

Norwegian Ministry of Health and Care Services,  
17 March 2015

**Consultation on the proposal for standardised  
tobacco packaging and the implementation of  
Article 5.3 of the Framework Convention on  
Tobacco Control**

**Consultation deadline: 9 June 2015**

## Table of contents

1. INTRODUCTION.....	4
1.1 Background.....	4
1.2 Further details about the main content of the Ministry’s proposal.....	7
2. BASIC FACTS.....	8
2.1 Tobacco use in Norway .....	8
2.2 Harmful health effects from tobacco use.....	10
3. STANDARDISED TOBACCO PACKAGING AND PRODUCTS .....	13
3.1 Existing law .....	13
3.1.1 EU legislation.....	14
3.1.2 The Framework Convention on Tobacco Control.....	15
3.2 Objectives and justification .....	17
3.3 Regulations in other countries .....	20
3.3.1 Australia .....	20
3.3.2 United Kingdom.....	21
3.3.3 Ireland.....	22
3.3.4 New Zealand .....	23
3.3.5 France .....	23
3.3.6 Sweden .....	23
3.3.7 Finland.....	23
3.4 Research on the effects of standardised tobacco packaging.....	23
3.4.1 Choice of colours .....	27
3.5 Regulation regarding smokeless tobacco .....	28
3.6 Public opinion.....	30
3.7 Norway’s international legal obligations in the area of trade law, trademark and design law, the Norwegian Constitution and the ECHR.....	31
3.7.1 EEA and EU law .....	31
3.7.2 WTO Agreements .....	32
3.7.3 Trademark and design legislation.....	33
3.7.4 The Norwegian Constitution and the ECHR.....	34
3.8 The Ministry’s proposals .....	36
3.9 Supervision and sanctions .....	40
3.10 Authority for seizure and destruction.....	40
4. ARTICLE 5.3 OF THE FRAMEWORK CONVENTION ON TOBACCO CONTROL.....	41
4.1 Background.....	41
4.2 Tobacco industry tactics .....	42
4.3 Applicable laws .....	50

4.4	FCTC Article 5.3 Guidelines .....	51
4.4.1	Purpose and scope .....	51
4.4.2	Overarching principles .....	52
4.4.3	Primary recommendations of the guidelines .....	52
4.4.4	Enforcement and monitoring.....	55
4.5	The WHO's assessment of Norwegian tobacco control work.....	55
4.6	Status of implementation of Article 5.3 in Norway.....	56
4.7	Proposal by the Norwegian Directorate of Health.....	57
4.8	The Ministry's proposals and assessments .....	59
5.	FINANCIAL AND ADMINISTRATIVE CONSEQUENCES .....	60
5.1	Standardised tobacco packaging.....	61

# 1. INTRODUCTION

The Ministry of Health and Care Services hereby submits for consultation a proposal to introduce mandatory standardised packaging of tobacco products in accordance with Act No. 14 of 9 March 1973 relating to Prevention of the Harmful Effects of Tobacco (the Tobacco Control Act). We also propose certain other amendments and specifications to the Tobacco Control Act and Regulations No. 141 of 6 February 2003 on the contents and labelling of tobacco products, as well as Regulations No. 989 of 15 December on the prohibition of advertising of tobacco products etc., in part to implement certain aspects of the new EU Tobacco Products Directive (2014/40/EU) related to the design of tobacco packaging and related products.

Norway is one of 180 parties to the WHO Framework Convention on Tobacco Control (FCTC), whereby the parties, under Article 5.3, pledge to implement measures in order to prevent the tobacco industry from influencing tobacco control policies. The Article 5.3 guidelines give recommendations for specific measures to implement this obligation. Various possible measures are discussed below, and we ask for contributions from interested parties with regard to measures that may be appropriate in a Norwegian context.

The Ministry also requests that all parties making a submission to the consultation report any direct or indirect links with, cooperation with, or financial support from the tobacco industry. Furthermore, we request that all assertions and statements be accompanied by documentation which includes source references with links, and particularly whether purported studies and reports were either wholly or partly financed by the tobacco industry, cf. the discussion in section 4 below. If this information has not been published on the internet, we request that the document be attached to the submission.

