mechanism at grass-roots level. The cancer leagues provided expertise and resources, especially in support of the European Week against Cancer, which came to be held each October. The anti-tobacco organisations did the same, providing knowledge and advice, and (to varying degrees) advocacy support within Member States. Meetings of the two main networks (national cancer organisations and national tobacco-control organisations) were held every 6 months, funded through the EAC programme and organised by the EAC team. This meant that key players from activist organisations got to know one another, learn from each other's experiences, and began to share and borrow from each other's resources. The networks were consulted regularly as the programme developed and as legislative proposals were submitted to the formal EC decision-making process.

In 1988 the Commission invited proposals for the establishment of a tobacco information service to provide data collection and analysis in support of the programme. The contract was awarded to a Brussels-based group: The European Bureau for Action on Smoking Prevention (BASP). BASP produced quarterly newsletters on tobacco-control developments within the EU, at Member State level and internationally. It also coordinated national anti-tobacco campaigns into a broader, Europe-wide movement<sup>17</sup>. Its budget was €150,000 in 1989, €225,000 in 1990 and €370,000 in 1991. In 1995 the budget was €175,000 for a period of 6 months.

In the Commission report on the second EAC action plan the role of BASP was described thus:

*“This office operates as an information centre in the area of smoking prevention and has made an important contribution to the improvement of the exchange of information and experience in this area. In addition to general information services and technical support to the services of the European Commission, BASP publishes a quarterly newsletter and regular reports on specific issues. These publications are distributed to all programme partners and to a large number of other organisations working in the field in Europe and internationally.”*

Between 1990 and 1995 BASP published 11 special reports (table 4)<sup>18</sup>. BASP supported tobacco-control policy at EC and Member State level. For example the BASP reports on advertising and smokeless tobacco were used by the Commission to support their legislative proposals in these two areas.

Table 4. - The European Bureau for Action on Smoking Prevention (BASP) special reports

1. Use of moist oral tobacco and its promotion among young people
2. The tobacco industry in Eastern Europe
3. Advertising of tobacco products and its impact on the uptake of smoking among young people
4. Smoke-free flights
5. Women and smoking
6. Differential insurance premiums for non-smokers
7. Smoking policies in the workplace
8. Taxation of tobacco products in the European Union
9. Passive smoking
10. The labelling of tobacco products in the European Union
11. A country profile of tobacco use in the European Union

Source: European Commission<sup>18</sup>.

#### 4.5. A high profile media strategy and systematic monitoring of prevalence

From the beginning of the EAC programme a high-profile media strategy was developed to ensure good media coverage of the issue and results of the programme. The strategy included, inter alia:

- the launch of the European Information on Cancer Year in 1989;
- a European Week Against Cancer each October;
- regular press releases highlighting the results of regular smoking prevalence surveys in the Member States (the EuroBarometer surveys);
- regular contact with journalists.

From the beginning of the programme smoking habits were systematically monitored through regular opinion surveys, the EuroBarometer surveys. The surveys were conducted on a sample of about 12,000 people throughout the Member States. These surveys also showed that almost three out of four Europeans were in favour of banning tobacco advertising and smoking in public places. Results of these surveys were released at press conferences and received much media attention.

The smoking prevention policy of the EC was part of a major, integrated programme against cancer, which contributed to the credibility of the tobacco-control measures. One of the cancer expert committee's first tasks was to draw up a 10 point "European Code Against Cancer". The first point of the Code was "don't smoke". This message was promoted to millions of European citizens through the European Information on Cancer Year. The code provided healthy living advice, intended to improve personal and public health and thus reduce individual cancer risk and reduce cancer incidence and mortality throughout Europe.

The EAC programme was extremely successful in achieving high visibility of the cancer code, suggesting that its media strategy was itself effective. A 1990 EuroBarometer survey showed that 25% of those surveyed knew the European Code Against Cancer, and when the code was shown to interviewees this percentage rose to 43%.

In 1995 the European School of Oncology was invited to review the code and a revised text was subsequently adopted by the cancer experts committee. There was a second review in 2003 leading to further modification. At each review the goal was to consider and incorporate the latest understanding of cancer aetiology and of the best prospects for cancer prevention. Each of the three successive texts highlighted smoking as the greatest cancer risk, and recommended "no smoking" as the first and foremost step that individuals can take to protect their health. Tobacco control was central in the EAC programme.

The EuroBarometer surveys provided regular prevalence data permitting the monitoring of progress (table 5<sup>19,20</sup>), as well as data which informed the development of policy. For example these surveys showed in 1991 that almost 75% of Europeans were in favour of banning tobacco advertising and in 1992 that 84% of Europeans recognised that passive smoking can pose problems for non-smokers. It is important then to note that after the early 1990s the surveys were effectively discontinued. Lack of good data permitting the evaluation of effectiveness is such a fundamental point that we will consider the issue in more detail in the next chapter and in the recommendations.





Table 5. - Eurobarometer surveys on the percentage of smokers in the European Union in the Period 1987-2002

PERIOD	MALES %	FEMALES %	TOTAL %
Spring 1987	46	29	37
Spring 1988	44	28	36
Autumn 1988	43	28	36
Spring 1989	34	28	35
Autumn 1989	45	29	36
Spring 1990	41	26	33
Autumn 1990	44	28	36
Autumn 1991	42	28	35
Spring 1992	43	28	34
Autumn 1992	43	28	35
Spring 1994	42	28	34
Spring 1995	39	27	33
Autumn 2002	45	34	39

### 4.6. A legislative approach

Because of the controversy of proposed tobacco-control legislation (see Chapter 5), tobacco has probably received more attention than the other actions of the EAC programme on nutrition and cancer. Proposed directives on tobacco that arose from the first action plan included strengthening the health warnings on tobacco products, limiting the tar yield of cigarettes and restricting tobacco advertising. The proposed directives were not based on public health articles, as explained above, but on internal market measures designed to achieve the single market by 1993. Probably the most significant change in EU legislation, contained in the 1986 Single European Act, was the removal of the power of one state to veto and its introduction of qualified majority voting. This was intended to speed up progress towards a single market and meant in effect that use of the internal market article 100a as the legal basis for the tobacco directives was an innovative use of the 1986 Single Act (which itself modified the 1957 EEC Treaty).

### 4.7. The second action plan against cancer: a policy switch

In May 1990, the European Council adopted EAC's second action plan (1990-1994). The main aims of the second action plan were to develop information on cancer prevention and possible methods of early detection and treatment. It comprised 38 fields of action covering three main areas:

- cancer prevention, with priority given to anti-smoking measures;
- early detection and systematic screening of cancers;
- quality assurance for cancer treatment.

According to a 1995 Commission report, significant progress was noted in the following areas: action on smoking prevention with legislative support; information activities focusing on promotion of the European Code Against Cancer; development of health education strategies and teaching materials on cancer prevention at schools; establishment of breast cancer and cervical cancer screening networks; training of healthcare personnel; and studies concerning nutrition and cancer.

The general political environment in the EU changed during this period. Ratification of the 1992 Maastricht Treaty was only possible after consultations and referenda that highlighted national feelings and stressed the need for a diversified rather than a unified Europe. Some felt that the EC had become too powerful and that too many directives were adopted in the period 1986-1992. Following this it became more difficult to propose new directives because, from that point, action at Community level was only possible when the proposed objectives could not be achieved by the Member States themselves (the so-called subsidiarity principle).

As a result of these changes, and internal reorganisations within the Commission services, the profile of the EAC programme considerably reduced. The Eurobarometer surveys carried out between 1987 and 1990 showed that 37-38% of Europeans knew about the EAC programme. This percentage halved to 19% in 1995. A similar pattern was observed for knowledge of the European Cancer Code: 16% knew about the code in 1988, 25% in 1990, 19% in 1992 and 9% in 1995. And as we have seen, there were no more surveys carried out until 2002.

#### 4.8. The third action plan

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In 1996 the European Council and Parliament adopted the third action (1996-2000). The programme was extended in February 2001 until 31 December 2002. The plan contained 22 measures covering data collection, public information, education, cancer training for health-care workers, early detection and systematic screening, studies and measures relating to the quality of care, and research.

In this third plan the orientation of the tobacco policy changed. In 1994 the European Commission requested an evaluation of the twice-yearly meetings of the anti-smoking organisations. The results of the evaluation were presented at a conference of European smoking prevention organisations in Empoli, Italy, in May 1994. The conference recommended to the Commission two main principles for a future action plan<sup>21</sup>:

- The creation of a pan European structure to promote networking at European level.
- The necessity of creating national anti-tobacco coalitions.

The priority under the third action plan was to finance networks and projects with a clear European “added value”. One of the criticisms on the second action plan of the EAC programme had been the small size of the projects and the lack of a European dimension. A total of €8.5 million had been spent on 275 smoking prevention projects from 1990-1995, an average of €31,000 per project. According to the evaluation report, these small projects “tended to amplify the burden of running costs, involving duplication of administrative effort, ruling out any economics of scale and creating an unfavourable cost-benefit ratio in terms of management to project outputs.”<sup>12</sup> The report recommended strongly: “to prioritize those projects which have a clear European added value and can demonstrate both a partnership

and a concrete contribution to the EAC agenda arising from that partnership”<sup>12</sup>. To stimulate and coordinate joint projects at European level, the community financed two new organisations, the European Network for Smoking Prevention (ENSP) and the European Network on Young People and Tobacco (ENYPAT).

The objectives of ENSP are to:

- Facilitate the creation and operation of national alliances for smoking prevention and tobacco control in Europe.
- Promote collaboration amongst member organisations.
- Stimulate and coordinate joint projects at European level.
- Facilitate networks active in tobacco control and smoking prevention in Europe.
- Undertake the collection and distribution of information relevant for tobacco control to the members of the network, non-governmental organisations, intergovernmental organisations, national governments and the institutions of the European Community.

ENYPAT is a network for specialists working in the area of tobacco control in young people and it aims to prevent tobacco use by young people through European-wide collaboration, information exchange and programme building. The aims of ENYPAT are similar to ENSP, but focus on young people. ENYPAT coordinates smoking prevention and cessation programmes concerning young people, and produces common tools and methods for tobacco control in Europe. Approximately €2.5 million worth of projects were financed through ENSP and ENYPAT during the third action plan from 1996-2000.

#### 4.9. Legislative activity during the third action plan (1996-2002)

After the initial phase of intense legislative activity (which was common to many areas of Community policy as the Community prepared for the completion of the internal market by 1992), the European Commission sought to ensure that the proposal for a tobacco advertising directive was not abandoned. Following the change of government in the UK in May 1997, the Commission quickly mobilised to support the Luxembourg Presidency in ensuring that the measure was immediately placed back on the Council agenda. The directive was agreed by the Council only 7 months later.

At the same time the Commission services engaged in a wide-ranging consultation with the Member States to ascertain their views on the need to amend the existing directives on tar yields and labelling, and to monitor the success of its legislative output. They also carried out a mapping exercise to establish the extent of national legislation in other areas, such as nicotine and ingredients and any internal market problems arising therefrom. This was a time-consuming exercise, but the information collected helped form the basis of the Commission proposal for the 2001 Products Directive. It also ensured that the proposal received widespread support amongst Member State governments. Work progressed on the proposal for the Products Directive but its final adoption was held up by the resignation of the Commission in March 1999. For 6 months no new legislative proposals could be put forward. When the Commission proposal was finally agreed in November 1999, the directive was adopted by the Council and Parliament during the first semester of 2001. Negotiations

were complex and the directive was only agreed after the Conciliation Procedure was invoked.

Almost as soon as the Products Directive had been agreed, the Commission put forward a proposal for a new Tobacco Advertising Directive<sup>22</sup>. It proposed a general ban on tobacco advertising in the press and on the Internet. Advertising of tobacco products via radio and the sponsorship of radio programmes by tobacco companies were to be banned, along the same lines as television advertising. Additionally, it proposed to ban sponsorship of events with cross-border reach that aim to promote tobacco products. This proposal followed the advice of the European Court of Justice (ECJ) in its ruling of October 2000. Despite this, the proposal still came under fire from parts of the tobacco industry, and its partners in the advertising and media publishing sectors. A public hearing was held in the European Parliament on 15 April 2002 to debate the legality of the proposal<sup>23</sup>. The directive was finally adopted in early 2003 and was almost immediately challenged in the ECJ by Germany<sup>e</sup>.

## 5. THE ROLE OF THE HEALTH COUNCIL IN POLICY DEVELOPMENT

Tobacco control has been one of the top priorities of the Health Council since 1985 and it has played an important role in the development of EU policy in this area. From 1988 to 2003 the Health Council met 35 times and tobacco control was on the agenda on 31 of these occasions. Tobacco control directives, resolutions, recommendations, conferences, and the FCTC were all discussed<sup>f</sup>. Furthermore, the influence of (health) council meetings goes beyond the adoption of legislative texts. Contacts between health ministers at council meetings and the ensuing exchange of views, as well as proposed Commission actions, influenced what happened at national level. In most cases activities at council level led to more initiatives at Member State level. While a direct causal effect would be difficult to prove, it is part of the political process that Ministers monitor activities and ideas in other countries.

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Even the non-binding resolutions and recommendations are part of the political process. In 1992 and 1996<sup>24</sup> the Commission reviewed measures taken in the Member States and concluded that the 1989 Council resolution banning smoking in places open to the public had led to action in Member States. Most introduced regulations around the time of the adoption of the resolution. In France for example the resolution was adopted under French presidency when Claude Evin was chair of the Council of Health Ministers, resulting in a 1991 French law, the loi Evin, which banned tobacco advertising (one of the most complete bans in the world - it included a ban on Formula One motor racing), introduced restrictions on smoking in public places and increased the price of tobacco.

However, although resolutions do tend to create political momentum for Member States who want to change their legislation, as just described, they have less impact on countries with no pre-existing desire to act. Austria, Finland and Sweden, put new regulations into effect prior to joining the EU in 1995 and in the case of Sweden at least, this was done in order to implement the resolution<sup>24</sup>.

<sup>e</sup> Case C-380/03 Germany v Council and Parliament.

<sup>f</sup> Tobacco was not on the agenda at the meetings of the Health Council on 30 March 1994 and 2 June 1995 and on the meetings of The Employment, Social Policy, Health and Consumer Affairs Council on 6 March and 20 October 2003.

The role of the council has been described in the following way: “The ministers of health have the opportunity to meet amongst colleagues to make progress together, with the aid of the Commission and the Parliament, on issues which they consider important and which are difficult to handle at national level”<sup>25</sup>. A former health minister confirmed this positive dynamic in the health council, which had an impact both at national and international level. In Belgium for instance it reinforced the position of the health minister within the government not to allow an exemption for Formula One sponsorship (M. Aelvoet, Belgian Health Minister: 1999-2002, personal communication).

### 6. THE ADVERTISING BAN

#### 6.1. An overview

The debate on tobacco advertising in the EC has lasted for 15 years so far and is still not finished, because Germany has challenged the ban, Directive 2003/33/EC, in the ECJ. This section presents an overview of the story so far.

In 1989 the European Commission adopted a proposal designed to harmonise the laws of Member States on tobacco advertising. The Commission believed that a proposal for a total ban was impossible as only two countries (Italy and Portugal) had such a ban at that time. Television advertising was covered by another Commission proposal which was adopted as Directive 89/522/ECC in 1989. However, on the 14th March 1990 the European Parliament voted in favour of a total ban on tobacco advertising (170 in favour, 111 against, 17 abstentions). This clear vote by the Parliament received huge media attention and put pressure on the Council to agree a common position on tobacco advertising. However, the Council was unable to reach agreement as at least three countries (UK, Germany and the Netherlands) were opposed to the Commission proposal.

But developments in one important Member State influenced the debate at European level. In 1990 the French government announced its plan to ban tobacco advertising. According to a leading tobacco-control advocate, Albert Hirsch, this decision was itself influenced by the European Parliament vote 2 weeks earlier<sup>26</sup>. *Le Monde* said on 16 March 1990: “With the adoption of strong recommendations, the European parliament wants to accelerate the fight against tobacco”<sup>27</sup>. The French law, passed on the 10th January 1991, known as the loi Evin, was one of the strongest tobacco advertising bans in the world. It included for instance a ban on tobacco sponsorship for international events, such as Formula One.

In 1991 the European Commission, taking into account the vote in the European Parliament and the developments in Member States, adopted a new proposal to harmonise tobacco advertising, which included a ban on tobacco advertising in most media. Tobacco already had a special status: it was the only freely available product whose advertising had been banned on television in the EU since October 1991 (Directive 89/552/CEE).

During 1993-1995 the question was raised whether the advertising ban should be still on the Council agenda, as no progress was being made. Commissioner Flynn expressed this concern in a letter to the EU Presidency of the Health Council, the Belgian Health Minister Magda De Galan, on 9 September 1993, thus:

*“I would like to take this opportunity to return to the subject of the proposal for a council directive on the advertising of tobacco products which we discussed in some detail at our meeting. This proposal was originally made in 1989 and the fact that it is still under discussion indicates that it is a contentious and politically-sensitive issue.*

***I think we both realise, however, that a decisive move is now required to confront this issue*** [our emphasis] *and I am, therefore, very pleased that discussions are taking place which may lead to progress at the next council meeting.”*

Despite intensive industry lobbying<sup>28</sup> the proposal remained on the Council agenda. The most historic Health Council meeting was the meeting on 4 December 1997, which led to the adoption of a common position on a ban on tobacco advertising. The meeting started in the morning with the surprising announcement that Spain was no longer supporting the directive, but ended around midnight with agreement, despite the strong opposition of Germany and the request of the UK for an extended transition period for the ban on tobacco sponsorship of international events (essentially Formula One). Germany and Austria voted against, and Denmark and Spain abstained, the absolute minimum for a qualified majority was obtained.

The Advertising Directive 98/43/EC was annulled by the ECJ on 5 October 2000, following a legal challenge brought by Germany. This occurred just 11 days before the start of negotiations on the WHO FCTC in Geneva and worse timing was hardly possible. The opinion of Advocate General Fennelly on this case delivered on 15 June 2000 recognised advertising acts as an encouragement to consumption “Given the massive role of tobacco consumption as a mortality factor and as a cause of grievous health problems in the community, I consider that a potential reduction in consumption levels of 6.9% would be a significant gain for public health, probably resulting to the saving of thousands of lives,” but both the Advocate General and the Court felt that the legal basis for the directive (the internal market article 100a of the Single Act) was unjustified. According to the court, for numerous types of advertising of tobacco products (such as posters and cinema advertising), prohibition cannot be justified by the need to eliminate obstacles to the free movement of advertising media or the freedom to provide services in the field of advertising. According to the Court, although differences between regulations on tobacco advertising may give rise to distortion of competition and may justify the use of article 100a, the distortions foreseen were not such as to justify the use of article 100a for an outright advertising ban. The Court considered, however, that the Treaty provisions on the internal market allowed the adoption of a partial advertising ban.

The commission introduced a new proposal in May 2001 to restrict tobacco advertising and sponsorship, which was finally adopted 2 years later, Directive 2003/33/EC of May 26, 2003 (see above)<sup>29</sup>.

After the annulment of the directive banning tobacco advertising, another legal challenge was brought just 1 year later against the Products Directive. This legal challenge, against practically all the provisions of Directive 2001/37/EC (the Tobacco Products Directive) was brought by British American Tobacco (BAT) and several other tobacco companies. A separate challenge against the export provisions in article 3 brought by the German government was rejected for failure to lodge the case within the required time limit. The companies again claimed that the internal market legal base of the directive (now Article 95 EC) was invalid.

This time the result was different and the ECJ ruled on 10 December 2002 that the directive was legally valid. In particular, the Court reiterated the following points:

- That the measures referred in the Directive 2001/37/EC are intended to improve the establishment and functioning of the internal market.
- That the recourse to Article 95 as a legal basis is possible as the aim is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws, the emergence of such obstacles must be likely and the measure in question must be designed to prevent them.
- That the Community legislature cannot be prevented from relying on that legal basis because public health protection is a decisive factor in the choices to be made.

### 6.2. Dynamics within the Council

EU policy making is not always dry and predictable, and dynamics within the Council and the Parliament can be extremely important and affect the decisions eventually made. At a 2 day meeting of the Health (and Employment, Social policy, and Consumer affairs) Council in December 2002, the proposal for a tobacco advertising directive was on the agenda again. Only 11 days before this meeting, the European parliament had adopted the proposal with 311 in favour, 202 against and 39 abstentions. The vote in the Parliament was crucial, but not without problems. The lead Committee on the proposal in the European Parliament was the Legal Affairs committee which had delayed its adoption in the Parliament and proposed amendments to weaken the directive. At the plenary session on 21 November 2002 all relevant recommendations from the legal affairs committee were defeated and a slightly amended proposal was adopted. The Parliament approved the proposal in first reading and provided the opportunity for the Council to adopt a common position in their meeting in December 2002. Before the Council meeting it was known that several countries had reservations about the proposal. Germany was going to oppose it and Austria was probably going to vote with Germany, as it did in 1997. On the day of the meeting the health ministers even received a fax from the Australian Health Minister, Kay Patterson, demanding that the directive not be enforced until October 2006, as the international motor sport governing body FIA had requested. However, as the discussion started, several delegations, perhaps surprisingly, endorsed the commission proposal. Agreement was eventually reached by a qualified majority with only Germany and the UK voting against. Before the meeting this outcome would almost certainly not have been predicted.

The Austrian vote was so unexpected that Bernie Ecclestone of FIA announced in a television interview that Austria would lose its Formula One race after 2003. Ecclestone said: “Your health minister is the one to blame, because he agreed to bring forward the ban on tobacco advertising”<sup>30</sup>. FIA were as good as their word, and cancelled Austria's Formula One race from 2004 onwards. No other country that voted for the directive was blamed and punished in the same way as Austria.

### 6.3. Interactions between the European Community and Member States

Discussions on a tobacco advertising ban were probably the most difficult on the agenda in the Health Council. Over a rather lengthy period of deliberations, stretching from about 1990 to the present, the debate on advertising illustrates quite well the dynamic interactions between Member State and EU level.



In 1989 when the Commission introduced its first proposal to ban tobacco advertising only Italy and Portugal had banned tobacco advertising. By 2003 two-thirds of the EU (10/15) had adopted legislation to ban tobacco advertising: Italy (1963), Finland (1977), Portugal (1982), France (1991), Sweden (1994), Belgium (1997), Netherlands (2002), Denmark (2002), UK (2002) and Ireland (2003). By 2004 more than 70% (18/25) of EU countries had adopted legislation to ban tobacco advertising, the additional eight being: Lithuania (1995), Slovenia (1996), Estonia (1997), Poland (1999), Hungary (2001), Slovakia (2001), Cyprus (2002) and the Czech Republic (2003).

The adoption of the Advertising Directive in 1998 was considered by the global public health community as a very considerable victory for public health<sup>31</sup>, and its annulment in 2000 a disaster. But despite the annulment, the momentum generated by the Directive meant that an advertising ban was back on the political agenda in some Member States. Denmark, the Netherlands and the UK, which had strongly opposed a European ban at the beginning of the 1990s, implemented a ban 10 years later. Discussions on the Advertising Directive started a political process that facilitated the adoption of a ban at a later stage.

As a consequence of the EC proposals on advertising, nongovernmental organisations (NGOs) in these three countries focused their action on campaigning for an advertising ban. In the UK the campaign for an advertising ban had no effect on the ruling Conservative party but later influenced the Labour party, which included a tobacco advertising ban in their 1997 election manifesto. In the Netherlands the NGO tobacco control organisation, STIVORO, had not campaigned for a ban in the eighties but started campaigning for a total ban in 1990 in response to the Brussels proposals on tobacco advertising<sup>32</sup>. While the Dutch legislation on tobacco control was very weak in the 1980s, the Netherlands now has one of the most comprehensive tobacco control policies in Europe (see table 2 in Chapter 4: Tobacco-control policy components in place on 1 January 2004 and prevalence change from 1985 to 2003 in Europe: countries ranked by total tobacco control scores).

#### 6.4. The influence of the Advertising Directive on the new Member States

The influence of a possible tobacco advertising ban in the EU was already discernible in 1997:

*“The best thing that can be done in Europe would be to set a good example. If we had an advertising ban 5 years ago in the EU, it would have helped the countries in Central and Eastern Europe. During the debate in Poland two years ago on banning advertising, one of the arguments against the proposal was that there was no need to do so because even the EU does not have a ban, so why should we?”<sup>33</sup>*

The 1999 Hungarian law on the protection of non-smokers and the regulation of tobacco sales, marketing and use is a comprehensive tobacco control law. During the parliamentary debate many speakers stressed the impact of the EU and WHO on the development of the bill. They stressed the importance of taking the opportunity to adopt a law containing provisions in line with the EU regulations already in place.

The National Assembly of Hungary voted for a tobacco advertising ban 2 months after the European Court annulled the 1998 Tobacco Advertising Directive. The tobacco and advertising industries fiercely opposed the ban, claiming that the Hungarian regulation was stricter than that of the EU: “The new directive on tobacco advertising is weaker than the Hungarian



regulation which comes into force on 1 July 2001. According to the Association [the Hungarian Association of Cigarette Manufacturers] the industry should be regulated in a manner to remain competitive after the enlargement of the EU”<sup>34</sup>. Despite these arguments the Hungarian government maintained its advertising ban and in April 2004 it was the second of the new EU members to ratify the WHO FCTC<sup>g</sup>.

The political agenda in the Czech Republic was also determined by EU developments. The adoption of the 1998 EC Directive and its subsequent annulment in 2000 received huge media attention. Both the tobacco industry and “liberal” politicians used this by saying that even in the EU a total ban was overruled by the courts. The annulment was the main reason why a ban in the Czech Republic was only adopted in 2003 after many unsuccessful attempts. During discussion of the advertising bill in the Czech parliament in June 2002, MP Pavel Svoboda said<sup>h</sup>:

*“I guess that it will be useful to wait if this directive will be binding for EU states. It can easily happen that it will be refused by the majority of European countries and it will be necessary to withdraw this directive [...] this is why I suggest we refuse this bill.”*

The influence of the advertising directive on the WHO FCTC is discussed below.

### 7. THE LABELLING DIRECTIVES

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The European Commission made the EAC programme public at the end of 1986<sup>14</sup>. It contained 14 measures against tobacco, one of them on the labelling of tobacco products. The proposed directive was not based on health grounds, but on internal market measures. The creation of a single market required common trade rules, which should take into account a high level of health protection. At the time Ireland was leading the way with strong, unambiguous health warnings such as “Smoking causes cancer” printed in large characters on the largest surface of the pack. Other countries, such as Luxembourg, Greece and the Netherlands, had no laws on labelling. Having introduced legislation requiring health warnings, Ireland was unwilling to accept imported cigarettes which did not have health warnings. Article 100A EC, which concerned market harmonisation and included a paragraph on health, safety, environmental and consumer protection, taking as a base a high level of protection, was used to justify harmonised and stronger regulations on labelling. The directive was adopted in November 1989 and came into force on 1 January 1992<sup>13</sup>.

The labelling directive was slightly amended through Directive 92/41/EEC. Since January 1992, tar and nicotine yields must be indicated on cigarette packets and all tobacco products must carry the general warning “Tobacco seriously damages health”. Cigarettes packets also had to carry an additional specific warning to be chosen from a list. The warning had to be printed in the official languages of the country in which the tobacco was to be marketed (the end market) and had to cover at least 4% of each large surface of the packet, excluding the indication of the responsible authority. This percentage was increased to 6% for countries with two official languages and 8% for countries with three official languages. The warning was required to be clear and legible, printed in bold letters on a contrasting background.

<sup>g</sup> Hungary ratified the FCTC on 7 April 2004.

<sup>h</sup> E. Kralikova, Assistant Professor, Charles University School of Medicine, Prague, Czech Republic, personal communication.

They were not to be printed on a place where they may be damaged when the pack was opened or on a transparent wrapper or any other external wrapping. By 1 January 1994, tobacco products other than cigarettes were also required to carry supplementary specific warnings.

### 7.1. Support for the labelling directive and its initial impact

The labelling directive was welcomed by European smoking prevention organisations, and EC labelling legislation became the standard for the whole of Europe. In the report of the 1988 WHO Madrid conference one of the recommendations was “Health warnings should be rotating messages and be clearly legible. As a minimum, all Member States of the European Region of WHO should adopt the measures contained in the European Community’s directive on health warnings”<sup>35</sup>.

The impact of this first directive on tobacco labelling was enormous. As directives are binding on Member States, even countries with almost no tobacco-control legislation, such as the Netherlands, Denmark, Luxembourg and Greece, had to strengthen their health warnings. In addition to its direct impact on Member States, EC legislation was also becoming an example for many countries who wanted to join the EU such as EFTA countries and countries in Central and Eastern Europe. Most EFTA countries implemented the EC legislation on labelling and tar content in their national legislation.

The labelling directive also had repercussions on the UK, the only country which was against the common position agreement in May 1989 and which abstained in November 1989. The UK was one of the leading countries on tobacco control in Europe yet the government opposed this first tobacco-control directive. Even in the British parliament there was strong support for the directive. In a November 1988 debate the motion was passed that “This house takes note of the EEC Documents on the labelling of tobacco products; welcomes continued progress towards removing the remaining barriers to trade between Member States; and in the interest of public health, endorses the aims of reducing the tar yield of cigarettes and of ensuring that Community consumers are adequately warned of the dangers of smoking”.

The labelling directive forced the UK to supersede its discredited system of voluntary agreements by legislation. The UK’s lone dissent sparked debates on the front page of many British newspapers, most of which were critical of the UK’s opposition to the directive<sup>13</sup>. A British Medical Journal editorial stated: “The European Commission expected a rough ride for the tobacco directives from the tobacco industry. It had not expected the British government to do the industry’s job”<sup>36</sup>.

This debate was the first of many on EU tobacco policy in the UK. No other parliament has discussed European tobacco-control policy in such detail as the UK. In the short term the directive had another unexpected consequence. When the British government implemented it in 1991 they requested health warnings larger than the minimum laid down in the directive: 6% rather than the EU minimum of 4%. Tobacco companies challenged this implementation of the directive in the ECJ but lost the case in 1993<sup>37</sup>.

The size of health warnings is important. It is generally accepted that they should cover at least 25% of the front and back surfaces of cigarette packs. The small size of these new EU health warnings meant that in many cases they could barely be seen and were difficult to read, furthermore they did not have a contrasting background. It is perhaps an indication of how effective they were that the tobacco industry was very happy with the size. Whereas the industry had strongly opposed the directive when it was discussed in the European Parliament, it became clear at the beginning of the 1990s that they were happy with the 4% coverage. In the negotiations between the tobacco industry and the government in South Africa, the industry was willing to accept the EU 4% rule (Dr Zuma, South African Minister for Health, personal communication) and internal BAT documents also show their affinity for the EC health warnings. In a BAT Cameroon letter of 22 January 1993, it was stated “We should consider, in proposing to the government agreeing an EEC type health warning”<sup>38</sup>.

The directive stated that warnings must be clear and visible, printed in bold on a contrasting background. In the Oxford English dictionary “contrasting” is defined as “a juxtaposition or comparison showing striking differences”. In fact the most frequent choice of colour for the lettering was gold (68% of the warnings), which is a reflective colour and meant that the lettering changed with the light and at certain angles could hardly be seen at all. At the Ninth World Conference on Tobacco or Health in 1994, EU Commissioner Pdraig Flynn acknowledged the Commission's concern: “Nevertheless the commission has been concerned at recent reports of circumvention of the labelling rules, notably by printing the health warnings in ways which make it very difficult to distinguish the lettering. The Commission is now examining implementation and enforcement of the labelling laws and will bring forward proposals to strengthen the existing measures if this is considered necessary”.

### 7.2. Health warnings: the Polish example

On 9 November 1995 a law to protect public health against the effects of tobacco was enacted in Poland with an overwhelming majority. It included health warning on cigarette packs occupying 30% of two of the largest surfaces. Industry launched an aggressive campaign against health warnings, maintaining, as they did in Sweden, Finland and Norway, that the new legislation was inconsistent with current EU regulations and would hinder admission to the EU. In all, the tobacco lobby made three attempts to overturn the law between its promulgation and implementation<sup>39</sup>. In 1998 the Polish parliament finally confirmed the size of the health warnings at 30%. They were the largest in the world at that time and 3 years later influenced the size of the warnings in the EU.

### 7.3. The negative consequences of the labelling directive

In contrast, the EC labelling directive had the unintended effect of weakening stronger health warnings in countries such as Sweden, Finland and Norway. Although European directives do not preclude stronger measures in individual states and are intended to set minimum standards across the Union, in practice attempts by some countries to go further have been hindered for political reasons.

### **7.3.1. Sweden**

In 1977 Sweden was the first country in the world to introduce a system of rotating warnings. Each packet carried a framed health warning covering approximately 20% of the pack. Unfortunately, however, plans to strengthen these warnings by increasing their size and adding pictograms were abandoned following Sweden's decision to join the EU. Regulations on health warnings were the responsibility of the National Board of Health and Welfare, which had changed the wording of the rotating warnings three times between 1977 and 1985. In 1991 the Board issued new regulations to make the warnings much bigger than before (about 75% of one of the large surfaces of the package), printed in black on white and accompanied by a pictogram. Several tobacco companies immediately filed complaints against the new regulations. At the same time Sweden started negotiations to enter the European Economic Area, as a first step to joining the EU. During the negotiations both parties clearly and publicly stated that agreement would not force either party into downwards harmonisation, meaning accepting less stringent rules than those already existing in matters of the protection of public health or the environment. However there was a strong political commitment to enter the EEA agreement and the EC labelling directive was included in the "acquis communautaire" which Sweden had, in the course of the negotiations, agreed to adapt to. In December 1991 the Ministry of Health and Social Affairs overruled the Board, although stating in its press release that the decision was taken only because of the planned EEA agreement. The National Board of Health and Welfare's big, contrasting, pictorial warnings never appeared. In 2003 the new directive came into force, stipulating much bigger warnings, in black and white, on both sides of the package, with the prospect of including colour photos in the future. So after about 10 years EU standards are comparable to those the Swedish National Board of Health and Welfare tried to introduce at the beginning of the 1990s (P. Nordgren, Public Health Planning Manager, National Board of Health and Welfare, Stockholm, Sweden, personal communication).

### **7.3.2. Finland**

The Finnish health warning had to cover one third of the largest side of the packet. When Finland entered the EEA it had to harmonise its tobacco-control legislation to comply with the EU directives on labelling and tar yield. The changes, entered into force at the beginning of 1993, led to a considerable weakening of Finnish legislation. The most significant change was that the 33% health warning had to be reduced to only 6% of the package surface, the EU requirement for countries with two official languages<sup>40</sup>. In fact Finland could have produced larger warnings as the directive allowed higher health protection standards in Member States and just set minimum standards. Again, this was due to political pressure to conform on the eve of its accession to the EU.

### **7.3.3. Norway**

In a Parliamentary Proposition (No 27) of 1987-1988 the Norwegian Government stated: "The Ministry finds that the time is now ripe to replace the texts of the warning labels on tobacco products. The National Council on Tobacco and Health has already prepared an outline for such a program, and the Ministry accords high priority to its implementation." However, while the health ministry was working on the new law, the authorities were negotiating Norway's entry into the EEA. The National Council's proposal was therefore put aside and in December 1995 new labelling regulations were prepared in accordance with the

EU system, which greatly weakened the labelling programme, both with regard to the regulations that were already in place and particularly with regard to the National Council's 1986 proposal<sup>41</sup>. Ironically, while this was happening Norway voted against joining the EU.

### **8. THE LABELLING PROVISIONS OF THE 2001 TOBACCO PRODUCTS DIRECTIVE**

In 1996 the High Level Cancer Experts committee made recommendations on tobacco which included labelling similar to that currently in force in Australia: covering around 28% of the surface of the packs<sup>42</sup>. In 2000 the European Commission submitted a proposal for a directive<sup>43</sup> which recast two earlier directives on labelling (89/622/EEC and 92/41/EEC) and one on tar yields (90/239/EEC). The Commission proposed that the warnings should cover 25% of the surface of the two largest sides of the pack. However, new research from Canada showed that even bigger warnings were even more effective. A Canadian study which tested an increase of warning size from 30% to 60% concluded that there is a significant linear relationship between the size of the health warning message and its influence on the decision to stop smoking, in the range tested (30% to 60%, at 10% intervals). The larger the health warning the more effective it is at encouraging smokers to stop smoking<sup>44</sup>. This research influenced the debate in the European parliament, as well as attitude of the Rapporteur of the labelling directive in the parliament, Jules Maaten. Maaten proposed to increase the warnings to 60%. The Committee on the Environment, Public Health and Consumer Protection proposed 40 to 50%. In the debate Jules Maaten said:

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*“Health warnings need to be improved. The European Parliament has gratefully made use of Canadian research findings, and I feel we will go further down this line in time. We are not ready to go that far at this stage. That said, we do feel that health warnings should be at least as big as they are in Poland, where they now cover 30% of the packet and I am disappointed that the Council did not want to go further than 25%”<sup>i</sup>.*

A compromise between the Council and the Parliament resulted in a final text which stipulated that health warnings should cover 30% of the front and 40% of the back of cigarette packs (box 2<sup>45</sup>).

A discussion of the effectiveness of warning labels and pictorial warning labels in particular, along with recommendations for future EU action, can be found in Chapter 4.

<sup>i</sup> J. Maaten, Parliamentary debate on 11 December 2000.

## Box 2. - Main labelling provisions of the 2001 Tobacco Products Directive (2001/37/EC)

The tar, nicotine and carbon monoxide yields of cigarettes shall be printed on one side of the cigarette packet in the official language or languages of the Member State where the product is placed on the market, so that at least 10% of the corresponding surface is covered (12% for two official languages and to 15% for three official languages).

Warning labels should cover 30% of the front of the pack (32% for two languages and 35% for three languages) and 40% of the back of the pack (45% for two languages and 50% for three languages).

Warning texts should contain a general warning on the front - either “Smoking kills” (or “can kill”, depending upon transposition) or “Smoking seriously harms you and those around you” to be alternated on a regular basis; additional warnings on the back - a list of about twelve different texts, also to be alternated on a regular basis.

The text of warnings and yield indications shall be printed in black Helvetica bold type on a white background; in lower case type, except for the first letter of the message and where required by grammar usage; centred in the area in which the text is required to be printed, parallel to the top edge of the packet; surrounded by a black border not less than 3 mm and not more than 4 mm in width which in no way interferes with the text of the warning or information given; in the official language or languages of the Member State where the product is placed on the market.

The Commission produced rules for the use of colour photos (recently introduced in Canada and Brazil for example), graphics etc., in September 2003. Member States who wish to authorise the use of pictures and graphics will then be entitled to do so, but only within the context of the agreed rules and at the earliest from 1 October 2004. (To assist this, the Commission is preparing a library of colour photographs for use by Member States, which is expected to be ready by the end of 2004).

## 9. POLICY INTERACTIONS

### 9.1. The impact of European Union tobacco-control policy on countries outside the European Union

EC policy on tobacco also had an impact outside the EU. In Sweden for instance tobacco-control policy had reached a plateau in the 1980s. The EAC programme, which Sweden participated in, contained several proposals which from a Swedish perspective at the time appeared radical and controversial. These proposals included:

1. strengthening health warnings on tobacco packages;
2. maximum limits for tar in cigarette smoke;
3. a ban on tobacco advertising;
4. tobacco tax increases;
5. smoke-free public places;
6. a ban on duty-free sales of tobacco.

EAC re-invigorated tobacco control in Sweden. During 1991 and 1992 Swedish NGOs (including The Swedish Cancer Foundation, Doctors against Tobacco, A Non-Smoking Generation) starting lobbying for a Tobacco Act. The campaign emphasised the European perspective and portrayed the EU as a leader in tobacco-control policies. For example the Cancer Foundation ran a series of full-page advertisements in the press with the theme “Politicians! Take a stand against smoking!” One of the advertisements emphasised the European perspective: “Want to join the EC? They make much tougher demands than us.”

The Swedish Tobacco Act was introduced in 1993 and by 1994 was amended to include a ban on direct tobacco advertising and the right to a smoke-free workplace. Thus European tobacco-control policies contributed substantially to Swedish policy development during the last half of the 1980s and the first half of the 1990s (P. Nordgren, Public Health Planning Manager, National Board of Health and Welfare, Stockholm, Sweden, personal communication)<sup>46,11</sup>.

The influence of EC policy on the Member States that joined on 1 May 2004 was even greater. Government officials in Hungary often recognise in their speeches the positive role of the EU in facilitating their tobacco-control efforts. For example the Health Minister said:

*“In the past few years the Union has been proven to have an outstanding progressive role in the fight against smoking, in spite of the economic counter-interests of some countries. This professional, legal and moral background could ensure the success of the Hungarian tobacco control program as well”<sup>47</sup>.*

Poland was also influenced by activities in the EU, as was acknowledged by Witold Zatonski, an epidemiologist and specialist in public health medicine, and Poland's leading tobacco-control advocate:

*“A review of the history of tobacco control in Poland (similar trends could be observed in other CEE countries) indicates that action to reduce the health consequences of smoking was initiated and carried out from the very beginning in collaboration with EU countries”.*

### 9.2. The role of the European Community in the Framework Convention on Tobacco Control negotiations

In 1998 the WHO proposed the United Nation's first ever health treaty and invited its 192 Member States to develop a Framework Convention on Tobacco Control (FCTC). Negotiations were held under the remit of six International Negotiating Bodies (INBs) They began in October 1999 and took place at regular intervals until May 2003 when the world's first public health treaty was adopted by the World Health Assembly.

The Framework Convention covered all aspects of tobacco control. This presented a complex negotiating scenario for the Community and the Member States because some areas were subject to exclusive Community competence, some were shared between the Member States and others were exclusively the preserve of the Member States. In an attempt to streamline the negotiation process, two negotiating mandates were adopted by the Community and Member States in October 1999 and April 2001. These mandates were not made public, but by and large the Commission negotiated on behalf of the Member States plus the 13 accession and candidate countries in all areas covered by exclusive competence



(tar yields, labelling etc.) and the respective Presidencies in areas subject to shared and Member State competence only.

Generally, the Community and Member States sought to reach a consensus position on all points, but this sometimes proved challenging, especially in areas where unanimity was required, such as taxation, and contentious areas, such as comprehensive advertising bans. More often than not this meant that the Community agreed to negotiate on the basis of the existing body of Community law known as the *acquis communautaire*. However, this did not always provide a firm footing for negotiations. When negotiations began the *acquis communautaire* on tobacco advertising was the 1998 Tobacco Advertising Directive which banned most forms of tobacco advertising in the Community, but this was annulled in October 2000. The Commission quickly put forward a directive on cross border advertising and sponsorship, but this was not agreed by the Member States until 2003 and the extent to which this constituted an agreed position on advertising in the FCTC negotiations was disputed by Member States who had already introduced comprehensive bans before or after 1998 and those countries which had opposed the directive.

Article 13 of the FCTC, which was adopted in May 2003, requires that each party “in accordance with the constitution or constitutional principles, undertake a comprehensive ban on all forms of advertising, promotion and sponsorship”. The ban would occur within 5 years of the convention entering into force. The adoption of this article led to passionate discussions in the health group of the Council. This group is composed of representatives of the Member States and prepares Community legislation.

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Only Germany strongly opposed Article 13, and only agreed with it on condition that it would not apply to Germany, arguing that it was prevented from introducing such a ban under its Constitution. Furthermore, Germany insisted that its agreement does not mean that it recognises the legality of the advertising directive, which it is now challenging in the ECJ. The final discussions on Article 13 took place during the last round of FCTC negotiations in February 2003, just 2 months after the EC advertising directive was agreed by the Health Council in December 2002. The agreement in the council facilitated the EC's endorsement of the advertising provisions of the FCTC and it is expected that most of the 25 EU members will ratify the FCTC. This will result in an obligation to ban tobacco advertising within 5 years, except for countries with constitutional impediments to doing so.

Thus the interactions between EU tobacco-control policy and the WHO Framework Convention on tobacco advertising have been positive and EU legislation strengthened the WHO Framework Convention.

The situation on labelling and product regulation was also complex. The EU Commission adopted a proposal for an EU directive on these issues in November 1999 and a directive was finally agreed in Spring 2001. The provisions of this directive were very influential on the negotiations and in the final text.



### 9.3. The impact of the 2001 directive on the World Health Organization Framework Convention

One of the strongest provisions in the WHO Framework Convention on tobacco control is article 11, which recommends that health warnings should be 50% or more of the principal display areas, but requires that they be no less than 30% of the principal display areas and may be in the form of, or include, pictures or pictograms. Negotiations for this legally binding convention were concluded around 3 am on 1 March 2003. Without the endorsement of the EC for these labelling requirements, article 11 of the FCTC would have been much weaker. In fact during the last round of negotiations, which took place in Geneva at the end of February 2003, there was strong opposition from the USA and Japan to include a requirement that health warnings should occupy 30% of the principal display areas. Even Australia was hesitant, as the actual Australian legislation did not reach the 30% surface requirement (only 29%). During the first week of the last round of the negotiations in February 2003 attempts were made to weaken the provision by including the sentence “parties will endeavour to require that such warnings be” (no less than 30%). It was only on 28 February 2003 that an agreement on the labelling requirements was concluded, which maintained the initial strong obligations. The recommendation that health warnings should be 50% or more of the principal display areas but must be at least 30% of the principal display areas will become the world standard.

Article 11 (1) of the FCTC also states:

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*“ Each Party shall, within a period of 3 years after entry into force of this Convention for that Party, adopt and implement, in accordance with its national law, effective measures to ensure that:*

- (a) tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions[...] These may include terms such as 'low tar', 'light', 'ultra-light', or 'mild'”.*

At the time, only the Community and Brazil had introduced legislation banning the use of misleading descriptors. The inclusion of this important provision in the Convention would not have been possible without the pre-existing EU *acquis communautaire* in this area.