## 1.1 Background

Despite significant progress in the area of tobacco control in Norway, smoking continues to be a major risk factor and the single largest preventable cause of premature death and poor health. Snus also has harmful effects, and its use has increased over the past few years, especially among young adults. A significant decline in the number of tobacco users is therefore the single most important measure for improving public health.

The health risks of smoking are well known. In Norway, an estimated 6,600 deaths are attributed to smoking each year. Each of these lives were cut short by an average of 11 years, and nearly 50 % of heavy smokers die before the age of 70. Cardiovascular disease is clearly the leading cause of death.

Over the past few years smoking prevalence has steadily declined, but more than one-fifth of young adults ages 16 to 24 years continue to smoke. The use of snus among young people has also increased since the turn of the millennium. One-third of all young men are now using snus, while the percentage of young women using snus has increased from practically zero in 2000 to 18 % in 2014.

According to the Norwegian Institute of Public Health, tobacco smoke is most likely the single factor responsible for the greatest amount of harm to public health over the past decade. In the Public Health Report from 2010, the Institute stated that we are hopefully now seeing the “beginning of the end of the tobacco epidemic”, but added that major efforts are still necessary to end the era of tobacco-related diseases. If we are able to reduce the use of tobacco to a minimum over the next few years, the epidemic of tobacco-related diseases may be over by 2050.

The overarching vision of the national tobacco control strategy for the period 2013–2016 is a longterm goal of making Norway a tobacco free society. This is also part of the Tobacco Control Act objective, cf. Section 1. More specifically, one of the goals of the strategy is to reduce the percentage of children and young adults who smoke by half, to less than 6% by 2016, and to stop the increase in daily snus use among young people.

The first part of the strategy period focused on restrictions on the sale and use of tobacco. These measures have been important, but regulation of tobacco products in the current legislation is minimal. The next “stage” of the Ministry’s strategy will therefore involve making tobacco less appealing to children and young adults. Discouraging children and young adults from starting to use tobacco is the primary focus of the Ministry’s tobacco prevention efforts. Most individuals who begin using tobacco are minors, and research indicates that they tend to underestimate the risk of addiction. Tobacco packaging is one of the few remaining forms of tobacco advertising in Norway. The tobacco industry has invested considerable resources in development of packaging design targeted towards specific groups, including women and young people, and in the course of just a few years, snus has become a new trend product for the younger generation.

Due to the rise in snus use among young people, measures aimed at limiting the use of snus have gained a more central position in tobacco control efforts. In 2014, the Institute of Public Health carried out an evidence review of the health risks associated with snus.<sup>1</sup> The report concludes that snus is carcinogenic, leads to a poorer cancer prognosis, increases the risk of mortality following heart attacks and strokes, increases the risk of diabetes type 2, and can harm the foetus during pregnancy. In their report, the Institute of Public Health states that the prevalence of snus use in Norway has tripled over the last five years, with the highest increase among young people. The Institute adds that the sharp rise in snus use among young people could be characterised as an epidemic, and that there are indications that this use will continue to rise. The Institute believes there is every reason to be concerned about the number of cancer cases that may result from snus, given today’s many young snus users, and also about the number of women who use snus during pregnancy – a group that is likely to grow in number over the coming years.

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<sup>1</sup> Institute of Public Health, *Helserisiko ved bruk av snus* (2014): <http://www.fhi.no/dokumenter/35f7c1d9e4.pdf>

Norway is committed to the WHO's global goal of achieving a 25 % reduction in premature mortality from non-communicable diseases (NCD) by 2025. New international research indicates that in order to reach this goal, a reduction in the use of tobacco is crucial. Two effective measures, which Norway has yet to utilise, include standardised packaging and a ban on flavouring. The latter is covered by the EU's new tobacco product directive and will therefore not be discussed here.

Mandatory standardised tobacco packaging as a measure aimed at discouraging young people from using tobacco was considered in Norway as early as 2002. In a knowledge review published by the Norwegian Institute for Alcohol and Drug Research (SIRUS) of measures for reducing the prevalence of smoking among young people it was stated:

“Tobacco packaging is designed to be appealing and represents a kind of symbol. The overall effect of removing this symbol content is uncertain, but it is likely that we can reduce youths' interest in using these tobacco packs as means of expression.”<sup>2</sup>

In 2010, the World Health Organisation carried out an assessment of tobacco control efforts in Norway. In their report WHO recommended, among other things, that Norway should consider introducing standardised tobacco packaging.<sup>3</sup>

In 2012, the National Council on Tobacco and Health stated:

“Plain packaging: We believe there is too little focus on plain packaging, or brand-free products. A ban on current product labelling should be part of a strategy and long-term planning. Considering the industry's opposition to the idea, this is an extremely important measure.”<sup>4</sup>

The proposals included in this consultation paper will contribute toward fulfilling Norway's obligations as a party to the FCTC. The proposals will furthermore implement aspects of the EU Tobacco Products Directive 2014/40/EU. The Ministry will return with a separate consultation on the implementation of the remaining provisions of the directive.

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<sup>2</sup> Lund and Rise (2002), *En gjennomgang av forskningslitteraturen om tiltak for å redusere røyking blant ungdom*

<sup>3</sup> WHO (2010), *Evaluation of Norwegian tobacco control efforts*: <http://www.regjeringen.no/upload/HOD/CapacityAssessmReportNORWAY.pdf>, see section V.1.3.2 on page 27.

<sup>4</sup> Consultation response by the Norwegian National Council on Tobacco and Health, 23 March 2012: [https://www.regjeringen.no/contentassets/c09165b697834c56a8ae4b0415f9ad10/nasjonaltraad\\_tobakksforebygging.pdf](https://www.regjeringen.no/contentassets/c09165b697834c56a8ae4b0415f9ad10/nasjonaltraad_tobakksforebygging.pdf)

Tobacco products are legal, but differ substantially from other consumer products in that they pose significant health hazards, regardless of the type of use. There is no safe level for tobacco use apart from total abstinence. The Ministry emphasises that the harmful effects of tobacco use provide compelling and legitimate reasons for the government to further regulate the design of the tobacco packaging and related products, in order to make tobacco products less appealing to youth. Other legitimate reasons for regulating tobacco products include the fact that the choice to begin using tobacco is often made by minors who have misconceptions regarding risks, and that the freedom to quit is often limited by addiction. There is also the aspect of passive smoking, which affects the health of others.

In addition to the above-mentioned arguments, smoking imposes a significant economic burden on society. In a report from 2010 by the Directorate of Health, it is estimated that the total socioeconomic cost of smoking in Norway is between 8 and 80 billion NOK annually.<sup>5</sup> This is a broad estimate, and the lowest estimate involves only the cost of health care and loss of production due to increased morbidity and premature death, while the highest estimate also comprises an economic valuation of 150–180 000 lost years of life. This estimate is based on the prevalence of smoking over the last 10 to 30 years.

In the report it is further estimated that the decline in the number of daily smokers over the last 20 years, has led to potential socioeconomic benefits in the amount of approximately 26 billion NOK per year, and that the potential benefits of an even sharper decline in the number of daily smokers may have an annual social value of approximately 2 to 3 billion NOK per percentage point. However, it is important to note that it may take time before the effects of these measures on the smoking population become apparent, and that the most widespread smoking-related diseases appear only after several decades.

## **1.2 Further details about the main content of the Ministry's proposal**

The Ministry proposes the introduction of standardised tobacco packaging in Norway. This proposal will apply to all types of tobacco products. Standardised tobacco packaging involves a uniform layout and design on all tobacco packaging, as well as a ban on manufacturers' logos, trademarks, images, colours or other forms of advertising. Packaging shall only have one solid colour, and some of the products will be required to have specific packaging materials. Brand names and variant names, as well as manufacturer information, shall have standardised colour, placement, font and size. The Ministry also proposes standardisation of other elements such as barcodes, packing material, etc. The packaging shall retain the mandatory health warnings and other information in accordance with current legislation.