## 10. TAXATION POLICY

Taxation of tobacco products has been discussed in more detail in Chapter 2. In 1992 the European Council of Finance Ministers adopted three directives on the approximation of taxes on cigarettes and other products. These directives provide for a minimum harmonisation of the structure of tobacco tax in Europe. According to Article 4 of Directive 92/79/EEC two criteria are important in order to examine the existing excise duty for tobacco products: the proper functioning of the internal market and the wider objectives of the Treaty, which includes health protection. Commission reports reviewed the level of excise duties on tobacco products in 1995, 1999 and 2001<sup>48</sup>. The fact that tobacco poses a health risk and that taxation has to be seen as an important element of a policy aimed at reducing the consumption of tobacco was strongly underlined in these reports. It was a fortunate coincidence that the main discussions on tobacco taxation were held at a time when the EAC programme had

a very high profile. There was a fear that EU taxation rules would lead to lower prices in the community. The main conclusion of the November 1992 UK Presidency seminar on tobacco taxation was: “The seminar underlines the importance of a comprehensive approach in reducing smoking, and price as a key measure, especially recognising its cross-European dimension - the single market must not be allowed to push down tobacco prices”<sup>49</sup>. While an upward harmonisation to the high tax countries was not politically feasible the taxation directives have never led to lower prices. Rather, they have led to higher prices in the southern European countries<sup>50,51</sup> and will lead to higher prices in the new EU Member States that joined in 2004.

## 11. TOBACCO PRODUCT REGULATION

The EC began regulating tobacco products in 1990 when it established limits on maximum tar yields in cigarettes. This strategy was continued in the 2001 tobacco products directive, which mandated a further reduction in tar yields as well as reductions in nicotine and carbon monoxide yields. The ban on certain types of smokeless tobacco introduced in 1992 (see below) was maintained in all EU countries except for Sweden. The 2001 Tobacco Products Directive also required tobacco manufacturers and importers to disclose the ingredients used in their products, and provided for a review of the directive by the end of 2004. The remit of the review is extensive and includes methods for assessing and regulating toxic exposure and harm more accurately, assessing ingredients, potentially less harmful products, and consumer information. A detailed analysis of the EU's product regulation activities can be found in Chapter 5.

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### 11.1. The history and implementation of the ban on oral snuff (snus)

Article 8 of the Tobacco Product Regulation Directive (2001/37/EC) bans the placing on the market of “tobacco for oral use”, defined as “all products for oral use, except those intended to be smoked or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets, or in a form resembling a food product”<sup>52</sup>. Hence, in the EU, apart from Sweden which had a derogation because moist snuff (snus) was already commonly used, snuff is banned (although chewing tobacco is not banned).

Smokeless tobacco use is very common in many Asian and some African countries. It also used to be common in the US until the beginning of the last century, when people became aware that it could spread diseases like tuberculosis (because of the need to spit). As mass-produced cigarettes became available at the beginning of the 20th century, smokeless tobacco use declined, and it became limited mainly to some parts of Scandinavia and some American states. However, the tobacco industry continued to explore the potential of other tobacco products. In the 1970s and 1980s smokeless tobacco “teabags” became popular again in the USA, largely with teenage boys. The manufacturer of these products, US Tobacco, planned to manufacture these products in Scotland but negative publicity by tobacco-control advocates caused first the announcement of a voluntary agreement restricting promotion of the product, followed by an outright ban on oral snuff by the British government in 1990 under consumer protection legislation<sup>53</sup>.

Following an appeal by US Tobacco the ban was overturned, but EU legislation subsequently introduced a ban across the whole of the EU with a derogation for Sweden. The ban was based on evidence of carcinogenicity of oral snuff products together with the desire to ban new tobacco products before they became established in markets. In addition, there was a concern that US Tobacco was specifically targeting youth with its marketing of smokeless products.

More recently, some tobacco-control experts have argued that the ban on oral snuff acts against public health because cigarettes are a much more harmful means of delivering nicotine (see Chapter 1), and smokers could reduce their risks if instead of smoking they switched to highly manufactured forms of smokeless tobacco such as snus<sup>54</sup>.

Swedish Match, manufacturers of snus, along with a German tobacco wholesaler, are now challenging the EU ban on smokeless tobacco in the ECJ. They allege that snus is a much safer product than cigarettes and hence that the ban serves no internal market purpose, is disproportionate and discriminatory. An oral hearing took place on 8 June 2004. The Advocate General gave his Opinion on 7 September 2004 and a ruling is expected at the end of 2004<sup>55</sup>.

In his opinion the Advocate General concluded that article 8 of Directive 2001/37/EC can be based on Article 95 EC, is consistent with the principle of proportionality, is consistent with the equal treatment of similar products, but did not comply with the obligation to state the reasons on which the prohibition is based and therefore Article 8 should be declared invalid. However, the Advocate General recommends that the ban should be maintained until the Council and Parliament have replaced it with a new provision based on proper reasoning<sup>56</sup>.

## 12. WORKPLACE SMOKING RESTRICTIONS

In 1989 the EAC programme produced a (non-binding) resolution on smoking in public places (see above). This was followed up with a report into its implementation in 1996, which found that legislation had been introduced to restrict smoking in 14 out of the 15 EU Member States, the exception being the UK where a voluntary code was in force. The report did not, however, look at the effectiveness of enforcement of this legislation and called upon Member States to ensure that national laws were complied with.

The Single European Act provided the Community with a legal base to protect the health and safety of workers, and after its entry into force in 1987 the Commission moved quickly to introduce legislation to improve conditions for Europe's workers. A number of these directives (see table 1) restricted the right to smoke in the workplace or provided employees with theoretical protection from exposure to second-hand tobacco smoke. In practice, except for workplaces where dangerous substances such as flammable liquids and carcinogenic agents are handled, employees have not benefited from the provisions, and exposure to second-hand smoke has been little considered when carrying out risk assessments.

Importantly, the Community has not followed other bodies charged with the assessment and protection of occupational health and safety, such as IARC, the EPA and the Finnish and German governments, by classifying second-hand smoke as a workplace carcinogen. Mindful of the growing body of evidence proving that second-hand tobacco smoke exposure causes cancer, cardiovascular disease and respiratory illness (see Chapter 1), the Commission has recently initiated a consultation process to discuss whether existing EU legislation on car-

cinogens in the workplace should be amended to include second-hand smoke and other carcinogens. This opens up the possibility of either classifying second-hand tobacco smoke as a carcinogen in its own right or bringing some or all of the carcinogenic substances in it under the remit of the directive. The health risks of exposure to second-hand smoke in the workplace and national responses to them were discussed by the Senior Labour Inspectors of the EU at their annual meeting in May 2004. The Joint Research Centre in Ispra, Italy is also carrying out tests into levels of benzene in indoor air. They expect to make recommendations on exposure limits in early 2005.

### **13. THE TOBACCO RESEARCH AND INFORMATION FUND**

In 1993 the Council established the Community Fund for Research and Information on Tobacco (the Fund) with a small levy on the Community's raw tobacco subsidy. The Fund was set up as a result of the criticism that the Community heavily supported raw (or leaf) tobacco production, but did not give enough support to health initiatives. For instance in their 1994 report the Court of Auditors noted that the smoking portion of the 1993 EAC budget was just €1.5 million equivalent to 0.1% of total expenditure on raw tobacco subsidies<sup>57</sup>.

The Fund finances projects on the development of new tobacco varieties and cultivation methods, alternative uses for raw tobacco and alternative crops (until 2001), projects to help tobacco growers to switch to other crops or activities (since 2002), and projects improving public awareness of the harmful effects of tobacco consumption through education and information, and is managed by the Commission services. The percentage of funds allocated to each category of projects between tobacco growers and public health community is generally 50/50. Funds are only allocated following official calls for proposals or tenders.

The objective of the health projects financed by the Fund is to make EU citizens more aware of the harmful effects of tobacco consumption. Under the 1994/1996 first and second calls for proposals, co-financing of 25% by applying organisations was required and 17 projects were financed with a total expenditure of €7.4 million. For the 2001 call for tender, the Commission took the decision to focus on fewer, larger projects covering all 15 current Member States. In the event, one project, with 100% financing, was accepted (table 6).

Table 6. - The Tobacco Research and Information Fund

1992	EU Council regulation 2075/92: to set up a community fund for tobacco research and information financed from a levy of maximum 1% on the premium paid to tobacco growers (0.5% in 1993 and 1% from 1994 onwards).
1993	Commission regulation 2427/93 lays down detailed rules for the Fund.
1994	First call for proposals.
1996	First call: 11 health projects approved totalling €5.6 million
1996	Second call for proposals.
1997	Second call: 6 health projects financed totalling €2.8 million*
1998	Council regulation 1636/98 modifies article 13 of Council regulation 2075/92. It sets up the Community Tobacco Fund and increases funding to 2% of the premiums. The regulation applies from the 1999 harvest. It stipulates that the Fund must be used to inform the public of the dangers of smoking, support research to develop less harmful varieties (and production methods) better geared to market conditions, support research to develop alternative uses for raw tobacco, and support research on the possibilities of alternative crops or activities.
2000	Commission regulation 1648/2000 lays down detailed rules for the application of Council regulation 2075/92 on the Fund and repeals regulation 2427/93.
2001	Call for tender in June: to draft, produce and disseminate a communication campaign to prevent nicotine addiction in adolescents, of 12-18 years, for 3 years. Estimated value: €18 million.
2001	2001 tender won in December by Media Consulta GmbH, with the “Feel free to say No” campaign.
2002	Council regulation 546/2002 continued supporting the Fund for the 2002 and 2003 harvests. The agricultural part of the Fund changed to support only work on conversion of tobacco growers. The agronomic research was stopped and replaced with “measures to support specific initiatives allowing tobacco growers to switch from tobacco to other crops or other economic activities creating employment and studies of the possibilities for tobacco growers to do so”.
2002	Commission regulation 2182/2002 lays down detailed rules on the Fund and repeals and replaces regulation 1648/2000.  A call for tender is launched for the external and independent evaluation of the first year of the “feel-free campaign”. The firm EVALUA SARL is selected in December.
2003	Two calls for tender for a report on Tobacco Control in Europe and for technical and scientific support on the colour photographs/illustrations used as additional health warnings on packages of tobacco products.  Results of the evaluation of the “feel-free campaign” are published on SANCO website <sup>58</sup> .
2003	November Rome conference on Tobacco, Youth Prevention and Communication attended by 212 public health and media experts from 32 countries. The aim was to adopt recommendations that would help the European Commission define the criteria for the development of future campaigns <sup>59</sup> .  Council regulation 2319/2003 continues supporting the Fund for the 2004 harvest.
2004	Council regulation 864/2004 continues supporting the Fund for the 2005, 2006 and 2007 harvests. The Fund will stop in 2008 but funding for health projects will have increased from €14.4 million in 2005 to about €22.8 million in 2006 and €28.5 million in 2007.  30/07/2004, prior information notice published by DG SANCO for a further call for tender for an EU-wide mass information campaign amounting to €72 million from 2004-2008 <sup>60</sup> .  07/08/2004 publication of the full call for tenders <sup>61</sup> .
1993-2001	Total available for health projects: €42 million. Total spent on health projects: €8.4million.
2001-2002	Total available for health projects: €16.5m. Total spent on health projects: €13.3 m.

\*: One €5.1m project was suspended, which reduced spending from €7.9 million.

From 1993 to 2000 there were a number of problems with the administration of the Fund which resulted in very limited use of the available funds for public health. An evaluation of the Fund management highlighted that this was due to too few calls for tender, given the amount of money available, a long time-frame for approval of the projects and very delayed payments to contractors.

From 2001, the management of the Fund improved as a result of the decision to use tendering procedures rather than co-financed projects. At the same time, new regulations were also introduced which enabled the Fund to better respond to policy needs by broadening the range of public health topics for which it could be used. Utilisation of the available funds for health projects increased strongly since 2001. At the same time, the budget available for health projects has increased from € 3 million in 2000 to €14.4 million in 2004.

One project supported by the Fund is the “Feel Free to Say No” campaign, an information and awareness campaign aimed at young people, which started in May 2001. An external evaluation was carried out after its first year of operation in order to inform subsequent years. The findings highlight the difficulty of communicating health messages to teenagers: “The teenagers participating in the focus groups appreciated the easy-going and not moralising style of the campaign. The anti-tobacco objective of the campaign was understood; even if most elements of the campaign, taken separately, did not refer clearly to tobacco, including the claim ‘Feel Free to Say No’”. The evaluation also found that “After looking at the TV ads the image of the non-smokers remained unchanged. Professional footballers were seen as ‘compulsory’ non-smokers, and the fact that pop stars do not smoke was not judged credible by some”.

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Conclusions of the Media and Smoking Prevention conference in Rome provided recommendations that would help the European Commission develop future campaigns:

- “Youth prevention campaigns have to be part of a comprehensive tobacco control policy, and not be conducted in isolation. Media campaigns play a key role to build knowledge, change attitudes and behaviour in support of a tobacco-free society.
- Pan European youth smoking prevention campaigns should promote the visibility of tobacco control. Campaigns should contribute to change the social norm from smoking to non-smoking in the European Union.
- In order to maximize the benefit for all stakeholders, European campaigns should set the strategic framework and be adapted on national/regional level according to local cultural and social needs. Think globally - act locally.
- To achieve ambitious objectives we need important resources, long-term commitment and the involvement of expert groups and stakeholders, with the exception of the tobacco industry.
- To reach young people we need to do campaigns that target both adults and youngsters. We need to speak to young people as adults but use the media of their generation.
- We need to invest into public health, social and marketing research. This research needs to be integrated into campaigns from the beginning and be as widely defined as possible. The key words for research are ‘integration’, ‘independence’ and ‘dissemination!’”

It is difficult to measure the real impact of health information campaigns on target audiences, in terms of impact on behavioural change, and few external evaluations of the Fund have been carried out. One attempt to evaluate the Tobacco Fund's health projects by an external team was unsuccessful because insufficient data was available to measure the programme results<sup>61</sup>. However, results of the most important project from the first call for proposals, the European Smoking Prevention Approach (ESFA) have been published recently<sup>62</sup>, and more articles are expected to be published in the near future.

The Fund is due to come to an end in 2008 as a result of the Community decision to abolish Commission subsidies for raw tobacco production by 2010. The abolition of subsidies to tobacco production is an outcome long desired by the tobacco-control community. As a consequence, contributions to the Fund will cease following the 2007 tobacco harvest. However, in its final years, the annual budget available for health projects will dramatically increase to an expected budget of €28.5 million in 2007. This is a much needed investment in European tobacco control and discussions as to how the funds might be spent, particularly in the research field, were held at the workshops in Brussels and Limerick. The findings of the workshops are given in Chapter 4 and recommendations are given in Chapter 7.

### 14. DISCUSSION AND CONCLUSIONS

The European Community has undertaken an extensive range of tobacco-control measures in the last 20 years that have had an enormous influence within and outside the EU. In the absence of a public health legal base that permits the Community to adopt directives on tobacco-control measures, the internal market legal base has been used. The tobacco industry has tried to claim that this has been an abuse of power by the Community legislator and made extensive use of the judicial review provisions in the Treaty to attack these directives. The ECJ has largely rejected this argument and upheld all but one of the Community's tobacco-control instruments. However, the loss of the 1998 tobacco advertising directive was an enormous blow to European smoking prevention efforts and will result in a significant number of smoking-related deaths in the EU. The new article on public health, agreed at the meeting of the European Council in June 2004, may offer a way forward once the European Convention enters into force but the utility of the article for tobacco control remains to be clarified. In the meantime, Community legislators will continue to rely on the internal market legal base to tackle the tobacco epidemic.

It is clear from this account that developments in tobacco control in the EU since 1985 have been the result of complex interactions and that EC tobacco-control legislation, and the legal challenges it has faced, has had both a positive and negative effect on tobacco control in Member States, countries waiting to join the EU, and organisations like the WHO and its Framework Convention.

Effective tobacco control can only be achieved with high levels of political support. From its inception, the EAC Programme enjoyed this support. Successive Health Commissioners - Marin, Papandreou, Flynn and Byrne - have all appreciated the benefits that good smoking prevention strategies can bring for Europe's citizens and the need to tackle the smoking epidemic. Commissioner Manuel Marin initiated the EAC programme, Vasso Papandreou proposed the ban on advertising and Pdraig Flynn encouraged its ultimate adoption.

Most recently, Health Commissioner David Byrne has emphasised the crucial importance of tobacco control for Europe by placing it at the centre of his public health strategy and highlighting the enormous human and economic costs of smoking.



The EAC programme was a dynamic and innovative programme and the seven elements that seem to have been key to its success were:

- political commitment to tobacco control at the highest level of the Commission;
- the committee of cancer experts;
- a dedicated unit within the Commission;
- partnership with key stakeholders;
- a high-profile media strategy;
- a legislative approach;
- provision of research and evidence from an expert office to support legislative initiatives.

From the beginning of the EAC programme smoking habits were systematically monitored through regular opinion surveys, the EuroBarometer surveys. Not only did these surveys provide regular prevalence data, enabling the impact of tobacco-control measures to be monitored, but they also provided information that was useful to the Commission by supporting tobacco control. For example, they provided data, which were published, showing the high proportion of Europeans favouring banning tobacco advertising.

This chapter also reveals the excessive influence of Formula One on EU health policy and the lesson here may be that public health bodies and governments have not been as positive as they could have been in asserting their right to protect the health of their citizens without undue interference from external vested interests.

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EU legislation has had a positive impact on the WHO FCTC in the area of labelling and advertising. One of the strongest provisions in the Convention for instance - article 11, which bans misleading descriptors on the packages of tobacco products and recommends that health warnings should be 50% or more of the principal display areas, but requires that they be no less than 30% of the principal display areas - benefited from European Community support. The longer term impact of this article could be enormous as it will become the world standard.

Yet in two major areas of tobacco control - tobacco product regulation and workplace smoking restrictions - the Community can still do a great deal. As will be outlined in Chapter 5, European product regulation measures are still in their infancy. In particular, the absence of meaningful and effective EU regulation on workplace smoking stands out when compared to action taken in some countries around the world. Accordingly, tobacco product regulation and workplace smoking legislation will be the next two challenges for the Community as it continues to provide leadership in European tobacco control and if it wishes to become a world leader in smoking prevention policy.

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# THE IMPACT OF TOBACCO-CONTROL POLICY ON SMOKING IN THE EUROPEAN UNION

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## I. INTRODUCTION

In this chapter we examine the evidence of the impact of tobacco-control policies on smoking prevalence in Europe. Although this is a complex process and it is difficult to state precisely what worked and why in any individual country at any particular time, there are international data on what works and so it is possible to relate policies to consumption/prevalence change in a broad way. However as we will emphasise in the discussion, one characteristic of the tobacco-control field in many countries is the failure systematically to collect data on smoking prevalence and attitudes so that the effectiveness of tobacco-control programmes can be evaluated. Since such programmes are supported by tax payers' money they should be properly evaluated. Both governments and the people who pay for them need to know if the programmes are effective, if they provide good value for money and how they can be improved. In Europe we cannot compare smoking prevalence directly in different countries, since most countries use different methodologies to measure smoking. We have approached this problem in this chapter by looking at the percentage fall in smoking in individual countries since at least this measure masks differences between the prevalence measures used.

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## 2. WHAT TOBACCO-CONTROL POLICIES ARE EFFECTIVE?

The World Bank fact sheet “Tobacco control at a glance” describes six cost-effective tobacco-control interventions<sup>1</sup>:

- Price increases through higher taxation on cigarettes and other tobacco products.
- Comprehensive advertising and promotion bans of all tobacco products, logos and brand names.
- Bans/restrictions on smoking in public and workplaces.
- Better consumer information including counter advertising (public information campaigns), media coverage, publicising research findings.
- Large, direct health warning labels on cigarette boxes and other tobacco products.
- Treatment to help dependent smokers stop including increased access to medications.

International experience strongly suggests that the best results are achieved when a comprehensive set of measures are implemented together and this seems to be borne out by observing that many countries have succeeded in reducing smoking prevalence dramatically.

### 2.1. Price increases through higher taxation

Price increases through higher taxation are the most effective and cost-effective tobacco-control strategy according to the World Bank, especially for young people and others on low incomes, who must, of necessity, be highly price responsive. A price rise of 10% decreases consumption by about 4% in high-income countries. Price rises have the additional political advantage for governments of raising tax income<sup>2</sup>.

### 2.2. Comprehensive advertising and promotion bans

Comprehensive advertising and promotion bans have also been shown to reduce smoking. Empirical evidence shows that a fully comprehensive advertising ban covering all media and all forms of direct and indirect advertising reduces tobacco consumption. A comprehensive advertising ban also lessens the social desirability of smoking, in particular among young people. Along with the promotion of a smoke-free environment, the regulation of advertising contributes to making non-smoking an accepted social norm. The World Bank estimates that comprehensive bans can reduce tobacco consumption by around 7%<sup>2</sup>.

However as other types of tobacco advertising and promotion are curbed, package displays and adverts at the point of sale (POS) have become increasingly important in the marketing strategies of tobacco companies. The industry pays retailers for prominent display space, including displays behind the counter facing customers (“power walls”) and counter top displays. POS promotions increase overall tobacco industry sales, in part by increasing the social acceptability of tobacco products.

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POS promotions stimulate impulse purchases among ex-smokers struggling to resist craving, teenage experimenters and occasional, non-daily smokers.

In Canada, where information on marketing expenditure is reported to government, in 2002 the tobacco industry spent CAN\$77 million (€47 million) on payments to retailers for displays. This compares to the CAN\$60 million (€37 million) that the industry spent in 1996 on sponsorship, when sponsorship was the other major form of marketing expenditure (R. Cunningham, Canadian Cancer Society, personal communication). The tobacco industry sometimes claims that it does not want children to be exposed to tobacco promotion. Yet it opposes legislation prohibiting POS promotion in premises where children have access. Governments increasingly recognise the need to ban POS tobacco promotion, while the tobacco industry is responding with lobbying and legal challenges to prevent action in this crucial area.

Iceland has banned visible POS package displays since 2001. A British American Tobacco (BAT) legal challenge to the Icelandic legislation was dismissed on technical grounds but has been reintroduced and will be heard in the autumn of 2004. In Ireland a ban on POS displays is included in legislation but has not yet been implemented<sup>a</sup>. The tobacco industry has filed a legal challenge to this provision, including a claim that the provision is an unreasonable infringement of freedom of expression. In the UK existing legislation includes regulatory

<sup>a</sup> Public Health (Tobacco) Act, 2002, as amended in 2004. The Act includes regulatory authority to prescribe exemptions to the ban on POS displays, but no such regulations have been adopted. The 2004 amendments re-enact the provision adopted in 2002 but not proclaimed into force. The tobacco industry had initiated a legal challenge to the 2002 provision arguing in part that Ireland had not given the notice required by the European Community.

authority to ban POS displays<sup>3</sup> but no regulations have yet been adopted. Regarding POS signage, UK regulations permit a maximum of one sign, approximately no larger than A5. The tobacco industry has filed a legal challenge to this regulation, claiming that it is unreasonably restrictive. In Canada numerous provinces and territories have either adopted legislation to curb POS promotion or are considering legislation.

### 2.3. Bans/restrictions on smoking in public and workplaces

Bans/restrictions on smoking in public and workplaces do not just protect non-smokers. They also create an environment that encourages smokers to cut down or stop. Furthermore, as many public places are workplaces, a ban on smoking in workplaces will actually ban smoking in most public places. Clean indoor air laws may also prohibit smoking in public places and on public transport. The most extensive laws also include restaurants, bars and private workplaces. A review from the USA of 26 studies on the effect of smoke-free workplaces concluded that totally smoke-free workplaces are associated with reduction in smoking prevalence of almost 4%, when compared with no smoke-free workplaces at all<sup>4</sup>. Clean indoor air laws may also make smoking less attractive by reducing opportunities to smoke and by reinforcing nonsmoking social norms. A less-than-total ban is predicted to have half the effectiveness of a strict ban<sup>5</sup>. A large increase in the tax on cigarettes and a ban on smoking in bars and restaurants, which came into effect on 30 March 2003, are being credited with contributing to an 11% decline in the number of adult smokers in New York City from 2002 to 2003, one of the steepest short-term declines ever measured, according to surveys commissioned by the city. The surveys show that the number of regular smokers, after holding steady for a decade, dropped by more than 100,000 over the period. It is estimated that 19% of adults in New York smoked in 2003, down from 22% in 2002<sup>6</sup>.

In Europe complete bans on smoking in the workplace (including bars and restaurants) have been introduced in Ireland (since 29 March 2004), in Norway (1 June 2004) and will be introduced in Sweden on 1 June 2005. The Netherlands introduced a workplace ban excluding bars and restaurants on 1 January 2004.

### 2.4. Better consumer information/public information campaigns

There is convincing evidence from several countries that sustained and well-funded public information campaigns can reduce smoking prevalence substantially. All such data need to be interpreted carefully as the factors pushing prevalence reduction are so complex and it is not possible to do controlled experiments in the real world. With these caveats there is still impressive evidence of the effectiveness of education/information campaigns albeit in the context of a comprehensive approach to tobacco control. Per capita cigarette sales in Massachusetts and California, two USA states that have invested heavily in tobacco control, have fallen impressively since 1990. The reductions in these two states are about double that in the USA as a whole over the same period. Smoking prevalence is down to about 17% in California and 19% in Massachusetts. Although there is some evidence of possible confounding variables that may have contributed to (but not accounted solely for) the reductions in prevalence, these are still impressive reductions, testifying to the effectiveness of tobacco-control programmes.



### 2.5. Large, direct health warning labels

Large, direct health warning labels are an effective way both of informing smokers of the hazards of smoking (thus encouraging smokers to stop), and of discouraging non-smokers from starting to smoke. Evaluations of health warnings conclude that they are effective only if they contain multiple strong and direct messages that are prominently displayed. Evidence from Canada, Brazil, Australia<sup>7</sup>, the Netherlands<sup>8</sup> and Belgium<sup>9</sup> shows that the large warnings introduced recently are effective in discouraging smoking and increasing public awareness of the health effects of smoking.

### 2.6. Treatment to help dependent smokers stop

Treatment to help dependent smokers stop is effective and cost effective<sup>10</sup>. Many smokers want to stop but need help to do so because they are dependent. Quit rates can be substantially increased through help from healthcare providers, telephone “quitlines”, behavioural support and medications including nicotine-replacement (NRT) and bupropion. Some governments now provide treatment through their healthcare systems. Although treatment policies will have a relatively small effect on prevalence reductions (about 1-2%) this effect may grow over time and may be important in helping those heavier smokers who have the most difficulty cutting back or quitting smoking<sup>10</sup>.

## 3. FUNDING OF TOBACCO-CONTROL PROGRAMMES

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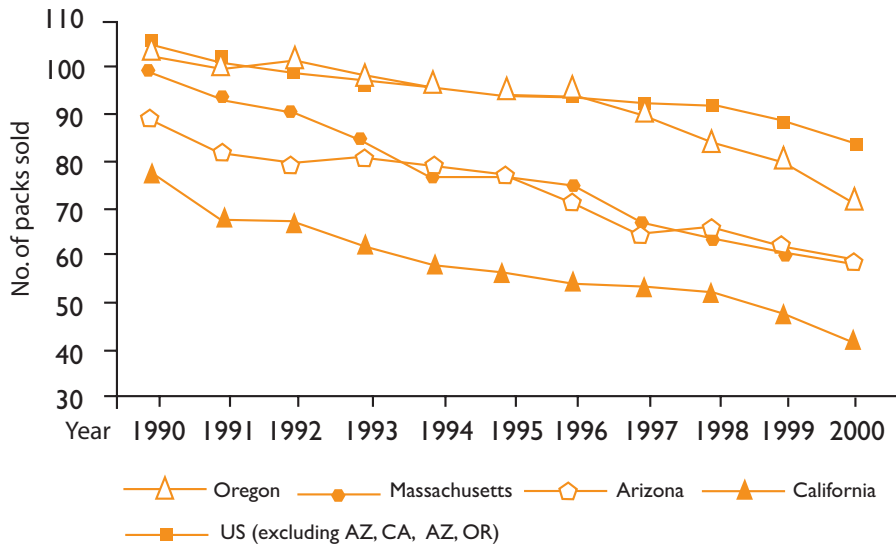
Experience from the USA and Australia shows that increased funding for tobacco-control programmes reduces tobacco use<sup>11</sup>.

In the USA several states have invested in large-scale comprehensive, tobacco-control programmes and include components such as media campaigns, school-based tobacco-prevention programmes, smoking-cessation support including telephone “quitlines”, and enforcement of smoking restrictions. Analysis of the data in the USA indicates a consistent pattern that tobacco-control expenditures impact cigarette sales<sup>12</sup>. The effectiveness of mass media campaigns will depend on their scale and duration. Expenditures have to be at a high enough level to reach smokers a sufficient number of times and of sufficient duration.

In Massachusetts a tobacco-control programme was created in 1992 with funding from an increase in state cigarette tax, with additional funding from the “master settlement agreement” reached with the tobacco industry in 1998. Over this period the annual budget has been in the region of €28 to €49 million with an additional €11 to €15 million from the master settlement agreement. Smoking prevalence fell from 23.5% in 1990 to just over 19% in 1999, a decline about 4 times greater than in other USA states (excluding California). Figure 1 shows the decline in per capita sales during the 1990s.

The Centers for Disease Control and Prevention (CDC) in the USA estimates that states need to spend between \$1 and \$3 per capita per year over a sufficient period of time (e.g. 3 years) to be fully effective. They have also recommended optimum tobacco policy expenditure, suggesting high and low estimates on the basis of population, smoking prevalence, and so on. For California they recommended a high expenditure of \$442 million and a low of \$165 million. California's actual tobacco policy spending in 2001 was \$116,448,610, about \$3.44 per capita.

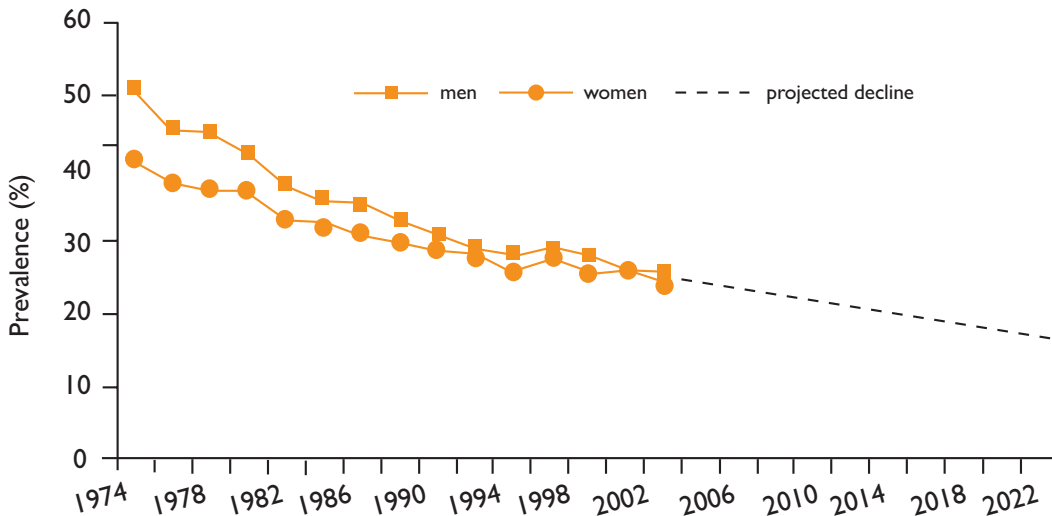
Fig. 1- Changes in per capita cigarette sales in states with large, comprehensive tobacco-control campaigns versus the rest of the USA



Reproduced with permission from Farrelly et al <sup>12</sup>.

The fall in smoking prevalence in the UK from 1970 to the 1990s was the largest fall in the world over that period, but it has now slowed considerably and the current rate of decline is very slow. Figure 2 shows this, with a levelling out at around 27% in 1994 (it should be noted that these data only show cigarette smoking prevalence; real prevalence, including other tobacco products, is higher)<sup>14</sup>. This graph is based on General Household Survey (GHS) data, which show prevalence of 26% in 2000. Office for National Statistics Omnibus survey data, which are more frequent and up-to-date than GHS, and appear to be comparable, suggest that smoking prevalence is again in decline, but a rather slow decline on a trend of about 0.4% per year. The graph projects the current decline and shows that to reach Californian levels will take another 20 years, which ought to be unacceptably slow progress considering the number of deaths that would mean.

Fig. 2 - Prevalence of smoking of manufactured cigarettes in Great Britain 1974-2022

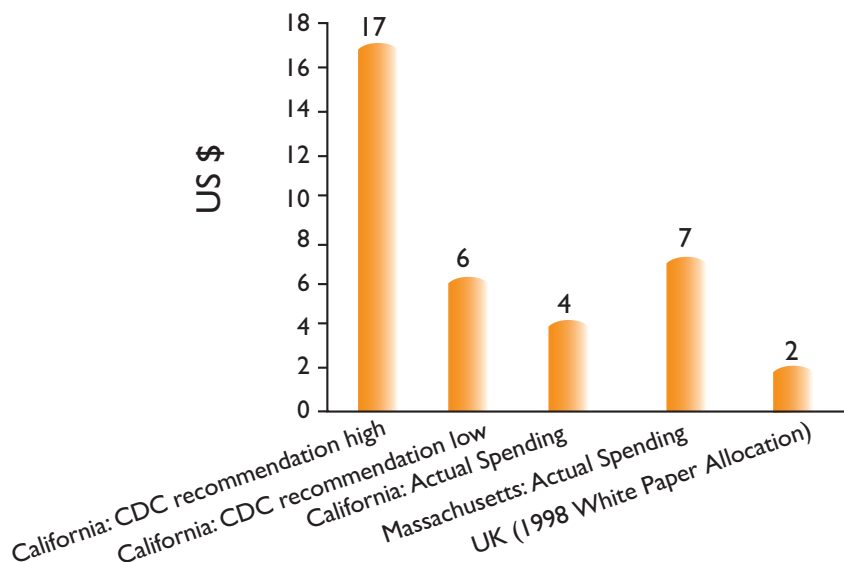


Source: ASH London.



The per capita tobacco-control spending data are even more sobering when it is realised that the UK is the highest spender in the European Union (EU) on tobacco control. Only the Netherlands, at just under €1 approaches the UK spending levels. Thus we are under-spending on tobacco control in the EU (Fig. 3).

Fig. 3 - Annual per capita tobacco-control spending in US \$



It is also important for civil society to invest more in tobacco control where it can. The major health charities in the USA spend vastly more on all aspects of tobacco control than their European counterparts. Clearly, there is a great difference in available income levels but European health organisations must also ensure that their tobacco control efforts are commensurate with the scale of the tobacco epidemic within their financial limits.

## 4. THE IMPACT OF POLICY ON SMOKING PREVALENCE

Table 1, from a report by the European Network for Smoking Prevention (ENSP)<sup>15</sup>, shows smoking prevalence in the 25 EU Member States and three European Free Trade Association (EFTA) countries (Iceland, Norway and Switzerland) from 1985 to 2003. Since each country used its own methods for measuring prevalence the countries cannot be compared with each other using these data. However within countries the data give an idea of what has been happening to prevalence over this period, and in Table 2, each country has been classified by the amount of decline in prevalence, thus giving a measure by which the countries can be compared.

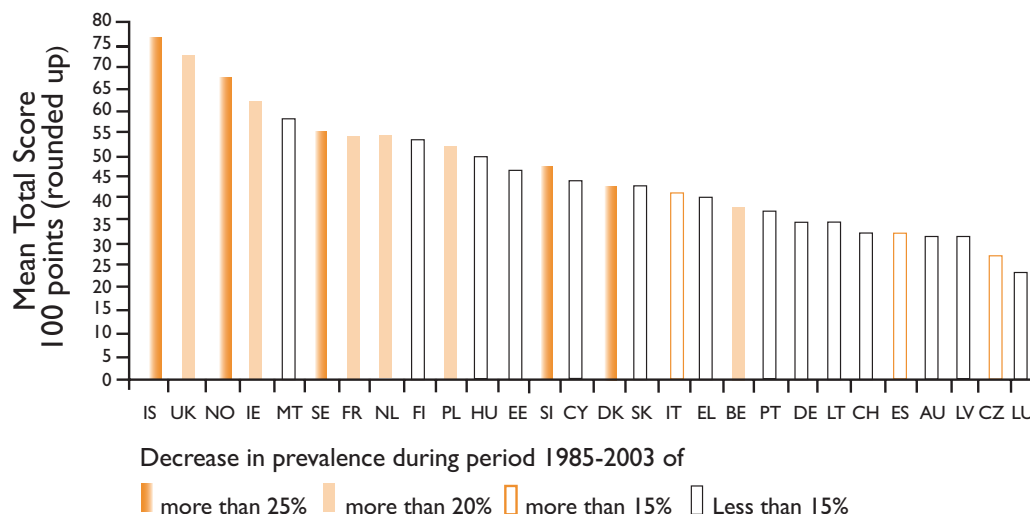
Table 2, also taken from the ENSP report shows the results of rating countries' tobacco-control efforts according to a scale. Tobacco-control experts, from different European regions, rated the various components of tobacco control, allocating a maximum points total to each. The components were: price/taxation policy, workplace/public place smoking bans, overall tobacco-control budget, advertising ban, labelling/health warning, and tobacco-dependence treatment. The maximum potential points score totals 100. Countries are then rated on each component using information supplied by tobacco-control specialists within each country. The last two columns of the table shows each country's total score and then the degree of fall in prevalence since 1985, in three categories. The advantage of this measure of prevalence change is that

it is intra-country and uses the same methodology to measure prevalence each time. Thus between country comparisons are not confounded by different methods of measuring prevalence. The countries' tobacco-control programmes were rated at 1 January 2004, so this does not show policy over the 20 year period. However since most countries have built up a range of tobacco-control policies gradually over many years, policy now reflects policy 20 years ago in the sense that active countries now are likely to be those active in the past and over a long period.

It is important to acknowledge that this is not a precise science. It only gives a general impression of a relationship between tobacco-control policy and smoking behaviour. Nor is it easy to quantify the relative importance of each policy element in each country and since we cannot do controlled trials on real-life interventions, this kind of precision will always be difficult within a country. However if these data are combined with the World Bank analysis described at the beginning of this section, then we can make an informed judgement on the policy components that influence outcomes in the successful countries.

Denmark, however, illustrates the danger of drawing simplistic conclusions based on what worked in a particular country, because it has had a large fall in prevalence and yet not had high cigarette prices, a policy known from scientific analyses to have a powerful and measurable effect on consumption. However prevalence was very high in Denmark 20 years ago and so there was room for a large prevalence fall. There is evidence from the UK that as prevalence falls average consumption rises. This is what would be expected if smokers who stop in response to health education and public information campaigns are lighter smokers. Eventually, when prevalence is low enough, we can expect that all smokers who can stop unaided will have done so. Then those still smoking will be addicted and need help. Thus it will be much easier for a country, like Denmark, to go from a smoking prevalence of 50% to 30%, a 20% reduction, than for the UK to go from 35% to 15%. The data show this. The UK has had a sustained and quite vigorous anti-tobacco campaign since at least the early 1980s, which has included taxation/price increases and relatively (compared to the rest of the EU, not to California or Massachusetts) generous government funding, two components much weaker in Denmark. Fig. 4 just shows countries in rank order by their total tobacco-control score.

Fig. 4. - Countries ranked by “effective tobacco-control policy” scores (out of 100)



Source: Joossens<sup>15</sup>.

Table 1. - Smoking prevalence % in Europe from 1985 to 2003

COUNTRY	MALE ADULT SMOKING 1985	MALE ADULT SMOKING 1995	MALE ADULT SMOKING 2002-2003	% + OR -	FEMALE ADULT SMOKING 1985	FEMALE ADULT SMOKING 1995	FEMALE ADULT SMOKING 2002 - 2003	% + OR -	REMARKS
AT	40	36 (1997)	32 (2000)	-20	21	23 (1997)	26 (2000)	+24	All smoker; 16 yrs+, statistik Austria, n=60000
BE	45	33	33 (2003)	-27	27	19	22 (2003)	-19	Daily smoker, 18 yrs+, n=2000, 1985-1995 CRIOC, 2003 Flemish Institute for health promotion.
CY	43 (1989)		39 (1997)	-9	7 (1989)		8 (1997)	+14	Daily smoker, 15 yrs+, Cyprus household survey
CZ	46	39	38	-17	26	23	23	-12	All smokers, 15 yrs+, Institute of health information and statistics of the Czech Republic
DK	51	38 (1994-1996)	30 (2003)	- 41	42	34 (1984-1986)	24 (2003)	- 43	Daily smoker, 15 yrs+, n=3000, PLS Ramboll, 2003 survey 13 yrs+
EE	46 (1990)	50 (1994-1996)	45	-2	15 (1990)	23 (1994-1995)	18	+16	Daily smoker; 16-84 yrs, n=2000
FI	32	29	26	-19	14	19	19 (2003)	+36	Daily smoker; 15-64 yrs, n=5000, KTL
FR	50 (1984-1986)	42	36	-28	32 (1984-1986)	31	25	-22	All smoker; 15-75 yrs, n=2000-3000, INPES
DE	42 (only West Germany)	43	39 (2000)	-7	27 (only West Germany)	43	30 (2000)	+11	All smoker; 25-69 yrs n=8000, national health service
EL	54	51 (1993)	51 (2001)	-5	20	31 (1993)	39 (2001)	+95	All smoker; 18-65 yrs, different sample sizes
HU	49 (1986)	44 (1994)	42 (2003)	-14	22 (1986)	27 (1994)	29 (2003)	+24	All smokers, 15 yrs+ (1994), 2003:18 yrs+, National health behaviour survey, n=7000
IS	43	29	27 (2003)	-37	37	29	21 (2003)	-43	Daily smoker; 18-69 yrs, n=1160-1170
IE	37	29 (1993)	28	-24	32 (1993)	28	26	-19	1985-1993: regular cigarette smoker 15 yrs+, n=6539, Market Research Bureau. 2002: regular cigarette smoker; 18 yrs+, n=5992, SLAN
IT	41 (1986)	34	31 (2001)	-24	17 (1986)	17	17 (2001)	-	Regular smoker; 14 yrs+, n=20000 families, Istat
LV		51 (1998)	51	-		19 (1998)	19	-	Daily smoker; 15-64 yrs, Finbalt Health Monitor

LT		43 (1994)	44	+2		6 (1994)	12	+100	Daily smoker, 20–64 yrs, Finbalt Health Monitor
LU	41 (1987)	32 (1993)	39 (2003)	-5	25 (1987)	26 (1993)	26 (2003)	4	All smokers, 15 yrs+, n=2600–3800, Luxembourg foundation against cancer
MT		26	30 (2003)	+15		11%	21 (2003)	+91	1995: all smoker, 25–5 yrs, census of population, n=324386, 2003: daily smok- er, 18–64 yrs, n=528, lifestyle survey
NL	46	40	33 (2003)	-28	35	32	27 (2003)	-23	All smoker, 18 yrs+, n=20000, TNS NIPO
NO	44	34	28 (2003)	-36	32	32	26 (2003)	-19	Daily smoker, 18–74 yrs, n=2400–5000, statistics Norway.
PL	54 (1996)	47	39	-28	27 (1996)	23	23	-15	All smoker, 15 yrs+, n=1000–1500, Cancer centre Warsaw
PT	44 (1988)	27	31 (1999)	-29	14 (1988)	8? (proba- bly around 15%)	9? (1999) (proba- bly around 15%)	?	Daily cigarette smoker, 1988 and 1993 CECP 15 yrs+, 1995 and 1999 INS 10 yrs+ based on household survey which may underestimate female smoking
SK	-	43 (1994 -1996: male and female)	48	+12		43 (1994 -1996: male and female)	32	-26	All smoker, 18 yrs+, n=1334, Markant-market research
SI	42 (1988)	35 (1994)	28 (2001)	-33%	27 (1988)	23 (1994)	20 (2001)	-26	Regular smoker, 1988, 1994: 18–64 yrs, Slovenian public opinion survey, 2001, 25–64 yrs, CINDI
ES	55	48 (1993)	39	-29%	23	25 (1995)	25	+8	Daily cigarette smoker, 16 yrs+, Encuesta nacional de salud
SE	30	22	16	-46%	27	24	19	-30	Daily smoker 16–84 yrs n=7500, Statistics Sweden
CH	40 (1987)	37 (1992)	36	-10%	28 (1987)	24 (1992)	26	-7	All smoker, 1987: 15 yrs+, n=8000, Swiss Health study, 1992–2002, 15–74 yrs, n=10000, SFA
UK	35	29 (1984 -1986)	26	-26%	31 (1984 -1986)	27	24	-23	Cigarette smoker, 16 yrs+, 3000 families, General household survey.

Data are presented as %. The decrease in prevalence (5th and 9th columns) has been calculated by subtracting the difference between the % in the first reported year and the most recent reported year, multiplied by 100 and then divided by the % in the first reported year, for example in Sweden in males:  $(30-16) \times 100 / 30 = 46\%$ . The increase in prevalence has been calculated by subtracting the difference between the % in the first reported year and the most recent reported year, multiplied by 100 and then divided by the % in the most recent reported year, for example: Malta, females:  $(11-21) \times 100 / 21 = +47\%$ . CRIOC: Centre for Research and Information of the Consumer Organizations; CECP: Centro de Estudos de Cardiologia Prevenção [Centre for Studies of Preventative Cardiology]; CINDI: Countrywide Integrated Noncommunicable Disease Intervention; SFA: Swiss Institute for Alcohol and Drugs; ISTAT: National Institute of Statistics. Source: Joossens<sup>15</sup>.

Table 2. - Tobacco-control policy components in place on 1 January 2004 and prevalence change from 1985-2003 in Europe: countries ranked by total tobacco-control scores

COUNTRY	PRICE (30)	PUBLIC AND WORKPLACE SMOKING BAN (22)	TC BUDGET (15)	ADVERT- ISING BAN (13)	LABELLING / HEALTH WARNING (10)	CESSATION TREAT- MENT (10)	TOTAL (100)	DECREASE IN PREVA- LENCE
IS	24	16	15	13	6	2	76	XXX
UK	26	3-6	14	11	6	10	72	XX
NO	23	16	6	12.5	6	3	67	XXX
IE	20	15	4	10-11	6	6-7	62	XX
MT	23	12	0	9.5	7	6	58	
SE	15	15	3	11-12	6	3-5	55	XXX
NL	12	12	7	11.5	6	5	54	XX
FR	20	6-7	4	11.5	6	5-6	54	XX
FI	13	16	2	12.5	7	2	53	
PL	13	15	0	11.5-12	5	7	52	XX
HU	14	7-11	1	10	6	9	49	
EE	16	16	2	9.5	1	2	47	
SI	12	15	0	8-10	6	4-5	47	XXX
CY	23	3-4	0	11-12	3	3	44	
SK	14	10-12	0	11	3	4	43	
DK	13	2	3	10	6	6-7	41	XXX
IT	11	7	2	10.5	6	4-5	41	X
EL	15	7	-	4-5	6	7	40	
BE	13	6	0	10	7	1-2	38	XX
PT	13	6-7	-	9	6	2	37	?
DE	15	2	0	3-4	6	8	35	
LT	12	4-6	0	11.5	6	0	35	
CH	13	5-7	5	3.5-5	3	4	35	
ES	14	2	-	3-4	6	6-7	32	X
LV	11	7	1	6	6	0	31	
AT	11	7	-	3.5-5	6	3	31	
CZ	11	6	1	4-5	2	2	27	X
LU	7	4	-	6.5	3	2	23	

The last two columns show the maximum points achievable out of 100 and the decrease in prevalence. X = a decrease in prevalence of more than 15% from 1985-2003; XX = decrease of more than 20%; XXX = decrease of more than 25%; ? = used different prevalence measures during the period so do not know prevalence change. In order to make the table easier to read halves have been round up in the total score column, but scores for the individual components have been left unaltered so that readers can see the actual totals. Source: Joossens<sup>15</sup>.

Table 3<sup>16,17,18</sup> shows that smoking prevalence from 1993 to 2002 has only fallen in 15-year-old females in Denmark and Scotland, and in males of the same age only in Austria, Belgium, Finland, Latvia, Scotland, Sweden and Wales. Very poor progress indeed and a worrying picture.

Table 3. - Percentage of 15 year olds who smoke at least once a week

COUNTRY	FEMALES			MALES		
	1993-94	1997-98	2001-2002	1993-94	1997-98	2001-2002
AT	31	36	37	29	30	26
BE (Flemish)	18	28	23	32	28	23
BE (French)	21		24	23		22
CZ	12	18	31	16	22	29
DK	24	28	21	14	20	17
England		33	28		25	21
EE	6	12	18	22	24	30
FI	26	29	32	30	25	28
FR	25	31	27	23	28	26
DE	29	33	34	21	28	32
EL		19	14		18	14
HU	19	28	26	25	36	28
IE		25	21		25	20
IT			25			22
LV	14	19	21	33	37	29
LT	4	10	18	15	24	35
MT			17			17
NL			24			23
N. Ireland	25	28		23	20	
NO	21	28	27	20	23	20
PL	13	20	17	23	27	26
PT		14	26		19	18
Scotland	26	28	23	21	22	16
SK	5	18		19	28	
SI			30			30
ES	27		32	20		24
CH	18	25	24	17	25	25
SE	19	24	19	15	18	11
Wales	27	29	27	18	22	16

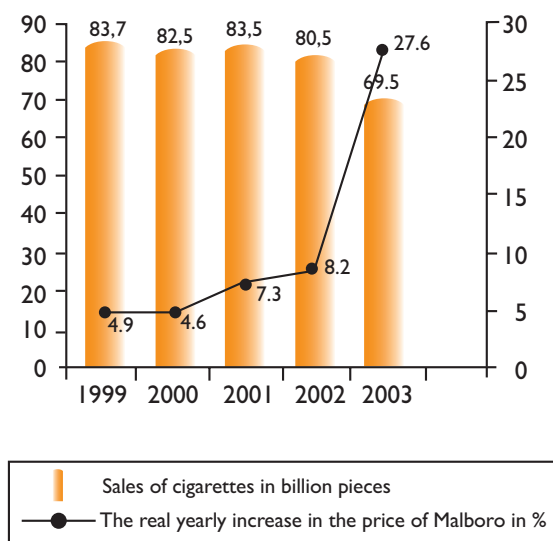
Sources<sup>16,17,18</sup>.

## 5. EUROPEAN EVIDENCE OF THE IMPACT OF SOME SPECIFIC POLICY ELEMENTS

### 5.1. Price

According to two surveys, undertaken among 3,000 people aged 15-75 years in November and December 1999 and 2003, the number of smokers in France has decreased from 15,300,000 in 1999 to 13,500,000 in 2003 (a decrease of 12% in smoking prevalence). More smokers wished to stop smoking in 2003 (58% in 1999 and 66% in 2003) and in 2003 the price became the top reason why smokers said they wished to stop smoking (compared to fourth place in 1999). In 2003 sales of cigarettes decreased by 13.5%<sup>19</sup>. In 2003 there was a real increase in the price of Marlboro of almost 28% (fig. 5)<sup>20</sup>.

Fig. 5. - Sales of cigarettes and the real yearly price increase of Marlboro in France



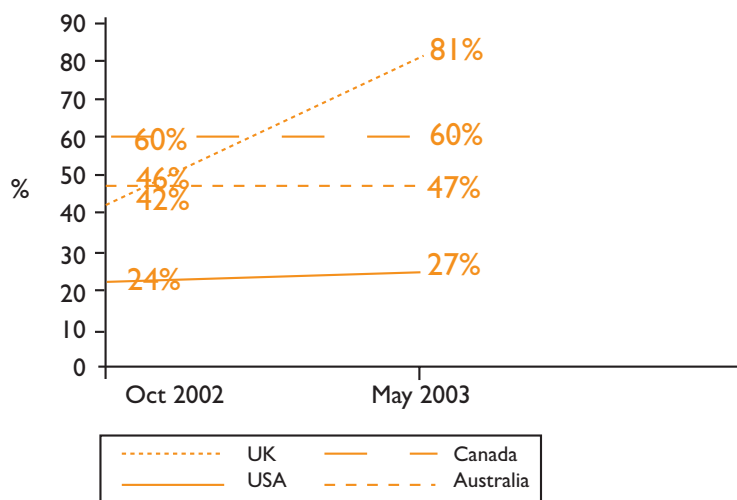
Source: Joossens<sup>20</sup>.

### 5.2. Health warnings

#### 5.2.1. UK

Emerging evidence from the UK indicates that the enhancement of the health warnings substantially increased their salience: smokers thinking about warning labels, reports of smokers forgoing a cigarette because of the labels, perceived effectiveness of the warning labels, and smokers considering warning labels as a motivation to quit<sup>21</sup> compared with reactions to warnings in countries outside Europe. Large health warnings on cigarette packs were introduced in the UK from 1 January 2003 (Fig. 6)<sup>22</sup>. The percentage of respondents noticing the warning labels increased from just over 40% in 2002 to just over 80% in 2003, compared with no change in Australia, Canada and the USA.

Fig. 6. - Percentage of respondents noticing the warning labels on cigarette packs “often” or “very often” in last month



Source: Fong <sup>22</sup>.

### 5.2.2. The Netherlands

In November 2002, a Dutch tobacco-control organisation, Defacto, presented the results of studies on the effects of the new health warnings. These studies indicated that some adult smokers said that they smoked less and were more motivated to quit by the new health warnings. They found an even stronger effect among those aged 13-18 years: 28% said that they smoked less because of the new health warnings<sup>8</sup>.

Another study in the Netherlands found that that the inclusion of the quitline number on the packs increased calls to the quitline. They also found that whereas previously the quitline had helped motivated smokers from middle income groups, when telephone numbers were included on the pack, lower income groups in particular called<sup>23</sup>.

### 5.2.3. Belgium

A Belgian study released in May 2004 confirmed the Dutch findings and found that bigger, clearer warnings motivated smokers to stop smoking and made cigarette packs less attractive to youngsters<sup>9</sup>. Warnings on cigarettes have been compulsory in Belgium since 30 September 2003, and cover an average of 55% of the front and back of the package, making them the largest in the world. The Flemish Institute of Public Health, in collaboration with the Belgian Federation against Cancer has conducted research among 608 smokers over 15 years of age in Belgium in December 2003 and January 2004 regarding the effects of the health warnings. Amongst the findings were the following:

- Warnings were particularly effective amongst young people between 15-24 years of age and amongst those who wished to stop smoking within the year.
- Young people found it easier to remember the messages than other age groups. Fifty-six per cent of the age group 15-24 years agreed with the statement that they had discussed



the new health warnings with family or friends. Forty per cent of all smokers felt the packaging was becoming less attractive to youngsters.

- Twenty-nine per cent of all smokers felt that warnings were an additional motivation to stop smoking. Amongst those who declared that they wished to stop smoking within a year, the percentage was even 46%.
- As a result of the new warnings 8% of those questioned smoked less, 2% more and 88% as much as before.

### 5.2.4. Poland

Large health warnings have been found to be strongly linked with smokers' decisions to stop or reduce their smoking. Among Polish male smokers, 3% said they had quit following the introduction of new very large warnings, an additional 16% said they had tried quitting, and a further 14% said they understood the health effects of smoking better because of the warnings<sup>2</sup>.

Outside Europe, according to the World Bank, evidence from Australia and Canada suggests that cigarette pack warning labels can be effective provided that they are large, prominent, and contain hard-hitting and specific factual information<sup>2</sup>.

The regulations in Australia provide that from 1 January 1995 all tobacco products must comply with a system of health warnings which require warnings printed in black and white background occupying the top 25% of the front of the pack and detailed health information on 33% of the back of the pack. Based on research among 500 smokers and 500 non-smokers in 1994-1995, surveyed before and after the implementation of the new Australian warnings covering not less than 25% of the top of the pack: "the results suggest the new (Australian) health warnings are resulting in better informed smokers and thus suggest that informative health warnings can play an important role in better informing consumers. More than a third of smokers reported being affected by the warnings, with reductions in consumption and talking about warnings being the most salient feature."<sup>24</sup>

A nationwide telephone survey among 2,000 Australians in 1996 found that the new health warnings had some direct effects on the smoking population including:

- Six out of 10 smokers believed that warnings and health information had improved their knowledge of the health effects of tobacco.
- Seventy-eight per cent believed that they had some effect on their behaviour.
- Thirty-three per cent of smokers believe the labels have helped them smoke less.
- Forty-five per cent of recent ex-smokers believe that the warnings have helped them give up smoking<sup>25</sup>.

According to a EuroBarometer survey among 16,230 EU citizens in the autumn of 2002, 38% believe that the addition of colour photographs to cigarette packages would be useful in persuading people either not to smoke, to smoke less or to stop smoking<sup>26</sup>.

Canada, in 2001, was the first country in the world to introduce health warnings accompanied by pictures, occupying 50% of the front and the back of the packs. The current Canadian warnings include 16 rotating messages with pictures in full colour. A study in 1999 found that warning messages with pictures were, on average, 60 times more encouraging to stop/not start smoking than messages without pictures<sup>27</sup>.

An evaluation of the new colour picture health warnings has shown they have an amazing impact on the smokers in Canada. According to a study among 2,031 Canadian adults, which was conducted after the introduction of the messages with pictures during the second semester of 2001, 90% of smokers and 49% of non-smokers had noticed changes to cigarette package warnings<sup>28</sup>.

### 5.3. Tobacco advertising bans

Tobacco advertising bans are effective according to the World Bank: "Since 1972 most high-income countries have introduced stronger restrictions (on tobacco advertising) across more media and on various forms of sponsorship. A study of 22 high-income countries based on data from 1970 to 1992 concluded that comprehensive bans on cigarette advertising and promotion can reduce smoking, but more limited partial bans have little or no effect. If the most comprehensive restrictions were in place, the study concluded, tobacco consumption would fall by more than 6 percent in high income countries. Modelling based on these estimates suggests that the European Union's (annulled) ban on advertising could reduce cigarette consumption within the European Union by nearly 7 percent"<sup>2</sup>.

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However an advertising ban alone will not necessarily lead to a drop in consumption as the effect could be overridden or neutralised by tobacco becoming cheaper, as a result of income growth for example. In a *British Journal of Addiction* editorial Murray Laugesen pointed out: "for Finns, real per capita incomes after the ban (1978-1996) rose 36%, Norwegian incomes (1975-1986) rose 50%, while Icelandic incomes (1971-1986), rose 56%. Tobacco taxation was raised more than once, but not often enough to keep up with both inflation and income."<sup>29</sup>. In order to maintain a downward trend an advertising ban must be part of a comprehensive tobacco-control policy.

Norway, Finland, New Zealand and France enforced an advertising ban that was part of a comprehensive tobacco-control strategy. Their strategies included price increases and the promotion of smoke-free places. All exhibited substantial falls in per capita sales (table 4)<sup>30</sup>.

Table 4. - Date of advertising ban and fall in consumption in four countries

COUNTRY	DATE OF ADVERTISING BAN	DROP IN SALES UP TO 1999 %
Norway	1 July 1975	-31
Finland	1 March 1978	-34
New Zealand	17 December 1990	-33
France	1 January 1993	-15

### 5.4. Action against smuggling

EU action against smuggling has also had an impact on smuggling at member state level. Spain is one of the few countries in the world to have tackled smuggling successfully. It did not do so by reducing tobacco tax, which is what the tobacco industry has lobbied governments to do. Despite Spanish cigarettes being among the cheapest in the EU, smuggled cigarettes in Spain had a market share of 16% in 1993<sup>1</sup>.

According to the EU lawsuit against Philip Morris, RJ Reynolds and Japan Tobacco, filed in November 2000 in New York under the US Racketeering Influenced and Corrupt Organization Act (RICO), Spain has been a primary destination for smuggled Winston cigarettes for so long that the smugglers are known as “Winstoneiros”. The EU lawsuit alleges that the Defendants, jointly and as individual corporations, control, direct, encourage, support, promote, and facilitate the smuggling of cigarettes into the European Community in a variety of way<sup>32</sup>. Smuggled cigarettes in Spain were mainly introduced through harbours and the border with Andorra.

In 1997-1998 there was concerted action at national and European levels to reduce the supply of contraband cigarettes. Close collaboration between the authorities in Spain, France, Britain, Ireland and Andorra and the European Anti Fraud Office (OLAF) reduced the supply of smuggled cigarettes from Andorra. Actions included sealing the Andorran border, civil guard brigades patrolling valleys and hills to make smuggling more difficult. OLAF led a first mission to Andorra in March 1998, accompanied by representatives from neighbouring countries (Spain and France) and from cigarette-exporting countries (Ireland and the UK). The enquiries revealed inadequate laws in Andorra to prevent and combat fraud. In November 1998 European Commission services visited the Andorran government and found that attitudes had changed fundamentally. The laws on customs fraud and the control of sensitive goods, and the law amending the criminal code and making smuggling a crime were published respectively in the Andorran Official journal on 4 March 1999 and 7 July 1999<sup>33</sup>.

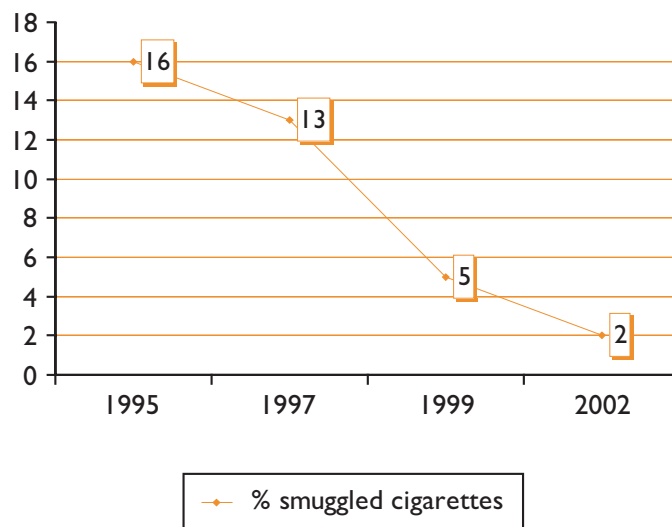
As a result of this cooperation between the EU and member states, contraband cigarettes, which had accounted for 16% of the Spanish market in 1995, are estimated by the Spanish customs authorities to have fallen to less than 2% of the market in 2002. According to the Spanish customs authorities, their success was not due to controlling distribution at street level, which is almost impossible, but to reducing the supply into the country at “container level” through intelligence, customs activity and cooperation, and technology (I. Garcia, Customs and Excise, Madrid, personal communication).

The EU legal actions on smuggling have now resulted in an agreement between the EU and Philip Morris International to reduce smuggling and counterfeiting (fig. 7<sup>34</sup>, see also Chapter 2).

### 5.5. The UK tobacco dependence treatment programme

In 1999 the government in England introduced new treatment services for dependent smokers through the publicly-funded National Health Service (NHS), free to smokers at the point of use, on an initial “pilot” basis. Over the next few years these services were extended to the entire country and nicotine-replacement therapy and bupropion were made available through NHS prescription. Thus any smoker, anywhere in the country, had access to treatment to help them stop smoking. Furthermore it was an explicit goal of these services

Fig. 7. - Percentage of smuggled cigarettes in Spain 1995-2002



Source: Bonvilla Penvela<sup>34</sup>.

that they should make a special effort to reach deprived smokers and so help to reduce inequalities in health. The story of the establishment of these services is told in more detail elsewhere in a World Health Organization (WHO) “best practice” paper<sup>35</sup>. The government also invested in a national evaluation of these services, conducted by a research team of about 10 experts and researchers over 4 years from 2001. Although the research is still being written some results are published and they are encouraging. Early results show that during 2000-2001 more than 132,000 smokers attended the services and set a quit date and that 53% were abstinent at 4 week follow-up (longer term follow-up is being conducted). Perhaps more importantly, treatment services in more deprived areas were reaching more smokers than those in more affluent areas. In other words the services were succeeding in reaching deprived smokers, although overall cessation rates were lower in these smokers. This initiative shows that treatment services can be developed fairly quickly and that they can successfully reach smokers from all social strata. However we would not know the results had there not been substantial investment in research to evaluate the services and so this serves also as an example of the value of well-funded and planned research to underpin policy initiatives.

## 5.6. The impact of tobacco-control interventions on health inequalities

Smoking is more common in lower socioeconomic groups in nearly all EU member states. As part of an ENSP project, Mackenbach and Kunst<sup>37</sup> created a data set with information on smoking behaviour by socioeconomic status, between 1985 and 2000, in eight European countries (Finland, Sweden, Norway, Denmark, the UK, the Netherlands, Germany, Italy and Spain). Using these data the authors reviewed socioeconomic inequalities in smoking in the eight countries as a whole and in some individual countries. In recent years, large socioeconomic inequalities in smoking were observed in all countries, except among older females in southern countries. Socioeconomic inequalities in smoking have emerged or widened among females in nearly all countries, while these inequalities have been stable among males during the last 15 years.

The report also assessed the extent to which tobacco-control policies may differentially effect smokers in lower socioeconomic groups. Five tobacco-control measures were found to have the potential to reduce inequalities (by having the greatest effect among lower socioeconomic groups). The five were: banning tobacco advertising, increasing the price of tobacco, restricting smoking in workplaces, providing cessation treatment and medications like NRT free, and providing telephone helplines<sup>37</sup>.

Mackenbach and Kunst<sup>37</sup> found that these tobacco-control measures were not fully implemented in Europe. For example few countries had a comprehensive tobacco advertising ban, and indirect forms of promotion persisted in most countries. Tobacco taxation rates vary greatly, with room for large price increases in many countries by the year. Workplace smoking bans and restrictions are voluntary in many countries, and commoner in professional and white-collar settings than in the manufacturing industry and other blue-collar settings. By 2002 NRT was only available free of cost at a national level in the UK and France (and bupropion in the UK). Finally, many countries do not have free, proactive national telephone quitlines.

One of the recommendations of the report was that socioeconomic inequalities in tobacco consumption should be monitored, with special attention paid to disadvantaged groups such as lone mothers and ethnic minority groups. Such a system could also be used to monitor the effects of new tobacco-control measures, such as price increases<sup>37</sup>.

## 6. OTHER POLICY INTERVENTIONS NEEDED IN EUROPE

### 6.1. Internet and vending machine sales

The previous sections outline proven smoking-prevention interventions. However the tobacco industry is one of the most innovative of industries and is keen to embrace new forms of doing business<sup>38</sup>. On past experience therefore it is reasonable to assume that it will do all it can to take advantage of new platforms for sales and marketing. It has already made great use of vending machines to increase sales (see below) and the internet also provides the manufacturers with great potential to attract new smokers and sell more products. European research on interventions is limited but on new forms of selling such as the internet, it is non-existent. We therefore have to rely on evidence from the USA to assess the possible impact of internet sales. Nevertheless, given the predicted increase in internet use over the next 10 years and previous tobacco industry use of new media, we have included a discussion of internet sales research and policy interventions for the sake of completeness.

In 2002 the value of e-commerce in the EU was almost €100 billion<sup>39</sup>. We do not know what percentage of this was accounted for by tobacco product sales but according to recent reports the tobacco industry is leading the way in internet-based marketing<sup>40</sup>. Internet sales pose problems for tobacco control because they can undermine price and tax policies, advertising bans and youth access laws. They also hinder efforts to make smoking less socially acceptable and can interfere with cessation attempts if buyers attempting to quit are subjected to e-mail alerts about the latest offers and promotions from online cigarette retailers.

There is little or no European research on efforts by minors to purchase cigarettes but studies in the USA have found that children as young as 9 years were able to purchase

cigarettes online. A majority of the online cigarette retailers allowed purchase by money order and did not require evidence of age or other identification at point of delivery. Almost all sites permitted self-verification of age simply by submitting an order<sup>41</sup>.

Sales of tobacco products from vending machines encourage spontaneous and time-saving purchases of cigarettes<sup>42</sup> and make it easier for minors to evade youth access laws. For this reason, several member states have banned the sale of cigarettes in vending machines but many more continue to allow their use.

Germany has the highest number of vending machines in the world, almost 800,000. The vast majority of these sell cigarettes. They are weakly regulated and are frequently located within a few metres of school entrances, often placed next to vending machines selling sweets and soft drinks which attract children<sup>43</sup>. Spain also has a large vending machine sector with cigarette sales accounting for 89% of all retail vending machine sales in 2002. The sector is growing and increased by 34% between 1998 and 2002<sup>42</sup>.

A number of member states have entered into voluntary agreements with the vending machine industry aimed at preventing tobacco purchases by minors. These agreements often stipulate that vending machines should be located in shops, bars and restaurants in sight of staff who can check the age of potential purchasers. However, such guidelines are often ignored, enforcement is lax and it is easy for minors to evade notice. In response to criticisms the vending industry has sought to introduce machines which require smart cards available only to those of a minimum legal age to purchase cigarettes. All vending machines in Spain must be equipped with such technology as of 2004 but industry commentators believe that such cards will be duplicated and the effect on sales will be minimal<sup>42</sup>. Voluntary agreements aimed at restricting cigarette purchases by minors from vending machines have not worked and so it is recommended that member states ban the sale of cigarettes in vending machines as soon as possible.

One of the most serious problems with internet sales is their capacity to undermine effective high price and tax policies. Online purchasers are able to shop around for the cheapest cigarettes and to purchase tobacco products at below normal retail rates, either by bulk purchase or by purchasing cigarettes from a retailer located in a country with lower tobacco tax rates.

The extent to which purchases from lower tax countries poses a problem in the EU may be reduced by a ruling from the European Court of Justice in 1998 which declared that individual purchasers of tobacco products in the UK from a firm in Luxembourg were obliged to pay the full rate of UK excise duty, notwithstanding the fact that they had paid the lower rate of duty applicable in Luxembourg. The Court ruled that they could only take advantage of the Luxembourg rates if they purchased the cigarettes and transported them to the UK themselves. If they used an intermediary or agent to deliver the cigarettes they were not entitled to take advantage of the exemption from the higher UK tax rate provided in Directive 92/12/EEC<sup>44</sup>. However, some commentators have predicted that online tobacco sales could account for as much as 20% of all tobacco sales by 2010. If this happens, bulk buying at below conventional tobacco outlet prices could present a growing problem for smoking prevention strategies.

Directive 2000/31/EC<sup>45</sup> on e-commerce came into effect in January 2002 but does not include a prohibition on internet sales of tobacco products, and no EU member state currently bans the sale of tobacco products over the internet. In the USA, New York and Alaska have done so. In New York, which introduced a ban on non-face-to-face retail tobacco sales in 2000, shippers delivering cigarettes from internet vending companies to individual consumers can be fined under the statute. Other states have passed legislation restricting internet sales to minors including provisions such as a requirement for an adult signature at the point of delivery<sup>b</sup>. The 2002 Council recommendation on the prevention of smoking recommended that member states take action to restrict internet sales to adults only<sup>46</sup>. Given the ease with which provisions intended to restrict sales to adults can be evaded, it is recommended that member states follow the examples of New York and Alaska and ban all internet sales of tobacco products to individuals.

### 6.2. Advertising and promotion of smoking on the internet

Comprehensive advertising bans will be compulsory once member states have ratified the Framework Convention on Tobacco Control (FCTC)<sup>47</sup>. Such bans will have to include internet advertising under Article 3 of Directive 2003/33/EC<sup>48</sup>, which prohibits internet tobacco advertising in the Community with effect from 31 July 2005. However EU internet users will still be able to access smoking promotion internet sites located outside the Community in countries which have not ratified the FCTC.

## 7. RESEARCH SPENDING AND CAPACITY

Much of the evidence cited at the beginning of this chapter for the effectiveness of tobacco control comes from the USA, Canada and Australia and the key evidence linking level of expenditure with falls in prevalence comes from the USA. As the ENSP report cited above confirms, there are no standardised prevalence data available for the 28 European countries covered by this report. Thus we have difficulties in understanding what works in the EU because we do not collect and publish standardised prevalence or attitude data (either nationally or at European Community level) regularly. We therefore argue for the need not just to spend larger sums on tobacco control itself but to support our tobacco control efforts with research that underpins it by providing information for those developing policy. There are many areas where research is needed to inform policy development.

The workshop on tobacco research held at the High Level Irish Presidency and European Commission Conference on Tobacco Control in June 2004 found that:

- Regulators at national and EU level do not have the evidence they need to adequately assess the health and other effects of existing and new tobacco products. In many cases the evidence will not be available for many years to come.
- Current research capacity at national and European Community level is inadequate, fragmented and under-resourced.
- There is a need for a more strategic approach to research, from the limited funds available.
- More EU and nationally-funded research is needed to support policy initiatives and product regulation.

<sup>b</sup> Maine, California, Nevada, Rhode Island, Idaho, Virginia, Indiana, Texas.



- Research is needed to provide a better understanding of the socioeconomic impact of tobacco use and how best to reduce it.
- Strategic thinking is required on how best to spend the remaining money available from the Tobacco Research and Information Fund.

In preparation for this report a questionnaire was sent to the national counterparts to establish which European countries had national tobacco research strategies or a national coordinator, and/or had a high-level scientific advisory committee for tobacco and government-funded research into tobacco and tobacco control. According to the replies received it would appear that Ireland is the only EU country with a national tobacco research institute (Fig. 8) and that only four countries, Ireland, Iceland, Poland and Sweden, have a tobacco research strategy. Sixteen countries said that there was no existing tobacco research strategy in their country and no information was received from the remaining eight respondents. Only seven countries said that they had high-level advisory committees that looked at tobacco issues<sup>c</sup>. Nine countries replied that their countries had no government-funded research body carrying out tobacco research. Thirteen countries replied that they did<sup>d</sup>. National public health institutes carried out most of this research. In the UK and the Netherlands this included research carried out by private tobacco-control organisations such as Action on Smoking and Health (ASH) and STIVORO.

It was not possible within the time available to establish national funding levels for tobacco control for any of the 28 countries but informal approaches to some Ministries of Health indicated that such information is not easily available. This lack of information on the part of government officials, researchers who are members of the expert advisory panel for this report and national counterparts could be an indication that the funding available is small, spread between several agencies and not easily accessed.

Thus, few countries appear to have formal coordinated tobacco research strategies, or budgets.

Fig. 8. - Research Institute for a Tobacco Free Society (Ireland)

Limited partnership between the Office of Tobacco Control, ASH Ireland, Irish Heart Foundation and the Irish Cancer Society

Aims to form a multi-disciplinary academic community to support the development of a tobacco free society by engaging in research in all public health aspects of tobacco

Researchers drawn from chemistry, biochemistry, economics, law, behavioural sciences including advertising and marketing, education, actuarial, epidemiology, medicine

The report also surveyed individual researchers in an effort to gain an overview of national research funding and activity for tobacco control. A detailed research questionnaire was sent out to approximately 6000 members of the European Respiratory Society (ERS) based in over 90 countries, including all 28 countries covered by this report. The response rate was extremely low but replies received indicate that Europe's respiratory health specialists are prioritising research into

<sup>c</sup> Iceland, Malta, Norway, Poland, Slovak Republic, The Netherlands and the UK.

<sup>d</sup> Finland, France, Iceland, Ireland, Italy, Latvia, Norway, Poland, Slovak Republic, Slovenia, Sweden, The Netherlands, the UK.



the epidemiology and public health effects of smoking, risk assessment and disease prediction from second-hand smoke exposure, the effectiveness of smoking-cessation interventions and therapies, and prevention strategies. Some research is also being carried out into genetic factors and host susceptibility. There was far less evidence of research into tobacco product characteristics, emissions, human exposure measures (other than cotinine), biomarkers of biologically effective dose and potential harmful effects. This would suggest that our ability to properly evaluate the health risks of novel tobacco products is some way off and that current research activity is not reflecting the full range of regulatory requirements (see also Chapter 5).

Few of the researchers who replied to the questionnaire could identify any national tobacco research strategy, although it was indicated that the Health Research Council of the Netherlands (ZON) was consulting on the subject. Almost all of them identified the implementation of such a strategy as a priority. They were also in favour of the establishment of some sort of European coordinating tobacco research body. There was strong support for a European regulatory agency covering all tobacco and nicotine products (see also Chapter 5).

The researchers in this questionnaire were mainly funded by government bodies, including Ministries of Health and national research councils. Charities such as national cancer and asthma organisations were also contributing to funding, sometimes in partnership with the pharmaceutical industry.

Finally, we were able to identify some European research into smoker behaviour in response to advertising restrictions and increased label warning labels. The ITC (International Tobacco Control Policy Evaluation project) is currently assessing the impact of the 2003 tobacco advertising legislation and the introduction of new warning labels in the UK, as well as the impact of the workplace smoking ban introduced in March 2004 in Ireland. Other evidence from the Netherlands and Poland is also presented (see above).

At European level research is funded largely through the European Commission Research Framework Programmes (FP 4, 5, 6 etc.). Framework Programme 4 for research (1994-1998) had a total budget of €13.1 billion and included funding for biomedicine and health (the Biomed programmes). Some tobacco research projects were funded under this budget line. The current sixth Framework Programme (FP6, 2002-2006) has a total budget of 17.5 billion. Life sciences is a thematic priority and includes funding for research into major diseases such as cardiovascular disease and cancer but the focus of the programme is on genetic and biotechnological applications rather than public health projects. The extent of funding for tobacco-related research is not clear. A budget line exists for all health determinants research and has a maximum budget over the lifetime of the programme of €6 billion. Public health projects are also funded under the Policy orientated research strand. Within this, smoking or tobacco-related research is included under heading 2.1. on health determinants. The indicative budget for smoking-related actions is €1-2 billion. However, a search of the relevant website did not reveal any projects directly funded on smoking or tobacco<sup>e</sup>, 49.

Elsewhere, the Institute for Health and Consumer Protection in the Joint Research Centre, a specialised Directorate-General of the European Commission, provides research support to the European Commission and conducts research to support EU policy initiatives. In recent years it has carried out research into the effectiveness of ventilation in removing tobacco smoke

<sup>e</sup> So far, there have been three calls for tender since 2002. For more information see: Scientific support to policies, October 10, 2003. [http://fp6.cordis.lu/fp6/call\\_details.cfm?CALL\\_ID=83#infopack](http://fp6.cordis.lu/fp6/call_details.cfm?CALL_ID=83#infopack)

from the indoor environment and is currently carrying out studies on levels of benzene in indoor air. It also has the capacity to develop and validate testing methodologies and carry out total human exposure assessment studies.

Financing for tobacco research is also available from the Tobacco Research and Information Fund. Council Regulation 2182/2002 provides for the funding of information programmes and data collection projects. The Fund will end in 2008 with the phasing out of the tobacco subsidies regime but the annual budget until then is estimated on current subsidy levels to be 25 million to €30 million per year. However, the Commission has recently published a call for tender for a second media campaign to be financed by the Tobacco Fund and run over the next 4 years. The maximum budget for this campaign has been set at €72 million<sup>50</sup>. The remaining budget for other types of tobacco research permitted under the Fund is not known.

The tobacco research picture in Europe is extremely fragmented. For the purposes of this report it has only been possible to achieve the vaguest overview of the existence of research strategies, funding mechanisms and actual research carried out. Many of the expert contributors to this report are engaged in research and pointed out the paucity of information, funding and research during discussions on research in the product regulation workshop in Brussels, Belgium and the research workshop held in Limerick, Ireland. Similar research and evidence gaps were also identified by the Chapter Coordinators, particularly for Chapters 1 and 2.

These findings on the lack of European researchers and the lack of policy-related research are reflected elsewhere. Since 2001, only 12% of research papers accepted in the BMJ Journals publication *Tobacco Control* came from European authors (S. Chapman, Editor, to A. McNeill, European Regional Editor of *Tobacco Control*, personal communication). In an unpublished study into published research into nicotine, cigarettes and smoking, J.R. Hughes, K. Fagerstrom and P. Callas surveyed 309 publications from around the world on smoking and nicotine between 2000 and 2002. They found that for all the publications, smoking consequences (34%) and non-human research (32%) were the most common types of research followed by intervention research (23%) and human behavioural research (11%).

If we look at research spending and activity in the USA the picture is somewhat clearer and provides a potential benchmark for Europe. The principal health research body, the National Institutes for Health (NIH) had a total budget for all tobacco- and smoking-related research in the 2004 fiscal year of \$552 million (C. Backinger, NIH, personal communication). Of this, \$90 million was allocated to research into smoking behaviour and interventions, amounting to \$1.84 for each USA citizen. NIH funding was supplemented by private foundations and charities in the USA, such as the Robert Wood Johnson Foundation, the American Cancer Society, the American Heart Association and others.

If European (Community and Member State) spending matched 2004 NIH levels per capita the EU would be spending €680 million per year<sup>f</sup>.

Against this background, this report makes a number of recommendations on research and suggests the following blueprint for an EU research strategy:

<sup>f</sup> Calculation based on exchange rate of 1 Euro equals \$1.23 and a US population of 300 million and a EU population of 455 million

1. A strong science base for tobacco-control policy and interventions should be developed.
2. This will require the creation of national bodies to develop tobacco-control research strategies and oversee implementation. Research should be coordinated in conjunction with national tobacco task forces and existing national research bodies.
3. The European Commission should convene an international research seminar to assess EU and international tobacco research capacity, coordination, funding and development of a coordinated EU tobacco research strategy.
4. An increase in tobacco-control research funding will be required.
5. At EU level tobacco research should be given a dedicated budget line in the next Research Framework Programme (FP7: 2006-2010); funding should match that given by the NIH in the USA (currently €450 million per year); this should be in addition to increased funding at Member State level.
6. Tobacco-control research networks and research training networks should be developed across Europe.
7. In the short term, the remaining sums available in the Tobacco Fund (see also Chapter 3) should be used to fund the following research priorities: improved surveillance data, harmonised methodologies research (e.g. collection of prevalence and mortality data) and regular measurement of individual smoke exposure across populations, and measuring the impact of tobacco-control policies and interventions on gender and inequalities. Other existing research funding mechanisms such as the emerging priority budget line in DG Research could also be used to fund this research.

A tobacco-control research strategy should conduct research designed to provide the answers to questions which policy makers need, and an EU strategy might support research needed at national as well as pan European level

### **8. DISCUSSION AND CONCLUSIONS**

Measuring the impact of tobacco-control policies is complex and difficult. Single policies can rarely be evaluated in the absence of other policy changes crucial to success in reducing prevalence so that we can normally only speculate on the exact impact of a specific policy element. We must do so however. Worldwide millions of euros are now spent on tobacco-control policy and it is essential to understand, as far as possible, how effective these policies are overall, and which elements of them appear to have most impact. Otherwise it will be impossible to know if we are getting value for money, and not only will this be unacceptable for governments anxious to spend taxpayers money effectively and efficiently, but it may well deter other governments from taking action against tobacco at all.

Thus the lack of Europe-wide data collection on smoking prevalence, using a standard methodology, urgently needs addressing and should, we believe, be a very high priority. If standardised monitoring is not introduced we will not be able to measure the impact of policies within countries and within the EU as a whole nor be able to compare countries. Thus an urgent priority for the new EU of 25 countries is to agree standard questions for the measurement of tobacco use, start regular surveys across the EU as soon as possible, and repeat these surveys regularly, ideally annually, not less than once every 2 years. In addition, the results should be published so that European citizens can see the effect of these policies. Exactly what survey questions are used can be determined by survey experts across the EU but there is at least a case for examining the

EuroBarometer questions<sup>26</sup>, improving them where necessary and perhaps using them, or using them in an adapted form, in all 25 countries.

As smoking is increasingly concentrated among lower socioeconomic groups, reaching these groups with tobacco-control interventions is essential if tobacco consumption is to be reduced across Europe. To meet this challenge, comprehensive tobacco-control policies should fully implement measures tailored to the needs of lower socioeconomic groups. Future smoking prevalence surveys should include data broken down by socioeconomic status<sup>37</sup>.

Taking a broader overview of tobacco-control policy it does seem, as we have shown at the beginning of this chapter, that a core of tobacco-control policies are crucial in reducing tobacco use and that progress in reducing prevalence is broadly proportional to per capita tobacco-control expenditure.

The following interventions are core and should be prioritised in all tobacco-control programmes: price increases through higher taxation; comprehensive advertising and promotion bans of all tobacco products, logos and brand names; bans/restrictions on smoking in workplaces; better consumer information including counter advertising (public information campaigns), media coverage, and publicising research findings; large, direct health warning labels on cigarette boxes and other tobacco products; treatment to help dependent smokers stop, including increased access to medications.

On tobacco-control spending, the CDC in the USA estimates that states need to spend between \$1 and \$3 per capita per year over a sufficient period of time (e.g. 3 years) to be fully effective. They have also recommended optimum tobacco-policy expenditure, suggesting high and low estimates on the basis of population, smoking prevalence, and so on.

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For California they recommended a high expenditure of \$17 per capita per year and a low of \$6. The actual figure is \$4. For Massachusetts the actual figure was \$7 and the current figure in the UK is just under €2 per year, still three times less than the recommended California minimum. Within the EU the UK is the top spender, and only the Netherlands, at just under €1, approaches UK levels. In the EU the actual Massachusetts figure would mean €5.7 per capita (\$1.23 = €1 Euro, August 2004) or €2,600 million a year. The actual California figure would mean €1,500 million a year in the EU and the UK figure would translate at EU level to €740 million being spent per year on tobacco control, still only about one third of the annual total cost of smoking to the health system of one member state, the UK. Thus we are underspending on tobacco control in the EU and we have argued that we also underspend on research to underpin policy development.

The evidence from Spain, where the proportion of cigarettes sold on the contraband market has fallen dramatically, shows that when the real causes of smuggling are tackled, tobacco smuggling can be controlled. There is thus a sound basis for developing policy to combat smuggling, which at its peak accounted for a third of global exports and thus had a huge distorting effect on the price of cigarettes and thence on consumption, and from that on public health. Because smuggling is by its nature a global problem, crossing national borders, arguably it will have to be dealt with at global as well as national level and this is a policy area where the EU could contribute significantly.

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# TOBACCO PRODUCT REGULATION

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## I. INTRODUCTION

Until now, discussion on effective policies to limit ill health due to smoking has focused largely on strategies to influence smoking behaviour within the population. Tobacco product modification strategies represent a different approach aimed at ways to make the product less toxic to consumers.

There have been some successes with regulating the marketing and sale of tobacco products in Europe as a result of European Union (EU) Directives and Member State legislation. However, measures to regulate the toxicity of the cigarette itself have been limited and tobacco remains one of the least regulated consumer products in the world. Tobacco manufacturers are largely free to introduce new products onto the EU market at any time they choose and there is very little information available about the characteristics of cigarettes and most other tobacco products available in the EU.

This chapter aims to set out the state of scientific knowledge in the area of tobacco products regulation and to propose new approaches to be considered by national or EU policy makers. In doing so, it draws on a number of other reviews recently published<sup>1, 2, 3</sup> and a set of recommendations and principles produced by the World Health Organization's Study Group on Tobacco Product Regulation (WHO TobReg; formerly known as the WHO's Scientific Advisory Committee on Tobacco Product Regulation, WHO SACTOB)<sup>4, 5, 6, 7, 8</sup>.

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## 2. TOBACCO PRODUCT REGULATION

### 2.1 General principles

Tobacco product modification and harm reduction are subjects of some controversy amongst tobacco-control advocates. There are valid concerns that resources spent devising, implementing and monitoring product regulation strategies could detract from the use of proven tobacco-control strategies (as described in Chapter 4). However, these concerns should not result in regulatory inaction. There is widespread consensus amongst tobacco-control experts that some form of government regulation is needed for tobacco products<sup>9</sup>, if only to ensure that there is no increase in their toxicity. The EU has a history of trying to make the product less harmful and therefore there is an obligation on the EU to continue its efforts in this direction as it has already exerted its competence in certain areas which may make it more difficult for Member States to implement their own strategies.

Whilst there is an obligation on regulators and producers to reduce the harmfulness of tobacco use as much as possible, it is critically important that product regulation does not detract attention from other essential components of tobacco control aimed at encouraging smokers to stop, protecting non-smokers and preventing young people taking up smoking. Communications about the health risks of various tobacco products and any modifications made to them, which could affect the behaviour of smokers, therefore need to be under strict regulatory control.



Tobacco products are highly engineered and sophisticated nicotine delivery devices. As stated in Chapter 1, this was recognised by the tobacco industry over 40 years ago<sup>10</sup>, and only more recently by the tobacco-control community<sup>11</sup>. Tobacco product regulations must, therefore, take into account the fundamental role nicotine plays in tobacco use. Furthermore, many features have been manipulated to increase the appeal of tobacco products to the consumer and are known to influence both toxicity and addictive potential. It is therefore unlikely that any single test or measure can be used on its own to regulate the harmfulness and addictiveness of tobacco products.

Currently, the cigarette is the dominant form of nicotine delivery system in Europe. In recent years, there has been a proliferation of novel tobacco products launched onto the USA market with many more nicotine delivery devices in development. These products are likely to reach the EU very soon. The novel products include cigarettes with reduced concentrations of tobacco specific nitrosamines (see below), devices heating rather than burning tobacco and smokeless tobacco products. There is currently no regulatory framework within which these products can be meaningfully assessed. Therefore, new regulations need to examine not just cigarettes, but all nicotine delivering products across the range of delivery systems including therapeutic nicotine replacement therapies which are currently the least harmful forms but which are strictly regulated by medicines regulators.

### 3. EXISTING TOBACCO PRODUCT REGULATION

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As stated earlier, the objective of the regulation of tobacco products is to make them less toxic to the consumer. Since the early 1990s regulations in the EU have focused mainly on lowering tar yields. This was based on the belief that tar was the principle carcinogenic and toxic component of cigarettes (see also Chapter 3). It was argued that reducing tar yields would reduce the toxicity of cigarettes and, hence, the mortality and morbidity associated with smoking. This strategy was implemented earlier in some Member States, for example, in the UK it was first implemented in the 1970s.

The tar reduction strategy was further refined and extended by the Recommendations of the Cancer Experts<sup>12</sup> which were adopted by the Helsinki European Conference on Tobacco Control in 1996<sup>13</sup>. These recommendations provided the framework for the EU Directive in 2001 (37/EC)<sup>14</sup> which, while continuing with the tar reduction approach, also introduced maximum yields for nicotine and carbon monoxide (CO). In addition, the EU Directive 2001/37/EC mandated the publication of tar, nicotine and CO yields on the sides of packs, and introduced the requirement for the industry to disclose their ingredients to the competent authorities in Member States (with onward transmission to the European Commission). EU Directive 2001/37/EC also banned the use of misleading descriptors, such as “mild” and “light”, introduced more prominent health warnings and banned the sale of certain types of oral tobacco, a ban which had been introduced in the EU in 1992<sup>15</sup>. These latter aspects are described in more detail in Chapter 3. This chapter focuses on the tar reduction strategy, ingredients disclosure, and future tobacco product regulation.

Overall, understanding of the field of product regulation has advanced considerably since the late 1990s. In recognition of the growing base of evidence, the EU Directive 2001/37/EC also provided a review clause (Article 11) to take account of emerging scientific knowledge. Suggested areas to review included methodologies for more realistically assessing and regulating toxic exposure and harm, development of standardised testing methods to measure the

yields of constituents in cigarette smoke other than tar, nicotine and CO and the evaluation of tobacco products which may have the potential to reduce harm.

### 3.1. The tar yield reduction strategy

Reduction in the machine-smoked tar yields of cigarettes was the key strategy for reducing the harmfulness of cigarettes in the last century. As indicated earlier, this strategy was based on the scientific understanding that tar was the principle carcinogenic and toxic component of cigarettes and reducing tar would reduce the likelihood of smokers developing cancers and other diseases<sup>1</sup>. Likewise, setting a maximum yield of CO in the EU Directive 2001/37/EC was thought to limit the risk of developing cardiovascular disease (box 1 shows some selected relevant aspects of the EU tobacco products Directive 2001/37/EC).

Box 1. - EU Directive 2001/37/EC: Selected references to yield reduction strategy

#### *Preamble*

- (5) Directive 90/239/EEC established maximum limits for the tar yield of cigarettes marketed in the Member States with effect from 31 December 1992. The carcinogenic nature of tar makes it necessary to reduce further the levels of tar in cigarettes.
- (7) Several Member States have indicated that, if measures establishing maximum carbon monoxide yields for cigarettes are not adopted at Community level, they will adopt such measures at national level. Differences in rules concerning carbon monoxide are likely to constitute barriers to trade and to impede the smooth operation of the internal market. In addition, cigarettes have been shown to produce amounts of carbon monoxide which are hazardous to human health and capable of contributing to heart disease and other ailments.
- (9) There are differences between the laws, regulations and administrative provisions of the Member States on the limitation of the maximum nicotine yield of cigarettes. Such differences are liable to constitute barriers to trade and to impede the smooth operation of the internal market. Member States and scientific authorities have raised specific problems of public health in a field which has already been the subject of prior harmonization measures, which the Commission has examined.
- (10) Those obstacles should accordingly be eliminated and to that end the release for free circulation, marketing and manufacture of cigarettes should be made subject to common rules not only concerning tar but also concerning maximum nicotine and carbon monoxide levels.
- (14) For measuring the tar, nicotine and carbon monoxide yields of cigarettes, reference should be made to ISO standards 4387, 10315 and 8454, which are the only internationally recognised standards, it being understood that subsequent research and technological progress to be promoted should make it possible to develop and use more precise and reliable measurement methods for cigarette yields and to develop measurement methods for the other tobacco products.