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<sup>5</sup> Directorate of Health (2010), *Samfunnsøkonomiske kostnader av røyking*, IS-1825: [http://www.helsedirektoratet.no/vp/multimedia/archive/00312/IS-1825\\_Samfunns\\_ko\\_312409a.pdf](http://www.helsedirektoratet.no/vp/multimedia/archive/00312/IS-1825_Samfunns_ko_312409a.pdf)

The Ministry furthermore proposes that the design of tobacco products and smoking accessories should be standardised to a certain extent, including the colour of the cigarette paper and snus portions, as well as the specification of brand names and variant names. A legal basis for standardising tobacco surrogates is also proposed, but specific regulations are not proposed at this time. Tobacco surrogates include herbal cigarettes and herbal snus, among others.

The EU Directive 2014/40/EU includes specific regulations regarding a ban on misleading labelling (Article 13), shape and contents of tobacco packaging (Article 14) and size of the lateral surfaces of boxes with hinged lids (Article 9 no. 3 third paragraph). Since these regulations are closely linked with the regulation of standardised tobacco packaging, the Ministry also proposes the implementation of these regulations in this consultation.

Furthermore, it is proposed that certain labelling and advertising provisions be repealed as a result of the new legislation on standardised tobacco packaging.

The FCTC Article 5.3 states that effective measures must be implemented in order to protect tobacco policies from the vested interests of the tobacco industry. The Ministry outlines possible measures aimed at protecting tobacco policies in chapter 4 below, and asks for feedback on how Norway should implement its FCTC obligations.

## **2. BASIC FACTS**

### **2.1 Tobacco use in Norway**

There was a sharp decline in the percentage of daily smokers between 1973 and 2013. In 1973, 51 % of all men and 32 % of all women reported that they smoked on a daily basis. In 2014, 13 % of the population were daily smokers, and 9% smoked occasionally. This is the equivalent of 920,000 people. The group of people that smoke occasionally has remained stable, although the number of daily smokers has sharply declined during the same period. Smokers are also unevenly distributed by socioeconomic level. Among those with little education in 2014, 27 % were daily smokers, as opposed to 8 % of those with higher education.

According to statistics from the OECD, Norway has had the largest decline in the percentage of smokers of all OECD nations between 2000 and 2010.<sup>6</sup> Over the last decade, the percentage of daily smokers has been halved – from 26 % to 13 %. This is equivalent to about 400,000 people.

In 2014, 5 % of young people between the ages of 16 and 24 were daily smokers, in addition 12 % smoked now and then. This means that slightly more than 100,000 young people still smoke.

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<sup>6</sup> OECD (2014), *Health at a Glance: Europe 2014*: [http://dx.doi.org/10.1787/health\\_glance\\_eur-2014-en](http://dx.doi.org/10.1787/health_glance_eur-2014-en)

Over half of today's smokers and ex-smokers began smoking before the age of 18, and more than 70 % of them started smoking before they turned 20.<sup>7</sup> The median age of debut for each age cohort has fallen, so that those who begin smoking today are much younger than their parents were when they began smoking.<sup>8</sup> The average smoking debut age is about 16. Those with less education tend to begin smoking at a younger age than those with more education.

While fewer and fewer are smoking, an increasing number of people are using snus. In 2014, 9 % of the population were using snus on a daily basis. Snus is more widespread among young people. Among those between the ages of 16 and 24, 18 % were daily snus users, in addition 8 % used snus occasionally. This is equivalent to just over 150,000 young people. Snus use is more common among young men (a total of 33 % of this age group in 2014), however, over the past few years, there has been a sharp increase among young women as well (a total of 18 % of this age group in 2014). Fifteen years ago, 10 % of young men used snus daily, while scarcely any young women were snus users. The Institute of Public Health refers to the increase in snus use among young people as an epidemic.<sup>9</sup>

Statistics from Norway indicate that 34 % of those who use snus daily or occasionally have never smoked.<sup>10</sup> Statistics from Sweden indicate that nearly 40 % of male snus users have never smoked, while 10 % of young people who smoke began using snus first.<sup>11</sup>

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<sup>7</sup> SSB/Directorate of Health (statistics 2013)

<sup>8</sup> Directorate of Health (2013), *Tal om tobakk 1973-2012*, IS-2064

<sup>9</sup> Institute for Public Health (2014), *Helserisiko ved bruk av snus*: <http://www.fhi.no/dokumenter/35f7c1d9e4.pdf>