(15) There are no internationally agreed standards or tests for quantifying and assessing the yields of constituents in cigarette smoke other than tar, nicotine and carbon monoxide. A procedure for development of such standards, in consultation with the International Standards Organisation, is therefore necessary.

### Article 3

#### **Cigarettes: maximum tar, nicotine and carbon monoxide yields**

1. From 1 January 2004, the yield of cigarettes released for free circulation, marketed or manufactured in the Member States shall not be greater than:
  - 10 mg per cigarette for tar,
  - 1 mg per cigarette for nicotine,
  - 10 mg per cigarette for carbon monoxide.
2. By way of derogation from the date referred to in paragraph 1, as regards cigarettes manufactured within, but exported from, the European Community, Member States may apply the yield limits laid down in this Article as from 1 January 2005 but shall in any event do so by 1 January 2007 at the latest.
3. For Greece, as a temporary derogation, the date of application of the maximum tar yield of cigarettes manufactured and marketed within its territory, as referred to in paragraph 1, shall be 1 January 2007.

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### Article 4

#### **Measurement methods**

1. The tar, nicotine and carbon monoxide yields of cigarettes shall be measured on the basis of ISO standards 4387 for tar, 10315 for nicotine, and 8454 for carbon monoxide. The accuracy of the tar and nicotine indications on packets shall be verified in accordance with ISO standard 8243.

### Article 5

#### **Labelling**

1. The tar, nicotine and carbon monoxide yields of cigarettes measured in accordance with Article 4 shall be printed on one side of the cigarette packet in the official language or languages of the Member State where the product is placed on the market, so that at least 10% of the corresponding surface is covered. That percentage shall be raised to 12% for Member States with two official languages and to 15% for Member States with three official languages.

ISO: International Standards Organisation. Source: The European Parliament and the Council of the European Union<sup>14</sup>.

#### *3.1.1. Problems with tar yield reduction strategy*

Tar is defined as the cigarette smoke condensate, or total particulate material minus nicotine and water, collected on the Cambridge filter pad in smoking machines from mainstream smoke (defined as that drawn through the filter by the smoker, as opposed to sidestream smoke which arises from the lit end of the cigarette). The particles in the smoke larger than 1  $\mu\text{m}$  are trapped

with 99% efficiency, but the gas or vapour phase of the smoke passes mostly through the filter. Therefore, tar yields were measured using these machines by tests involving a set of parameters for the machines. These were introduced by the US Federal Trade Commission and adopted by the International Standards Organisation (ISO; table 1).

Table 1. - Parameters of the standard International Standards Organisation test

<b>PUFF VOLUME</b>	35 mL
<b>PUFF INTERVAL</b>	1 per minute
<b>PUFF DURATION</b>	2 seconds
<b>BUTT LENGTH</b>	23 mm for non-filtered and 3 mm above filter overlap for filter tipped cigarettes (there are slightly different specifications for butt length for the Federal Trade Commission test).

Reproduced with permission from McNeill *et al.*<sup>3</sup>

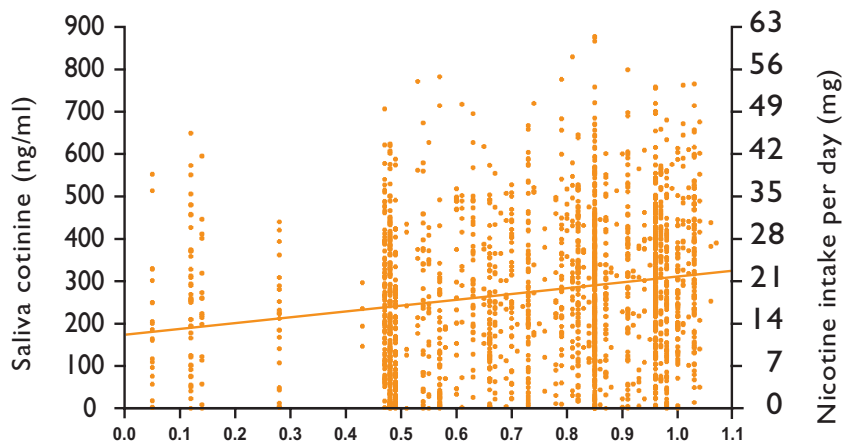
Manufacturers achieved the reduction in machine-measured tar yields using several techniques, such as increasing the ventilation of the filter, increasing the burn rate, decreasing the tobacco density, increasing the porosity of the wrapping paper, changes in tobacco blending and changes in filter efficiency, such as pressure drop alterations. However, the main method used was to dilute the smoke by placing ventilation holes in cigarette filters<sup>16</sup>. This resulted in air also being drawn in through the filter causing a reduction in the machine-registered yields. Both gas and particulate yields were reduced roughly in proportion to the degree of ventilation. On the whole, as tar yields decreased, so did nicotine yields.

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Most smoking behaviour is driven by an addiction to nicotine. As most smokers regulate their nicotine intake to maintain a relatively constant intake of nicotine each day, they alter the way they smoke to achieve their preferred nicotine level, a process referred to as compensation. Cigarettes with reduced tar and nicotine yields are smoked more intensively by, for example, taking more and deeper puffs and/or blocking the ventilation holes in cigarettes, to achieve a satisfactory dose of nicotine. The ventilation holes are positioned in the filter where smokers place their fingers, and are, therefore, easy to block. Cigarette-testing machines cannot take account of this relationship between nicotine intake and behaviour as the machine puffing patterns are standardised and with the standard ISO test the ventilation holes were not covered. The ISO machine smoking protocol, therefore, fails to take account of cigarette smoking as predominantly nicotine-seeking behaviour and the cigarette as a delivery system for nicotine<sup>1</sup>.

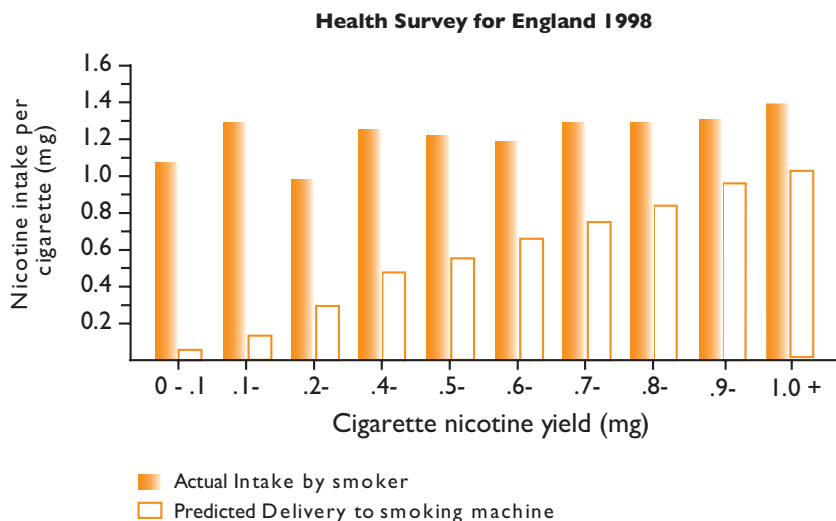
An illustration of the differences between machine-delivered measurements and smoke intake by smokers is given in figures 1 and 2. Jarvis *et al.*<sup>17</sup> showed that in a representative sample of smokers in England there was a very wide range in nicotine intake ranging from just above 0 to 50 mg nicotine per day for cigarettes having the same machine measured nicotine yields (fig. 1). Figure 2 shows that the actual nicotine intakes differed greatly from the predicted nicotine intakes and were broadly similar across the range of machine-delivered nicotine yields. These graphs indicate that the machine tests cannot be used to measure what smokers are actually taking in from their cigarettes.

Fig. 1. - Scatterplot relating cigarette nicotine yields and saliva cotinine concentrations in 2031 smokers participating in the 1998 Health Survey for England



Cotinine=173.5+138.7 (nicotine yield);  $r=0.19$ ,  $r^2=0.034$ . Adapted from Jarvis *et al.*<sup>17</sup>

Fig. 2. - Predicted and actual nicotine intakes per cigarette smoked by nominal nicotine yield of usual brand



Adapted from Jarvis *et al.*<sup>17</sup>

The other main problem with the reduction in tar yield approach is around the concept of reducing “tar”. More than 2,000 chemical constituents exist in tobacco and about twice that number when tobacco is burned during smoking<sup>2</sup>. “Tar” has markedly different compositions across different products and across different countries. Hence, it is misleading to view “tar” as a consistent homogeneous toxic substance.

### 3.1.2. Public health impact of reductions in yields

Recent reviews have concluded that there is no convincing evidence of any benefit to public health from the strategy of reducing machine-based tar yields<sup>1,18</sup>. Reductions in machine-smoked tar yields can be achieved relatively easily by changing the design of the cigarette, and together with compensatory changes in smoking behaviour, these do not result in differences in exposure to the smoker. Although in some countries in Europe lung cancer rates have decreased over the last few decades, there are many competing explanations for the decline, foremost among them being the decline in prevalence of smoking, but possibly also the introduction of other changes in the manufacture of cigarettes. Indeed, despite reductions in machine-based tar yields in the USA, no corresponding decrease has been found in lung cancer rates there<sup>18</sup>.

## 3.2. Regulation of nicotine

A central issue in tobacco product regulation is what approach should be adopted towards nicotine. Nicotine is clearly the reason why most smokers smoke but it does not cause most of the harm.

Some experts had envisaged that the most effective approach to the regulation of nicotine would be to eliminate nicotine addiction by progressively reducing the levels of nicotine in tobacco products to zero, or a level approaching zero<sup>12,19</sup>.

Most scientists and tobacco-control experts now reject this approach. This is because of the basic premise that nicotine addiction drives smoker behaviour, so if nicotine yields are reduced then smokers are likely to compensate by inhaling more, resulting in no change or an increased toxicity (see earlier and Chapter 1). Among those experts are some of the previous most ardent promoters of the elimination approach. For example, recently, Henningfield *et al.*<sup>20</sup> came to the conclusion that “a more politically feasible option is that regulated products would retain the capacity to sustain addiction in existing tobacco users and hence some level of addiction risk”.

However, regulating nicotine is important in being able to shape the market for nicotine products. Hence, the nicotine limit implemented through the EU Directive 2001/37/EC<sup>14</sup> was an important harmonisation measure, which has, in principle, brought the nicotine delivery of cigarettes under regulatory control. The WHO TobReg acknowledges that a broad and comprehensive regulatory framework is required to enable policy options for controlling nicotine to move forward in ways that minimise the risks<sup>5</sup>. The committee calls for further study on how best to do this since “it remains uncertain at this time whether public health would be better served by increased or decreased levels of nicotine”<sup>21</sup>.

### 4. A NEW REGULATORY FRAMEWORK FOR REGULATING NICOTINE AND TOBACCO PRODUCTS

To date, as described earlier, regulation of the product has focused mainly on one aspect of the cigarette: emissions, in the form of tar, nicotine and CO, and their measurement by machine-based tests.

The complexity of cigarettes requires that regulation to reduce their harmfulness should instead focus on a number of dimensions and be grounded in a proper understanding of smokers' behaviour. Therefore, a comprehensive assessment of the product needs to be made across a wide spectrum of parameters. Table 2 outlines the parameters that would need to be assessed as part of a comprehensive regulatory framework for tobacco products. These dimensions are inter-related. For example, the physical design characteristics interact with the chemical constitution of the product and influence exposure.

Table 2. - A comprehensive regulatory framework for nicotine and tobacco products

- PRODUCT CHARACTERISTICS AND EMISSIONS
- EXPOSURE
- INJURY
- DISEASE RISK
- CLAIMS
- RESEARCH, EVALUATION AND MONITORING

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Assessment of some of these factors is largely in its infancy. This section only briefly describes some of the key issues involved and the reader should refer to the recent Institute of Medicine report<sup>2</sup> and the WHO TobReg guidelines<sup>6</sup> for more details.

As discussed at the outset, this regulatory framework should apply to all types of nicotine delivery systems, including new and modified tobacco products<sup>6</sup> and nicotine replacement therapies, which are currently regulated separately by medicines regulators.

**Recommendation:** A new comprehensive regulatory framework for all tobacco and nicotine products needs to be implemented.

#### 4.1. Product characteristics and emissions

There are many aspects of the design and make up of cigarettes that affect exposure to tobacco constituents and the harm caused by smoking.

Full disclosure of the physical, chemical and design characteristics of tobacco products is required (table 3).

Too little is currently known about each aspect to enable regulators to devise appropriate strategies. Strengthening the information requirements from the tobacco industry to cover the above issues and increasing compliance are, therefore, important first steps in order to be able to shape effective tobacco regulation in the future<sup>22</sup>.

Table 3. - Full disclosure of tobacco products

FULL DISCLOSURE OF TOBACCO PRODUCTS COMPRISES:
<ul style="list-style-type: none"> <li>• The type of tobacco used</li> <li>• The way the tobacco is processed</li> <li>• Ingredients/additives</li> <li>• Product engineering - filter ventilation, pH, etc.</li> <li>• Physical and chemical characteristics of emissions</li> <li>• Availability of nicotine and of other psychoactive constituents</li> <li>• The mode of use: smoked, chewed, etc.</li> <li>• Behaviour of the user</li> </ul>

**Recommendation:** Comprehensive disclosure of the physical, chemical and design characteristics of all tobacco products should be required and made public. This should include, inter alia, the type of tobacco used, the way the tobacco is processed, ingredients added, product engineering, physical and chemical characteristics of the emissions of all tobacco products, the availability of nicotine and other psychoactive constituents, the mode of use and the behaviour of the user.

So far, the EU has focused on requiring manufacturers to disclose additives (“ingredients”). This requirement and the industry response are described in the next section. However, as can be seen from table 3, additives are only one very small aspect of tobacco product engineering.

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#### 4.1.1. Ingredients

The definition of ingredients used in this report is that given by the EU Directive 2001/37/EC<sup>14</sup>. Accordingly “ingredient” means:

*“any substance or any constituent except for tobacco leaf and other natural or unprocessed tobacco plant parts used in the manufacture or preparation of a tobacco product and still present in the finished product, even if in altered form, including paper, filter, inks and adhesives.”<sup>a</sup>*

The term “ingredient” encompasses the commonly used term “additive” and the EU Directive 2001/37/EC<sup>14</sup> (and this chapter) uses these two terms interchangeably (box 2). These two terms have different meanings in Canadian tobacco-control legislation. The term “additive” has a slightly less comprehensive definition than the EU definition of “ingredients” (box 3) as it does not consider paper and filter materials to be additives. The Canadian legislation defines “ingredients” as the materials of tobacco products which are not additives. There is no corresponding term for these in the EU legislation.

<sup>a</sup> The EU Directive 2001/37/EC<sup>14</sup> is not entirely consistent in its use of the term “ingredients”, in that it applies the term also to tar, nicotine and carbon monoxide (Article 6, point 3) and uses both this term and the term “additives” inconsistently in the preamble (box 2).



### Box 2. - Content of EU Directive 2001/37/EC: references to ingredients or additives

#### *Preamble*

- (22) The situation varies in the different Member States regarding the ingredients and additives used in the manufacture of tobacco products. A number of Member States have neither existing legislation nor voluntary agreements in place on those substances. Several Member States in which such legislation or voluntary agreements exist receive no information from tobacco manufacturers on the quantities of such ingredients and additives present in particular tobacco products on a brand name by brand name basis. An approximation of the measures applicable in this field should be introduced, resulting in greater transparency.
- (32) As regards the other ingredients, including additives, the drawing up of a common list ought to be considered, with a view to subsequent harmonisation.

#### *Article 6*

##### **Further product information:**

1. Member States shall require manufacturers and importers of tobacco products to submit to them a list of all ingredients, and quantities thereof, used in the manufacture of those tobacco products by brand name and type. This list shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients in those tobacco products. It shall indicate their function and category. The list shall also be accompanied by the toxicological data available to the manufacturer or importer regarding these ingredients in burnt or unburnt form as appropriate, referring in particular to their effects on health and taking into account, inter alia, any addictive effects. The list shall be established in descending order of the weight of each ingredient included in the product. The information referred to in the first subparagraph shall be provided on a yearly basis and for the first time by 31 December 2002 at the latest.
2. Member States shall ensure the dissemination of the information provided in accordance with this article by any appropriate means, with a view to informing consumers. Due account shall nevertheless be taken of protection of any information on specific product formulae which constitutes a trade secret.
3. Member States shall ensure that the list of ingredients for each product, indicating tar, nicotine and carbon monoxide yields, is made public.
4. Each year Member States shall communicate all data and information submitted pursuant to this Article to the Commission, which shall take account thereof when drawing up the report referred to in Article 11.

#### *Article 11*

##### **Report [pay special heed to... (inter alia):]**

- evaluation of the addictive effects of those ingredients which encourage addiction

- toxicological data to be required from manufacturers on ingredients and the manner in which they should be tested in order to allow public health authorities to assess their use

### Article 12

#### **Common list of ingredients**

In the framework of the first report referred to in Article 11, at the latest by 31 December 2004, and with a view to the proper functioning of the internal market, the Commission is invited to submit, on the basis of the information provided under Article 6, a proposal providing for a common list of ingredients authorised for tobacco products, taking into account, inter alia, their addictiveness.

### Article 13

#### **Import, sale and consumption of tobacco products**

3. In particular, Member States may provide for the prohibition, pending the establishment of the common list of ingredients referred to in Article 12, of the use of ingredients which have the effect of increasing the addictive properties of tobacco products.

Source: The European Parliament and the Council of the European Union<sup>14</sup>.

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### Box 3. -Terminology of ingredients and additives in tobacco products in Canadian legislation

#### **Additive means**

“any substance, chemical or compound, other than tobacco, water or reconstituted tobacco sheet, that is introduced by a manufacturer into the tobacco, paper or filter of a cigarette or into cigarette tobacco during the processing, manufacturing or packing of the cigarette or cigarette tobacco.”

#### **In Canada, contrary to the EU, ingredient means**

- a) “tobacco, water or reconstituted sheet and
- b) any substance, chemical or compound, other than additives, in the paper or filter of a cigarette.”

Modified from the Canadian Tobacco Sales Act<sup>23</sup>

Few ingredients were used in cigarettes before 1970. In 1979, the UK was among the first countries in Europe to publish a list of approved tobacco additives (around 350 in total)<sup>24</sup>. This followed the setting up of a voluntary agreement between tobacco manufacturers and importers and UK Health Ministers not to introduce new products containing additives, other than those found acceptable to the Independent Scientific Committee of Smoking and Health. The Committee at that time recognised that some additives could improve the acceptability of lower tar cigarettes or be used for technological reasons in the manufacture of cigarettes, for example, to prevent the fall of ash, to control the rate of burning or inhibit the formulation of mould. Today, additives may constitute >15% of weight of cigarettes<sup>25</sup> in the EU. Potentially, hundreds

of additives are commonly used<sup>26</sup>. Although most of them are used in very small amounts (<0.01% of total weight), a small group of additives are used at much higher levels, such as sugars, humectants, ammonia compounds, cocoa, licorice and menthol.

In 1997 the Commission Services wrote to all Member States regarding their policy on additives in cigarettes. The analysis of the replies indicated that there was a wide variety of rules concerning additives between the Member States<sup>14</sup>. Common to all these rules was that the issuing authorities were only concerned with the toxic effects of the ingredients in their natural state, i.e. in unburned form (as generally practiced in the regulation of additives to foodstuff). However, none of the rules consider the effects of these additives when used as intended i.e. their uptake by the smoker in the burnt form, when these substances are likely to be considerably more toxic than their unburned form.

To the credit of the European Commission and following the recommendation of the cancer experts committee, EU Directive 2001/37/EC introduced regulations to take into account the effect of ingredients in their burnt form (Article 6, point 1).

EU Directive 2001/37/EC further improved upon previous practice. Up until then, regulations had concentrated only on the “direct” toxic effects of ingredients, thus ignoring the indirect effects of ingredients on the health of smokers, such as enhancement of addictiveness, which might result in increased consumption and harm. EU Directive 2001/37/EC explicitly requires the indirect effects to be now taken into consideration (Article 6, point 1).

The remainder of this section focuses on the major requirements of EU Directive 2001/37/EC regarding ingredients: first, the requirement for disclosing amount and function of ingredients, secondly, their toxic effects and, thirdly, the call for establishing of a common “positive” list of ingredients. It concludes by making other recommendations for further development.

#### *4.1.1.1. Disclosure of amount and function*

A fundamental issue in guiding requests for information is to ensure that the definition of ingredients is sufficiently broad. In this respect, the EU Directive 2001/37/EC reflected the state of regulatory awareness at that time, essentially limiting ingredients to substances which were added during the manufacturing process alone. Since then, it has emerged that some substances may enter the product during earlier phases, such as through agricultural practices. These substances are excluded from the definition, and, therefore, from regulation despite the fact that they are present in the final product, and ingested by the smoker. One example of an ingredient of this kind is ammonia, a substance known to alter the form of nicotine and hypothesised to increase the addictiveness of nicotine<sup>27</sup>. Ammonia is present in the tobacco leaf itself and ammonium salt may be added to the growing process<sup>28</sup>.

A more comprehensive definition of ingredients, such as that developed by the WHO RegTob<sup>7</sup> (formerly SACTOB), will ensure that all substances, potentially harmful to human health, can be captured by the regulatory process. According to the RegTob definitions: “ingredients include all product components, materials used to manufacture those components, residual substances from agricultural practices, storage and processing, and substances that can migrate from packaging into the product.”

**Recommendation:** The current EU Directive 2001/37/EC should be improved by adopting the WHO TobReg definition for ingredients.

Article 6 of the EU Directive 2001/37/EC also calls on Member States to require a list of all ingredients and the quantities used from tobacco manufacturers and importers (box 2). This had to be provided by brand name and type, and explain why each additive was used. Member States were to ensure that this information be disseminated to inform consumers. But the requirement to do so was qualified by reference to trade secrecy.

To date, tobacco companies have not complied with this part of the EU Directive 2001/37/EC, arguing that a comprehensive list of ingredients is too detailed for the consumer and that authorities do not give enough guarantees that the confidential information on quantities will not be leaked to outsiders.

**Recommendation:** The tobacco industry is required to fully disclose additives used in their products according to the letter and spirit of the EU Directive 2001/37/EC. In view of the high risk potential of tobacco products, such detailed information should take precedent over trade secrecy.

#### *4.1.1.2. Disclosure of toxic and addictive effects*

Article 6 of the EU Directive 2001/37/EC also stipulates that the list of additives should be “accompanied by the toxicological data available to the manufacturer or importer regarding these ingredients in burnt or unburnt form as appropriate” with particular reference to their effects on health and addictive effects (box 2).

One major shortcoming of the regulation is that the industry is asked only to provide *available* scientific data on the toxicology or addictiveness of ingredients. Thus, the regulations give no precision around which information should be transmitted, which methods for measurement should be used, and whether data should be present for each ingredient or all ingredients taking into account their synergistic effects.

How toxicity is defined for regulatory purposes remains highly controversial. Tobacco companies submit that the toxicity of ingredients should be evaluated relative to that of the overall toxicity of tobacco products, rather than on the basis of their own absolute toxicity. Under this premise, the industry compares the toxicity of tobacco products and tobacco smoke in the presence or absence of a mixture of ingredients<sup>29, 30, 31, 32</sup> and claims that any ingredient which does not cause excess toxicity could be authorised for use. This means that authorised ingredients might be as toxic and carcinogenic as the tobacco smoke constituents themselves. Such an approach is clearly not acceptable. Tobacco products, albeit extremely toxic and addictive, are legal because they could not be banned in view of the hundreds of millions of tobacco addicts. However, this is entirely different for additives. According to good regulatory practice additives should not be harmful. There is no good reason why this practice should not apply to tobacco additives in their unburnt and burnt form. In essence, the toxicity of tobacco and tobacco smoke cannot be the standard for evaluating the toxicity of ingredients as proposed by the tobacco industry. The additives have to be tested for their own toxicity, as is required for additives for any other consumer product.

The information on addictiveness is even more likely to be unsatisfactory as the official position of the tobacco industry has always been that they never add ingredients which enhance addictiveness.

A further shortcoming in this context is a lack of regulatory capacity to cope with the volume of information which will be received. It is doubtful whether Member States have the competence and capacity to examine, check and control the data provided by the industry, at present and, indeed, whether there are enough independent laboratories across the EU to examine the industry data (see section Regulatory capacity in Europe).

In conclusion, the information provided by the tobacco companies, thus far, is insufficient to form the basis for further regulations for ingredients and, in particular, the drawing up of a common list of ingredients, another requirement of the EU Directive 2001/37/EC as described in the next section.

**Recommendation:** Member States and the European Community should agree a harmonised system for receiving the required information on ingredients in, and emissions from, tobacco<sup>22</sup>. This system should specify the exact form and content of the information to be transmitted, which methods for measurement should be used and that the data should also take into account synergistic effects of the ingredients. The information provided should allow comparability between different tobacco companies. A harmonised system should also be established for Member States to analyse, verify and then report this information to the European Commission.

#### *4.1.1.3. A common list of ingredients*

Article 12 of the EU Directive 2001/37/EC calls for the Commission to submit, on the basis of information provided in Article 6 of the EU Directive 2001/37/EC, “a common list of ingredients authorised for tobacco products, taking into account, inter alia, their addictiveness” (Box 2). This proposal was to be made at the latest by 31 December 2004.

The requirement for a common list came about because of concerns that an additive approved in one EU Member State had to be permitted in all states and there was a concern that this would lead to tobacco companies seeking approval in the weakest regulatory regime.

It is not yet clear which additives should be on the common list. As discussed in the previous section there are no clear criteria for measuring toxicity and addictiveness. In particular, methodologies for assessing toxicity and addictiveness of ingredients have to be established and validated for sensitivity, specificity, and comparability across different laboratories. This is a demanding task requiring skills and expertise not currently widely available among tobacco-control scientists, researchers and regulators. Methodologies for assessing addictiveness are not well developed and not applicable to routine, large-scale monitoring and it may take years for them to be agreed.

However, test procedures for assessing carcinogenicity, likely to be the most important toxic effect of ingredients, are well established and can readily be applied in the first instance to test ingredients. Methodologies for assessing addictiveness and other toxic properties should be applied as they become available.

One starting point for the development of a robust regulatory framework for ingredients would be the tests used by cosmetics or medicines regulators for pharmaceutical products.

**Recommendation:** A common list of ingredients cannot be produced until scientifically agreed criteria have been drawn up to assess the toxicity and addictiveness of ingredients and their public health impact (see below).

#### 4.1.1.4.A *public health test for additives*

As indicated above, regulations previously ignored the *indirect* effects of additives on the health of smokers. Ingredients may increase harm in more ways than by enhancing direct toxicity and addictiveness. They may increase the uptake of toxic constituents of tobacco smoke. This is the case, for example, with menthol, which causes respiratory depression resulting in greater exposure to toxicants in tobacco smoke<sup>33,34</sup>. Even more importantly, additives may enhance overall consumption and subsequent harm by making the product more palatable and attractive to the consumer<sup>35</sup>.

As the toxicity of most additives is greatly outweighed by the toxins present in tobacco smoke, then what is important is if the ingredient acts in such a way that leads to increased smoking. Such a mechanism of action would have a far greater impact on public health than the direct toxicity of the ingredients.

However, it is important to note that additives are sparingly used in some countries such as Canada and certain types of cigarettes (e.g. the brand named “Natural American Spirit” manufactured by Santa Fe Natural Tobacco Company, Inc., Santa Fe, NM, USA) claim to be free of additives. Thus, the majority of ingredients do not seem to be necessary for the manufacture of cigarettes and their acceptance by consumers.

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The criteria for assessing existing and new additives should, therefore, be extended to include a test of public health or public interest (with the burden of proof resting on the industry) or be withdrawn from use. Exemptions should only be made for ingredients which are necessary for the manufacture and storage of tobacco products providing they are safe.

**Recommendation:** Any future regulation of ingredients should be based on the principles that the substance is not toxic, does not enhance the addictive properties of tobacco products and does not make the product more attractive. Further research and analysis is needed to create scientifically sound criteria for any approval or prohibition of ingredients.

#### 4.1.2. *Ignition propensity*

One characteristic of cigarettes that should be regulated is ignition propensity<sup>22</sup>. Smoking is a leading cause of residential and total fire death<sup>36</sup>. The number of smoking-related fire deaths in Canada and the USA amounts to 25% and 30%, respectively, of total fire deaths. Assuming a proportion of 20% of smoking-related fire deaths in EU Member States, fires caused by smoking claim more than 1,000 victims annually in the EU. Many of the smoking-related fires could be prevented through the introduction of a fire safety standard for cigarettes.

Internal documents of the tobacco industry reveal that low ignition propensity cigarettes could have been produced as early as 1985<sup>37</sup>. The documents also indicate that the production of such

cigarettes would not be significantly more costly or affect their taste. It took two decades until “fire safe” cigarettes reached the USA market. New York has now enacted a law requiring that only self extinguishing cigarettes can be sold. Other USA states such as Massachusetts, Minnesota, New Jersey and Rhode Island are considering taking similar steps. Canada will be the first country to follow suit by permitting only self-extinguishing cigarettes on the market in 2005. Testing methodologies for cigarette fire safety have been developed in the USA and Canada that can be readily adopted elsewhere.

**Recommendation:** In view of the fact that it is technologically and economically feasible for cigarettes to meet fire safety standards, tobacco manufacturers should be required to produce and market only “fire safe” (or “reduced ignition propensity”) cigarettes in the EU.

### 4.1.3. Emissions

The term emissions covers all the substances produced when the tobacco product is used. As described earlier, to date, the regulation of emissions has been limited to measuring tar, and more recently nicotine and CO, relying on the inadequate machine tests.

Two main approaches have been suggested to overcome the current limitations. The first approach involves changing the operating parameters of the machine to make it more closely mimic smoking behaviour. The second uses the ratio of the standard ISO tar and nicotine yields as an indicator of potential harm. These approaches are described briefly below.

#### 4.1.3.1. Intense machine smoking regimens

Some countries have introduced more intense standards for machine cigarette testing. The first to do this was British Columbia, in 1998 through the Tobacco Testing and Disclosure Regulation 26<sup>38</sup>. This Regulation, inter alia, required Canadian tobacco manufacturers to disclose the constituents of tobacco and the levels of potentially toxic chemicals in tobacco smoke (both mainstream and sidestream), for a number of smoke constituent chemicals, using both the standard ISO test as well as a modified ISO or intense puffing test (table 4). The Modified ISO test was designed to assess the maximum yields of a cigarette that could be made available to a smoker so the parameters of the test were set to try to maximise the amount of smoke that could be inhaled.

Table 4. - British Columbia modified International Standards Organisation (ISO) conditions

	STANDARD ISO	MODIFIED ISO (1) <sup>#</sup>	MODIFIED ISO (2) <sup>†</sup>	MASSACHUSETTS MODIFICATIONS
Puff volume	35 mL	56 mL	55 mL	45 mL
Puff interval	60 seconds	20 seconds	30 seconds	30 seconds
Puff duration	2 seconds	2 seconds	2 seconds	2 seconds
Ventilation holes	Not blocked	Fully blocked	Fully blocked	50% blocked

<sup>#</sup>: Used for the 1998 and 1999 reporting years; <sup>†</sup>: used for the 2000 and beyond reporting years. Modified from British Columbia Tobacco Testing and Disclosure Regulations<sup>38</sup>.



Health Canada subsequently adopted the Modified ISO (2) test method in their Federal Tobacco Reporting Regulation<sup>39</sup> and required both standard and modified measures to be made available to consumers on packs in the form of a range.

The Massachusetts Department of Health proposed reporting requirements for smoke constituents using a further modification of the ISO test which reduced the parameters of the Canadian modifications to make them more realistic (table 4), but this has not yet become legislation.

#### 4.1.3.2. Tar/nicotine ratios

As early as 1976 it was proposed that the yield of tar should be determined relative to that of nicotine and that cigarette smoking could be made less hazardous by reducing tar and other toxins relative to nicotine<sup>40</sup>. This approach is based on the evidence that smokers tend to regulate their nicotine intake to obtain a “satisfactory” dose level which is constant over time and that they will compensate for reductions in nicotine yield by inhaling more from their cigarettes to maintain a relatively consistent dose of nicotine. So if the nicotine level is maintained whilst reducing the tar yields then smokers would not need to compensate and so their inhalation of tar would be reduced. This strategy is referred to as regulating the tar/nicotine ratio of emissions. A ratio of 10 would mean that for each unit of nicotine, 10 units of tar would be delivered, whereas a ratio of 20 would mean 20 units of tar being delivered for each unit of nicotine. Hence, a lower tar/nicotine ratio is preferred because this would mean less tar per unit of nicotine inhaled. A limit of 10 could be set for the ratio, together with individual tar and nicotine yield limits (in order to avoid possible combinations of high tar and high nicotine yields).

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However, this approach has some pitfalls which were not known at the time. The tar/nicotine ratio can also vary depending on how the cigarette is smoked. In 1986 Rickert *et al.*<sup>41</sup> indicated that a tar/nicotine ratio of 6.1 on a smoking machine could become 9.7 in a smoker trying to increase the amount of nicotine in an ultra-light cigarette. Instead of using the standard ISO tests to construct the ratio, it may be preferable to use the modified ISO tests so as to better mimic smoking behaviour.

Recently, the Laboratory of the Government Chemist in England tested 12 cigarette brands available on the UK market in 1999 using standard, British Columbia and Massachusetts modified testing (Modified ISO (1) on table 4) regimes and compared tar and nicotine yields and tar/nicotine ratios with each test<sup>42</sup>. Table 5 details the findings of this study.

The misleading nature of the lower yielding brands (table 5, column 1) is demonstrated when the standard ISO tar/nicotine ratios are considered (table 5, column 3). There is little difference between the higher and lower tar yield brands when the standard ISO tar/nicotine ratios are considered.

The tar/nicotine ratios of lower yielding brands appear to have slightly lower tar to nicotine ratios than higher yielding brands when using the standard ISO tests (table 5, column 3). However, when comparing the tar/nicotine ratios constructed using the standard ISO tests, compared with the British Columbia (BC) modified test, the very intense human smoking regimens, (table 5, column 10) the tar/nicotine ratios from lower yielding cigarettes are considerably greater; and for some low yield brands indicate greater tar per dose of nicotine being delivered than with the higher tar yield brands.



Table 5. - Tar (T) and tar/nicotine (T/N) ratios of a selection of UK brands using the standard International Society Organisation (ISO) machine tests, and the more intensive British Columbia (BC) and Massachusetts (Mass) smoking regimes

	1	2	3	4	5	6	7	8	9	10	11
	ISO Tar	ISO Nic	ISO T/N	BC Tar	BC Nic	BC T/N	Mass Tar	Mass Nic	Mass T/N	BC/ISO T/N <sup>#</sup>	Mass/ ISO T/N <sup>#</sup>
Silk Cut Ultra KS	1.01	0.11	9.18	31.18	1.95	15.96	9.11	0.84	10.89	1.74	1.19
Mayfair Ultra KS	1.19	0.12	9.92	30.34	1.8	16.87	8.97	0.79	11.37	1.7	1.15
Silk Cut Ex Mild KS	2.91	0.29	10.03	32.73	2.04	16.1	12.86	1.14	11.31	1.6	1.13
Superkings Ultra	3.36	0.31	10.84	28.77	1.7	16.97	11.18	0.94	11.91	1.57	1.1
Red Band Lights S/K	5.73	0.53	10.87	40.16	2.56	15.66	18.3	1.46	12.57	1.44	1.16
Embassy Ex Mild KS	7.8	0.7	11.14	33.51	2.3	14.57	19.34	1.63	11.86	1.31	1.06
Balmoral Lights KS	8.09	0.64	12.64	36.9	2.35	15.69	19.78	1.51	13.08	1.24	1.03
Superkings Lights	8.29	0.82	10.11	37.03	2.9	12.8	20.57	1.97	10.42	1.27	1.03
Benson & Hedges KS	10.66	0.85	12.54	39.91	2.64	15.13	24.33	1.89	12.89	1.21	1.03
Rothmans KS	11.02	0.95	11.6	41.48	3.03	13.67	24.7	2.19	11.26	1.18	0.97
Marlboro KS	12.01	0.86	13.97	45.31	2.71	16.73	27.86	1.95	14.26	1.2	1.02
Raffles 100's	12.36	1.1	11.24	42.45	3.52	12.08	26.84	2.47	10.89	1.08	0.97

<sup>#</sup>: These columns show the relationship between the tar/nicotine ratios from the two modified testing regimes and the tar/nicotine ratios from the standard ISO tests. Modified from Laboratory of the Government Chemist<sup>42</sup>.

The differences between the tar/nicotine ratios for the “more realistic” Massachusetts test and the standard ISO test are more closely approximated (table 5, column 11).

It is worth noting that in this sample of cigarette brands the ratios vary considerably less (1.4 fold) than the actual tar yields (12 fold), so the ratio measurement may have more validity.

Introducing a ratio limit could take many more brands off the market within the EU than are affected by the current EU Directive 2001/37/EC. If a tar/nicotine ratio of 10 was introduced into the EU, column 3 (table 5) indicates that only two of the brands tested in the UK study would comply. If the same limit was applied to the ratio of yields determined by the BC

Modified ISO tar/nicotine protocol (table 5, column 6) none of the brands tested would comply.

Therefore, both the intense smoking tests and the tar/nicotine ratio offer improvements on the standard ISO tests. As these approaches do not require the development of new technologies they could be implemented quickly, thereby putting an end to the present highly unsatisfactory situation. At present, it is unclear which approach (BC Modified, Massachusetts modified or tar/nicotine ratio using standard, BC or Massachusetts tests) is the best protocol to follow or whether a combination of the different approaches would be the best way forward. This is an urgent issue which needs to be clarified by European experts, drawing on the experience of those in Canada and Massachusetts who have used the modified ISO tests, and in coordination with other international bodies concerned with tobacco product regulation, such as WHO TobReg.

The protocols described above continue to rely on “tar” as the key indicator of toxicity. As explained earlier in this chapter, the concept of “tar” needs to be supplemented with a more sophisticated understanding of the different constituents of tobacco and/or smoke as described in the following section.

#### *4.1.3.3. Disclosure and reduction of individual smoke constituents*

On this basis, experts now prefer to examine and regulate the disclosure and reduction of individual smoke constituents<sup>43</sup>. Disclosure requirements should, therefore, also include details of a variety of smoke constituents. This is an approach followed by Health Canada. The following major types of constituents should be disclosed:

- Polycyclic aromatic hydrocarbons (e.g. benzo[a]pyrene, 5-methylchrysene)
- N-Nitrosamines (e.g. 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) and N-nitrosornicotine (NNN))
- Aromatic amines (e.g. 4-aminobiphenyl, 2-naphthylamine)
- Organic solvents (e.g. benzene, toluene, styrene)
- Volatile organic compounds (e.g. 1,3-butadiene, isoprene)
- Aldehydes (e.g. acetaldehyde, formaldehyde)
- Gaseous constituents (e.g. hydrogen cyanide, nitrogen oxide)
- Inorganic compounds (e.g. arsenic, cadmium, polonium-210)

In addition to disclosure, upper limits should be set for single constituents or a “representative” set of constituents drawn from the list above. These limits should then be progressively lowered to minimise harm and addictiveness of the tobacco product.

Exemplary candidates for early mandatory reduction are the tobacco specific N-nitrosamines (TSNAs). TSNAs are found in the particulate phase of tobacco smoke but also in non-combustible tobacco. TSNAs are not present in freshly harvested tobacco<sup>44</sup> but are formed during tobacco curing. The TSNA yield is dependent on the amounts of nitric oxide in the heated air and the amounts of nitrates and nicotine in the tobacco. The main TSNAs thought to be carcinogenic are NNK and NNN. These compounds can largely be removed from tobacco, i.e. they can be prevented from being generated by taking appropriate precautionary measures during manufacture. Combustible and non-combustible tobacco products

distinguished by very low levels of TSNA are already on the market in the USA and Europe, respectively.

It has been recommended that a mandatory reduction of TSNA should be an immediate priority for the EU, provided that in doing so the overall toxicity of cigarette smoke is not increased<sup>22,45</sup>. A precedent for this already exists as EU legislation has been passed to reduce nitrite/nitrate levels in some meat products<sup>46</sup>.

Since the public health impact of the TSNA removal cannot be predicted with certainty at the present time, the move should not be accompanied by any communications by the tobacco industry to the public implying a health benefit (see below).

**Recommendation:** Harmful constituents of tobacco and tobacco smoke should be reduced and ultimately removed where feasible. As a first step, the immediate reduction of TSNA in tobacco products, without increasing the overall harm caused by these products, should be made mandatory.

### 4.2. Exposure

The WHO TobReg defined the difference between emissions and exposure as:

*“Emissions’ are substances that are produced when the product is used and this is distinguished from ‘exposure’, a term that in this context refers to the fraction of emissions that is actually absorbed by the user.”<sup>7</sup>*

Increasing the understanding of the actual exposure of smokers to toxins and nicotine and the impact of this on their health is critically important. It will also be necessary to monitor smokers' exposure to nicotine and cigarette smoke toxins over time. The failure of the low tar strategy hinged on the fact that only emissions to cigarette-testing machines were measured over time, rather than the actual exposure of smokers to various smoke constituents. Measuring exposure is an indicator of potential harm and disease, and can also indicate how smokers and the industry are responding to product regulation. This can help assess the effectiveness of product regulation strategies and enable changes to the strategies to be made relatively quickly if unforeseen consequences are being observed.

There is an approach for assessing exposure which is independent of machine measurements and based on the actual behaviour of the smoker. This approach involves the measurement of tobacco smoke constituents trapped in the filter during actual smoking. In principle, such measurements reflect closely the behaviour of the smokers. A first attempt at this has been made using solanesol as an indicator, a naturally occurring component of tobacco that is deposited during smoking in the filter butt<sup>47</sup>. The amount of solanesol trapped on a filter was found to be related to the mainstream deliveries of tar and nicotine under a variety of ISO standard and modified smoking conditions. Currently it has only been tested with cigarettes containing cellulose acetate filters.

Uptake of toxic tobacco constituents by smokers can be determined directly by measuring their levels, for example in body fluids. At present, the number of constituents which can serve as “biomarkers” is greatly limited. Furthermore, many of the salient methodologies are not yet applicable to large scale, routine measurements. However, saliva cotinine (a non-

invasive indicator of nicotine exposure) testing over time is feasible. The saliva cotinine test is easy to administer and it enables a quantitative measure of nicotine intake to be monitored in smokers over time.

### 4.3 Injury and disease risk

There are three main major health outcomes of tobacco consumption which need to be monitored: cancer, cardiovascular disease and lung disease. Ideally, smokers' risks of suffering from one of these diseases should be determined by epidemiological studies. However, because of the length of time for such diseases to manifest themselves, it is not feasible to do this for regulatory practice and one has to resort to surrogate measurements.

For assessing carcinogenicity, well established bioassays are available, such as in vitro genotoxicity/mutagenicity tests or in vivo tests for the development of tumours. Such tests should be routinely used to assess the products currently on the market and new ones before entry.

Bioassays are not yet available for the pathogenesis of cardiovascular disease and lung disease. Although a number of bio-indicators for these diseases are known, such as inflammation, oxidative stress and malfunction of endothelial cells, tests for these indicators are still in an exploratory stage. They have to be validated and standardised. At present, this is one of the greatest challenges in developing a scientific base for evaluating and regulating potential harm reduction products, i.e. to distinguish relative injuries caused by different exposures to toxic tobacco constituents. The Institute of Medicine has estimated that the development of these tests will take a number of years before they can be applied to regulatory practice<sup>2</sup>.

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It is not the purpose of this report to review the status of the bioassays for the various smoking-related diseases, but this should be an urgent task within the regulatory framework.

**Recommendation:** Member States and the European Commission need to begin to assess injury risk from tobacco products. A stepwise procedure should be used, starting with established tests e.g. for cytotoxicity and genotoxicity, and then continuing with testing for other adverse effects, including enhancement of addiction.

### 4.4. Claims

The EU has already banned all use of misleading descriptors, but ISO yields still remain on packs (see Article 5 of the EU Directive 2001/37/EC<sup>14</sup> and Box 1). Based on the evidence provided above, these yields provide misleading information to smokers and should be removed from cigarette packs as soon as possible. This recommendation was a conclusion of the recent EU conference in Limerick, Ireland<sup>22</sup> and has also been made by WHO TobReg<sup>8</sup>. The remaining space on packs should be reserved for consumer information mandated by the European Community.

Communication related to health aspects of different tobacco and nicotine products and any changes in their characteristics should be strictly regulated to prevent consumers being misled into believing products are significantly less harmful (as occurred with lower yielding cigarettes) and, therefore, continuing to use the products rather than attempt to quit.

**Recommendation:** The requirement for tobacco manufacturers and importers to print tar, nicotine and CO yields on packs should be rescinded, and the Commission should mandate the remaining space on packs to be reserved for consumer information provided by Member States and the European Commission.

**Recommendation:** Communication relating to health aspects of different tobacco and nicotine products and any changes in their characteristics should be strictly regulated. The mandatory phasing out of toxic constituents recommended in this chapter should not be accompanied by any health claims.

### 4.5. Research, evaluation and monitoring

An essential element of the regulatory framework will be the ability to monitor for unintended consequences of modified products as well as to verify industry claims of reduced toxicity in their products. Therefore, changes will need to be monitored and evaluated within a comprehensive system of surveillance which will assess the impact of the regulation and correct any unforeseen consequences.

This comprehensive surveillance system would monitor disease risks and profiles, and the prevalence of initiation, relapse and switching behaviour. In addition, a programme of continuous tobacco product surveillance should be established to enable regulators to keep up to date with product changes.

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A new tobacco product of any kind, including new brands of cigarettes, should only be allowed onto the market if a comprehensive description of its characteristics and emissions is given (as described earlier) and if the manufacturer can demonstrate to the regulator that it offers the potential of reduced harm by comparison with currently available cigarette brands.

**Recommendation:** Any new tobacco product of any kind, including new brands of cigarettes must be given prior approval by regulators before entry to the market.

## 5. REGULATORY CAPACITY IN EUROPE

A comprehensive and meaningful tobacco products regulatory strategy, such as the one set out above, can only be implemented if regulatory capacity is adequate, multi-disciplinary and well funded. This is currently not the case.

In most Member States, government regulation of tobacco control is handled by one or two civil servants and this task is often carried out alongside others, such as alcohol policy. A similar situation applies within the Commission, where tobacco-control policy is coordinated by a team within the Public Health Directorate, located within the Health and Consumer Protection Directorate-General. In practice, most tobacco actions at national and European level require the inputs of a number of other sectors in different parts of governments, such as trade, taxation and legal services.

A few Member States have set up dedicated national tobacco-control agencies. The Irish Office of Tobacco Control and the Norwegian Tobacco Control Agency in the Health Ministry are two such examples. In addition, other Member States have established scientific

committees of experts in tobacco control to provide advice and risk assessments, for example, the Scientific Committee on Tobacco or Health in the UK and the Tobacco Control Task Force of Iceland. The provisions of the EU Directive 2001/37/EC also provided for the establishment of a regulatory committee consisting of representatives nominated by the Member States, usually civil servants working on national tobacco policy. In addition, the EU Directive 2001/37/EC allows the Commission to be assisted by experts in the drafting of the report on its application.

However, even in those Member States with a larger than average staff contingent dedicated to tobacco control and even amongst the various scientific and regulatory committees that have been set up, the technical expertise needed to fully assess and regulate tobacco products is lacking. The complexity and sophistication of cigarettes and other tobacco products require a wide range of technical skills including toxicology, pharmacology, psychology and law. Those working on tobacco product regulation would need to work closely with those working on other areas of tobacco control, such as taxation and cessation policies.

Tobacco products differ from every other consumer product in that they kill half of all their consumers when used as directed by the manufacturer. However, they are no different in their need for regulation to food, pharmaceuticals and other consumer goods that enjoy far greater regulatory resources at national and EU level. Meaningful tobacco product regulation will require much greater and dedicated human and financial resources than is currently the case.

Increased capacity could be positioned alongside the current civil servants working on tobacco control both at Member State and at European Commission level. Alternatively, a dedicated European tobacco and nicotine products agency could be set up which could quickly build up relevant skills. The remit of such an agency could include all aspects of tobacco and nicotine product design, marketing and monitoring as described above. Staff drawn from a wide range of disciplines would initially be responsible for risk analysis and assessment. This is the most desired option and would put tobacco, correctly, on a par with the European agencies for drugs, medicines, and food products. According to the Treaty establishing the European Community, competence for regulation at European level lies with the European Commission and so the regulatory functions around tobacco products could not be transferred to an agency outside the Commission.

Until regulatory capacity can be increased, a multidisciplinary tobacco product regulation advisory committee should be set up at European level to advise on the development of the new staff and the short-term implementation of the regulatory recommendations outlined in this chapter.

Independent government laboratory capacity to test tobacco products is also lacking in the EU. Some laboratories have been closed down in recent years and others have been privatised<sup>b</sup>.

<sup>b</sup> For example, cigarette testing used to be carried out by the Laboratory of the Government Chemist in the UK, but it is now performed by Arista, which is owned by Molins, a company with extensive commercial links with the tobacco industry.

In its most recent set of recommendations (yet to be published) the WHO TobReg has recommended that a series of regional laboratories be established to enable Member States to meet their product regulation obligations under the Framework Convention on Tobacco Control<sup>8</sup>. One option would be for the EU to host an independent tobacco testing laboratory on behalf of itself and the WHO European region. The facilities offered by the Commission's Joint Research Centre in Ispra, Italy, could serve as the basis for such a laboratory and offer additional research support to staff working on tobacco and nicotine product regulation in the future.

The costs of increased regulatory capacity should fall to the tobacco industry, for example through taxation or through a licensing system, but it is critically important that the regulators and regulatory process be completely independent from the industry.

**Recommendations:** Capacity to assess and regulate nicotine and tobacco products in the European Commission and Member States needs to be greatly increased and include the range of technical skills needed. At Member States level such staff could be housed in dedicated tobacco-control agencies (see also Chapter 7). At European level the preferred option would be for the establishment of a European tobacco and nicotine products agency. Until regulatory capacity can be increased, a multidisciplinary tobacco regulation advisory committee needs to be set up urgently across Europe to advise on tobacco regulation. The availability of independent laboratories to test tobacco products also needs to be increased.

The costs of increased regulatory capacity should be met by the tobacco industry but regulators and the regulatory process must be completely independent of all sectors of the tobacco industry.

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# THE INFLUENCE OF THE TOBACCO INDUSTRY ON EUROPEAN TOBACCO-CONTROL POLICY

*Gerard Hastings, Kathryn Angus.*

## I. INTRODUCTION

This chapter examines the extent, nature and effects of the tobacco industry<sup>a</sup> influence on European public health policy over the last 20 years. It uses internal industry documents to show that their efforts in this area have been energetic, concerted and systemic. It also shows that, in at least one major policy area, i.e. the control of advertising, it has been successful. In the process, it raises crucial questions for future European tobacco control.

Arguably, the tobacco industry's efforts to influence policy are only to be expected. The business community has long recognised that economic success is not only dependent on their consumer marketing, i.e. getting the right product to the right people in the right place at the right price, but also on the macro-economic environment within which the company operates. The political and regulatory culture is a crucial element of this environment and so, as Jobber<sup>1</sup>, a leading business academic explains, “close relationships with politicians are often cultivated by organisations both to monitor political moods and influence them”. Certainly European officials are very familiar with commercial interests wanting to offer advice and suggestions regarding the regulation of their industry. It would have been unthinkable, for example, for recent consideration of research ethics procedures to have taken place without consulting the pharmaceutical companies.

Thus lobbying or “stakeholder marketing” is as much standard business practice as consumer marketing. As Jobber<sup>1</sup> goes on to note: “the cigarette industry, for example, has a vested interest in maintaining close ties with government to counter proposals from pressure groups such as ASH”. Any industry would do the same in such circumstances, even if the tobacco industry's methods, which, as we will see, include a predilection for smuggling, would be unacceptable in other corporate sectors.

However, tobacco is not a standard business. Cigarettes are uniquely harmful, in that they kill even when used precisely as the manufacturer recommends. No other product does this. Alcohol, cars and even food products (given the obesity epidemic) kill people, but only when abused. In addition, as Chapter I details, the sheer scale of the harm done by tobacco is unprecedented. It is this public health threat that has led to increasingly severe limitations on tobacco's consumer marketing. However, by contrast, stakeholder marketing remains entirely unfettered, and, arguably, from the tobacco industry's perspective, all the more important.

As stakeholder marketing is a standard business practice, the next section of this chapter (see section 2, The plan: how the industry approached the task) is structured as a business plan. It is based on the industry's own internal planning documents and written from their perspective. This approach underlines the strategic and deliberate nature of stakeholder marketing, and that, as with consumer marketing, its ultimate aim is to influence behaviour. The only difference is that the target is not the public, but policy makers and those who may be able to influence them.

<sup>a</sup> This chapter refers exclusively to the smoked tobacco market.

Ultimately, however, the impact of course is on the public. If policy makers are persuaded against introducing effective tobacco-control measures, more people will be harmed by smoking. The final section (see section 3, The future: what should be done about tobacco influence?) picks up this issue and looks to the future. Specifically, given the severe controls that are now placed on the tobacco industry's consumer marketing, it asks what should be done about its stakeholder marketing? It goes on to argue for comprehensive regulation of the tobacco market.

### **2. THE PLAN: HOW THE INDUSTRY APPROACHED THE TASK**

The industry did not construct one unified plan to guide their campaign of influence. This is partly because the European tobacco industry actually comprises a number of different companies who are, at least in other contexts, fiercely competitive. That said, one company, Philip Morris (PM), has held a dominant position in the European Union (EU) 15 over the last 20 years, with a 36.5% share of the market at the beginning of 2003; the other major (but much smaller) operators being Gallaher, Imperial, British American Tobacco (BAT) and Japan Tobacco (table 1). A similar pattern emerges in the new Member States, where the break up of state monopolies has resulted in PM emerging as market leader in six of the ten countries and second in two.

A recent Datamonitor<sup>b</sup> analysis<sup>2</sup> notes PM's leading position and this tendency for consolidation.

The industry's response to the business environment also had to be flexible and organic because it was fluid and changing. Their intentions and methods, therefore, had to be extracted from numerous source documents.

In addition, it seems that the tobacco industry was slow to develop its stakeholder marketing activities, and that early tobacco-control successes in labelling (Directive numbers 89/622/EEC and 92/41/EEC), advertising (Directive 89/552/EEC), tar yields (Directive 90/239/EEC) and taxation (Directives 92/78/EEC, 92/79/EEC and 92/80/EEC) can partly be attributed to their slow response<sup>4</sup>.

Nonetheless, the various source documents reveal a systematic and carefully planned approach to the challenge of influencing EU policy from the early 1990s. The environment was scanned to identify the principal threats facing the industry, and the corresponding opportunities (see section 2.1, Threats and opportunities). The aim was to minimise the former, whilst exploiting and maximising the latter. Achieving these objectives was dependent on key people outside the industry behaving in certain ways, e.g. politicians favouring a particular legislative option or trade union leaders opposing a given working practice restriction. These people were identified, their needs understood and effort focused on those who were perceived as being susceptible to influence. In marketing this process is known as "segmentation and targeting" (see section 2.2, Segmentation and targeting). Strategies were then formulated (see section 2.3, The formulation of strategies) to address the needs of these "customers". It was equally important to identify those groups or competitors (See section 2.4, Competitive analysis) who could interfere with the company's aims and objectives but with whom it was not possible to do business. The only option here was to eliminate, or at least reduce, their power.

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<sup>b</sup> Datamonitor is a leading syndicated source of market information.

Table I. - Philip Morris Dominance in the European Union Tobacco Market

COUNTRY	TOBACCO COMPANY (% Share of the market)
AU	Austria Tabak: 53; <b>PM: 29.5</b> ; BAT: 3.7; RE: 3.4; Other: 10.4
BE	<b>PM: 45</b> ; BAT: 32; CINTA RE: 9.6; Seita: 4.8
CY	BAT: 86; <b>PM: 13</b> ; Other: 1
CZ	<b>PM: 79.5</b> ; STI: 10; BAT: 5.5; RJR: 3; Other: 2
DK	<b>PM: no share</b>
EE	<b>PM: 63</b> ; Austria Tabak: 27; Other: 10.1
FI	<b>AMER group (PM): 75.4</b> ; BAT: 14.2; Seita Tupakka: 10.4
FR	<b>PM: 37.6</b> ; Seita: 30.7; BAT: 16.4; JTI: 8.8; Other: 6.5
DE	BAT: 22.9; <b>PM: 37</b> ; RE: 22.2; RJR/JTI: 3.6%; Other: 14.3
EL	<b>PM (including Papastratos): 38.3</b> ; BAT: 16.3; JTI: 9.5; Other: 35.9
HU	BAT-PD: 39.7; <b>PM: 30.1</b> ; RE DEBRECENI: 21.5; V Tabak: 8.1; Other: 0.6
IE	Gallaher: 48.3; Imperial: 30; BAT: 21.7
IT	<b>PM: 60.3</b> ; AAMS: 29.9; BAT: 4.4; RJR/JTI: 4; Other: 1.4
LV	<b>PM: 47</b> ; House of Prince: 34; Other: 19
LT	<b>PM: 84.1</b>
LU	<b>PM: 41.6</b> ; BAT: 11; CINTA RE: 10.3; Tobacofina: 25.2; Other: 11.9
MT	BAT/RO: 96.4
NL	BAT: 40.4; <b>PM: 40.4</b> ; RJR/JTI: 14.2; Other: 5
PL	<b>PM: 33.3</b> ; WWT Poznan (RE): 19.3; BAT: 15.2; House of Prince: 13; Other: 19.2
PT	Tabaqueira: 90.2; Other: 9.8
SK	<b>PM Slovakia: 55</b> ; SIT (RE): 44; Other: 1
SI	Tobaena Ljubljana (RE Seita): 80; Other: 20
ES	Tabacalera/Altadis: 45; <b>PM: 31.2</b> ; RJR/JTI: 8; BAT: 6.2; Other: 9.6
CH	House of Blend: 75.3; <b>PM: 24.7</b>
UK	Gallaher: 39.9; Imperial Tobacco: 39.7; Rothmans: 13.8; Other: 6.6

Data are presented as %. PM: Philip Morris; BAT: British American Tobacco; RE: Reemsta; STI: STI/Reemtsma International Praha (Czech); RJR: RJ Reynolds; JTI: Japan Tobacco International; RE DEBRECENI: Reemsta Debreceni; CINTA RE: Cinta Reemsta; RO: Rothmans (Malta); SIT (RE): SIT/Reemtsma (Slovakia). Modified from Shafey *et al.*<sup>3</sup>

In short, despite its fragmented authorship and evolving nature, the industry's stakeholder marketing efforts can be laid out as a conventional business plan, and this section of the chapter does exactly that. It is written from the perspective of the tobacco industry and concludes with a section examining whether or not this plan actually delivered results (see section 2.5, The evaluation of effectiveness).

### 2.1. Threats and opportunities

A “situation analysis” of the business environment facing tobacco companies over the last 20 years shows that, of all the forces at play including physical, economic, social, technological and political/legal, the latter has been of particular importance. Greater public health concerns about the hazards of smoking have made regulation more politically acceptable, if not inevitable, and, from the industry's perspective, increasingly constraining. In this context, the industry was concerned about the Commission's awakening interest in tobacco issues as long ago as 1977. A letter between the BAT offices in Germany and the UK remarks on the “startling ... impact with which the EC [European Community] action in this field seems to be gaining speed since the last few months” and highlights the need “to invest some substantial amount of thinking on how we counteract”<sup>5</sup>.

The worry was that Europe would follow the strong anti-smoking lead of the USA, and the need was “to avoid or delay a 'USA situation' from developing in European countries”<sup>6</sup>. To do this the tobacco industry argued that they “must prevent unreasonable EC intervention”<sup>6</sup>. This unreasonable intervention focused around three pressure points: marketing freedoms, smoking in work and public places and tax harmonisation.

#### 2.1.1. Threats

##### 2.1.1.1. Marketing freedoms and 'The Ad Ban'

Advertising and promotion is a vital part of the tobacco industry's business effort. They know that smoking satisfies a clutch of psycho-social needs for smokers. At one end of the age spectrum are new smokers, who, as the industry's market research reveals “smoke Marlboro Lights” because they “are looking for reassurance... searching for an identity” and it “represents having passed a rite of passage”, not being “something done by immature smokers”<sup>7</sup>. At the older end, potential quitters are retained because “the emotional territory of 'very low' is ownable as a higher-level benefit which cannot be usurped by rivals”<sup>8</sup>. The tobacco companies satisfied these needs by building evocative brands: “If a brand of cigarettes does not convey much in the way of image values, there may well be little reason for a young adult smoker to persist with or adopt the brand”<sup>9</sup>. Advertising and other promotional activity were a vital component of this brand building.

Crucially, continued advertising also helped support the idea that tobacco is a legitimate, socially acceptable product, just like any other. Keeping promotional freedom was seen to be vital to maintaining a buoyant market and offered “the best long-term chance of preventing a fast, steep fall in the overall European cigarette market as a result of bans and decreased social acceptability”<sup>6</sup>.

Any threat to their promotional freedom is, therefore, taken seriously. One document warns that “Advertising, merchandising, and sports sponsorship for tobacco brands is coming under increasing pressure at both the national and EC levels”<sup>10</sup>. By contrast, setbacks for the Ad Ban

(as controls on tobacco marketing communications became known) were, therefore, welcomed:

*“The ad ban was considered today by the Health Council, and it appears we have turned the corner”<sup>11</sup>.*

Proactive plans were also made to prevent any erosion of marketing communications. A presentation from Philip Morris (box 1) is headed “Marketing Freedoms” and explores in detail how to fulfil its “Objective: [to] Preserve major marketing freedoms in Europe”<sup>12</sup>. It goes into great detail on how the threat can be reduced, including recommendations on alliance building, “preparing” the European Parliament and legal options.

Box 1. - Philip Morris presentation: Marketing Freedoms

*Objective:*

**Preserve major marketing freedoms in Europe**

- Maintain the blocking minority against the EC Ad Ban directive.
- Use the European summit subsidiarity process to weaken or kill the ban.
- Secure agreement on a minimum harmonisation directive, voluntary code or another acceptable compromise.
- Modify the proposed Belgian Ad Ban and weaken the French loi Evin.

*Major Actions:*

**Blocking minority:**

- Lobby UK cabinet, deregulation czar and European affairs minister. Expand contacts with labour party.
- Use all possible German influence to prevent a weakening of the blocking minority. Work with Chancellor Kohl to put Ad Ban directive on Commission subsidiarity list.
- Work with Greek billboard interests, growers and the Greek ambassador to shore up Greece. Follow up with the economics minister and the special advisor to the prime minister.
- Use successful revision of Dutch code and contacts with the economics ministry to keep the health minister from undermining the Dutch position. Develop plan to maintain Dutch vote after 1994 election.
- Work through TSA president Perez to encourage a shift in the Spanish and Portuguese positions.
- Use supportive deputies and publishers seeking changes in the loi Evin to lobby for a moderation in the French position at EC level.
- Organise all economic interest in Italy that would be hurt by a genuine Ad Ban to push for a shift in the Italian position.
- Use the successful resolution of the Belgian Ad Ban to separate the government from the pro-ban camp.
- Lobby the Danish parliamentary EC and health committees to deepen the Danish reservation to the ban.



### **Compromise proposals:**

- Persuade the Germans to table their minimum harmonisation proposal, and blocking countries to support it in the bilateral meetings to take place after the December 13 health council.
  - Create support for British “state-of-nation” approach.
  - Convince Flynn and other commissioner that the impasse can only be resolved via political compromise.
  - Work with key bureaucrats in DG-V to undermine their confidence in pro-ban studies and data, and inform them of political changes that make compromise feasible.
- 
- Bring ally network fully on board the minimum harmonisation proposal and push them to intensify their lobbying.
  - Continue lobbying all country EC ambassadors and health attachés to work for a consensus in coreper.
  - Lobby EC applicant countries on the compatibility of minimum harmonisation with their existing restrictions.
  - Prepare European parliament to accept compromise council position.

### **Legal and collateral issues:**

- Prepare and disseminate legal argument that Article 129 of Maastricht prevents the EC from banning advertising.
- Re-invigorate contingency planning for legal challenge to EC Ad Ban at national level and in the European Court of Justice.
- Work with DG-XV on green paper on advertising policy.
- Stop the fremion initiative on sponsorship in the European parliament.

EC: European Community; DG-V: Directorate General 5 of the European Commission (Employment and Social Affairs).  
Source: TobaccoDocuments.org<sup>12</sup>

#### *2.1.1.2. Work and public place controls*

Controls on smoking in public and work places also undermine tobacco's social acceptability. Statutory controls in particular isolate and stigmatise the product. In addition, they have a very direct impact on the tobacco companies' bottom line, threatening both the amount of cigarettes each individual smokes (consumption) because “workplace smoking bans represent the most serious threat to smokers' opportunities to smoke...”<sup>13</sup> and the number of smokers (prevalence). “When smoking restrictions in the workplace, public transport and restaurants are implemented, enforced and respected, demand for cigarettes decreases and incidence among adult smokers falls...”<sup>6</sup>.

The resulting (permanent) loss of sales has extremely serious financial consequences for the tobacco industry. “Conservatively assuming one out of every ten cigarettes is smoked in the

workplace, a total ban in all EC workplaces would reduce the overall market by 70 billion units.... If one assumed that smoking restrictions and social acceptability in Europe reach the same levels as they have in North America, it could result in a total market drop of 150 billion units by the end of this decade. In such a case, the lost volume is unlikely to ever be recovered”<sup>14</sup>.

As a result, workplace activities formed a crucial focus of industry efforts to influence public policy, with “workplace action plans ... across Europe and individual countries”<sup>10</sup> and suitably generous funding. In 1991, the public place smoking category of the Philip Morris Environmental Tobacco Smoke (ETS) program had a total cost of \$3,950,000. A total of 58% of that (\$2,285,000) was spent on 'Workplace Objectives' and the rest split between restaurants and transportation<sup>15</sup>.

Great efforts were also made to undermine arguments that ETS is harmful to health.

### *2.1.1.3. Tax Harmonisation*

At base, tax on tobacco is a problem for the industry because it restricts their capacity to use price as a part of their marketing effort. The heavier the tax, and the more inflexible the application, the greater this restriction becomes. Thus upwards harmonisation and specific, rather than ad valorem regimes, were particular problems, at least for the multinational operators.

As with public places, taxation has a very direct impact on profitability. As Geoffrey Bible, Managing Director of Philip Morris (later to become Chief Executive Officer) expressed it: “I cannot emphasize enough how very concerned I am about the path that the EEC [European Economic Community] tax harmonization is likely to take between now and 1992. The implications for us are extraordinary and could in fact dwarf our operating income or close to it if everything went wrong.”<sup>16</sup>.

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### **2.1.2. Opportunities**

Recognising these threats was the first step in the tobacco industry's attempts to deal with them; it focused executive minds, which then moved on to look for opportunities. Indeed, being such accomplished marketers, they were often able to turn threats into opportunities. The benefits of doing this are proportionate to the original threat. As Bible's memo on taxation goes on to say: “On the other hand, if it (taxation) went right, it could mean hundreds of millions of dollars to us and consequently I am of the view that success to the tobacco industry in this exercise is probably the single most important matter for PMI [Philip Morris International] over the next five years... Accordingly, I would like you to think about the issue and see how we can develop a means that you and I are actively involved with Ian Sargeant and the EEC Region on placing our best brains to bear...” and identify the best way of “...ensuring a successful outcome for the industry in general and for PM in particular on this issue”<sup>16</sup>.

In a similar way, whilst the EU interest in tobacco control was clearly a problem, two of its other characteristics, i.e. its complex decision making processes and its relatively weak health competency, were great potential opportunities. As, interestingly, was the taxation issue, in that it engendered smuggling.

### 2.1.2.1. EU Decision Making Processes

The complexity of the EU decision making was arguably a mixed blessing for the tobacco industry. On the one hand, it meant that threats could come from many directions; on the other, it offered multiple points of potential influence. However, given that the industry was trying to prevent rather than introduce legislation, the complexity tended to help them. They could work at constructing legislative obstacles for at least six different levels: the Member States, the Council of Ministers, the European Parliament, the European Commission, EU officials or civil servants and a range of advisors and expert committees.

There is evidence that the industry has tried to influence all these groups. However, they have put most energy into, and had most success with, the first two.

The Member States have a fundamental impact on EU decision making, so the general principle of encouraging moderation about tobacco control at country level is attractive. It makes sense “to lobby for a moderation in the French position at EC level”<sup>12</sup> recognising that “proactive, long-term programs at national level offer the best chance...” and “stronger national programs will also bolster our defence against EC-level threats”<sup>6</sup>. Virtually every European state was subjected to appropriate attention, as were (what were referred to as) “applicant countries” (box 2).

#### Box 2. - The Member States as tobacco targets

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*“Modify the proposed Belgian Ad Ban and weaken the French Loi Evin”<sup>17</sup>.*

*“Use supportive deputies and publishers seeking changes in the Loi Evin to lobby for a moderation in the French position at EC level”<sup>17</sup>.*

*“Lobby UK Cabinet, deregulation Czar and European Affairs Minister. Expand contacts with Labour Party”<sup>17</sup>.*

*“Lobby the Danish Parliamentary EC and Health Committees to deepen the Danish reservation to the ban”<sup>17</sup>.*

*“Work through TSA President Perez to encourage a shift in the Spanish and Portuguese positions”<sup>17</sup>.*

*“Organize all economic interest in Italy that would be hurt by a genuine Ad Ban to push for a shift in the Italian position”<sup>17</sup>.*

*“A local coalition of opinion leaders in the Netherlands, 'Multiple Choice', which undertook communications efforts and lobbied the Dutch government on the EC directive”<sup>18</sup>.*

*“Lobby EC applicant countries on the compatibility of minimum harmonization with their existing restrictions”<sup>17</sup>.*

The opportunity was greatly increased and was, therefore, embraced with enthusiasm, when qualified majority voting enabled blocking minorities to prevent legislative action. Thus the industry readily used “all possible German influence to prevent a weakening of the blocking minority”<sup>12</sup>. The principle of subsidiarity, introduced in the Maastricht Treaty of 1992, also enhanced the value of country level interventions, and made it possible to use “the European summit subsidiarity process to weaken or kill the ban”<sup>12</sup>.

Influencing the Council of Ministers was also extremely helpful from an industry perspective. The Ministers present each country's position and are key to leveraging qualified majority voting and subsidiarity. However, this would depend on contacts at the highest possible level; the Ministers will reflect the position of their leaders. Nonetheless, it is clear that the tobacco industry succeeded in making and exploiting such illustrious contacts. Carefully reviewed academic papers have been published showing that Chancellor Kohl of Germany, and Margaret Thatcher, along with her then Minister of Health Kenneth Clarke (currently deputy Chairman of BAT and still a British Member of Parliament), were deeply supportive of the tobacco industry and directly implicated in the travails of the European Ad Ban<sup>4, 19</sup>.

### 2.1.2.2. The Treaty of Rome

The Treaty of Rome, establishing the European Community (now the EU), was, first and foremost, a trade agreement. In 1992, the Treaty of Maastricht, whilst instituting additional public health competences, failed to give the Community the ability to adopt binding health legislation. As a result major legislation is vulnerable unless it answers to internal market priorities. From the industry's perspective, this presented and still presents an enormous opportunity, which they were quick to identify:

*“Unlike smoking at work which is presently treated as a worker safety and health matter, the EC does not seem to have legal competence to legislate public smoking, which it would have to treat as a public health matter”<sup>6</sup>.*

There was evident pleasure from Philip Morris at the affirmation of this stance when “The Belgian Health Minister, chairing the Council, cited the recent Council Legal Service Opinion that the existing directive has a legal defect in that it cannot be justified under the provisions of the Maastricht Treaty giving the Commission jurisdiction over health matters.... any redraft cannot significantly restrict advertising without contravening Article 129 of Maastricht, which prohibits harmonization legislation on health issues; which is the position we have been arguing for the past several months”<sup>11</sup>.

### 2.1.2.3. Taxation and Smuggling

Perhaps surprisingly, taxation could also be turned into an opportunity. Heavy levels of duty motivate smuggling. As Gilmore and McKee<sup>4</sup> point out, this has advantages for the tobacco industry. Smuggling “stimulates consumption through the sale of cheap cigarettes” and the industry still receives the revenue whether the product was sold legally or not. This stimulated demand allows the industry to put “pressure on governments not to increase tax because of the loss of revenue, which may also result in lower prices and higher consumption... then the industry uses this to urge governments to reduce, or not to increase, taxes”<sup>20</sup>. Additionally, if the contraband tobacco is intercepted, it has to be replaced, thus creating more sales<sup>20</sup>.

Indeed the tobacco industry has been implicated in both large and small scale smuggling. The UK Health Select Committee (HSC), for example, noted the unrealistically large quantities of the UK companies Gallaher and Imperial Tobacco's cigarette brands going into Andorra. These exports “rose from 13 million cigarettes in 1993 to 1,520 million in 1997 - vastly more than the Andorran population of 63,000 could conceivably consume”<sup>21</sup>. In other parts of the world, tobacco executives have been successfully prosecuted for similar offences. In the USA,

two Brown & Williamson Tobacco Corporation's sales managers pleaded guilty to aiding smugglers<sup>22</sup>. BAT faced legal action in Florida for alleged tobacco smuggling in Ecuador<sup>23</sup>. And, in Hong Kong, a BAT export director was convicted for receiving bribes from rival traders smuggling cigarettes into China<sup>24</sup>.

On a smaller scale, other documents released by the HSC show that when market conditions demanded, tobacco companies would exploit the illicit trade in tobacco. In the UK's hand-rolled tobacco market during the late 1990s, around three quarters of tobacco was being bought from "informal sources" such as street markets, door-to-door or in public bars. These outlets were supplied by bootleggers, who brought back cut-price product from the cheapest continental source (typically Belgium). Therefore, they became crucial targets for Gallaher when launching their new "Amber Leaf" brand of hand-rolling tobacco.

"Bootleggers (who account for over 70% of the market in most areas) only bother with big brands - Old Holborn and Golden Virginia. We need to create a demand for Amber Leaf among the newer, younger consumers to encourage both shop purchase and a willingness among bootleggers to sell Amber Leaf"<sup>25</sup>.

### Box 3. - Targeting bootleggers

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<p>AMBER LEAF</p> <ul style="list-style-type: none"> <li>• Gaining share of Duty Paid</li> <li>• Not chosen by bootleggers</li> <li>• Product liked by G.V. Golden Virginia smokers</li> <li>• New packaging next month</li> </ul>	<p>AMBER LEAF</p> <p><b>KEY ISSUES</b></p> <ul style="list-style-type: none"> <li>• UK Distribution</li> <li>• Adoption by bootleggers</li> <li>• Awareness and trial</li> <li>• Brand Positioning</li> </ul>
<p>AMBER LEAF</p> <p><b>A Co-ordinated Approach</b></p> <ul style="list-style-type: none"> <li>• <u>Trial through bootleggers</u> and Duty Free</li> <li>• UK promotion/direct mail</li> <li>• Packaging changes</li> <li>• Media</li> </ul>	<p>AMBER LEAF</p> <p><b>Belgium</b></p> <ul style="list-style-type: none"> <li>• Introduction of 50 g new design from January 1998</li> <li>• Introduction of 25 g pack from April 1998</li> <li>• Free papers available (boxed) from April 1998</li> </ul> <p><b>Duty Free</b></p> <ul style="list-style-type: none"> <li>• Promotions, probably March/April/May using free tin "kit"?</li> </ul>

Source: TobaccoPapers.com<sup>26</sup>.

This last observation is dramatically born out by a marketing presentation that clearly identifies bootleggers in Belgium as a route into the UK market (box 3). It talks of the key importance of “adoption by bootleggers” and “trial through bootleggers” for the success of Amber Leaf.

## 2.2. Segmentation and targeting

If the situation analysis identifies *what* needs to be influenced, segmentation and targeting reveals *who* can bring about these changes. These are typically individuals or groups who have, or can be brought to feel they have, a shared agenda with tobacco. These potential allies have to be distinguished from those who explicitly oppose tobacco interests (see the section 2.4, Competitive analysis). Occasionally, particular groups may fit into both categories; politicians with economic interests may be seen as potential allies, but not those with a health portfolio, for example.

Allies are extremely valuable for two principal reasons. First, they offer credibility. Tobacco industry lobbying is inextricably linked with business self interest and this does not measure up well against something as emotive and worthwhile as public health. But a Trade Union arguing for their members' rights, e.g. to smoke at work, is much more convincing. Secondly, they are cost effective. If allies can be convinced that their own interests will be well served, they will expend their own resources to achieve mutually desirable goals.

*“We increasingly seek sponsorship and financial support for meetings and events from outside governmental and other neutral sources. This significantly reduces the budgetary demands and adds substantial credibility”<sup>27</sup>.*

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*“Avoids placing PM in the front lines of defence by using an industry cover”<sup>6</sup>.*

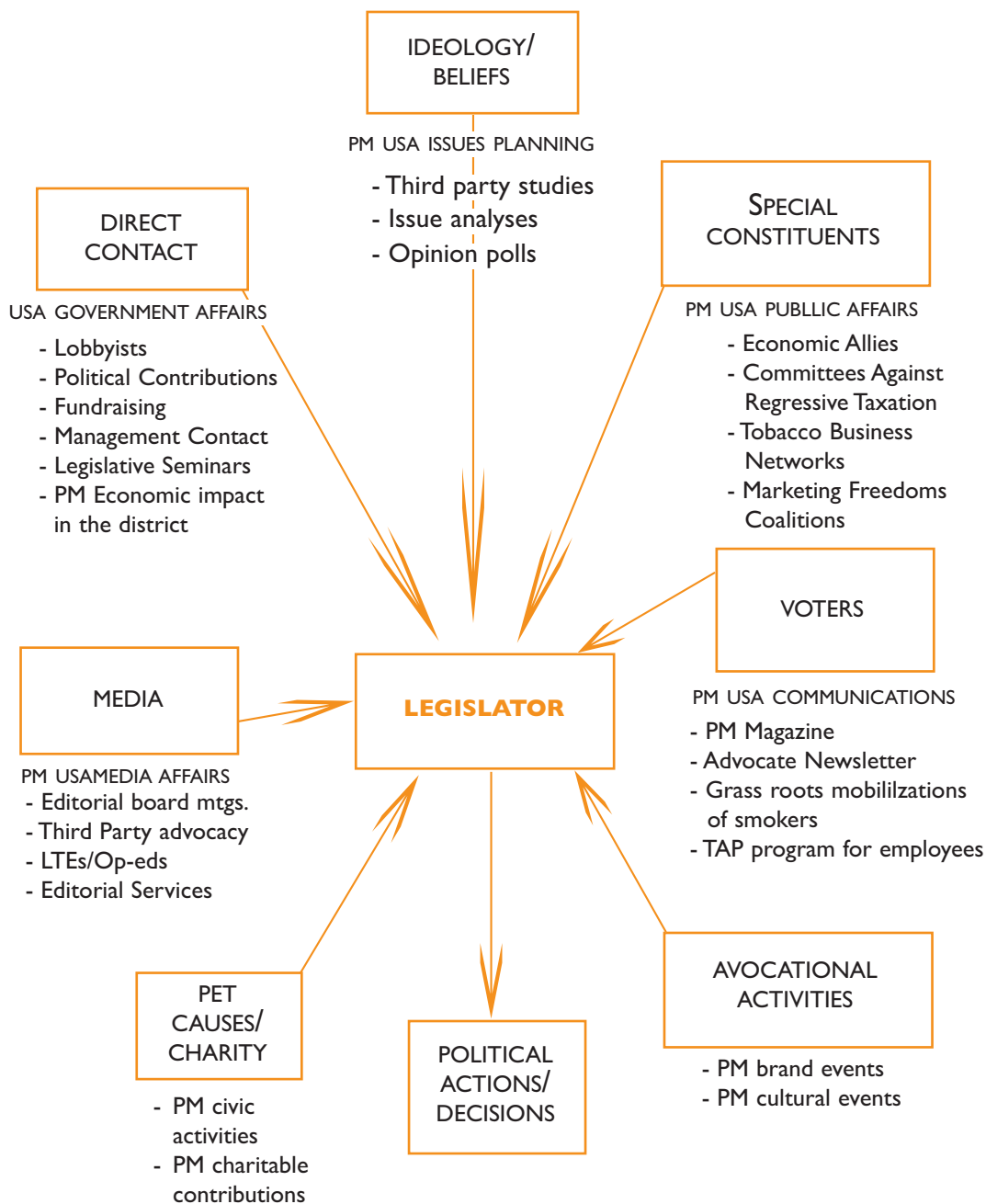
In addition, allies can operate at both a national and European level, neatly complementing the industry's desire to exploit the full complexities of EU decision making. Therefore, they were sought out with enthusiasm, using an opportunistic and hydra-headed strategy.

Fortunately for the tobacco industry, potential supporters were numerous and varied, and serious efforts were made to “build allies...” among groups as diverse as “unions, industrialists, regulators”<sup>28</sup>. Figure 1 provides a vivid diagrammatic illustration of this process from Philip Morris. It is like a spider's web, with legislators the fly caught at the centre<sup>29</sup>.

Most fundamentally, the companies formed self-interest groups among themselves within Europe. The Confederation of European Community Cigarette Manufacturers Ltd (CECCM) was established in the UK in 1988 with a membership of private manufacturing companies and national manufacturing associations. Funded by membership fees, the CECCM states its objective in the Commission's civil society organisations directory<sup>30</sup>, as “to monitor EU developments relevant to the tobacco sector; to communicate common viewpoints and positions of its members to the EU institutions as appropriate.” Other tobacco organisations listed in the directory include the France-based Groupement des Industries Européennes du Tabac, and the Germany-based Europäischer Tabakwaren-Großhandelsverband e.V. Following Commission Decision 98/236/EC<sup>31</sup>, the Groupe Permanent du Tabac was established with a 5-year mandate. CECCM represents the industry's interests in this Commission consultative framework.

Fig. 1. - Key targets for Philip Morris

## PM programs to affect legislation decisions





The Co-operation Centre for Scientific Research Relative to Tobacco was founded in 1956 (under French law) to “promote international cooperation in scientific research relative to tobacco”<sup>32</sup>. Its international membership includes companies and institutes with research and development activities relating to the areas of tobacco plants, manufacturing and materials and scientific results are presented annually. Similarly, the International Committee on Smoking Issues was formed by RJ Reynolds International, BAT, Philip Morris, Reemtsma, Rothmans, Imperial and Gallaher in 1978, and renamed the International Tobacco Information Centre (INFOTAB) in the early 1980s. INFOTAB's aims included establishing an “early warning” system for anti-smoking initiatives worldwide, and “to take industry programs to the grass roots and municipal levels” to help the industry to prevail over public health<sup>33</sup>.

There were also industries that shared direct concerns about particular regulatory issues, i.e. the advertising and media industries about Ad Bans, e.g. the hospitality trade about indoor air legislation and farmers about tobacco control in general. On the advertising front, for example, links were established with an array of interest groups, including “EAAA [European Association of Advertising Agencies] (R. Beatson), IAA [International Advertising Association], EAT [European Advertising Tripartite] (A. Tempast), the Tobacco Advisory Council, the IPA [Institute of Practitioners in Advertising], the EAT Domino Task Force (J. Ritchie), and the coordination of messages and programs” was thereby “improved”. In addition an “information kit” was “circulated across all these organisations and affiliates (over 200 agencies in Europe), the EGTA (European Group of Television Advertising), and numerous press associations”<sup>10</sup>. LIBERTAD (Liberty to Advertise), American European Community Association (AECA) and the New York Society for International Affairs (NYSociety) were also supported/sponsored by Philip Morris<sup>34</sup>.

The degree of support this alliance building received is witnessed by the fact that “An ad signed by advertisers and agencies on the freedom of commercial speech is now being regularly published, free of charge, by over twelve newspapers”<sup>10</sup>.

Farmers were brought into the equation by working “with Greek billboard interests, growers, and the Greek Ambassador to shore up Greece. Follow up with the Economics Minister and the Special Advisor to the Prime Minister”<sup>12</sup>. Similarly, “Philip Morris EEC [kept] in close touch with Federation Nationale de l'Industrie Hoteliers in Paris”<sup>10</sup>.

In addition, there were potential allies in totally unconnected industries such as alcohol, food, and even toys, which may be resistant to regulation *per se*. There was, for example, the opportunity “to make the communications and business communities in Europe appreciate the dangers of the 'domino effect'”, [the danger that legislators concerned about tobacco today will move on to other industries tomorrow] “and to activate them in the defence of marketing freedom for tobacco”<sup>10</sup>.

This broadened out into the wider business community who could also be encouraged to appreciate the difficulties being faced by the tobacco industry and the potential danger of the “domino effect”. Supplying “spokespeople to speak ... at established conferences for business people”, developing “relationships with UNICE [Union of Industrial and Employers' Confederations of Europe] and place articles in their newsletter”<sup>10</sup> and using another ally, Le Centre de Documentation et d'Information sur le Tabac (CDIT), sending “the largest Belgian companies a letter with a copy of their courtesy campaign and a coupon to order more”<sup>10</sup> were all felt to be worthwhile investments. Indeed prospects seemed good “as many regulations referring to the domino theory are progressively planned by EC and national authorities”<sup>10</sup>.



Interestingly, the image of the tobacco industry seemed to be important here, just as brand image matters in consumer marketing. In particular, there was a desire to be seen as a diversified, blue chip and genuinely international enterprise.

Industry involvement in the International Tax and Investment Centre (ITIC) extends this broader business networking policy. The ITIC was founded in 1993 and claims to be an independent non-governmental organisation; its mission is to “serve as a clearinghouse for information and as a training center to transfer Western taxation and investment know how to improve the investment climate of transition countries, thereby spurring formation and development of business and economic prosperity”<sup>35</sup>. Key sponsors include Altria (Philip Morris), Philip Morris International, Japan Tobacco International and Imperial Tobacco, (as well as numerous other transnationals the Norwegian and Dutch Ministries of Foreign Affairs and the UK Department for International Development)<sup>35</sup>. In February 2004, its Director called for the EU to rethink its policy of offering only limited derogations on tobacco taxes to new CEE member states. An article in the influential *European Voice* newspaper claimed that the new entrants would suffer significant tax revenue losses following enlargement, as higher cigarette taxes would increase smuggling in the region<sup>36</sup>. Other articles on their website attack the seminal World Bank report and its tobacco tax policies<sup>37</sup>.

Not all allies were self-seeking. Trade unions might have an interest in looking after their smoking members and workplace professionals their smoking staff, so the former could become “important allies to support the adoption of policies accommodating smoking in the workplace”<sup>38</sup> and the latter could be targeted by “placing articles in specialised press targeting personnel managers”<sup>10</sup>. “The likely journals to be used would be those whose target audience includes decision makers, politicians, top business figures, etc. Papers such as...*The Financial Times* (London)... *The Times* (London), *Le Monde* (Paris), *The International Herald Tribune* (Paris)... etc.”<sup>39</sup>.

Higher ideals also motivated another group of potential allies, those stimulated by libertarian concerns. Many people genuinely object to what they see as the unwarranted advance of “big government” into people’s lifestyle choices. Much of the opposition to tobacco control by Margaret Thatcher’s Conservative Party was motivated by this type of political philosophy, and its sentiments are still prevalent today.

The industry could and did also take the opportunity to stimulate such discontent, funding existing interest groups and even founding their own. For example, it developed an active interest in smokers’ rights groups across Europe<sup>4</sup>. The groups were seen as a crucial channel in the industry’s view as “they have no commercial interest and as such are a more credible voice than the tobacco industry”<sup>38</sup>. The tobacco industry continues to fund them today<sup>40</sup>.

Given this interest in winning hearts and minds, journalists are also a very valuable source of potential allies. Philip Morris, for example, saw benefits in “developing a communications program to educate journalists on the specific scientific issues surrounding ETS. The first step is a visit to Neuchatel with a group of Dutch journalists”<sup>10</sup>.

Scientific opinion was also courted, with similar educational exercises. In conjunction with the German trade association *Verband der Cigarettenindustrie*, for example, “a toxicology forum” was organised “in Budapest with over 300 scientists. The subject of the congress was ETS and they concluded the ETS did not constitute a health risk based on the available science”<sup>10</sup>.

Similarly, Philip Morris<sup>41</sup>, set up the International Institute for Rational Risk Policies in 1988 to counter the bans on smoking and marketing by identifying scientists and other experts in Europe for an advisory board to further this cause and promulgate the position that: “The solution is not to ban smoking (particularly since ETS has not been shown to be a health hazard), but to improve ventilation”<sup>41</sup>.

Likewise, as already noted, relationships could be built with politicians. As well as Thatcher, Kohl and Clarke, Gilmore and McKee<sup>4</sup> show how Martin Bangemann, head of Directorate General III and Professor Karl Überla, president of the Bundesgesundheitsamt (Germany's Federal Health Office), were also successfully courted.

In the final analysis, the tobacco industry could simply buy allies as well as seduce them, in the same way as armies can employ mercenaries as well as volunteers. There are numerous examples of consultants, lawyers, public relations firms and communication agencies being retained to advance their stakeholder marketing activities.

### 2.3. The formulation of strategies

As any good marketer would, the industry then designed appropriate offerings for each target group. Just as consumers are offered different brands, so stakeholders have their needs defined and satisfied. Three examples, the business sector, politicians and journalists illustrate the process:

(i) Business allies, especially those in associated industries are relatively straightforward. The threat from tobacco-control regulation has to be pointed out and resistance facilitated. The aim here was to identify potential quid pro quos that would bring the various groups and organisations into alignment on the relevant issues. Campaigns were run across Europe on the benefits of advertising, as the links with the array of advertising groups, above (see section 2.2, Segmentation and targeting), shows. For example, “sympathetic lobbying and media relations”<sup>10</sup> efforts were supported, “and the restaurant industry was mobilised by informing them of 'economic drawbacks of government intervention in this area’”<sup>10</sup>.

This was not an ad hoc exercise. The industry documents talk of keeping “in close touch with”, “permanent contacts”, “coalition building” and developing “relationships”<sup>10</sup>. As discussed in the previous section, this networking was spread very widely using the threat of the “domino effect” to pull in many disparate industries

Underpinning all this is the continuous development of strong relationships that ultimately increase the tobacco industry's leverage. This long-term relationship building, as we shall see, is a recurring theme in the industry's stakeholder marketing.

(ii) Politicians and EU officials have a difficult job to do and friendships could be built up by helping them do it more easily, by, for example, working “with DG-XV [Directorate General XV of the European Commission] on Green Paper on advertising policy”<sup>12</sup> or “working with key bureaucrats in DG-V to undermine their confidence in pro-ban studies and data, and inform them of political changes that make compromise feasible”<sup>12</sup>.

Ultimately, these friendships can be developed into “a self-interested partnership” in this case “among the German Presidency, the Commission and the Parliament”<sup>42</sup> or “Excellent relations LB/PM [Leo Burnett/Philip Morris] with full coordination.” and “Good contacts have been developed with Coreper [Committee of Permanent Representatives] and selected ministers”<sup>10</sup>. As with the business sector, the aim is to develop long-term, mutually beneficial relationships.

The formal consultancy contract agreed between Margaret Thatcher and Philip Morris typifies the way in which such quid pro quos were transformed into long-term relationships. Margaret Thatcher received substantial sums of money paid to her private office enabling her to promulgate her ideas across the globe. In return, Philip Morris received access to her status, experience and contacts, especially in Eastern Europe (box 4).

#### Box 4. - The Relationship between Philip Morris and Margaret Thatcher

Following initial negotiations in 1991<sup>43,44</sup> a consultancy arrangement was set up in November 1992 between Philip Morris Companies Inc. and Margaret Thatcher for an annual fee of \$250,000, plus expenses<sup>45</sup>.