<sup>10</sup> Report from 18.3.2011 from the Institute of Public Health to the Ministry of Health and Care Services

<sup>11</sup> The Swedish National Institute of Public Health, web case 23.11.2010:

<http://www.fhi.se/Aktuellt/Nyheter/Snus-bidrar-till-att-fler-ar-tobaksberoende/>

## 2.2 Harmful health effects from tobacco use

### *Harmful health effects of smoking*

In Norway, smoking continues to be the major risk factor for premature death and loss of healthy years of life.<sup>12</sup> Statistics from the Global Burden of Disease project indicate that an estimated 6,600 deaths in Norway are attributed to smoking each year, which is equivalent to 16 % of all deaths. In a report entitled “How fatal is smoking?” from 2006, the Institute of Public Health states that those who die from smoking-related diseases have their lives cut short by an average of 11 years.<sup>13</sup> Smoking is the cause of 26 % of all deaths among women between the ages of 40 and 70, while the corresponding figure for men is 40 %. Men in this age group who die from smoking lose an average of 14 years of life, while women lose an average of 20 years. New research from Australia has shown that two-thirds of those who smoke for an extended period of time will die of smoking-related diseases, and the risk of premature death for this group is three times as high as for those who have never smoked or who have quit.<sup>14</sup>

More than 40 diseases, including 20 fatal diseases, are directly linked to smoking.<sup>15</sup> Major diseases include various types of cancer, respiratory diseases, and cardiovascular diseases. The World Health Organization estimates that approximately 20 % of cardiovascular diseases are caused by smoking, and that heart attacks and strokes are the most common among these diseases. The risk of heart attack is considered to be two to three times higher among smokers than among non-smokers, but other studies have found this risk to be up to seven times higher for both men and women, regardless of age (the younger the smoker, the higher the relative risk), and number of cigarettes smoked per day. Smoking increases the risk of cancer in a number of different organs. Lung cancer is the type of cancer that is most strongly linked to smoking. Roughly 80 to 90 % of all lung cancer is due to smoking.

In addition to cancer, smoking leads to several respiratory diseases. One of the most serious is COPD (Chronic Obstructive Pulmonary Disease). Approximately 370,000 people in Norway have COPD, which is primarily caused by smoking. Smoking causes and exacerbates other lung diseases as well, such as asthma and chronic bronchitis.

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<sup>12</sup> WHO (2009), *Global health risks: mortality and burden of disease attributable to selected major risks*: [http://www.who.int/healthinfo/global\\_burden\\_disease/GlobalHealthRisks\\_report\\_full.pdf](http://www.who.int/healthinfo/global_burden_disease/GlobalHealthRisks_report_full.pdf)

<sup>13</sup> Vollset SE m.fl, *Hvor dødelig er røyking? Rapport om dødsfall og tapte leveår som skyldes røyking*, Report 2006:4, Institute of Public Health: <http://www.fhi.no/dokumenter/F96A862E2C.pdf>

<sup>14</sup> Banks E et al, *Tobacco smoking and all-cause mortality in a large Australian cohort study: findings from a mature epidemic with current low smoking prevalence*, BMC Medicine 2015,13:38: <http://www.biomedcentral.com/1741-7015/13/38>

<sup>15</sup> U.S. Department of Health and Human Services (2004), *The health consequences of smoking: A report of the Surgeon General*: <http://www.surgeongeneral.gov/library/smokingconsequences/index.html>, Storrøll E m.fl, *Skader og problemer forbundet med bruk av alkohol, narkotika og tobakk*, Sirius-rapport nr. 3/2010: [http://www.sirus.no/filestore/Automatisk\\_opprettede\\_filer/sirusrap.3.10.pdf](http://www.sirus.no/filestore/Automatisk_opprettede_filer/sirusrap.3.10.pdf)

In general, there is a clear link between smoking and the risk of mortality. The risk of death is relatively higher for heavy daily smoking. Although the risk of mortality from smoking is highest among heavy smokers, there is a significant excess mortality even among those who smoke 1 to 4 cigarettes per day.<sup>16</sup> Health risks from smoking even fewer cigarettes per day have also been identified. According to a report from 2010 by the U.S. Surgeon General, occasional smoking and passive smoking can both cause immediate damage to the body which may lead to serious illness or death.<sup>17</sup> Inhaling even small amounts of tobacco smoke may damage DNA, which may later lead to cancer.