“Her strongest contribution might be in providing use with risk analyses relating to countries in which we might be considering investments, particularly Eastern Europe, Russia and China. She... knows the current leadership, and should be in a position to advise us about possible future political and economic developments which could affect a potential investment”<sup>44</sup>.

A lunch in Chicago with Thatcher provided Geoff Bible, PM's Executive Vice President, with “helpful advice” resulting in a “wonderful outcome” from discussions with Turkey's Prime Minister<sup>46</sup>.

Other ideas for using the new “Consultant” were sought within the company<sup>47</sup>. The PM EEMA (Eastern Europe, Middle East & Africa) office requested Thatcher's services in Eastern Europe<sup>48</sup>:

- She would be useful for convincing Czechoslovakia to approve foreign ownership of the state-owned tobacco industry as the Minister of Finance was “an admirer of Mrs Thatcher”.
- In Poland, work with the Customs Director and the Ministry of Finance on taxation was not “advancing to our satisfaction” and Thatcher was valuable coming from the UK, a country with “a favourable specific element”.
- Following her “excellent relations” with Gorbachev, she may also give Yeltsin “a firm recommendation...on all issues concerning our industry” in Russia.

(iii) Journalists were also helped with “a complete media relations program” including “regular briefings” and access “to top PM executives” and “PM-sponsored cultural and sports events”<sup>10</sup>. These meetings were regular and well planned:

*“A program of regular press luncheons, on a monthly or bi-monthly basis, currently exists in France, Germany and Belgium. An issues briefing program exists for Spain. In addition, the HQ team has had frequent contact with selected journalists in Italy, with Pan-European publications, and with wire-service journalists operating out of Brussels”<sup>10</sup>.*

Similarly, a study of internal documents by Muggli *et al.*<sup>49</sup> looks specifically at Philip Morris' efforts to influence journalists; particularly to promote industry research to counter the World Health Organization (WHO) and the International agency for Research on Cancer (IARC)'s ETS study. “The European journalist intern program should facilitate the “care and feeding” of trained journalists who would write articles supporting the industry's position.” This tactic had already been successful in the USA, at the National Journalism Center which had a record of “15 years worth of journalists at print and visual media throughout the country...to get across our side of the story”<sup>49</sup>.

The key challenge was that “The tobacco industry, in general” lacked “credibility in speaking to the media”. However, PM's willingness to speak out has been rewarded by better media relations, with journalists often spontaneously turning to PM as the official 'spokesman' of the industry”<sup>10</sup>. And, the return for “the increased quality and frequency of our contacts with the media and a greater flow of usable information to key journalists” was that the press include the industry's “side of any tobacco-related story”<sup>10</sup>. The ultimate aim was to make “the industry into a legitimate voice in the smoker/non-smoker debate”<sup>6</sup>.

Box 5 presents a similar pattern of networking and allegiance development in Hungary as it prepared for EU membership.

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All these relationship building strategies were informed by one guiding principle. There was a strong desire to appear reasonable: to suggest compromises, propose a middle way and “de-dramatise the issue”. This was partly a matter of logistics and the need to provide “practical solutions to the business community”<sup>9</sup>. It is also aimed at getting “gentler” regulation by, for example, securing “agreement on a minimum harmonization directive, voluntary code or another acceptable compromise”<sup>12</sup> or convincing “Flynn and other commissioners that the impasse can only be resolved via political compromise”<sup>12</sup>.

What might be termed “alternative products” also come into play here. Ventilation as opposed to smoke-free initiatives and voluntary controls instead of Ad Bans, for example, have the great strength of apparently meeting public health goals, without stigmatising tobacco or seriously impeding the industry. However, the calculated cynicism of such offerings is perhaps best illustrated by low tar cigarettes, which were actively promoted by the industry as less harmful, or even by inference and imagery, healthier, despite their (then secret) knowledge that smoker compensation completely removes any potential benefit<sup>55</sup>.

However, at a more fundamental level, this diplomacy and apparent reasonableness is about maintaining the “social acceptability of smoking in Europe” which “is threatened by anti-smoking strategies designed to polarise smokers and non-smokers”. The industry was keen to “respond with campaigns that attempt to preserve peace and amity between smokers and non-smokers and programs that consistently rebut misleading claims about smoking”<sup>6</sup> and “protect and support smokers in a reasonable, responsible and consistent way”<sup>6</sup>.

### Box 5. - Tobacco Industry influence in European Union (EU) accession country Hungary

#### Opportunities

The penetration of new Central and Eastern European (CEE) markets: “The task ahead is monumental... Investments in these [CEE] countries are mandatory if we are to effectively exploit the potential... I am confident that we will achieve these objectives and that the aggressive growth targets we have set for this part of the World will be met in the years ahead”<sup>50</sup>.

#### Threats

PM claimed that the freedom to advertise is essential for the continuous influx of capital to be used for the modernisation of the Hungarian tobacco industry:

“A critical factor for the successful implementation of the Philip Morris proposal to modernise the Hungarian tobacco industry is the complete freedom of manufacturers to advertise their products... consumers must be provided with the essential characteristics of the product entries in an impactful way”<sup>51</sup>.

#### Segmentation and Targeting

The hiring of economic expertise in the support of industry views:

After the negotiations with the EU on accession of Hungary, tobacco companies hired local and international auditing firms, including Deloitte and Touche and KPMG Hungary, to prepare reports calling for slow alignment with the EU regulation<sup>52</sup>.

#### Formulation of Strategies

A strategic partnership with the Ministry of Agriculture (MoA):

An RJR letter indicates that, within the government, the MoA helped tobacco companies prevent any “premature” decrease of the nicotine and tar content of cigarettes sold in Hungary. Additionally, the MoA was opposed to any further increase in the size of the health warnings on cigarette packages.

“As indicated earlier, the meetings with the representatives of Agricultural and Welfare Ministries... brought up the following questions:

1. There were [sic] some intention to speed up the timing to decrease tar contents of cigs to 12 mg/cig, and finish the process until the end of 2000... In case of getting to 12 mg/cig tar target the Agricultural Ministry will back our original proposal, it would mean no speeding up...
4. The surface to write up these figures, and that of health warnings would be doubled... Agricultural Ministry will oppose any increasing of surface for the mentioned writings”<sup>53</sup>.

*Creating further new partnerships:*

“In Hungary, we will seek through direct lobbying and action with third party allies to amend obsolete tobacco advertising legislation...”<sup>54</sup>.

“Continue to identify and work with opinion leaders, as well as the International Chamber of Commerce, the International Advertising Association and their local chapters to fight legislative attempts to prevent tobacco products from being consumed by, or marketed to informed adults, and to offer viable alternatives through voluntary restraints and common courtesy”<sup>54</sup>.

In the area of passive smoking, for example “failure to grab control of the middle ground on smokers' issues and failure to defuse the conflict over smoking” could have catastrophic consequences, shrinking “the EC cigarette market by as much as 150 billion units over the next 7 years, irrespective of tax increases and ad bans”<sup>6</sup>.

Colonising emotive issues like freedom of commercial speech and individual liberty are popular approaches used here. For example, in Germany “the creation of a Libertad-style coalition of individuals for free commercial speech” was mooted, along with an “advertising and direct mail campaign on constitutional freedoms”<sup>10</sup>. The encouragement and seeding of an “EC network of national 'cells' or information centres to defend smokers' issues”<sup>6</sup> fitted in with this strategy, as did smokers rights groups (see above).

Corporate social responsibility efforts also served their purpose:

*“The Philip Morris Marketing Prize, created in 1989, resulted in substantial benefits both for the Corporate Affairs and Marketing functions. The Marketing Prize allows Philip Morris to distance itself from the tobacco manufacturer image by showing PM to be a world-class consumer goods company. This promotion also provides the company with potential management recruits in the marketing area”<sup>9</sup>.*

More radically and recently, self-inflicted health warnings, an anathema according to older internal documents<sup>56, 57</sup>, are another way of winning hearts and minds. A recent PM pack insert explicitly and categorically states that “Smoking causes many serious and fatal diseases including lung cancer, heart disease and emphysema. Your risk of getting a disease from smoking is very high. Do not think that smoking won't affect your health”<sup>58</sup> and the accompanying press ad argues that “it also requires education about the serious health effects of smoking, including addiction”<sup>59</sup>.

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Youth prevention is another important, and recent, plank in this strategy. It is patently desirable. What right-minded politician or voter would argue against protecting our children? With 80% of smokers starting in childhood it is also inevitable, so the tobacco industry may as well do it and get the credit. The fact that tobacco control, for very genuine reasons, has increasingly shied away from youth prevention<sup>60</sup> in recent years has also left the field, this middle ground, open for exploitation.

Experience in the courtroom underlines the value of such apparent self harm to the industry. In the recent McTear case in Scotland, Imperial Tobacco's principal defence rested on the litigant knowing the risk. Screeds of press coverage were lodged to show how readily available the information about the ill effects of smoking was during the 1950s and 1960s. Unfortunately for them, this stance was seriously undermined by the recurrence in the self same press articles of denials of these very risks by the tobacco industry. Indeed, they even went as far as claiming health benefits for tobacco<sup>61</sup>. It was difficult for the Imperial attorney to maintain that Alf McTear should have known of the health risks when his own bosses were clearly claiming they did not. In today's circumstances it would be very difficult to undermine the argument that smokers are being fully informed about the health risks, and that at least some elements of the tobacco industry are playing an apparently responsible role in providing the information.

Marc Fritsch, PM's Head of Corporate Communications spelt out the strategy in a recent interview in the business press: “We are providing information to respond to consumer



concerns which is good for long-term business. We're not telling them something they don't already know. They simply want us to be more transparent. Yes, it's frank but why should we say anything different"<sup>62</sup>. As Interband's Deputy Chairman Tom Blackett, explains: "I suspect that their focus groups have told them that they're fed this information all the time. If Philip Morris decides to be open and honest, then as consumers they may feel inclined to think better of that brand"<sup>62</sup>.

In many ways this is classic marketing, i.e. making an opportunity out of a threat. In this case the threat is the toxicity of tobacco which is jeopardising the tobacco company's legitimacy as a business, and the opportunity is to regain legitimacy by tackling the health issue in an apparently responsible way. Arguably, this strategy is continuing with Philip Morris' offer to the Commission to make substantial and ongoing financial contribution to combat smuggling (see also chapter 2). In essence, the tobacco industry, with Philip Morris at its head, is applying for readmission to the respectable business community. As an anonymous industry source put it: "They're playing whiter than white and it's clear they're using it for competitive advantage"<sup>63</sup>. "But ultimately", as the journalist Morag Jones points out, "the promotions and news paper ads serve to reinforce the corporate, not the product, brand"<sup>63</sup>.

Philip Morris' own press advertising expressed it thus: "The fact is it also makes good business sense to try to stop kids from smoking. In today's world, if we don't do what we can, then our business will be at risk. Governments, regulators and the public may stop us from selling cigarettes to adult smokers"<sup>59</sup>. This last comment highlights the great fear of the tobacco industry, i.e. that regulators will realise the need to control them completely and shut down all their marketing activity, not just to consumers, but also stakeholders. Their aim in recent years has been to counteract this with the adoption of an apparently reasonable and diplomatic style to build long-term, mutually beneficial relationships with all the key stakeholders.

### 2.4. Competitive analysis

However, some organisations and individuals defied the tobacco industry's blandishments, and offered no hope of being recruited to the tobacco cause: the WHO and what are referred to vaguely as "anti-smoking extremists" or "alliances"<sup>6</sup>, as well as the Commission themselves and other politicians. In these instances, the strategy is one of attack and undermining where possible, and appropriate self defence when not.

The WHO was recognised to have "extraordinary influence on government and consumers" and the pressing need was to "find a way to diffuse this and re-orient their activities to their prescribed mandate". One way to do this was to use their "food companies, size, technology, and capabilities with governments by helping them with their food problems and give us a more balanced profile with the government than we now have against WHO's powerful influence"<sup>62</sup>.

The systematic nature of this anti-WHO campaign was uncovered after an extensive independent enquiry. A committee of experts reviewed the collections of tobacco company documents that were made available as a result of lawsuits in the USA against the industry. The documents revealed that "tobacco companies have focused significant resources on undermining WHO tobacco-control activities to achieve their goal"<sup>64</sup>. Tactics included: establishing relationships with WHO staff and wielding financial power to influence policy; using other United Nations agencies to influence or resist tobacco control; discrediting

WHO and its officials; influencing WHO decision making through surrogate organisations; distorting WHO research; media events; and surveillance of WHO activities. The report concluded that “the attempted subversion has been elaborate, well financed, sophisticated, and usually invisible” demonstrating that “tobacco is unlike other threats to health” in that, in this case, the industry as well as its public health effects have to be tackled<sup>64</sup>.

There is also evidence in Philip Morris's internal documents that the activities of both European Bureau for Action of Smoking Prevention (BASP) and its head, Luk Joossens, were closely monitored by the tobacco industry<sup>65, 66, 67</sup>. Bitton *et al.*<sup>19</sup> note that “PM regarded BASP's efforts as so effective in influencing EC tobacco-control policy debates that they advocated for the creation of a “BASP-style information bureau” of their own, as shown in the following PM Corporate Affairs 1994-1996 Plan: 'Convince other tobacco companies to help us create a BASP-style 'information bureau' to regularly publicize all favourable findings to media, EC officials, and allies”.

Gilmore and McKee<sup>4</sup> show how the industry systematically tried to undermine a crucial Environmental Tobacco Smoke study conducted by the IARC. They describe how the three pronged attack was developed, noting in the process that it cost twice as much to execute as was spent on the original study<sup>4</sup>!

The industry also steeled themselves against the activities of a re-invigorated Commission, who “with both the Maastricht debate and the main part of enlargement negotiations behind them ... will again be forward looking and confident to introduce new measures stretching their legal competence. Furthermore, the effects of the EPA classification as well as the IARC ETS Study will have filtered through to provide further justification of Community-level initiatives”<sup>38</sup>.

It is not clear what they did about this impending threat, but in another instance a troublesome politician was at least considered for a direct attack. In the UK, Tessa Jowell had the responsibility for shepherding a national Ad Ban onto the statute. Gallahers' advertising agency generated a proposal to “undermine Jowell” and “position her as the minister of bans”<sup>68</sup>. During the UK HSC's enquiry into the tobacco industry the representative from the ad agency in question, M&C Saatchi, dismissed this as part of an agency “brainstorm”, one of “a list of ideas” and none of which “saw the light of day”<sup>21</sup>.

However, internal papers disclosed by the Committee show that a range of such ideas (box 6) were taken into consumer research and one directly attacking Tessa Jowell was only dropped because it did not work. Other ideas attacked the UK Government more generally. In a similar vein, another Gallaher campaign deliberately set out “to ensure that people are made aware of the, in effect, closing date for Gratis<sup>c</sup>, and in so doing lay down some ground work deflecting people's anger towards the Government and not at their brand”<sup>70</sup>.

Certain sections of the media were also seen as strongly opposed to the tobacco industry, and in this case the defensive reaction was comprehensive media training.

<sup>c</sup> Gallaher's loyalty scheme catalogue. Source: TobaccoPapers.com <sup>69</sup>.



## Box 6. - Anti-UK Government advertising concepts taken into consumer research

<p><b>The restrictions on cigarettes is just the beginning</b></p> <p>How soon will it be before the government starts to interfere in other areas of our lives?</p> <p>Soon all foods that are potentially “dangerous” (like butter, coffee and sugar) may be restricted in the same way as cigarettes are.</p>	<p><b>Will restrictions on cigarettes be limited to marketing?</b></p> <p>Although the government is only talking about restricting marketing on cigarettes at the moment, we may well see other restrictions soon.</p> <p>Are smokers going to be forced to buy cigarettes in plain packs, and hide them from view like criminals?</p>
<p><b>Smokers are being used as pawns in a political power struggle</b></p> <p>Tessa Jowell believes that the tobacco issue is her ticket to the top. She knows that public support is her key to success.</p> <p>So far, in her quest for power, she has increased the harshness of any proposed marketing ban at every stage and presented a biased case.</p>	<p><b>The Government is restricting our rights to freedom of speech</b></p> <p>Any potential marketing ban imposed by the government is a denial of the right to free commercial speech.</p> <p>Even extreme political parties are given this basic liberty, which is going to be denied the tobacco industry.</p>

Source: TobaccoPapers.com <sup>69</sup>.

*“PM EEG/HQ has been regularly organizing media training for headquarters and affiliate executives since 1986. The basic objective is for PM to have the managing director ready to face the toughest media in every market (currently the case in France, Germany and Holland), to have the marketing/sales/promotions executives trained as a back-up and for specific marketing related interviews, and in addition to have a Brussels-based 'corporate team' ready to face the media (MDH, PAM, ICS)”<sup>10</sup>.*

If all else fails, the final arena in which an adversary can be challenged is the courts. As box 7 shows there are currently a number of cases being brought by the tobacco industry to challenge what they see as unreasonable, or at least legally unjustified, tobacco-control policies. Prosecuting these cases will involve bringing expert witnesses to support their argument, a process that will be in turn dependent on their corporate reputation. Even in this highly regulated and supposedly very objective forum, the stakeholder marketing discussed in this chapter, with its capacity to enhance corporate reputation, will bring crucial benefits.

But the biggest, and from an industry perspective, most successful legal challenge in recent years was that to the Directive on the Advertising and Sponsorship of Tobacco Products (98/43/EC) brought by the German Government to the European Court of Justice (Case C-376/98 Germany versus Parliament and Council (2000), ECR I-8419). This ultimately succeeded

## Box 7. - Current litigation by the tobacco industry in Europe

1. European Court of Justice hears two joined cases on 8 June 2004, one from UK and the other Germany, to decide whether national laws enacting Article 8 of the Directive, banning the sale of snus, are invalid. [See Case C-210/03: R v. Secretary of State for Health ex parte 1) Swedish Match AB 2) Swedish Match UK Ltd and Case C-434/02: Arnold André GmbH & Co. KG v. Landrat of the Herford Local Authority]<sup>71</sup>.
2. PJ Carrolls, John Player & Sons and Gallaher (Dublin) Ltd jointly lodged a statement of claim on 22<sup>nd</sup> April 2004 at the Irish High Court in objection to the advertising ban on the in-store advertising in the Public Health Tobacco Amendment Act of 2004<sup>72</sup>.
3. British American Tobacco (UK) Ltd, Gallaher Ltd, Imperial Tobacco Ltd, Philip Morris Ltd, Seita and Cherwell Tobacco Ltd applied to the High Court in London for a Judicial Review of the Tobacco Advertising and Promotion (Point of Sale) Regulations 2004<sup>73</sup>.

in destroying the directive, resulting in what was probably the biggest single setback to European tobacco control of recent years. Although the case was brought by the German Government, many in tobacco control would argue that the influence of the tobacco industry was present in the move. They cite, for example, the fact that, shortly after the case had been lodged the Stuttgart-based Studienkreis für Presserecht und Pressefreiheit (Institute for Media Law and Press Freedom) organised a weekend seminar in Baden-Baden, Germany during which leading German and European lawyers attacked the proposed ban. The proceedings were later published and very widely circulated among Commission officials and lawyers<sup>74</sup>.

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Furthermore, although Neuman *et al.*<sup>75</sup> did not find evidence in the released industry documents to confirm that “Philip Morris sought to influence the European Court of Justice's decision”, the document record “does show that the industry anticipated a German case before the European Court of Justice as the ultimate means of defeating the advertising directive”. and “In preparation for such a challenge, CECCM allocated DM50,000 for two studies to determine if there was a sufficient basis for a legal challenge to prove the advertising ban to be 'null and void on constitutional' grounds”. This again underlines the success of the industry's stakeholder marketing which, as we have already noted, reached the highest levels in Germany.

## 2.5. The evaluation of effectiveness

It is extremely difficult to establish what effect the tobacco industry's stakeholder marketing activities have had on European tobacco-control policy. It defies conventional approaches to evaluation. There is patently no possibility of a control group, not least because the tobacco industry operates globally. Nor are the normal tools of consumer marketing, such as usage and attitude surveys or marketing communication awareness monitors, much help. Stakeholder marketing is too subtle and covert for such open approaches to bear fruit.

Instead, we have to fall back on the industry's own claims of success and the view of expert observers. The internal documents certainly include a number of self congratulatory remarks about the successful implementation of their stakeholder marketing, and the achievement of desired outcomes.

Thus their courtship of journalists “resulted in substantial and very positive press coverage and in building up close, personal contacts with prominent journalists”<sup>10</sup>, for example, and the early success of the science prize initiative led to it being renewed and extended:

*“Following the success of the launch, two years ago, of the French and the Italian Prizes, we are now studying the possibility to create a Science Prize also in the Benelux (or two separate Prizes in Belgium-Luxemburg and the Netherlands)”<sup>10</sup>.*

The success of their science prize in France is shown in that it “has officially received the patronage of the Ministry of Industry and Scientific Research”<sup>76</sup> and provided “excellent contact with the scientific advisor to President Mitterand”<sup>10</sup>. In Italy, high value is placed on the associations with “top Italian state institutions”<sup>77</sup> during the prize's development. Finally, reporting back to the Board of Directors, one executive at the 1993 prize-giving in Germany remarks on the attendance of “400 elected officials, the press, university lecturers, scientists and industrialists”<sup>78</sup> and sees the fact that “not one anti-tobacco phrase was uttered during or in the coverage of the prize” as a surprising success and “probably impossible in America”. However, he laments the fact that throughout the ceremony, there was nothing about PM Companies, Kraft or Jacobs Germany displayed or in the programme materials. The opportunity was missed to indicate that “PM stands for anything beyond tobacco in Germany”<sup>78</sup>. The research prize continues to be awarded in Germany<sup>79</sup>.

In terms of affecting tobacco-control policy in Europe, measures of the industry's success can be taken from how they viewed their own lobbying. Bitton *et al.*<sup>19</sup> state that “the tobacco industry lobbied effectively to reduce impact and scope of the labeling directive. The Phillip Morris Corporate Affairs Department... describes PM's success in achieving their desired result: ‘Considerable success was achieved with regard to the size of the warnings compared to the original Commission's draft directive which required a minimum print size of 3 mm and would have occupied up to 50% of the large surfaces’”<sup>19</sup>.

Gilmore and Mckee<sup>4</sup> cite the industry journal Tobacco International's description of lobbying the tax directives as a “triumph for the national industries”. It noted that, while Member States generally intervene or respond only after the European Commission has formulated a proposal, the industry intervened earlier in this case: “while the Commission was in the process of formulating its proposals the industry could, and did, intervene—this time successfully”<sup>4</sup>.

The website of the ITIC<sup>37</sup> (see above) also claims great success in persuading governments to adopt their policies on taxation:

*“The tangible results of ITIC's work are evident in many of the changes that CIS nations have made to their tax codes. And the consistent attendance at ITIC programs by the most senior tax officials of transition countries testifies to the unique position ITIC occupies.*

*While other groups do policy work in the former Soviet Union and transition countries, ITIC does more. Its strategy of serving as a neutral forum for discussion and resolution of legislative, regulatory, and administrative problems in tax and investment policy has been extraordinarily effective”.*

Similarly, with the Ad Ban, once the industry was convinced of German support to maintain the advertising directive blocking minority in the Council of Ministers, “it focused its efforts on gaining the support of other member states... The industry’s success in achieving Danish opposition offers a fascinating insight into its efforts to foster and support libertarian arguments”<sup>4</sup>. Philip Morris created a large Danish coalition called “Committee for Freedom of Commercial Expression” that managed to appear distinct from the industry.

*“The coalition conducted media briefings, participated in debates, wrote articles, and undertook and publicized an opinion poll that showed more than 70 percent of Danes opposed the EEC Advertising Directive... The industry saw it as a great success in the fight against the advertising ban, describing it as “instrumental in securing the commitment and public declaration of the Minister of Health to oppose an advertising ban”<sup>4</sup>.*

And the European Ad Ban is probably the biggest success for the industry’s stakeholder marketing effort. As Neuman et al.<sup>75</sup> say, “while the industry’s attempts to block the ban through lobbying ultimately failed”, the ban was defeated in the courts “as anticipated in tobacco industry strategies from an early stage”. What is more, in the interim their efforts had ensured that the ban was delayed for many years.

The industry has also had some success in blocking smoke-free workplace legislation at EU level as box 8 shows.

#### Box 8. - Smoke-free workplace legislation: Netherlands case study

Since 1990, smoking has been banned in all public buildings and commonly used areas of governmental buildings in the Netherlands<sup>80</sup>.

In 1996, Philip Morris tried to demonstrate that ETS did not pose a significant health risk to non-smokers by placing adverts in the main Dutch newspapers (and across Europe). A STIVORO (Dutch Foundation on Smoking and Health) survey found that “the number of people who said that ETS is harmful to health had fallen after the campaign, although not significantly”<sup>81</sup>. However, PM’s goal failed as more people said that “separate areas for smokers and non-smokers in public places are needed... and that employees should be able to work without being bothered by cigarette smoke”<sup>81</sup>.

From the 1 January 2004, workers by law now have the right to work in a smoke-free workplace. However, there is one major exception: workers in the hospitality industry, or Horeca (Hotels, Restaurants and Cafes). Ventilation is the main issue Horeca is trying to promote to avoid smoke-free workplace legislation in their sector and this is an issue the tobacco industry would support.

It is not clear from the internal documents if the tobacco industry is involved in the current discussion on ventilation in Holland, however, it is evident that they played a prominent lobbying role previously. PM’s strategies to prevent further market and consumer restrictions in Holland include to “intensify strategic alliance with Royal Horeca Nederland and mobilize them when appropriate” and “introduce and further expand Courtesy of Choice program in Horeca sector”<sup>82</sup>. Also, to “identify messages and appropriate vehicles to communicate that the diverse expectations regarding smoking public venues can be accommodated and the role ventilation can play”<sup>83</sup>.

### 3. THE FUTURE: WHAT SHOULD BE DONE ABOUT TOBACCO INFLUENCE?

This chapter has shown that industry efforts to influence tobacco-control policy in Europe have been extensive, varied and well resourced. There has been a coherent marketing strategy to target stakeholders, just as there has been one to target consumers. And, in both cases, the objective is the same, to influence behaviour: in the case of consumers their smoking behaviour; in the case of stakeholders their regulatory, lobbying and professional behaviours. The combined aim of these activities is the greater profitability and longevity of the corporation.

It is also clear that in at least one vital policy area, i.e. the control of marketing communications, they have been extremely successful. The implications of this success could not be more serious. When a comprehensive Ad Ban was introduced in the UK in 2003 the Government calculated it would save some 3,000 lives per year<sup>84</sup>. By the same logic, the tobacco industry's successful campaign to delay, and then overturn, a European Ad Ban has cost tens of thousands of lives. Furthermore, industry attempts to influence policy will, inevitably, continue. As noted at the outset of the chapter, such stakeholder marketing is routine commercial practice. You can no more expect the industry to voluntarily stop lobbying than you can expect them to voluntarily stop advertising. However, given the well rehearsed and appalling toll from tobacco-related disease, this is completely unacceptable.

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In the case of advertising, and other consumer marketing activity, the solution is, at least notionally, straightforward: you ban the practice. The UK Ad Ban for example, severely curtails most forms of tobacco promotion. However, it is impossible to ban stakeholder marketing: you cannot stop Heads of State or even Members of European Parliament going to meetings, mutual benefit organisations being formed or journalists being courted.

Two alternative options suggest themselves. The first is what might be termed the voluntary route. This would rely on people's good judgment and the increasing unpopularity of the tobacco industry to make lobbying ineffective or even impossible. Ideally, tobacco influence and funding would become politically and socially unacceptable.

The prospects for this are not good. Lessons from across the Atlantic are instructive. In the USA the tobacco industry is on the back foot in some key states and cities (e.g. Florida, California and New York), but in most of the country it is retrieving things quite well (witness the slashing of tobacco-control budgets). The situation in Europe is also very different from the USA. We have not had, and are unlikely to have, the swathe of litigation which seems to have driven public opinion and media coverage there; nor a campaign like Truth (which has run high profile mass media campaigns exposing "big tobacco"). In addition, Philip Morris is now leading public relations offensive that includes youth prevention, voluntary health warnings, corporate social responsibility (CSR) and substantial financial support to the Commission to combat smuggling. This has the specific purpose of buying back their credibility. Furthermore, the marketplace will inevitably undermine this voluntary approach, at least while the most consumer acceptable form of nicotine delivery (the modern manufactured cigarette) is also the one that does the most long term damage to health.

Given that tobacco is so harmful to public health it is unacceptable to rely solely on such an unpromising voluntary strategy.

At the other extreme is the option of outlawing tobacco, its manufacture and marketing altogether. However, this would be impractical. There are >200 million smokers in the newly enlarged EU, most of whom are heavily addicted. Prohibiting their access to tobacco could potentially cause serious social unrest, and would certainly feed a black market that has been brought into being merely by variations in price.

A more workable alternative is to accept that the tobacco market must continue, at least for the foreseeable future and to fully regulate it. One example<sup>85</sup> proposes a public sector agency which would procure cigarettes for smokers using a tendering process to the (competing) tobacco companies. The tender could be designed to minimise harm (e.g. by prescribing nitrosamine levels and those of other harmful chemicals) and thus enhance public health. Crucially, it would also completely remove all forms of marketing, including both the residual efforts targeting consumers and the currently completely uncontrolled marketing to stakeholders. In this way the tobacco companies would become generic commodity producers, and public health needs could be given precedence over those of tobacco shareholders.

This form of market regulation also cuts to the quick of the tobacco problem: the pursuit of profit. As long as powerful multinational corporations are free to use stakeholder and consumer marketing to leverage rich returns from tobacco the toll from smoking will continue. As the independent committee of experts concluded when they uncovered the industry's systematic subversion of the WHO: "Reversing the epidemic of tobacco use will be about more than fighting addiction and disease; it will be about overcoming a determined and powerful industry"<sup>64</sup>.

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## RECOMMENDATIONS

The previous chapters of this report have set out the health and economic effects of tobacco use in Europe, the history of European Union (EU) action to counteract these effects, compared Member State actions in tobacco-control policy and highlighted tobacco industry strategies aimed at obstructing effective interventions to protect and promote health.

Chapter 1 presented the evidence that smoking remains the largest single cause of death and disease in Europe and will continue to do so for the foreseeable future. As this chapter points out, epidemiologists now calculate that over 650,000 deaths are caused by tobacco each year in the EU25 Member States. Deaths among women are still rising in many European countries and tobacco is one of the major contributors to health inequalities across the EU.

Evidence from Chapter 2 shows the huge economic burden caused by tobacco. While economic data are still limited for Europe, Chapter 2 presents an initial analysis indicating that the cost of smoking in Europe can be estimated to be ~ €100 billion or 1% of the Gross Domestic Product of the entire EU. There is convincing evidence that tobacco control is cost effective, that money well spent will result in greater savings either directly in the health system or indirectly in greater productivity in the workplace.

Chapters 3, 4 and 5 report the experiences of countries in the European region and internationally in developing and implementing policy to control tobacco. This experience points to a number of cost-effective measures for which evidence of an impact at population level exists. At the same time, however, Chapter 4 reveals that European investment in tobacco control falls well short of recommended and actual levels, internationally. Countries such as Thailand, Canada and parts of the USA and Australia with a higher level of expenditure per capita on tobacco control can report correspondingly reduced levels of smoking prevalence. It is clear that increased funds, wisely spent, have the potential to increase the range, coverage and quality of tobacco-control interventions and to have an impact on smoking levels. Overall, international comparisons indicate that greater and more sustained levels of investment lead to a dramatic impact on smoking prevalence, and consequently on mortality and morbidity.

Chapter 6 highlights the lengths to which the tobacco industry has gone to influence policy making at all levels, and the considerable success it has achieved.

This chapter presents a series of recommendations for action by the European Community (EC) and the Member States that are needed to significantly reduce the death and disease caused by smoking. All recommendations here are the result of a wide consensus that emerged in the course of extensive consultations during the development of this report. This resulted in a dialogue amongst leading tobacco-control experts both in Europe and from around the world, in particular from the USA, Canada and Australia and from a wide range of disciplines. A list of the experts and national counterparts consulted are in Annexes 1 to 3. The development of this report drew on five workshops on specific themes: in Brussels in March 2004 on tobacco product regulation; in Cracow in May 2004 on smoking in the workplace; and in Limerick in June 2004 on research, product regulation and the role of civil society in tobacco control (Annexes 4-6).

Some recommendations have explicit implications for Member State and European resource allocation but the massive burden of death and disease caused by the tobacco epidemic in Europe justifies a stepwise change in response needed across the EC. The recommendations are both short term and long term and focus on specific actions that need to be taken. The following recommendation from a recent report commissioned by the UK Treasury “Securing Good Health for the Nation”<sup>1</sup> perfectly describes the current situation for tobacco-control policy in Europe and the need for action:

*“After many years of reviews and government policy documents, with little change on the ground, the key challenge now is delivery and implementation, not further discussion [...] The key threats to our future health such as smoking [.....] need to be tackled now. Where the evidence exists on how to do this cost-effectively, it should be used; where it does not, promising ideas should be piloted, evaluated and stopped if the evidence shows that to be appropriate.”*

The authors and contributors to this report wholeheartedly endorse these words and take them as the baseline for the recommendations that follow.

### **I. ORGANISATIONAL AND STRUCTURAL RECOMMENDATIONS: INVESTMENT AND REGULATORY CAPACITY**

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1. Member States and the EC need to affirm their commitment to tobacco control and to reducing tobacco-related morbidity and mortality by ratifying and implementing the Framework Convention on Tobacco Control (FCTC) at the earliest possible opportunity. In order to implement the FCTC, all Member States will need to develop and implement comprehensive tobacco-control strategies encompassing prevention, protection, cessation and harm reduction. Implementation of the FCTC should be according to the strictest standards possible within national constitutional limitations (Chapter 4).
2. Implementing comprehensive tobacco-control strategies will require much greater levels of investment in tobacco control across the EC. Economic evidence indicates that tobacco-control interventions are the second most cost-effective way to spend health funds, after childhood immunisation. The US Centers for Disease Control have set recommended levels at €4.8-12.73 per capita for spending in the USA and these levels should be adopted in the EU. In recognition of the current low levels of funding for smoking prevention in the Member States, it is recommended that Member States immediately increase per capita spending by €1-3 (Chapter 4).
3. Implementing comprehensive tobacco-control strategies will also require much greater regulatory capacity and expertise. A preferred option is for Member States to create national dedicated agencies to coordinate the tobacco-control strategy. Such organisations could be situated within the ministry responsible for smoking prevention policy, a public health institute or be set up as an independent body. An appropriate mix of regulatory skills would be necessary to reflect the diverse nature of tobacco regulation (Chapter 5).
4. The European Commission has a clear role to play in coordinating and supporting strategies at national level and facilitating cooperation between Member State governments. Resources available for tobacco-control actions at European level fall far

short of the levels available in other jurisdictions, such as the USA and Canada. Activity at the European level is critically important because of the transnational nature of the tobacco industry and the need to facilitate an exchange of information and dissemination of best practice. There are a number of cost-effective actions that can be taken at supranational level. Therefore, the report recommends that resources at European level are secured and sustained in the future. Existing European sources of funding, such as those available from the Tobacco Fund, should be targeted at the most effective smoking prevention measures and used to complement Member State actions. Levels of resources set for tobacco control should continue at the level foreseen for the Tobacco Fund between 2006 and 2008 (Chapter 3).

5. There is a need for greater capacity dedicated to tobacco control at EC level to support this work. In particular, capacity to assess and regulate nicotine and tobacco products in the Commission and Member States needs to be greatly increased and include the range of technical skills needed. At Member States level, such staff could be housed in the dedicated tobacco-control agencies described in Recommendation 3. At European level this could be provided by an extension of existing capacity within the European Commission and/or the establishment of a European tobacco and nicotine products regulatory agency. The consensus of the expert contributors to this report is that a European agency would be the best and most proportionate response within the framework of existing EU regulation of other products such as pharmaceuticals, food and cosmetics (Chapter 5).
6. The remit of such an agency would include all aspects of tobacco and nicotine product design and marketing, as well as risk analysis and risk assessment. Ultimately, it could have powers to commission and carry out research into all aspects of tobacco and nicotine products, tobacco-control policy and interventions and approve market authorisations for products (Chapter 5).
7. Until regulatory capacity can be increased, a multidisciplinary tobacco product regulation advisory committee should be set up urgently at European level to advise on tobacco regulation (Chapter 5).
8. It is essential that all regulatory, scientific and advisory capacity at Member State and European level be independent of all tobacco industry influence (Chapters 3, 5 and 6).
9. Increased capacity is needed at civil society level for tobacco control. Partnerships are needed with a wider range of stakeholders in society to ensure the success of smoking prevention strategies. Non-governmental organisations, professional organisations and other stakeholders working in fields affected by the tobacco epidemic should endeavour to ensure that their response is appropriate to the scale of the problem to the extent that financial resources permit (Chapters 4 and 5).

## **2. THE NEED FOR GREATER RESEARCH CAPACITY**

10. While historical experiences of the European region, and activities in countries around the world provide considerable material to analyse what works in relation to tobacco-control policy at population level, the report uncovers a major lack of European research on which to base tobacco-control policies and test interventions. A strong science base

for tobacco-control policy and interventions is, therefore, essential to improve societal understanding of the effects of tobacco on health and to best direct resources towards its control (Chapters 3, 4 and 5).

11. A research seminar should be convened at European level to assess EU and international tobacco research capacity, coordination and funding, and develop a coordinated EU tobacco research strategy (Chapter 4).
12. In the short term, until such a strategy can be developed and implemented, a number of immediate research priorities have been identified to clarify the true scale of the tobacco epidemic: improved surveillance data, harmonised methodologies for research, e.g. collection of prevalence and mortality data using standardised methodology, regular measurement of individual smoke exposure across populations, and measuring the impact of tobacco-control policies, and interventions, including on gender and inequalities. In order to finance these research priorities, funding needs to be identified within the EC or remaining sums of the Tobacco Fund should be used (Chapter 4 and 5).
13. An increase in tobacco research funding is required. At EU level tobacco research should be given its own budget line in the next Research Framework Programme (2006-2010). Funding should match that given by the National Institutes of Health in the USA (currently €450 million per year or, pro rata per capita, €680 million). European budget lines, such as the sixth framework programme, should be applied to tobacco research (Chapter 4).
14. A better organisational structure for research targeted at tobacco use would comprise the following: the creation of tobacco-control research networks and research training networks across Europe. Strengthened national capacity is needed to develop tobacco-control research strategies, coordinate national programmes and oversee implementation, in coordination with national tobacco-control bodies [see above] and national research organisations. This will require increased funding at Member State level (Chapter 4).

### **3. RECOMMENDATIONS ON SPECIFIC SMOKING PREVENTION INTERVENTIONS**

#### **3.1. Taxation**

15. Regular increases in tobacco taxes should be an implicit part of government efforts at EU and Member State level as these underpin other tobacco-control measures (Chapter 2).
16. Differences in tax rates should be harmonised on the basis of specific rates as opposed to ad valorem (Chapter 2).
17. The tax on “roll your own tobacco” should be raised to prevent substitution towards this form of tobacco products (Chapter 2).
18. Tobacco should be removed from the Consumer Price Index (Chapter 2).
19. Increased international cooperation to coordinate taxation policies and combat smuggling is needed. The EC should develop European legislation building on the

agreement between the European Commission, 10 Member States and Philip Morris International (PMI) to combat smuggling and counterfeiting (Chapter 2).

20. Early negotiation of an FCTC protocol on illicit trade, taking as a minimum the provisions of the EU-PMI agreement and any subsequent directive based upon it, should be a priority for the EU to stem the huge losses to the Member States and EC from international tobacco smuggling (Chapter 2).

### 3.2. Advertising and sales promotions

21. All Member States that have not done so should enact comprehensive tobacco advertising bans, including bans on point of sale displays, in line with the conditions of FCTC ratification (Chapter 4).
22. All types of tobacco sales promotions should be banned. The proposed EU Regulation on Sales Promotions currently under discussion in the European Parliament and the Council provides a suitable mechanism for doing so (Chapter 4).

### 3.3. Tobacco outlets

23. Internet sales of tobacco products should be prohibited as well as the sale of tobacco products in vending machines (Chapter 4).

### 3.4. Smoke-free work and public places

24. The EU and Member States should follow the Environmental Protection Agency, International agency for Research on Cancer and the Finnish and German governments and classify secondhand smoke as an occupational carcinogen (Chapters 1, 3 and 4).
25. Legislation prohibiting smoking in all workplaces would have most impact if enacted at European level. The legislation developed in Ireland and Norway should serve as the model for a European directive (Chapters 1, 3 and 4).
26. EC legislation should be supplemented by Member State legislation to include public places that are not workplaces (Chapter 4).

### 3.5. Cessation strategies

27. All Member States that have not done so should develop national smoking cessation and treatment strategies. These should include training of health professionals, development of a national network of smoking cessation treatment services, increasing the accessibility of nicotine replacement therapies and removing inequalities in the provision of these services (Chapters 1 and 4).

### 3.6. Tobacco product regulation

28. A new comprehensive regulatory framework for all tobacco and nicotine products needs to be implemented (Chapter 5).



29. Comprehensive disclosure of the physical, chemical and design characteristics of all tobacco products should be required and made public. This should include, inter alia, the type of tobacco used, the way the tobacco is processed, ingredients added, product engineering, physical and chemical characteristics of the emissions of all tobacco products, the availability of nicotine and other psychoactive constituents, the mode of use and the behaviour of the user (Chapter 5).
30. Directive 2001/37/EC should be improved by adopting the World Health Organization's Study Group on Tobacco Product Regulation definition for ingredients (Chapter 5).
31. The tobacco industry is required to fully disclose additives used in their products according to the letter and spirit of the directive. In view of the high risk potential of tobacco products, such detailed information should take precedence over trade secrecy (Chapter 5).
32. Member States and the EC should agree a harmonised system for receiving the required information on ingredients and emissions from tobacco. This system should specify the exact form and content of the information to be transmitted, which methods for measurement should be used, and that the data should also take into account synergistic effects of the ingredients. The information provided should allow comparability between different tobacco companies. A harmonised system should also be established for Member States to analyse, verify and then report this information to the Commission (Chapter 5).
33. A common list of ingredients cannot be produced until scientifically agreed criteria have been drawn up to assess the toxicity and addictiveness of ingredients and their public health impact (Chapter 5).
34. Any future regulation of ingredients should be based on the principles that the substance is not toxic, does not enhance the addictive properties of tobacco products and does not make the product more attractive. Further research and analysis is needed to create scientifically sound criteria for any approval or prohibition of ingredients (Chapter 5).
35. In view of the fact that it is technologically and economically feasible for cigarettes to meet fire-safety standards, tobacco manufacturers should be required to produce and market only "fire-safe" (or "reduced-ignition propensity") cigarettes in the EU (Chapter 5).
36. Harmful constituents of tobacco and tobacco smoke should be reduced and ultimately removed where feasible. As a first step, the immediate reduction of tobacco-specific nitrosamines (TSNAs) in tobacco products, without increasing the overall harm caused by these products, should be made mandatory (Chapter 5).
37. Member States and the European Commission need to begin to assess injury risk from tobacco products. A stepwise procedure should be used, starting with established tests e.g. for cytotoxicity and genotoxicity, and then continuing with tests for other adverse effects including enhancement of addiction (Chapter 5).
38. Communication relating to health aspects of different tobacco and nicotine products and any changes in their characteristics should be strictly regulated. The mandatory phasing

out of toxic constituents recommended in this chapter should not be accompanied by any health claims (Chapter 5).

39. Any new tobacco product of any kind, including new brands of cigarettes must be given prior approval by regulators before entry to the market (Chapter 5).

### 3.7. Labelling and packaging

40. Effective pictorial health warnings should be made mandatory on both sides of all tobacco products. These warnings should cover at least 50% of each of the two largest surfaces. New warnings should be introduced on a regular basis. In the long term (within 10 years) the whole cigarette pack should become a platform for mandatory health promotion messages (Chapter 4).
41. The requirement for tobacco manufacturers and importers to print tar, nicotine and carbon monoxide yields on packs should be rescinded. The remaining space on packs should be reserved for health and consumer information messages to be agreed upon by the Commission and Member States (Chapter 5).

### 3.8. Tobacco industry surveillance

42. There is a need for ongoing, comprehensive surveillance of tobacco industry activity across the European region (Chapter 6).
43. Member States and the Community must ensure the fullest possible levels of transparency in all dealings with the tobacco industry (Chapter 6).

Table I overleaf summarises the report recommendations and provides the authors' view of the lead actor(s) responsible for their implementation. However, bringing about an end to the tobacco epidemic will only become possible if all sections of society, including politicians, the public and civil society, engage with each other and work constructively and with determination to make tobacco caused death and disease history.

Table I. - Summary of report recommendations and lead actor(s) in implementation

ACTION	LEAD ACTOR(S)
<b>Investment and regulatory capacity</b>	
Ratify and implement FCTC	Member States and European Community
Increase sustained investment in tobacco control	Member States and European Community
Create tobacco-control agencies	Member States
Facilitate exchange of information and dissemination of best practice	European Commission
Create a European tobacco and nicotine products regulatory agency	European Commission
Create a multidisciplinary nicotine and tobacco product regulation advisory committee	European Commission
Increase capacity for tobacco control at civil society level	Civil society, Member States and European Community
<b>Research capacity</b>	
Convene research seminar	European Commission
Develop coordinated EU research strategy	European Commission
Implement immediate tobacco-control research priorities	Member States and European Community
Increase research funding for tobacco control	Member States and European Community
Develop organisational structure for tobacco research	Member States and European Community
Collect regular prevalence data using standardised methodology	Member States and European Commission
<b>Taxation</b>	
Implement regular tax increases	Member States and European Community
Harmonise differences in tax rates on the basis of specific rates rather than <i>ad valorem</i>	Member States and European Community
Increase tax on “roll your own” tobacco to prevent substitution to this form	Member States and European Community
Remove Tobacco from the Consumer Price Index	Member States
Introduce legislation aimed at combating smuggling and counterfeiting	Member States and/or European Community according to Treaty competence

ACTION	LEAD ACTOR(S)
Propose an FCTC protocol on illicit trade	European Community
<b>Tobacco sales and promotion</b>	
Enact comprehensive tobacco advertising, sponsorship and promotion bans	Member States
Ban all types of tobacco sales promotions	Member States and European Community
Ban tobacco sales from internet and vending machines	Member States and European Community
<b>Smoke-free work and public places</b>	
Classify second hand smoke as an occupational carcinogen in line with IARC and Finnish and German governments	Member States and/or European Community according to Treaty competence
Introduce workplace smoking bans	Member States and/or European Community according to Treaty competence
Introduce smoking bans in all public places	Member States
<b>Cessation Strategies</b>	
Implement national smoking cessation and treatment strategies	Member States
<b>Tobacco Product Regulation</b>	
Implement a new and comprehensive regulatory framework for all tobacco and nicotine products	European Community
Comprehensively disclose the physical, chemical and design characteristics of all tobacco products and make this information public.	Tobacco Industry, Member States and European Community
Adopt new (WHO's TobReg) definition of ingredients	Tobacco Industry, Member States and European Commission
Harmonise the system for receiving information on ingredients and emissions from tobacco, and for transmission to the European Commission	Member States and European Commission
Develop criteria to assess toxicity and addictiveness of ingredients and their public health impact	Member States and European Commission
Introduce requirement for all cigarettes marketed and produced to be fire-safe	Member States and/or European Community according to Treaty competence

ACTION	LEAD ACTOR(S)
Introduce requirement for the reduction and removal of specific harmful constituents of tobacco and tobacco smoke, beginning with TSNAs	European Commission
Assess injury risk of tobacco products beginning with established tests	Member States and European Community
Require prior approval before new tobacco products are allowed on market	Member States and European Commission
Strictly regulate health claims for different tobacco and nicotine products	Member States and European Commission
<b>Consumer information, labelling and packaging</b>	
Implement mass media counter advertising and consumer information campaigns	Member States
Introduce mandatory pictorial health warnings on tobacco products	Member States and European Commission
Over 10 year period require whole pack to be available for health promotion messages	Member States and European Commission
Rescind the requirement for tar, nicotine and carbon monoxide yields to be displayed on cigarette packs	European Commission
<b>Tobacco industry surveillance</b>	
Implement ongoing comprehensive surveillance of tobacco industry	Member States and European Community
Ensure all dealings with tobacco industry are transparent	Member States and European Community

FCTC: Framework Convention on Tobacco Control; EU: European Union; IARC: International Agency for Research on Cancer; WHO's TobReg: World Health Organization's Study Group on Tobacco Product Regulation; TSNAs: tobacco-specific nitrosamines.

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- <sup>1</sup> Wanless D. Securing good health for the whole population. Final Report. Her Majesty's (HM) Treasury, HM's Stationery Office, 2004.



## ANNEX I: Expert Panel members for the ASPECT (Analysis of the Science and Policy for European Control of Tobacco) report

NAME	COUNTRY	ORGANISATION
Dr Amanda Amos	UK	Reader in Health Promotion, University of Edinburgh
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Robert Cunningham	CA	Senior Policy Analyst, Canadian Cancer Society
Prof. Gérard Dubois	FR	Professor of Public Health, University of Amiens
Fiona Godfrey	LU	Consultant to the European Respiratory Society
Prof. Gerard Hastings	UK	Director of Cancer Research UK Centre for Tobacco Control Research, University of Stirling and the Open University
Andrew Hayes	UK	Tobacco Policy Manager, Regional Public Health Group for London
Prof. Martin Jarvis	UK	Professor of Health Psychology, University College London
Luk Joossens	BE	Tobacco Control Manager, Belgian Cancer Federation



Prof. Dr Ulrich Keil	DE	Chair of Epidemiology and Social Medicine, University of Munster
Dr Eva Kralikova	CZ	Assistant Professor, Charles University School of Medicine, Prague
Dr Ann McNeill	UK	Honorary Senior Research Fellow, University College London
Dr Stefano Nardini	IT	Head Pulmonary and Tuberculosis Unit, Vittorio Veneto General Hospital
Paul Nordgren	SE	Public Health Planning Manager, National Board of Health and Welfare
Dr Pekka Puska	FI	Director General, National Public Health Institute
Dr Martin Raw	BR	Honorary Senior Lecturer, Department of Public Health Sciences, Guy's King's and St Thomas' School of Medicine, University of London; Visiting Professor, Escola Paulista de Medicina, Universidade Federal de Sao Paulo
Dr Hana Ross	CZ/USA	Economist, International Tobacco Evidence Network, University of Illinois, USA
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## ANNEX 2: National Counterparts for the ASPECT (Analysis of the Science and Policy for European Control of Tobacco) report

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Blazej Slaby	SK	President	Stop Smoking - NGO	Bebravska 10	821 07 - Bratislava
Aurelijus Veryga	LT	MD	Kaunas University of Medicine Department of Preventative Medicine	Eiveniu 4	LT-3000 - Kaunas
Elaine Caruana	MT	Ms	Health Promotion Department	1, Crucifix Hill	CMR02 - Floriana
Hans Storm	DK	Vice-Chair	Danish Cancer Society	Strandboulevarden, 45	DK - 2100 - Copenhagen O
Trudy Prins	NL	Managing Director	Stivoro voor een rookvrije toekomst	Parkstraat 83	2514 JG Den Haag
Mevi Hara	FI	Director	Finland's ASH	Karjalankatu, 2C 63	FIN - 00520 - Helsinki
Bertrand Dautzenberg	FR	Président	Paris sans Tabac	rue du Château d'Eau, 7	F - 75010 - Paris

Martina Pötschke Langer	DE	MD, Head of Executive Office Cancer Prevention	Deutsches Krebsforschungs-zentrum	Im Neuenheimer Feld 280	D - 69120 - Heidelberg
Maria Pilali	EL	Project Coordinator	Hellenic Cancer Society	18-20, Tsoha Street	GR - 11521 - Athens
Elizabeth Tamang	IT	Director	Centro Regionale di Riferimento per la Prevenzione (CRP)	Azienda ULSS12 Veneziana - Rio Tre Ponti, Dorsoduro 3494/A	I - 30123 - Venezia
Maurizio Laezza	IT	Dr	Consulta Italiana sul Tabagismo	Viale Aldo Moro 38	I - 40127 - Bologna
Marie-Paule Prost	LU	Directrice	Fondation Luxembourgeoise contre le Cancer	209, route d'Arlon	L - 1150 - Luxembourg
Joan Villalbi	ES	President CNPT	Institut Municipal de Salud Pública	Plaça Lesseps, 1	E - 08023 - Barcelona
Luis Lopes	PT	Mr	Conselho Prevenção do Tabagismo	Av.Estados Unidos da América, 77-6° Dto	P - 1700 - Lisboa
Margaretha Haglund / Paul Nordgren	SE	Head of the Tobacco Control Programme	National Institute of Public Health	Olof Palmes Gata, 17	S - 10352 - Stockholm
Verena El Fehri	CH	Ms	Association Suisse pour la Prévention du Tabagisme	Effingerstrasse, 40	CH - 3001 - Bern
Ben Youdan	UK	Mr	No Smoking Day	59 Redchurch Street	E2 7DJ -London
Rita Lindbak / Kari Huseby	NO	Ms / Ms	Directorate of health and Social Affairs	Mollergata 24 PO BOX 8025 DEP	N - 0030 - Oslo
Vidar Jenson / Thorsteinn Njalsson	IS	Ms / Dr	Tobacco Control Task Force of Iceland	Skogarhlif, 8 Box 5420	IS - 125 - Reykjavik
Valerie Coghlan / Luke Clancy	IE	Ms / Prof	ASH Ireland	5, Northumberland Road	Dublin 4
Andrus Lipand	EE	Chief Specialist	Ministry of Social Affairs	Public Health Department - 29, Gonsiory Street	EE-15027 - Tallinn
Janis Caunitis	LV	Ms	Health Promotion Centre	Skolas Street, 3	LV - 1010 - Riga
Vesna Petric	SI	Head of the WHO Office	Ministry of Health of the Republic Slovenia	5 Stefanova Street	SI-1000 - Ljubliana
Tibor Szilágyi	HU	Mr	Health 21Hungarian Foundation	65 Afonya Str.	H - 2030 - Erd

### ANNEX 3: International Experts for the ASPECT (Analysis of the Science and Policy for European Control of Tobacco) report

NAME	COUNTRY	ORGANISATION
Dr Ron Borland	AU	Director of Vic Health Centre for Tobacco Control, Anti-Cancer Council of Victoria
Prof. David Burns	USA	Professor of Medicine at the School of Medicine, University of California
Prof. Simon Chapman	AU	Professor of Medicine in Public Health at the University of Sydney; Editor of the BMJ specialist journal, <i>Tobacco Control</i>
Greg Connolly	USA	Instructor, Harvard School of Public Health, Massachusetts
Dr Michael Cummings	USA	Department of Health Behaviour at the Roswell Park Cancer Institute in New York; Deputy Editor of the BMJ specialist journal, <i>Tobacco Control</i>
Prof. Geoffrey T. Fong	CA	Associate Professor of Psychology at the University of Waterloo
Prof. Prakash Gupta	IN	Senior Research Scientist at the Tata Institute of Fundamental Research in Mumbai; President of the Action Council Against Tobacco in India
Dr Lesley Owen	UK	Tobacco Research and Management at the Health Development Agency
David Sweanor	CA	Adjunct Professor of Law and Medicine, University of Ottawa
Dr Judith Mackay	CN	Director of the Asian Consultancy on Tobacco Control
Dr Vera Luiza Da Costa E. Silva	BR/CH	Director of the World Health Organization's Tobacco Free initiative



## ANNEX 4: Tobacco product regulation workshop, Brussels

ASPECT Consortium

Workshop on Product Regulation, Borschette Centre, 36 Rue Froissart, Brussels,  
22/23 March 2004

<b>MONDAY</b> <b>22ND MARCH</b>		<b>Morning Session</b> <b>Session Chair: Archie TURNBULL</b>
10:45-11:00	<b>INTRODUCTION</b> <ul style="list-style-type: none"> <li>ASPECT Consortium</li> <li>Project Outline</li> <li>Role of the Experts' Committee and network of National Counterparts</li> </ul>	
11:00-13:00	<b>CHAPTER CONTENTS; CONSULTATION MECHANISMS</b> <ul style="list-style-type: none"> <li>* Tobacco use and effects on health <i>Ann McNeill</i></li> <li>* The economic aspects of tobacco use in Europe <i>Hana Ross</i></li> <li>* Past and present tobacco-control policy of the EU <i>Andrew Hayes</i></li> <li>* Policy impacts <i>Luk Joossens</i></li> <li>* Tobacco industry influence on EU policy <i>Gerard Hastings</i></li> <li>* Future EU tobacco-control policy <i>Fiona Godfrey</i></li> </ul>	
13:00-14:00	Lunch	
		<b>Afternoon Session</b> <b>Session Chair: Paul NORDGREN</b>
14:00-16:00	<b>INGREDIENTS</b> <ul style="list-style-type: none"> <li>What we should have by now</li> <li>What we have got - problems</li> <li>Criteria for the evaluation of additives in tobacco products</li> <li>Recommendations for the future (including common reporting and lists)</li> </ul> <p><i>Speakers:</i> Luk Joossens, Murray Kaiserman <i>Discussants:</i> Wim Vleeming, Friedrich Wiebel</p>	
16:00-16:30	Break	
16:30-18:00	<b>ISO YIELDS</b> <ul style="list-style-type: none"> <li>Current situation (new yields implemented 1st Jan 2004 in EU)</li> <li>Public health benefits of these reductions and nicotine regulation</li> <li>Recommendations for the future</li> </ul> <p><i>Speaker:</i> Martin Jarvis. <i>Discussant:</i> Dave Burns</p>	

<b>TUESDAY 23 MARCH</b> Morning Session Session chair: Archie TURNBULL	
09:00-11:00	<p><b>ALTERNATIVE APPROACHES TO TOBACCO PRODUCT REGULATION</b></p> <ul style="list-style-type: none"> <li>• Tar to nicotine ratios</li> <li>• Intensive smoking regimes</li> <li>• Other approaches, e.g. measuring elasticity, solanesol, etc.</li> <li>• Full characterisation of tobacco products: content emissions, exposure</li> <li>• Regulating individual carcinogens</li> <li>• Developing a regulatory framework for evaluating tobacco products</li> </ul> <p><i>Suggested speaker:</i> Dave Burns <i>Discussant:</i> Murray Kaiserman</p>
11:00-11:30	Break
11:30-13:00	<p><b>ALTERNATIVE NICOTINE DELIVERY SYSTEMS</b></p> <ul style="list-style-type: none"> <li>• Non-combustible tobacco products and risks</li> <li>• Setting standards for non-combustible tobacco products</li> <li>• Therapeutic nicotine and risks</li> <li>• The need for a common regulatory framework for all nicotine delivery systems</li> </ul> <p><i>Speaker:</i> Ron Borland <i>Discussants:</i> Gérard Dubois</p>
13:00-14:00	Lunch
Afternoon Session Session chair: Judith WATT	
14:00-16:00	<p><b>REGULATORY FRAMEWORK/AUTHORITY</b></p> <ul style="list-style-type: none"> <li>• Need for greater regulatory capacity for tobacco product regulation</li> <li>• What would a regulatory framework look like?</li> <li>• Institutional options for a regulatory authority</li> <li>• The need for a regulatory authority to cover all aspects of tobacco control</li> <li>• The Regulated Market Model</li> </ul> <p><i>Speakers:</i> Fiona Godfrey, Gerard Hastings, Ron Borland <i>Discussant:</i> Paul Nordgren</p>
16:00-16:15	Break
16:15-17:00	<p><b>CONCLUSIONS</b></p> <p>Plenary discussion and summary</p>

**LIST OF SPEAKERS AND CHAIRS****Chairs**

Archie Turnbull	Executive Manager, European Respiratory Society, Switzerland
Paul Nordgren	Public Health Planning Manager, National Institute of Public Health, Sweden
Judith Watt	Programme Head, SmokeFree London, UK

**Speakers**

Ann McNeill	Independent Consultant in Tobacco Control, Honorary Senior Research Fellow, University College London, UK
Hana Ross	Economist, International Tobacco Evidence Network, University of Illinois, USA
Luk Joossens	Tobacco Control Manager, Belgian Cancer Federation, Belgium
Gerard Hastings	Director of Cancer Research UK, Centre for Tobacco Control Research, University of Stirling and the Open University, UK
Fiona Godfrey	EU Policy Advisor, European Respiratory Society, Luxembourg
Murray Kaiserman	Director of Tobacco Research, Health Canada
Wim Vleeming	Pharmacologist, National Institute of Public Health and Environment, The Netherlands
Friedrich Wiebel	Toxicologist, former Acting Head of Institute of Toxicology, German National Research Centre for Environment and Health, Germany
Martin Jarvis	Professor of Health Psychology, University College London, UK
Dave Burns	Professor of Family and Preventive Medicine, University of California, USA
Ron Borland	Nigel Gray Distinguished Fellow in Cancer Prevention, Cancer Control Research Institute, The Cancer Council Victoria, Australia
G�rard Dubois	Professor of Public Health, University of Amiens, France





## ANNEX 5: Workshop on smoke-free places, Krakow

ASPECT

**Friday May 7, 2004, 09:00 - 12:30**

*Workshop on Smoke-Free Places Chaired by Susanne Logstrup, EHN. This workshop is coordinated by the ASPECT Consortium (ENSP, ERS, EHN, GOPA-CARTERMILL)*

**VENUE: DEPARTMENT OF LAW, JAGIELLONSKI UNIVERSITY, 12 BRACKA STREET, CRACOW**

09:00-09:10	Welcome and introduction
09:10-09:25	Latest evidence on the health effects of second-hand smoke, Ann McNeill, University College London
09:25-09:40	What can be done at EU level? Should anything be done at EU level? Fiona Godfrey, ERS
09:40-09:50	Questions and discussion
<b>SMOKE-FREE WORKPLACES - EUROPEAN CASE STUDIES:</b>	
09:50-10:00	Classifying second-hand smoke as a workplace carcinogen in Germany, Friedrich Wiebel, GMASH, Germany
10:00-10:10	The Irish Example, Valerie Coghlan, ASH Ireland
10:10-10:20	The Dutch Example, Dominique Hamerlijnck, STIVORO
10:20-10:30	Examples from a Southern European and Accession Country, Elaine Caruana, Health Promotion Department, Malta
10:30-10:50	Questions and discussion
10:50-11:20	Coffee Break
11:20-11:30	Medical Community campaign for Smoke-Free Workplaces, Tanith Muller, BMA, UK
11:30-11:40	Trade Unions campaign for Smoke-Free Workplaces, Tom Mellish, TUC
11:40-11:50	Industry documents on Smoke-Free Workplaces, Gérard Dubois, France
11:50-12:00	Economic aspects of Smoke-Free Workplaces, Hana Ross
12:00-12:30	Development of a campaigner's toolkit: 10 key points in favour of workplace smoking bans
12:30	Close of Session



## ANNEX 6: Workshops involving ASPECT at the tobacco control conference “Change is in the Air”, Limerick

### **Change is in the Air**

*Future Directions in Tobacco Control in the EU  
European Union Presidency Conference*

**Radisson SAS Hotel, Limerick, Ireland  
17-18 June 2004**

### **PARALLEL SESSION 1**

Building the evidence base - tobacco control research

**Chair:** Prof. Luke Clancy

- An overview of EU funded research to date: Luk Joossens, Belgium Federation against Cancer
- Redefining the research agenda at EU and national level: Prof. Luke Clancy, Research Institute for a Tobacco Free Society, Ireland
- Current economic research needs: Dr Hana Ross, University of Illinois, USA
- Research on second-hand smoke: Dr Shane Allwright, Trinity College Dublin
- Co-operation in tobacco control research between the EU and US: Dr Scott Leischow, US National Cancer Institute

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Discussion and recommendations

### **PARALLEL SESSION 2**

Building capacity for a regulatory response to the toxicity of tobacco

**Chair:** Prof. Michael P. Ryan

- Smoker behaviour and what it means for product regulation and harm reduction strategies: Prof. Martin Jarvis, Cancer Research UK
- What the regulators need to know: Prof. Friedrich Wiebel, German Medical Action Group on Smoking and Health
- Current regulatory capacity for tobacco products in the EU and how to improve it: Fiona Godfrey, European Respiratory Society and Co-ordinator of ASPECT
- What can we learn from national and EU regulation of pharmaceuticals and food?: Prof. Michael P. Ryan, University College Dublin

Discussion and recommendations

## PARALLEL SESSION 3

Civil society and advocacy in tobacco control

**Chair:** Dr Fenton Howell

- The role of civil society and advocacy activity: Dr Fenton Howell, Faculty of Public Health Medicine of Ireland
- Building effective coalitions for tobacco control (ENSP): Trudy Prins, Dutch Foundation on Smoking and Health (Stivoro)
- The view from a new Member State: Dr Eva Kralikova, Charles University of Prague
- The role of trade unions in successful tobacco control measures: John Douglas, MANDATE Trade Union, Ireland
- Tobacco control advocacy in the US: Danny McGoldrick, Tobacco Free Kids, Washington
- Striking the right balance: bringing the public with us on tobacco control: Andrew Hayes, Regional Public Health Group for London

Discussion and recommendations

## ANNEX 7: National legislation

*The information in this Annex has been edited from material provided by the National Counterparts.*

### I. TOBACCO LEGISLATION IN AUSTRIA

The Austrian Tobacco Law (431/1995, updated: 98/2001, 74/2003) regulates tobacco product quality, labelling and advertising, and was updated according to European Union (EU) directives. Its weakest point is non-smoker's protection, although it prohibits smoking in rooms dedicated for teaching and education, conferences or school sports (and in multifunctional rooms and halls during these uses), in offices open to the public, in schools or similar institutions, open for children and juveniles, in universities and other educational institutions and in institutions for public presentation, exhibition or performance (except in separated rooms dedicated for smoking, if smoke cannot escape from these rooms), however, no sanctions are given in case of violation. In hospitals, only individual regulations according to the Hospital Law (801/1993) are in force and the initiative for a smoke-free hospital is left to the province or hospital director. The Tobacco Law (Ministry of Health) intended to ban smoking from all publicly accessible buildings such as hospitals, banks, railway stations and public transport stops and also from designated zones in restaurants, but fines for violators are missing and the Ministry of Economic Affairs, who are responsible for this, did not find an agreement with the interest group of innkeepers. The Ministry of Economic Affairs and Labour is also responsible for work inspection.

The Employee Protection Law (450/1994, updated: 159/2001) only requires the employer to take care of protection from environmental tobacco smoke (ETS) at the workplace "in far as possible in the kind of enterprise", but clearly states that smoking is forbidden in office-like work rooms shared by smokers and non-smokers if these rooms are used by employees only. In sanitary rooms and dressing rooms smoking is prohibited, and in other common rooms adequate technical and organisational measures are required for protection of non-smokers from ETS. However, tobacco smoke is not classified as a workplace carcinogen with the argument that it is not produced from work. Also, restaurant and bar workers are not protected at all, because their working rooms are used by customers. Only non-smoking pregnant women have to be protected from ETS by either room separation or appropriate orders of the employer to her work mates (Mothers' Protection Law, 434/1995). Youth Protection Laws of Austrian provinces ban the sale of tobacco to children aged less than 16 years, which is of no use because vending machines are not banned.

## 2. TOBACCO LEGISLATION IN BELGIUM

The law of December 10, 1997 forbids advertising for tobacco products in all media except at the point of sale. Tobacco sponsorship of international events is allowed until July 31, 2005. Incidental advertising during international events which take place in foreign countries is allowed. Advertising in tobacco trade journals and in foreign print media that are not mainly destined for the Belgian market is also allowed.

Indirect advertising was banned by the law of December 10, 1997, but this provision was annulled by the court decision (Court d'arbitrage) of September 30, 1999 for technical reasons (the court felt that the legislator could regulate indirect advertising, but that a ban on indirect advertising should allow the same exceptions as the ban on direct advertising). A law which was voted in the parliament in June 2004, but which is not yet published, forbids indirect advertising. The health minister can allow derogations on the ban of indirect advertising.

A Royal Decree of March 31, 1993 regulates smoking at the workplace. This stipulates that a formal policy on the workplace should be adopted. These measures should be based on mutual tolerance, respect of individual liberties and courtesy. The Royal Decree does not promote smoke-free workplaces and provides almost no health protection for the non-smoker. The Royal Decree is under review now, as part of the federal plan against tobacco. The Federal Government announced in January 2004 that a new Royal Decree will ban smoking at the workplace, except in specific closed offices and with the exception of cafes and restaurants.

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Smoking in cafes, hotels and restaurants is regulated by the Royal Decree of May 15, 1990 (Ministerial Decree of January 2, 1991 and Royal Decree of February 9, 1991) and stipulates that cafes and restaurants which are greater than 50 m<sup>2</sup> should provide 50% non-smoking areas, which are clearly indicated as such. All cafes and restaurants should also have a smoke extraction or air ventilation system. Smoking in other public places is also regulated by the Royal Decree of May 15, 1990; smoking is banned in enclosed public places. A Royal Decree of February 7, 1997 forbids smoking in places where food products are produced, stored or sold. A Royal Decree of September 15, 1976 forbids smoking on buses, trams and the subway. In 2004, the national train company banned smoking on domestic trains. Most flight companies in Belgium apply a smoke-free policy on their flights on a voluntary basis.

A Royal Decree of May 29, 2002 implements EU Tobacco Products Directive 2001/37/EC. Larger warning labels are required on all tobacco products; descriptors suggesting that one tobacco product is less harmful than another are banned; manufacturers and importers must submit a list of all ingredients used in the manufacture of tobacco products. Maximum levels of tar, nicotine and carbon monoxide (CO) are established for cigarettes (10 mg tar, 1 mg nicotine and 10 mg CO per cigarette). The Royal Decree of 29 May 2002 bans the sale of cigarette packs which contain less than 19 cigarettes. A Royal Decree of 13 August 1990 publishes the list of the ingredients which are authorised in tobacco products and stipulates that vending machines are only authorised in places where tobacco products are normally sold. A law which was voted in the parliament in June 2004, but which is not yet published, forbids the sales of tobacco products to children under the age of 16 years.

A Royal Decree of March 12, 2004 foresees the reimbursement of payments for bupropion (Zyban) by chronic obstructive pulmonary disease (COPD) patients of stage II, III and IV.

### 3. TOBACCO LEGISLATION IN CYPRUS

The law that refers to the measures to be taken for the control of smoking in Cyprus is “The Protection of Health (Control of smoking)” Law of 2002 (N75(I)(2002)). This law includes provisions of the first law enacted in 1980 for the control of smoking as well as provisions derived from EU Directives.

The main provisions of this Unified Law of 2002 are the following:

- It prohibits advertising of tobacco products by any means
- It prohibits smoking in all public places including places of entertainment, in all government buildings, in all public transport and in private cars when any of the passengers is under 16 years of age
- It prohibits the sale of tobacco through vending machines and the sale of tobacco to minors aged less than 16 years.
- It prohibits the free distribution of tobacco products as well as the sale or free distribution of imitation cigarettes
- It regulates smoking in workplaces
- It regulates the quantities of nicotine, tar and other substances in cigarettes
- It regulates the inscription of health messages on every packet of cigarettes in accordance with EU Directives on the subject. Trespassers are brought before the court and if found guilty they are sent to prison for a period not exceeding 6 months and/or fined with a sum not exceeding CYP1000 (€1700) or both

With regard to taxation and tobacco subsidies, they fall within the jurisdiction of the Ministries of Finance and Agriculture, respectively, and are approached accordingly in their budgets. There is no specific law or regulation for the sale of nicotine replacement therapies (NRT).



#### 4. TOBACCO LEGISLATION IN THE CZECH REPUBLIC

Law Number 132/2003 concerns the advertising regulations in the Czech Republic (in power from July 1, 2004). It bans all kinds of tobacco advertising including sponsorship and free samples with the exception of the points of sale and motor racing, including advertising activity locally in the place of the motor race; advertising has to have a 20% cover warning: "Ministry of health warning: smoking causes cancer". Penalties up to 10,000,000 CZK still apply, according to Law no. 40/1995 about the advertising regulation. Law 321/2001 bans tobacco advertising on TV and other broadcasting media. Notice 344/2003 about tobacco products includes health warnings according to the EU (effective: May 1, 2004).

Law no. 37/1989 details the protection from alcoholism and other toxicomanias. It bans smoking on all public transport, including indoor air spaces (except of special railway wagons), during indoor working meetings, in workplaces where non-smokers could be exposed to tobacco smoke, in schools, healthcare facilities and indoor sport areas (except dedicated smoking areas), in restaurants during breakfast, lunch and dinner time. Also, working law §133 bans smoking in workplaces where non-smokers work. Law no. 37/1989 bans the sale of tobacco products to anyone under 18 years of age.

Law no. 353/2003 details consumer tax (in power since May 1, 2004). It regulates cigarette tax, according to §104 odst. 2. The excise duty is calculated from the final price for the consumer. It is written on the label, is the same for one brand in all shops in the whole country and includes taxes. Price for the consumer includes the following taxation: excise duty (specific excise duty plus ad valorem) and Value Added Tax (19% of the final price). Specific excise duty is 0.48 CZK/piece and ad valorem is 23% of the final price. However, excise duty has to be at least 0.94 CZK/piece (18.80 CZK/20 cigarettes; in the case of specific excise duty plus ad valorem would be lower than 0.94 CZK/piece)

No tobacco subsidies are provided as tobacco is not planted in the Czech Republic.

Law no. 79/1997 on medication allows over-the-counter sale of NRT in pharmacies only (NRT not explicitly mentioned in the law). It is available as a patch, sublingual tablet, inhaler and gum.

## 5. TOBACCO LEGISLATION IN DENMARK

Act no. 436 on smoke-free environments on public premises and means of transportation (effective July 1, 1995) and, in addition, Act no. 1313 (effective August 1, 2001):

The aim of these acts is to reduce involuntary smoking. Smoking is prohibited inside all governmental buildings in premises where the public have free access. Smoking is allowed in designated areas. Smoking is prohibited in governmental workplaces in rooms where more than one person is working unless the persons concerned give their consent. Furthermore, county- and municipal-owned institutions, means of transport, etc., must have a defined policy on smoke-free environments. Children are not allowed to smoke in daycare centres or other institutions for children, such as schools and out-of-school care institutions, whereas the staff may smoke in designated rooms where the children have no access.

The Ministry for Health had to issue guidelines following the latest mentioned act to clarify the prohibition in daycare, clubs and out-of-school care institutions for children.

Act no. 492 prohibiting tobacco advertising (effective: January 1, 2002):

The law prohibiting tobacco advertising was enacted in parallel with the proposed EU Directive on tobacco advertising. Direct advertising of tobacco products is prohibited except at the point of sale (where regulations apply). Sponsorship by the tobacco industry promoting tobacco sales is prohibited, but is permitted until July 2003 if the contract was signed before the law was enacted. The same applies to indirect advertisement in place before the law was enacted.

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Act no. 375 on the manufacture, presentation and sale of tobacco products (effective: September 30, 2002):

The Danish Parliament adopted the EU Directive 2001/37/EC on the manufacture, presentation and sale of tobacco products, including lower limit values for tar and nicotine, reporting requirements for ingredients, health warnings and the prohibition of the use of misleading product descriptions such as “mild” or “light”.

Statutory Order no. 817 on limit values, measurement methods, labelling, product descriptions, etc., for tobacco products (effective: October 5, 2003) is a further specification and clarification of Act no. 325.

Act no. 213 prohibits the sale of tobacco and alcohol to persons aged below 16 years (enacted March 31, 2004; effective: July 1, 2004):

Denmark signed the Framework Convention on Tobacco Control (FCTC) in June 2003 and, in order to ratify the treaty legislation, an age limit for sales of tobacco products had to be in place. Furthermore, the Act attempts to rectify the problems following reduction of taxes on tobacco products to reach a comparable retail price to neighbouring countries. In order to enforce the Act a national identification card has been issued for young people to use when purchasing tobacco or alcohol products.

Tobacco growing is not subsidised in Denmark. A duty stamp is on each package of tobacco and the products are subject to VAT. NRT products are “over the counter” whereas pharmacotherapies are by prescription.

## 6. TOBACCO LEGISLATION IN ESTONIA

Estonia has a national tobacco action plan, with specific targets on tobacco in government policy, a national coordination body for tobacco control and interventions has been made to prevent initiation of tobacco use and to protect non-smokers.

The Advertising Act (effective: January 1, 1998) imposes a complete ban on the advertising of tobacco products on national TV and radio, in local magazines and newspapers, on billboards and outdoor walls, at points of sale and kiosks, and in cinemas. The Act also bans product placements on TV or in films and non-tobacco product brand names used for tobacco products.

The Broadcasting Act (effective: June 15, 1994) also bans the sponsorship of events with a tobacco brand name.

A Tobacco Act (effective: January 1, 2001 and further amended before May 1, 2004) imposes a complete ban on vending machines and the sale of single or unpacked cigarettes. It sets the minimum number of cigarettes in a pack at 20 and the minimum age for buying tobacco products at 18 years old. There are also penalties and fines for selling to minors in Estonia. This Act also imposes a complete ban on smoking in healthcare, education and government facilities, in indoor offices and workplaces, as well as in theatres and cinemas, although in all of these places, special smoking areas are permitted. There is also a partial restriction on smoking in restaurants, pubs and bars (e.g. clear signage, negatively pressurised rooms, etc.) Smoking is also completely banned on Estonian public transport (including taxis).

The Tobacco Act was amended in order to transpose the EU Directive 2001/37/EC into Estonian law. This means that the same rules regarding large health warnings, messages, bans on misleading descriptors, measurement, regulation and disclosure of tobacco product ingredients and smoke constituents apply in Estonia as in other Member States.

The Alcohol, Tobacco and Fuel Excise Duty Act imposes excise duty on tobacco products and ensures that a “revenue stamp” is applied to all tobacco products entering Estonia, to show that revenue has been paid. Tobacco taxes are earmarked: 3.5% of tobacco taxes are used for the Cultural Endowment of Estonia, of which 0.5% is dedicated to physical fitness and sport. A licensing system exists and licenses are required for wholesale and distribution of tobacco products, for their import and export, and for their manufacture. The Estonian government does not have any ownership in tobacco companies, nor does it provide financial incentives for growing or manufacturing tobacco. Trained health professionals, cessation clinics, helplines and pharmacotherapies are available to help smokers quit. The latter are available in pharmacies without prescription, although bupropion requires a medical prescription.

## 7. TOBACCO LEGISLATION IN GERMANY

At the moment there is no specific tobacco-control legislation, but several regulations and laws as follows:

There has been a ban on tobacco advertising in radio and TV since 1972, and restrictions in cinemas not to show tobacco advertising before 18:00 hours, however, there are no restrictions in outdoor places, print media, point of sale, on the internet and no restrictions on sponsorship of national and international events and no ban of indirect advertising.

There is a non-smokers protection act of 2002 for workplaces, excluding the hospitality industry and public areas. There are no laws to ban smoking in trains, aircraft, public transport systems, healthcare facilities, government buildings, educational facilities or other public places.

EU Directive 2001/37/EC was accepted by the German parliament. The health warnings in Germany are the same as suggested by the EU commission.

The German parliament decided to ban all cigarette packs under 17 cigarettes as well as the distribution of single cigarettes cost-free and this regulation will be realised from July 2004.

In 2003, the German parliament decided to increase the tobacco taxes in three steps: one in April 2004, one in December 2004 and one in June 2005. The taxation increases are 10% in each step.

The sale of NRT products is regulated by the Arzneimittelgesetz, and covers patches, gums and sublingual tablets, only allowed to be sold by pharmacies.

## 8. TOBACCO LEGISLATION IN GREECE

There is no national tobacco action plan or specific target on tobacco in government policy in Greece. However, a national coordination body for tobacco control exists and interventions are made to prevent initiation of tobacco use and to protect non-smokers.

Article 3 of Law no. 1730 of the Greek Broadcasting Commission joint stock company (effective: September 4, 1987) imposes a complete ban on tobacco product advertising on national and cable TV, radio and through product placements on TV and in films. There are no restrictions on outdoor advertising or point of sale. The Decree on rules and requirements for the tobacco products advertising (effective: May 29, 1989) restricts tobacco advertising during films targeted at children.

There are several pieces of legislation in Greece that include complete bans on smoking in specific public places, although all allow for special smoking areas:

- The Ministerial Decision on hygiene provisions concerning the banning of smoking in public areas, means of transport and healthcare services (adopted: August 8, 2002).
- The Ministerial Decree on the prohibition of smoking in public hospitals and private clinics (effective: May 28, 1979).
- The Ministerial Decision on banning of smoking in healthcare facilities (effective: October 22, 1993).
- The Ministerial Decree on the prohibition of smoking in closed public areas (effective: May 25, 1980)

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These bans restrict smoking in healthcare, education and government facilities, in workplaces and offices, theatres and cinemas. The Ministerial Decision on hygiene provisions imposes a partial restriction on smoking in restaurants, pubs and bars, by ensuring that spaces are reserved for non-smokers. A Ministerial Decree on health measures in all types of transport vehicles (effective: November 11, 1952) includes a complete ban on smoking in all forms of public transport, including taxis.

Three major pieces of legislation bring Greece in line with the EU Directive 2001/37/EC concerning the contents, presentation and sale of tobacco products (incl. Health warnings cover 50% of packaging etc.) These are:

- The Ministerial Decision on the manufacture, presentation and sale of tobacco products (enacted: January 13, 2003), which also includes the measurement of product ingredients and their disclosure.
- The Ministerial Decree on marking of tobacco products (effective: February 19, 1989)
- The Ministerial Decision on health warning on tobacco products (effective: May 27, 1997)

There is a complete ban on the sale of single or unpacked cigarettes and partial restrictions on the free sampling of cigarettes and on the sale of duty-free tobacco products, however, the legal source for these restrictions is unavailable at this time.

All tobacco products in Greece are required to carry duty stamps and 0.02% of tobacco taxes are earmarked for the Social Insurance Fund. The Greek licensing system requires the licensing of all retail, wholesale and distribution, import and export sales as well as the manufacturing of tobacco products. While the Greek government does not own shares in tobacco companies, no data is available as to whether either the Greek government or the tobacco industry provide incentives or subsidies to tobacco farmers in Greece.

Interventions are made to support smoking cessation and these include the training of health professionals, the existence of cessation clinics and the availability of pharmacotherapies from pharmacies, with and without prescription. Bupropion requires a medical prescription.

## 9. TOBACCO LEGISLATION IN FINLAND

Finland has a national tobacco action plan and the Finnish government has set specific targets on tobacco in government policy, with interventions to prevent initiation of tobacco use and to protect non-smokers. There is no national coordinating body for tobacco control.

The Finnish Act on measures to reduce tobacco smoking (effective: March 1, 1977; amended in 1995, 2000) ensures a complete ban on tobacco advertising on national and cable TV, on national radio, in local magazines and newspapers, on billboards and outdoor walls, at point of sale, kiosks and in cinemas. The Act also bans product placements on TV and in films, bans the sponsorship of events with a tobacco brand name, and a non-tobacco product brand name being used for tobacco, direct mail giveaways and promotional discounts. The indirect advertising of tobacco products through the branding of non-tobacco products with tobacco brand names is partially restricted. Free samples of cigarettes are completely banned. The Act sets the minimum age for buying tobacco products at 18 years old, with penalties for selling to “minors”. Additionally, smoking is completely banned in healthcare, educational and government facilities, indoor workplaces and offices, as well as theatres and cinemas, although separate areas for smoking may be established. There are partial restrictions on smoking in restaurants, pubs and bars; smoking is currently allowed, although venues with areas of over 50 m<sup>2</sup> must reserve half their seats for non-smokers. Discussions are underway regarding a complete smoking ban. Smoking is completely banned from public transport, although special areas for smoking may be established in buses, trains and on water transport.

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This Act, together with the Decree on measures to reduce tobacco smoking (enacted: February 25, 1977 and amended later) bans vending machines unless they are in restaurants licensed to sell alcohol or other sales premises where the sale of cigarettes is under supervision. The latter decree also bans the sale of single or unpacked cigarettes. These restrictions, along with the Finnish Ministerial decision on labelling the retail packages of tobacco products and on methods for assaying tar and nicotine content (effective: January 1, 1993), have resulted in there being health warnings on tobacco products that outline the size, colour, contrast, font size and area covered. Warnings must be in Finnish and Swedish. The measurement, regulation and disclosure of tobacco product ingredients in Finland are in line with those outlined in the EU Directive 2001/37/EC, and smoke constituents are measured, according to Chapter 4 of the Act on measures to reduce tobacco smoking.

Tobacco products must pay excise duty and bear duty stamps. The tobacco taxes are earmarked: 0.75% is used for smoking prevention and health promotion. No licensing system exists in Finland. The government does not own part of any tobacco companies and does not offer financial incentives for the growth or manufacture of tobacco products.

Health professionals and medical students are trained, and cessation clinics and help lines exist to help smokers quit. Whilst there is no established price incentive or reduced cost for treatment, pharmacotherapies are available for cessation, some without prescription and some with prescription (bupropion and nasal spray require a prescription).

Self-service displays are partially restricted, as are the sales of duty-free tobacco products.

## 10. TOBACCO LEGISLATION IN FRANCE

For centuries, the sale of tobacco has been a monopoly of the French state. Only 33,000 private “buralistes”, acting as agents for the government, may sell cigarettes. Since 1976, public advertising is prohibited in France (loi Weil). In 1991, the main law for tobacco regulation, the loi Evin, was enacted. This law came into force in 1992. This law regulates no smoking in public or the workplace. Smoking areas can be introduced in places such as bars and restaurants under certain conditions of ventilation. This law totally prohibits tobacco advertising in the press and puts a price index on tobacco. European legislation has recently been implemented and well enforced (e.g. labelling). The only tobacco subsidies for agriculture are regulated by the EU, but tobacco growing has decreased dramatically in France.

All medications, including NRT, are regulated by the Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS). NRT have been sold without prescription since December 1999 (oral form and patches). A nasal spray is not available in France. NRT is available for pregnant women and acute cardiac situations. There is no reimbursement for NRT, but a lot of public or private initiatives exist to increase the availability of NRT. The daily price of NRT is now half the price of a packet of cigarettes.

A new regulation, the “loi de santé publique”, is in discussion. This law could help to implement a smoke-free workplace by introducing a smoking ban into the workplace regulations.



## II. TOBACCO LEGISLATION IN HUNGARY

Act CIII of 1997 on excises and on special rules of distribution of excised products introduces measures in line with EU Directives 92/12/EEC, 92/79/EEC and 92/80/EEC. This includes the definition of various forms of indirect taxation, rules of the introduction of tax stamps and sets the amount/level of tax for 1998.

Act XLII of 1999 is on the protection of non-smokers and the regulation of tobacco sales, marketing and use. Relevant provisions include: the sale of tobacco products is forbidden in educational establishments, social, welfare and healthcare institutions; no tobacco product can be sold to persons under the age of 18; adequate proof of age can be requested by sellers; and tobacco products cannot be marketed as commercial samples. Act CIII of 1997 on excises and on special rules of distribution of excised products forbids use of vending machines for selling tobacco products as of December 31, 2001. Act I of 1996 (§13) bans tobacco advertising on radio and TV.

Act I of 2001 amends Act LVIII on economic advertising activities. It states that: all forms of direct and indirect advertising of tobacco products are forbidden; exemptions can only be made with advertising aimed at distributors of tobacco products and advertisements related to world sport events (e.g. Hungarian Formula-1 race); and point-of-sale advertising is allowed only for product and price information display.

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Act CXLV of 2000 on sports (§75) stipulates that during marketing activities related to sponsored sport events: "it shall be forbidden to depict sport in connection with a service or lifestyle that is harmful to one's health".

Act LVIII of 2002 is on the amendment of some laws concerning healthcare and social insurance (amending Act XLII of 1999 and introducing the regulation included in EU Directive 2001/37/EC). Its main provisions include size of health warnings, which must be 30% and 40% of the front and back surface of outside packaging, respectively, whilst 10% of one of the sides must be covered by information on nicotine, tar and CO contents of cigarettes; two general warnings should be published in a rotating manner, these are "Smoking might kill!" and "Smoking seriously damages your health and that of those around you!"; rotating warnings must be chosen from 14 sentences given in the annex to this law and general warnings must also be displayed at the point-of-sale.

Joint Decree no. 86/2003 amends Joint Decree no. 36/1996 (XII.11) and Joint Decree 43/2002. (V.14.) of the Ministries of Agriculture, Health and Social Care and Industry and Transport on the production, distribution and control of tobacco products. The Decree ensures alignment with EU Directive 2001/37/EC of the European Parliament and Council. It refers to: rules of manufacturing and importation of tobacco products; The "Veterinarian and food products checking station of Heves county" is made responsible for the control of nicotine, tar and CO content of cigarettes and is requested to report these data every year to the Ministry of Agriculture, and every year manufacturers or importers are requested to disclose all ingredients and additives used during the cigarette manufacturing process.

Act XCIII of 1993 on industrial safety (§38) requires employers to provide adequate protection to non-smokers in the workplace. Designating smoking areas for smokers can be a solution, not least because of fire prevention reasons. Act XXXI of 1997 on child protection

and management of legal guardianship (§6, §10) includes the provisions that: every child has the right to be protected against harms of environment and society as well as against substances harmful to health; and every child is obliged to refrain from behaviours damaging health and from consuming substances detrimental to health.

Act XLII of 1999 on the protection of non-smokers and the regulation of tobacco sales, marketing and use determines the rules for consumption of tobacco products. Smoking is banned with the exception of areas designated for smoking: within any indoor facility of public institutions that is open for the users of services; on public conveyances; during functions taking place within an indoor facility; in the workplace, as provided for by separate legislation and as regulated by the employer's policy. It is not allowed to designate a smoking area or smoking room: within primary healthcare and outpatient specialist care units; in retail pharmacies that are open for access by patients; within premises of institutions of public education that are accessed by students; in daycare or residential care service units for children; in social care units; on public transport facilities, including commuters' trains as well as buses in scheduled domestic interurban public traffic; and in indoor areas of sports facilities designed for carrying out sports activities. A smoking area cannot be designated within the same premises (e.g. in a restaurant), except if the indoor air of such an area can be separated from the remaining part thereof, or if separation can be executed by using appropriate ventilation techniques. The National Public Health and Medical Officer Service is named the responsible authority for enforcing this legislation and applying fines as stipulated by this law. Young people aged less than 18 years are not allowed to smoke, even in places where otherwise smoking is permitted.

Act XXV of 1998 (on pharmaceutical products for human use) regulates the sale of NRT. There is no separate mention of NRT, which is considered and regulated like other pharmaceutical products.

The Joint Decree no. 86/2003 of Ministries of Agriculture, Health and Social Care and Industry and Transport on the production, distribution and control of tobacco products states that tobacco companies may continue distribution of cigarette packages with old health warning designs until December 31, 2004 (instead of the April 30, 2004 target date)

## 12. TOBACCO LEGISLATION IN ICELAND

Tobacco Control Act 002, no. 6. Originally Act no. 74/1984; amended most recently by Act no. 164/2002 (took effect: January 1, 2003):

The objective of this Act is to reduce damage to health and fatalities caused by tobacco, by reducing tobacco consumption and protecting people from the effects of tobacco smoke. Every person's right not to have to inhale air polluted by tobacco smoke from others must be respected. Those who have care of a child must seek to ensure that the child's rights are observed, including in places where smoking is not prohibited under this Act. This Act refers to tobacco plants and all products made entirely or in part from them, for consumption, such as cigarettes, cigars, smoking tobacco, snuff, oral tobacco and smoking accessories (i.e. tools and equipment relating to smoking of tobacco, such as cigarette papers, pipes, equipment for rolling cigarettes).

This Act does not apply to tobacco used as a medication under the Pharmaceuticals Act nor as a toxic substance under the Toxic and Hazardous Substances Act.

The highest authority in this field under this Act lies with the Minister of Health and Social Security. The Minister appoints a Tobacco Control Board for a term of 4 years. The board comprises three people, of whom at least two have expertise in the field of the harmful effects of tobacco or tobacco control. Deputies are appointed in the same manner. The Minister appoints one member of the board to be chair. The role of the Tobacco Control Board is primarily: to advise the government, the Minister of Health, [the Environmental Agency] Act no. 164/2002, art. 27, the Occupational Safety and Health Administration and other public bodies on all matters concerning tobacco control; to submit proposals to the authorities on measures to counteract tobacco consumption, in accordance with the provisions of this Act; to urge and encourage a campaign of tobacco control, and to seek to coordinate tobacco-control programmes in Iceland; to provide advice and guidance regarding tobacco control, e.g. by providing literature and other sources of information; to monitor tobacco consumption in Iceland; and to apply the experience and knowledge of other nations in the field of tobacco control.

The Minister of Finance confers with the Tobacco Control Board regarding policy formation on importation and pricing of tobacco. The board's opinion must be elicited with regard to all regulations relevant to tobacco control and sales of tobacco. The Tobacco Control Board collaborates with [the Environmental Agency] Act no. 164/2002 and the Occupational Safety and Health Administration. The Minister may issue regulations containing further provisions on the role and work of the Tobacco Control Board.

Tobacco is only made available for sale or distribution if a warning appears on the packaging regarding the harmfulness of the product. A cigarette packet must be specifically labelled with information on tar and nicotine content. The Minister states in regulations (719/2002) more detailed provisions on such labelling, including the warning text, size, type of lettering and other factors which may be significant. A party who manufactures, imports or sells tobacco may not, without the consent of the Minister of Health and Social Security, place his own information regarding the health effects of consuming the product on the product's packaging, in words or symbols. Tobacco manufacturers must meet the costs of labelling.

All forms of advertising of tobacco and smoking accessories are prohibited in Iceland. However, this does not apply to publications published abroad by foreign parties in foreign languages, provided that their primary purpose is not the advertising of such products. Notwithstanding, the State Wine, Spirit and Tobacco Authority is authorised to issue a price list for tobacco and to publish a register of harmful substances in tobacco products. It is also prohibited to show consumption or any form of handling of tobacco or smoking accessories in advertisements or information on goods or services of other kinds and in illustrations on goods. Advertising refers to, among other things: any form of information addressed to the public or to a specified target group, including product promotions, window displays in shops, signs of any kind and comparable items; all use of traditional tobacco trademarks (name and logo) or parts of them, products manufactured under such trademarks are, however, exempted, but the advertising-limitation provisions of the Act otherwise apply to them; any form of media coverage of individual products for other purposes than to warn of their harmful effects; and distribution of samples of goods to consumers. It is prohibited to place tobacco on the Icelandic market under trademarks which are known or used as trademarks for other goods or services. Any form of contribution to an event or activity whose objective, or direct or indirect effect, is to promote tobacco, is prohibited. Tobacco and tobacco trademarks must be so placed at points of sale that they are not visible to the customer.

Tobacco cannot be sold or delivered to individuals under the age of 18 years. Identification must be shown where the purchaser's age is in doubt. The importation, manufacture and sale of toys or confectionery made to resemble cigarettes, cigars or pipes, or intended to refer to tobacco by other means, e.g. pictorially, is prohibited. The sale of tobacco from self-service machines and in units of less than 20 cigarettes is prohibited. The importation, manufacture and sale of fine-grained snuff and all oral tobacco is prohibited, with the exception of chewing tobacco. Tobacco may not be sold in schools, institutions for children and teenagers, or at health institutions. Only persons who are at least 18 years of age can sell tobacco.

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The Minister of Health and Social Security issues regulations in consultation with the Tobacco Control Board and in accordance with current EU directives, stating the maximum permissible levels of harmful substances in tobacco and tobacco smoke, and how measurements and monitoring of the observation of these limits are to be carried out. For retail sale of tobacco, a special permit is required from the board of health of the relevant region. A permit is granted for a term of 4 years, and will only be granted to individuals or businesses who/which fulfil the general requirements of legislation on commercial employment and wholesalers of tobacco can only sell or deliver tobacco to those who have a permit. Local authorities are permitted to collect a fee for permits and for monitoring the activities of permit-holders, on receipt of recommendations from boards of health.

Smoking is prohibited in the service areas of institutions, business and voluntary organisations, and also in restaurants and places of entertainment, and where cultural and social activities take place, including sports and leisure activity. Smoking may be permitted in restaurants and places of entertainment within specified areas, but adequate ventilation must be ensured. The majority of the space must, however, invariably be smoke free, and it must be ensured that access to it is not via a smoking area.

Smoking is permitted in specified guest rooms of hotels and guesthouses. In hostels, smoking is not permitted in rooms or dormitories. Where smoking is permitted under this article, ventilation must be ensured that meet the requirements of the health inspectorate and it

must be ensured that smoke does not pollute the atmosphere of non-smoking areas. Restaurant management must seek to protect staff against tobacco smoke.

Smoking is entirely prohibited: in primary/lower secondary schools, local authority summer work-training programmes for children, pre-schools, all daycare facilities for children, and on premises primarily intended for children's and teenagers' social, sports and leisure activities; at public gatherings indoors which are primarily intended for children or teenagers; in upper-secondary schools and other secondary-level schools; at healthcare centres, doctors' surgeries and other places providing health services. This does not apply, however, to the rooms where residents of nursing homes and old people's homes live, but non-smokers must be offered non-smoking rooms; in hospitals, although smoking by patients may be permitted under special circumstances; in prison, although smoking may be permitted in cells, non-smokers must be offered non-smoking cells. Every person has a right to a smokeless atmosphere indoors in his/her workplace, and the employer must ensure that his/her right is observed.

Smoking is prohibited in public transport facilities for which a fare is charged. Aircraft operators may permit smoking in a part of the passenger cabin on international commercial flights which do not land in Iceland. It must always be ensured, however, that this does not cause discomfort to non-smokers.

The Ministry of Education, in consultation with the Ministry of Health and Social Security and the Tobacco Control Board, ensures that regular educational activity takes place with the objective of reducing tobacco consumption: in Icelandic schools, with special emphasis placed upon such education in primary/lower-secondary schools, and in colleges which train people for work in the child care, education and health sectors; in the media; and at healthcare centres and hospitals.

It is compulsory to allocate at least 0.9% of gross tobacco sales to tobacco control. The funds are allocated by the Tobacco Control Board in consultation with the Minister.

Local authority boards of health, under the supervision of [the Environmental Agency] Act no. 164/2002, monitor places where tobacco is sold, and monitor the labelling, advertising and sale of tobacco. In the case of a violation, when the local authority board of health's instructions are not complied with, the board may revoke the permit. Cases which may arise in connection with violations of this Act and regulations issued on the basis of the Act are subject to the rules of procedure in public cases.

### 13. TOBACCO LEGISLATION IN IRELAND

Public Health (Tobacco) (Amendment) Act 2004:

This Act prohibits smoking in a wide range of workplaces, including pubs, restaurants, offices and shops. The Act does not apply to hotel bedrooms, prisons or psychiatric hospitals.

Public Health (Tobacco) Act 2002:

This Act updates Irish tobacco-control legislation and provides for the making of regulations by the Minister for Health and Children. The Act contains detailed provisions that: prohibit advertising and sponsorship with limited exemptions; restrict the marketing and sale of tobacco; provide for product specification and testing; provide for health warnings, and restrict labelling of tobacco products.

Health (Miscellaneous Provisions) Act 2001:

Section 3 of this Act amended the 1988 Act by making it an offence to sell tobacco products to anyone less than 18 years of age. Tobacco (Health Promotion and Protection) Act 1988 provided the statutory framework for the making of regulations by the Minister for Health and Children to either prohibit or restrict the consumption of tobacco products in particular locations. It also makes provision for controls on the importation, manufacture and sale of tobacco products.

Tobacco Products (Control of Advertising, Sponsorship and Sales Promotion) Act 1978:

This Act provided the statutory framework for the making of regulations by the Minister for Health and Children to control and regulate the advertising of tobacco products and other means of promotion, including sponsorship. The Act also conferred on the Minister the authority to designate the form and content of health warnings.

European Communities Act 1972:

The European Communities Act 1972 enables the transposition of European directives by regulation.

Medicinal Products (Prescription and Control of Supply) Regulations 2003 SI 540 of 2003: This governs the method of sale of all NRT products and states that all NRT products must be sold under the supervision of a pharmacist. In addition, the Poisons Regulations 2003 SI 351 of 2003 also stipulates that NRT products can only be sold from pharmacies.

There are a number of legal challenges arising out of the recent workplace smoking ban. This includes a prisoner who is challenging the ban because it does not apply to prisons and he is, therefore, not protected from secondhand smoke. The point of sale advertising legislation is being challenged by the industry.

## 14. TOBACCO LEGISLATION IN ITALY

The Italian Constitution (1947, art. 32 and 41) establishes health as a fundamental individual right and interest for the community. No private financial initiatives should bring harm to the safety, liberty and human dignity.

Law 11, November 1975, no. 584 enforces a smoking ban on public transportation and in specific places (hospital wards, school rooms, waiting rooms in railway stations, closed areas for public meetings, cinema, theatres, etc.). A Ministerial Decree (18 May 1976) gives dispositions for air conditioning system or ventilation regarding the Law 11 dealing with the smoking ban in fixed places and public transport.

All regional, inter-regional and direct trains are smoke free. The new Intercity trains and all Eurostar trains are completely smoke free since March 1, 2004. A Presidential Decree (11 July 1980, no. 753) enforces a smoking ban in compartments and railway carriages not reserved for smokers. This is also applicable in trams, cable cars, aerial funiculars, subways, and waiting rooms of the stations and stops.

A Presidential Directive (14 December 1995) establishes a smoking ban exclusively in places that are used by the public administration, public firms and private firms offering public services that are open to the public. This directive referred specially to the Local Health Units of the National Health Service.

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Interpretation and enforcing of existing legislations in matters concerning the smoking ban were included in a Ministerial Circular no. 4 (March 28, 2001).

Financial Law no. 448 (December 28, 2001, art. 52) updates the administrative sanctions given by Law 11 from €25 to €250 (for smokers) and from €200 to €2000 (for those responsible for enforcing the law and making it visible), and the fine is doubled if smoking is carried out in the presence of a pregnant woman or children under 12 years.

Law 16 (no. 3, art. 51, January 2003 and successive modifications with art. 7, Law no. 306, October 21, 2003) gives dispositions in matters of public administration for protection and safety of non-smokers from environmental smoke. Smoking is forbidden in workplaces and in public services and exercise excepting private places not open to the public or to clients and areas reserved strictly for smokers. Smoking will be banned in the majority of space (more than 50%) in bars, restaurants, pizzerias, discotheques, pubs and in all types of places open to the public. Smoking will be allowed only in areas reserved for smokers, physically separated from others rooms and provided with appropriate separate ventilation. This will enter into force from January 13, 2005.

Law no. 626 (September 19, 1994, art. 33, 64, 65) on the health and safety of workers states that employers are obliged to protect the health of their employees from all carcinogenic agents, including ETS. It also indicates that in the rest rooms non-smoking workers should be protected from tobacco smoke. If there are no restrooms available, workers should have the possibility to rest in other smoke-free rooms.

Law no. 242 (March 19, 1996) includes modifications and integration of the Law no. 626 adopting the EU directive regarding improvement in health and safety of workers.



Constitutional Court Sentence no. 399 (December 11-12, 1996) provides protection for non-smokers against health hazards from passive smoking.

Law no. 4, January 10, 1983, art. 8 (superseded Law 165, April 10, 1962) totally bans advertising of any kind of national or foreign tobacco product. For those not respecting the ban, the penalty goes from €2,500 to €25,000.

The Ministerial Decree no. 425 (November 30, 1991), according to the EU Directive no. 522 of 1989, bans both direct and indirect TV advertising of tobacco products, the use of names, brands, symbols or any other elements that characterise the tobacco products or the industries that manufacture or sell such products.

Law no. 74 (January 25, 1992, art. 5) states that the publicity of products that may endanger consumers' health and safety without giving proper information is misleading and can induce consumers to be less careful and prudent about their own health and safety.

Law no. 581 (December 9, 1993, art. 8) bans the sponsoring of programmes by persons physical or legal whose principal activity is to produce or sell tobacco. This does not cover the ban on sponsoring of persons, sport or cultural events.

Regio Decreto no. 2316 (December 24, 1934, art. 25) forbids the sale of tobacco to those aged less than 16 years and smoking in public places by under 16 year olds.

Regio Decreto no. 1398 (1930, art. 730) implements a fine of Lire 200,000 (€105,00) for selling tobacco to children aged under 14 years. Furthermore, any person authorised to sell or commerce in medicines caught handing out any poisonous substance or drugs, even with medical prescriptions, to minors aged 16 years and below are punished with a fine of €516,00.

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Law no. 384 (July 23, 1980) allows tobacconists to install vending machines both inside the shops and immediately outside the shop, within 10 m from the centre of the entrance.

Law no. 907 (July 17, 1942) and later modifications (Law no.724, December 10, 1975) ban the sale of tobacco products outside authorised and licensed retailers.

Ministerial Decree of December 16, 1998 no. 500 regulates the quantity of cigarettes and tobacco products a person may buy and carry from outside the EU; the same amount that is permitted to the EU people, i.e. 200 cigarettes or 100 cigars of maximum 3 g a piece, or 50 cigars or 250 g of tobacco.

Ministerial Circular no. 25137 (May 25, 2003; Ministry of Finance) integrates and regulates vending machines and tobacco sales of manufactured tobacco to minors.

Law no. 50 (January 18, 1994) followed by Law no. 92 (March 19, 2001) forbids the sale and distribution of smuggled cigarettes.

Law no. 428 (December 29, 1990, art. 46) dictates the labelling of tobacco products. It came into force on January 1, 1993 for cigarettes and on January 1, 1994 for other tobacco products.



Law no. 184 (June 24, 2003) adopts the EU Directive 2001/37/CE of June 5, 2001 regarding manufacturing, maximum levels of nicotine, tar and CO, and the labelling and selling of products.

A Presidential Decree (309/1990, art. 104) regulates psychotropic substances, the prevention, cure and rehabilitation of addiction, and requires the Ministry of Education to provide health education and information on health hazards from substances including tobacco. The Ministry of Defence is obligated to carry out training and informative actions to inform young people on the problems and health hazards related with the use of tobacco (art. 107).

## 15. TOBACCO LEGISLATION IN LATVIA

There is no national tobacco action plan in Latvia. Tobacco-control legislation in Latvia rests mainly on the Law on Restrictions Regarding the Sale, Advertising and Use of Tobacco Products (effective: January 7, 1997). This law was then amended to come into line with the EU Directive 2001/37/EC on November 26, 2003 to be effective gradually as of May 1, 2004 until January 1, 2007. It also integrates measures included in the EU Tobacco Advertising Directive 2003/33/EC.

The advertising of tobacco products was completely banned in Latvia from August 1, 2004. This includes a complete ban on direct advertising of tobacco products on national TV, radio, cable TV, in national newspapers and magazines, on billboards and on outdoor walls, in cinemas, at points of sale and on kiosks. The law bans indirect tobacco advertising through product placements on TV and in films, the sponsorship of events with a tobacco brand name, direct mail giveaways and promotional discounts. There is a complete ban on vending machines, the sale of single or unpacked cigarettes (with the exception made for cigars and cigarillos) and a ban on free samples of cigarettes. The minimum age for buying tobacco products in Latvia is 18 years of age, however, there is no penalty or fine for selling to minors. Furthermore, there is no restriction on self-service displays, mail order or electronic sales or on the sale of duty-free tobacco products.

Regarding smoke-free places, the law imposes a complete ban on smoking in healthcare, educational and governmental facilities, indoor workplaces, theatres and cinemas, as well as partial restrictions in restaurants, pubs and bars. In all of these areas, however, special areas for smoking are allowed. Smoking is banned on buses and taxis, however, smoking is allowed in some areas of trains, water and air transport for long distances.

Warnings on tobacco product packaging, the measurement, regulation and disclosure of tobacco products and ingredients, etc., are also included in this law, in line with the EU Directive 2001/37/EC.

Five per cent of tobacco taxes are allocated for the treatment of smoking-related illnesses, prevention and anti-smoking campaigns, but the money is not specially earmarked. It goes to the total healthcare budget.

Regulation 298 on the Trade of Tobacco Products, which was adopted on August 29, 2000, sets out a national licensing system for the wholesale, distribution, importation and export of tobacco products. All tobacco products must be labelled with excise duty stamps. The government does not own tobacco companies and it does not pay to subsidise Latvian tobacco farmers.

Regarding cessation, the Latvian government has no official intervention for smoking cessation (cessation clinics, help lines, price incentives for cessation products, etc.) at this time. Pharmacotherapies are available in Latvian pharmacies, some of which require a prescription e.g. bupropion.

### 16. TOBACCO LEGISLATION IN LITHUANIA

Lithuania has a national action plan and specific targets on tobacco within its government policy, and interventions have been made to prevent initiation of tobacco use and to protect non-smokers.

Lithuania's Law on Tobacco Control (enacted: May 11, 1999; amended: 2002) includes a complete ban on the direct advertising of tobacco products on national and cable TV, radio, in local and international magazines and newspapers, on billboards and outdoor walls, at points of sale, kiosks and in cinemas. Indirect advertising through product placements on TV and in films are banned, as are sponsored events with tobacco brand names targeted at under 18 year olds, direct mail giveaways and promotional discounts. Vending machines are banned, as is the sale of single or unpacked cigarettes and free cigarette samples. The minimum age for buying tobacco products is 18 years of age and there are penalties for selling to minors.

Smoking is completely banned in healthcare and educational facilities. There is a complete ban on smoking in government facilities, indoor workplaces, offices, theatres and cinemas, although there are special areas for smoking. Smoking is completely banned on public transport; however, long distance trains and air transport may provide special areas for smoking.

A New Law on Tobacco Control (effective: May 1, 2004) introduced smoke-free legislation for restaurants and bars. However, it states that if this is not possible, these premises should have “specially equipped” smoking areas. This law also brought Lithuania in line with EU Directive 2001/37/EC relating to tobacco product ingredients and their disclosure, as well as health warnings on tobacco products. It includes a ban on misleading descriptors such as “light” and “mild”, large sized warnings, etc.

Tobacco products must bear duty stamps but tobacco taxes are not specifically earmarked. Lithuania possesses a comprehensive licensing system that requires licensing for retail, wholesale and distribution, the import, export and manufacturing of tobacco products.

The Lithuanian government does not own tobacco companies or subsidise/provide financial incentives for the growth or manufacture of tobacco products.

There is little data available regarding interventions to support smoking cessation in Lithuania. Cessation clinics exist and some pharmacotherapies are available for cessation in pharmacies without prescription. However, bupropion requires prescription.

## **17. TOBACCO LEGISLATION IN LUXEMBOURG**

Grand-Ducal Regulation of September 16, 2003 concerns the implementation of the amended law of March 24, 1989 on restrictions on the advertising of tobacco and its products, a prohibition of smoking in certain places and a prohibition on the marketing of oral tobacco. The law applies to tobacco advertising, tobacco labelling and smoking restrictions in public places

Grand-Ducal regulation of November 4, 1994 concerns minimum health and safety provisions at the workplace. The law applies to smoking at the workplace.

Law on the organisation of customs and duties: Belgian law of April 3, 1997 concerns the tax arrangements for manufactured tobacco. The law applies to tobacco taxation.

A government working group is responsible for elaborating a new law applying to smoking in the workplace. It is still uncertain if the bill will pass.

## 18. TOBACCO LEGISLATION IN MALTA

There is no national tobacco action plan in Malta at this time. However, there is a national coordinated body for tobacco control and interventions are made at national level to prevent initiation of tobacco use.

Tobacco-control legislation in Malta is contained in Act XLII “to make provisions in respect of the control of tobacco smoking and for matters connected therewith”, known as the Tobacco Act (effective: December 12, 1986 and amended since then through various legal notices). Legal notices helped to bring Maltese legislation in line with EU Directives 2001/37/EC. Three were enacted in 2003: Legal Notice 243 (“Labelling of Tobacco Products Regulations”) concerning the labelling of tobacco products; legal notice 244 (“Smoking in Public Places Regulations”) concerning smoking in public places; and legal notice 245 (“Tobacco Products Regulations”) concerning the composition of tobacco products.

The Tobacco Act imposes a complete ban on the direct advertising of tobacco products on national TV, radio, in cinemas and partial restriction (only if they contain a health warning) on advertising in local magazines and newspapers, on billboards, outdoor walls, point of sale or kiosks. The indirect advertising of tobacco products through product placements on TV and in films, direct mail giveaways and promotional discounts are completely banned.

Tobacco products can only be sold in vending machines if these are in premises holding a valid licence to serve alcoholic beverages or in premises where machines are kept under supervision. The minimum age for buying tobacco products is 18 years of age (amended on April 5, 2004 from 16 years of age). There are no fines or penalties for selling to minors. The sale of single or unpacked cigarettes is banned, as is the distribution of free samples of cigarettes.

Smoking in public places is regulated by Legal Notice 244, which was enacted on April 5, 2004. Smoking is banned in healthcare, education and government facilities, indoor offices, workplaces, theatres and cinemas, although each of these places may have a smoking area. There are partial restrictions on smoking in restaurants, pubs and bars, with smoking permitted only in designated areas. However, the entry of these restrictions into force has been delayed in the hospitality sector. The original Tobacco Act banned smoking on public transportation.

Health warnings and the regulation and disclosure of tobacco products are in line with EU Directive 2001/37/EC as of Legal Notices 243 and 245.

Tobacco products must bear duty stamps, however tobacco taxes are not earmarked. There is a licensing system for the wholesale and distribution of tobacco products and for vending machines. No information is available regarding the government ownership of tobacco companies in Malta or of government subsidies for tobacco manufacture or production.

Regarding interventions to support smoking cessation, health professionals and medical students are trained in smoking cessation, cessation clinics and national cessation help lines exist in Malta, as do pharmacotherapies for cessation. Many of these are available in pharmacies without prescription. However, bupropion is only available by prescription.

## 19. TOBACCO LEGISLATION IN NORWAY

An act on the prevention of the harmful effects of tobacco became effective on July 1, 1975 (amended: 1996 and 2003). This act contains provisions on the following subjects: advertising ban, including a total ban on direct and indirect advertising, including inter alia, a total ban on all free distribution of tobacco products; health warnings; delegation provision; an age limit for sale of tobacco of 18 years; clean indoor air provision, with a total ban in all public establishments/workplaces and means of transportation, including bars, restaurants, pubs, etc.; provision for tobacco ingredients reporting (in accordance with the EU Directive 2001/37/EC); provision for imposing administrative fines for breach of the Act; export ban on oral tobacco to other EU countries (Sweden exempted); and penalty provision.

Norwegian legislation is in accordance with EU legislation concerning health warnings (Directive 2001/37/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products). Includes a ban on “light” and “mild” labelling of tobacco products (Norway is party to the EEA agreement and thus bound by law to enact all EU legislation).

Tobacco-control regulations have also been issued. They contain detailed provisions on the subjects regulated in the Act. These include: the regulation on prohibition of tobacco advertising (effective: January 1, 1996), regulation on prohibition of new tobacco and nicotine products (effective: November 13, 1989) and the regulation on ingredients and labelling of tobacco products (effective: February 6, 2003).

Sale of NRT is regulated in the Norwegian Act on Medicinal Products (effective: January 1, 1994 with latest amendments effective on January 1, 2004). Licensed drug stores can sell all NRT products including patches, gum, lozenges, inhalators, etc. Convenience shops can sell NRT products that do not exceed 2 mL per dose.

### **20. TOBACCO LEGISLATION IN POLAND**

A Law on the Protection of Public Health against the effects of Tobacco Uses was passed by the Polish Parliament on November 9, 1995 (amendments: November 5, 1999 and November 28, 2003).

This law includes the following: a ban of smoking in public places; a ban of selling tobacco products to minors; a ban on selling tobacco in vending machines; a ban on selling single or unpacked cigarettes; a ban on the production and selling of smoke-free tobacco; a ban of selling tobacco products in healthcare settings, education facilities and sport and recreation places; a ban on tobacco advertising and promotion on TV, radio, cinema, press for children and youth, healthcare settings, schools, sport and recreation places; 30% health warnings on cigarette packs; 20% health warnings on ads on the top; a National Tobacco Control Programme; and a tobacco-control fund from excise tax for tobacco products (0.5%).

The November 5, 1999 amendment incorporates a total ban on: tobacco advertising; sponsorship by tobacco industry of sport and culture events; and sponsorship by tobacco industry of political parties.

The November 28, 2003 amendment (harmonisation to EU law) bans the use of terms and symbols (“mild”, “light”, “ultra light”, etc.) suggesting that product is less harmful than others. The tobacco industry is obliged to disclose each year to the government the ingredients of cigarettes and list of all the additives in tobacco products and justification for using them. It enforces EU standard (size and content) health warnings.

There is no legislation regulating the sale of NRT. There is only general legislation, which regulates sale of all medical products.

## 21. TOBACCO CONTROL IN PORTUGAL

Portugal has a national tobacco action plan, specific national targets on tobacco in government policy, a national coordinating body for tobacco control and interventions are made at national level to prevent initiation of tobacco use and to protect non-smokers.

Portuguese Law no. 22/82 on Prevention of Tobacco Use (effective: July 20, 1982) and the Decree Law 226/83 (effective: May 27, 1983; amended in 1988) that accompanies it introduced partial restrictions on tobacco product advertising on national and cable TV, as well as on national radio. Tobacco product advertising on billboards and on outdoor walls, indirect advertising through TV and film product placements, as well as at sponsored events is completely banned and there are partial restrictions on advertising at point of sale, at kiosks and in cinemas, as well as for the naming of non-tobacco products with tobacco brand names. This law imposes a complete ban on smoking in healthcare, education and government facilities, as well as in indoor workplaces, offices, theatres and cinemas, with special areas for smoking available. Smoking is banned on buses, trains, on water transport and in taxis if the journey lasts less than one hour. If the journey lasts more than one hour, smoking is permitted in special areas. There are partial restrictions on smoking on domestic air transport; however, the legal source for this is not Decree law 226/83.

Promotional discounts of tobacco products are completely banned and duty-free sales are partially restricted in Portugal. Decree Law 566/99 imposes a partial restriction on the free sampling of cigarettes.

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Decree Law 25/2003 (effective: January 1, 2004) restricts vending machines selling tobacco products in certain places. This law also bans the sale of single or unpacked cigarettes and imposes a minimum of 20 cigarettes per pack. This law, together with Law no. 22/82 on Prevention of Tobacco Use and the Decree Law 226/83 bring Portugal in line with EU Directive 2003/37/EC concerning the labelling of tobacco products.

Tobacco products require duty stamps, and taxes are earmarked to the extent that 1.1% of tax revenue is used to support programmes and initiatives for the prevention, control and treatment of cancer and for action related to health and to the prevention of smoking. The licensing system in Portugal requires that the wholesale, distribution, import, export and manufacture of tobacco products require licenses.

Although the Portuguese government does not have shares in tobacco companies, it provides financial incentives for growing and manufacturing tobacco. Additionally, Portuguese farmers are supported by the tobacco industry.

Regarding interventions to support smoking cessation: cessation clinics, help lines, trained health professionals and pharmacotherapies are available in Portugal to help smokers quit. There is, however, no price-incentive or reduced cost for treatment. Pharmacotherapies are available in pharmacies without prescription, except for bupropion, which is only available with prescription.



### **22. TOBACCO LEGISLATION IN THE SLOVAK REPUBLIC**

The latest Act in tobacco legislation in Slovakia is act 67/1997 on protection of non-smokers. Regarding the new EU membership and global world movements towards a smoke-free life, Slovak legislative bodies created a new act accepting the EU Directive 2001/37/EC. Act 570/2004 on the protection of non-smokers came into force on July 1, 2004. It deals with the following: providing information about tobacco products (producers and distributors have to provide the Ministry of Health with a report the content of these products); warnings (at least 30% on the front of the pack and at least 40% on the back of the pack); harmful substances (maximum allowed content of these substances: 10 mg tar per cigarette, 1 mg nicotine per cigarette, 10 mg CO per cigarette); selling of the tobacco products; smoking bans; responsibilities of corporate entities and enterprisers; control; regulation delictum; and violations.

Act 147/2001 on advertising (effective: May 1, 2001) deals with advertising globally, a ban on advertising of tobacco products in all media and information carriers, and a ban on distributing samples of these products. It is allowed to mark specialised tobacco selling shops with the word “tobacco”, use trade marks on the distributors' cars, distributing leaflets and brochures about tobacco products, but only among the tobacco distributors and producers.

Act 330/1996 on the safety and protection of health in the workplace (effective: January 1, 1997) forces the employer to ban smoking in workplaces where non-smokers work.

## **23. TOBACCO REGULATION IN SLOVENIA**

Restriction on the Use of Tobacco Products Act:

The Act is laying down measures both to restrict the use of tobacco products and prevent the harmful effects of tobacco products on health. It is dealing with: advertising of tobacco products; smoking bans (hospitals, schools, etc.) and restrictions in public places (for example restaurants where areas are defined as reserved for smokers); age limit 15 years; labelling; product regulation (tar, nicotine and CO yield, warnings), list of substances in tobacco products demanded by law; and a ban on the sale of tobacco products from automatic vending machines.

An act on Earmarked Taxes deals with the taxation of tobacco products.

The Medicinal Products and Medical Devices Act regulates the sale of NRT. Gum is available without medical prescription but only in pharmacies. Regulation of patches is in procedure.

### 24. TOBACCO REGULATION IN SPAIN

Spain has a national tobacco action plan, and specific targets and interventions are made to prevent the initiation of tobacco use and to protect non-smokers.

Translations of the relevant portions of Spanish law relating to tobacco products, if available, can be obtained from the WHO country profiles website.

Law 25/1994 (July 12, 1994) incorporating the Directive 89/552/CE and regulating the radio-TV broadcasting (as amended in 1999) and the Law on Advertisement (effective: November 15, 1988) together impose a complete ban on tobacco advertising on national and cable TV and national radio, as well as tobacco product placements on TV and in films.

A Royal Decree limiting the sale and use of tobacco to protect the health of the population (enacted: March 4, 1988; amended 1999) sets the minimum age for buying tobacco products at 16 years of age. It also imposes partial restrictions on cigarette vending machines, only allowing them in enclosed spaces and prohibiting cigarette sales to minors aged under 16 years. There are penalties or fines for selling to minors. The same Royal Decree imposes a complete ban on smoking in healthcare and educational facilities, in theatres and cinemas, on buses and air transport, as well as in some taxis. Smoking is allowed in certain parts of trains. There is a partial restriction on smoking in government facilities and in indoor workplaces and offices; smoking is not allowed in public areas and areas where pregnant women are working.

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There is a partial restriction on the sale of duty-free cigarette products, but, regrettably, no further information is available as to the extent of this restriction or its legal base at this time.

The Royal Decree 1079/2002 concerning content measurements, labelling and packaging of tobacco products (enacted: October 18, 2002) imposes a restriction on CO content from November 11, 2004 and also regulates the measurement of product ingredients and smoke constituents.

This decree, together with the Royal Decree regarding limitations on the sale and use of tobacco to protect the health of the population, transposes the EU Directive 2001/37/EC. They regulate the labelling of tobacco products to show the nicotine and tar contents per cigarette and health warnings (message, colour, contrast, font and warning size, which cover at least 30% of the main side and at least 40% of the other side of the package). It also includes full disclosure to the government and on packaging, in accordance with EU Directive 2001/37/EC.

A licensing system exists in Spain, with licenses required for retail sales and vending machines. Tobacco products must bear duty stamps; however, tobacco taxes are not specifically earmarked.

The Spanish government does not own tobacco companies; however, it provides financial incentives for growing and manufacturing tobacco products to its farmers.

Cessation clinics and trained health professionals are on hand to help Spanish smokers quit, and pharmacotherapies are available for cessation in pharmacies with and without prescription. However, bupropion is only available by prescription.

## 25. TOBACCO REGULATION IN SWEDEN

The Swedish Tobacco Act was introduced in 1993, replacing earlier legislation on health warnings and a partial ban on advertising. The Act was amended in 1994, 1997 and 2002. It contains rules on smoke-free public premises, a ban on direct and indirect tobacco advertising, regulations concerning health warnings and tar limits, etc. A ban on tobacco sales to minors has been in effect since 1997.

Smoking is prohibited in daycare centres, schools, and other premises for children and young people, including school grounds and other outdoor areas near such premises. Smoking is also prohibited in healthcare centres and hospitals, in the common areas of homes for the elderly and in public transportation facilities. In schools and similar facilities, smoking may be permitted in designated rooms or areas, provided that children and young people do not have access to them. The same rules apply to other public premises, e.g. those in which cultural or sporting events take place, smoking is prohibited but designated areas may be set aside where smoking is allowed. Hotels are required to provide some non-smoking rooms for their guests. Currently, all food service facilities must set aside a no smoking area. From June 1, 2005 all such facilities (restaurants, cafes, bars, etc.) must be completely smoke-free, except for enclosed smoking rooms.

Employers are required to ensure that employees are not involuntarily exposed to tobacco smoke in the workplace. In practice, most workplaces are smoke free, but smoking is often allowed in separate smoking rooms or “cabins”.

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It is illegal to sell tobacco products to persons less than 18 years of age. All tobacco retailers are required to register with the municipality in which the sales take place. It is the responsibility of Sweden's municipalities to supervise the sale of tobacco products.

Advertising and promotion of tobacco products is prohibited (except at point of sale). Indirect advertising for tobacco products is prohibited as of January 1, 2003. Businesses may not market such products as shoes and clothing if they include a tobacco trademark.

The EU Directive 2001/37/EC has been implemented. Consequently, rules apply on labelling (health warnings) and content (maximum limits for tar, etc.) in accordance with the directive. Also, misleading labels such as “light” and “mild” are prohibited.

There must be a message informing the purchaser of the health risks associated with the use of tobacco that occupies at least 40% of the front side and 30% of the back side of the cigarette package, and a declaration of the harmful substances which the tobacco product contains. It is the responsibility of the manufacturer or importer to ensure the tobacco product has a warning message and a contents declaration otherwise it cannot be sold in Sweden.

The Tobacco Ordinance (SFS 2001) enforces a duty to list ingredients in manufacturing tobacco products. The Tobacco Act 1993 and Regulation of Labelling (FHIFS 2001) limit hazardous substances to 10 mg tar, 1 mg nicotine and 10 mg CO per cigarette. There is a 25% sales tax and a 39.2% plus 4 SEK per pack excise tax added to the retail price of cigarettes sold in Sweden.

There are no tobacco subsidies. NRT can only be bought at the pharmaceutical monopoly

“Apoteket”. This law is under the authority of the Medical Authority in Sweden. Laws to regulate snus are under the authority of Food.

New legislation adopted includes a smoking ban in all restaurants, cafes and pubs. The Riksdag has approved the Government's proposal, which will mean no smoking in all premises where food and drink is served. The ban will come into force on June 1, 2005. Restaurant owners will have to construct special smokers' rooms, in which no food or drink may be consumed. The smokers' rooms will have to be located in areas through which all guests do not normally have to pass.

## 26. TOBACCO REGULATION IN SWITZERLAND

There is a national tobacco action plan in Switzerland, with a national coordinating body for tobacco control, interventions to prevent initiation of tobacco use and to protect non-smokers, but no general policy.

Tobacco-control legislation in Switzerland rests on several key pieces of legislation:

The Federal Law on Radio and TV (effective: October 1, 1992 and further amended by later regulations) imposes a complete ban on tobacco product advertising on national and cable TV and national radio, including the sponsorship of events with tobacco brand names on TV or radio.

The Swiss Regulation on Tobacco and Tobacco Products (further to the 1995 Federal Law on Food Products, effective: January 1, 1998) imposes partial restrictions on the advertising of tobacco products in local magazines and newspapers (only in publications not targeting youth), on billboards and outdoor walls (not in places visited by under 18 year olds), as well as at points of sale, kiosks and in the cinema (not for films attended by under 18 year olds). Direct mail giveaways of tobacco products and free samples of cigarettes targeted or addressing youngsters under 18 years of age are banned. However, there is not an official minimum age for buying tobacco products. However, a law is planned for 2005, to be adopted by the Parliament in 2006. It is not yet clear whether the minimum age will be 16 or 18 years of age. Additionally, there is no minimum number of cigarettes in a pack of cigarettes. However, a revision of this regulation is expected to be enacted in 2004 and this would possibly fix the minimum to 20 cigarettes per pack.

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This law orders the disclosure of ingredients to the government and to some extent to consumers through tobacco products packaging. It also imposes general health warnings on tobacco products in the three official languages (French, German and English) to cover at least 1% of the total surface of the package and if the surface is over 300 cm<sup>2</sup>, at least 18 cm<sup>2</sup>. Nicotine and tar content must be listed on the side of the package to cover at least 8% of the package. Packets of cigarettes and rolling tobacco must also carry additional rotating warnings (e.g. "Smoking provokes cancer"; "Pregnant women: smoking damages the health of your child") covering at least 8% of each side. Misleading descriptors such as "light" and "mild" that do not relate to the actual nicotine (e.g. "low in nicotine", "nicotine-free") are banned. The revision of these regulations in 2004 is expected to bring Switzerland's laws regarding tobacco product labelling in line with the EU Directive 2001/37/EC.

The Swiss Regulation related to the Federal Labour Law (effective: October 1, 1993) imposes partial restriction on smoking in government facilities and in indoor workplaces and offices, in order to protect employee non-smokers. Additional details complete this regulation, in the form of a directive of interpretation.

In the absence of Federal Laws, Voluntary Agreements restrict the self-service displays, mail order and electronic sales of tobacco products. Voluntary agreements in some regions (Cantons) have imposed smoke-free restrictions on healthcare and educational facilities, restaurants, bars, pubs, theatres and cinemas in Switzerland. Whilst there are no restrictions on smoking in taxis, voluntary agreements exist to restrict smoking in some areas of public transport.

There is no duty to be paid or earmarking of tobacco taxes, however, a licensing system exists for the import, export and manufacturing of tobacco products in Switzerland. Although the Swiss Government does not support tobacco farmers or subsidise their work, farmers are supported by the tobacco industry.

Health professionals, smoking cessation support and help lines are available to smokers in Switzerland, with pharmacotherapies widely available in pharmacies without prescription. However, there is no price incentive or reduced cost for treatment, and bupropion and nicotine inhalers are only available by prescription.

## 27. TOBACCO REGULATION IN THE NETHERLANDS

Tobacco control is the competence of the Ministry of Health, Welfare and Sport. Taxation and tobacco subsidies are the competence of the Ministry of Finance and the Ministry of Agriculture, respectively. Hence, these aspects of tobacco control are not regulated by the Tobacco Law. Excise duty rates are based on the Law on Excise Duty and European Directives 92/12 and 95/59. There is no law governing tobacco subsidies, but in the Netherlands there is no growth of tobacco, so involvement of the Netherlands concerns activity on the EU level only.

The Tobacco Law (amended: 2002) is the framework law regulating most aspects of tobacco control including: advertising ban; sale restrictions; restrictions of smoking in public places; a smoke-free workplace; smoke-free public transportation; enforcement and fines; and product regulation, including health warnings.

The Tobacco Law delegates certain aspects of tobacco control to general decrees, a synopsis of which will cover most of the content of the Tobacco Law itself.

### Indications on Tobacco Products:

This decree came into force on May 1, 2002 and regulates the labelling of tobacco products with health warnings (harmonising Dutch law with EU Directive 2001/37/EC).

### Maximum Levels of Tar, Nicotine, Carbon Monoxide in Cigarettes and Smoking Tobacco:

This decree came into force on May 1, 2002 and regulates the maximum levels of tar, nicotine and CO for cigarettes and hand-rolled cigarettes. Since January 1, 2004 the tar, nicotine and CO level of one cigarette cannot not exceed 10 mg, 1 mg and 10 mg, respectively. Since May 1, 2004 the tar level of one hand-rolled cigarette of 750 mg cannot not exceed 12 mg.

### Limitation of Sale and Use of Tobacco Products:

This decree came into force in 1990 and was amended in 1998. This decree restricts the sale and use of tobacco products in governmental and other (semi-) public institutions. The sale of tobacco products is limited to packages containing a minimum of 19 cigarettes. The decree stipulates that competent authorities must implement and enforce a smoking ban in areas accessible to the public. The decree lists which areas are considered accessible to the public and provides some limited options for smoking facilities. It is applicable to governmental facilities, subsidised sports facilities, schools, hospitals, etc.

### Exceptions Smoke-free Workplace:

On January 1, 2004 the smoke-free workplace legislation (Tobacco Law) came into force at the same time as this decree, which regulates exceptions to the smoke-free workplace. The Tobacco Law stipulates that employers must take such measures that employees can carry out their work-related duties without being inconvenienced by tobacco smoke.

The decree lists the following areas as exceptions to the smoke-free workplace: areas designated for the public in hotels, bars and restaurants (hospitality industry); hospitality areas designated for the public in certain non-public theaters and entertainment facilities (as defined by law); areas designated for the public in slot machine halls; areas designated for the public in tobacco specialty stores (as defined by law); international public transportation fulfilling



certain conditions; areas in which the employer has no say; areas considered to be private; separated and designated smoking facilities; and the outdoors.

### Exceptions Smoke-free Public Transport:

On January 1, 2004 the smoke-free public transportation legislation (Tobacco Law) came into force. This decree regulates any exceptions to the smoke-free public transportation. The Tobacco Law stipulates that travellers must be able to travel from one destination to another without being inconvenienced by tobacco smoke. The decree lists the following areas as exceptions: means of public transportation exploited by international consortia or a foreign company as long as these means of transportation are only used for cross border transportation, and the outdoors or open means of transportation

### Tobacco Vending Machines:

Since January 1, 2003 the Tobacco Law bans the sale of tobacco products to persons under the age of 16 years. The decree came into force on June 1, 2004 and forbids the sale of tobacco products by means of a vending machine unless the vending machine is locked and can only be unlocked for the purpose of selling tobacco products to persons who have reached the age of 16 years.

### Advertising ban:

This is regulated in the Tobacco Law itself. The ban of advertising came into force on November 7, 2002. The ban is general and complete and includes the sponsoring of events, a system of fines, the use of tobacco brand names for other products and vice versa, promotional discounts, free distribution of tobacco products, etc. There is one exception: advertising tobacco products is allowed in tobacco specialty stores but under certain conditions only, e.g. advertising that does not specifically target the youth. Furthermore, racing circuits are temporarily (until July 30, 2005) given the possibility to ask the Minister of Health to be exempted from the advertising ban due to long-term sponsoring contracts with the tobacco industry (dating from before April 10, 1999).

The Inspectorate for Health Protection and Veterinary Public Health is responsible for the enforcement of compliance with the Tobacco Law and related decrees. A system of fines came into force on November 7, 2002.

The regulation of NRT is embedded in the general regulations on healthcare, health insurance and pharmaceutical products. Gum, patches, lozenges and microtab are registered and available over the counter at drugstores and pharmacies. Bupropion is only available by prescription.

## 28. TOBACCO LEGISLATION IN THE UK

ACTS of Parliament (primary legislation):

- Tobacco Advertising and Promotion Act 2002  
Restricting the promotion and advertising of tobacco products.
- Children and Young Persons Act 1933  
Prohibiting sale of tobacco to children aged less than 16 years.
- Children and Young Persons (Protection from Tobacco) Act 1991  
Ordering displays at point of sale to say that tobacco products will not be sold to under 18 year olds. This clarifies the penalty for selling tobacco to underage persons and holds the vendor responsible.
- Finance Act 2003  
Tobacco product duty and duty stamps.
- Transport Act 2000  
Giving strategic rail authorities the right to prohibit tobacco use on trains.
- Tobacco Products Duty Act 1979  
Defining tobacco duty.

Statutory instruments and regulations (secondary legislation):

- The Tobacco Advertising and Promotion (Point of Sale) Regulations 2004  
Defines restrictions on point of sale advertising under the Tobacco Advertising and Promotion Act 2004.
- The Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002  
Defines tar, nicotine and CO yields for cigarettes sold in the UK. Defines the regulations concerning stating of yields on the tobacco product packet. Defines procedures for testing tobacco products by the government. Defines the warnings on packets under EU regulations.
- The Tobacco Products (Descriptions of Products) Order 2003
- The Excise Duty Points (New Member States) Regulations 2004  
Clarifies tobacco products for purposes of duty.
- The Customs and Excise Duties (Travellers' Allowances and Personal Reliefs) (New Member States) Order 2004  
This Grants relief on persons bringing tobacco products into the UK for personal consumption from within the EU (Under EU directives).
- The Tobacco for Oral Use (Safety) Regulations 1992  
Prohibits the supply of oral tobacco. Implements Council Directive 92/41/EEC.
- The Cigarettes (Maximum Tar Yield) (Safety) Regulations 1992  
Prohibiting sale of tobacco products exceeding maximum tar yields.
- The Tobacco Products Regulations 2001  
Control of tobacco manufacture and import for duty purposes.

- The Oral Snuff (Safety) Regulations 1989  
Banning the sale of oral snuff.
- The Construction (Health, Safety and Welfare) Regulations 1996  
Provide rest areas where construction workers are not exposed to tobacco smoke.

The Medicines Act 1968 and Health and Medicines Act 1988 regulate the sale of NRT. This legislation covers, inter alia, the systems by which licences to manufacture, market, distribute, sell and supply medicinal products are granted by Ministers ("the Licensing Authority"; or, in the new centralised system, by the relevant Community institutions), once they are satisfied about the safety, efficacy and quality of the product.

In the UK, the Medicines Licensing Authority controls the sale of medicines. This is effectively the Secretary of State for Health who acts upon the advice of the Medicines Commission, the Medicines Control Agency, the Committee on Safety of Medicines and the Medicines Act, in addition to relevant EU regulation and EU-related bodies. Regulatory approval usually requires applications to be made by pharmaceutical companies, which must provide evidence to satisfy the regulators. Under this framework, guidelines for the use of and sale of NRT are governed.

The following legislation has been adopted (date enters into force): Brand sharing Regulations (July 31, 2005); Point of Sale regulations (December 21, 2004); and the Tobacco Advertising and Promotion Act 2002 (on sponsorship, July 31, 2005). The latter Prohibits sponsorship; currently sponsorship agreements predating July 11, 2001 are exempt until this date.

The Tobacco Advertising and Promotion (Point of Sale) Regulations 2004 is under challenge from a coalition of tobacco companies led by the Tobacco Manufacturers Association.

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