In the introduction to a 2014 report by the U.S. Surgeon General it is stated that the tobacco epidemic was initiated and maintained by the tobacco industry's aggressive strategies, which wilfully misled the population about the adverse health effects of smoking.<sup>18</sup> The report states that research evidence is now able to prove a causal relationship between smoking and disease in nearly every organ of the body. Evidence from recent research indicates that smoking increases the likelihood of treatment failure for all types of cancer, that smoking may lead to arthritis and an impaired immune system, and that it increases the risk of tuberculosis and death from tuberculosis, the risk of ectopic pregnancy and reduced fertility, and cleft palate in fetuses early in pregnancy.

A major American study from February 2015 shows that the list of diseases caused by, and exacerbated by smoking is even longer than previously assumed, and that the number of deaths due to smoking is most likely much higher than currently estimated.<sup>19</sup>

Furthermore, a 2014 report by the U.S. Surgeon General states that even though today's smokers smoke fewer cigarettes than the average number 50 years ago, they still have a higher risk of developing lung cancer. This is partly due to changes in the design and content of cigarettes since the 1950s. Studies indicate that ventilated filters may be contributing to a higher risk of lung cancer, since smokers inhale more strongly and therefore inhale the carcinogenic chemicals deeper into their lung tissue. At least 70 of the chemicals in cigarette smoke are carcinogenic. The level of some of these chemicals has increased, since production processes have changed over time.

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<sup>16</sup> Bjartveit Tverdal, *Health consequences of smoking 1–4 cigarettes per day*, *Tobacco Control* 2005;14:315–320.

<sup>17</sup> U.S. Department of Health and Human Services (2010), *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General*: <http://www.surgeongeneral.gov/library/tobaccosmoke/index.html>

<sup>18</sup> U.S. Department of Health and Human Services (2014), *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*: <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html>

<sup>19</sup> Carter B et al., *Smoking and Mortality — Beyond Established Causes*, *N Engl J Med* 2015; 372:631-640, 12.2.2015: <http://www.nejm.org/doi/full/10.1056/NEJMs1407211>

### *Harmful health effects from snus use*

Although the use of snus is far less harmful to health than smoking, the use of snus also increases the risk of serious disease. The Institute of Public Health published a report in November 2014 about the adverse health effects of snus use.<sup>20</sup> This report concludes that snus is carcinogenic, and evidence shows that snus use increases the risk of cancer in the pancreas, oesophagus and mouth. There is also evidence that snus use may increase the risk of cancer in the stomach, colon and rectum. However, it is not possible to determine how high the risk would have to be in order to develop cancer. The degree of increased cancer risk would most likely depend on how early a person began to use snus, as well as the frequency of use, the amount of snus used, the number of years snus has been used, and the content of dangerous chemicals in the snus product. There is some evidence that snus users have a poorer prognosis in the event of cancer diseases.

There is convincing evidence that snus use may lead to a higher risk of mortality from heart attack or stroke. Quitting snus after surviving a heart attack may reduce the risk of mortality by half.

The report also provides significant evidence that use of snus during pregnancy can lead to reduced birth weight, and an increased risk of premature birth and still birth. There are indications that use of snus during pregnancy may lead to pre-eclampsia, increased risk of respiratory failure in newborns, cleft palate, and in the long-term, behaviour problems and other disorders. The developing brain is very sensitive to nicotine. We have limited knowledge of the extent of snus use during pregnancy, but there are indications that the use of snus among pregnant women is rising. Statistics from 2009 show that around 20 % of users continued using snus during pregnancy. The sharp rise in snus use among young women over the last few years increases the likelihood that more pregnant women will be using snus in the years to come.

There is little or no evidence that the use of snus leads to an increased risk of cardiovascular diseases or stroke. There is, however, significant evidence that snus use leads to an increased risk of mortality from heart attack and stroke. Quitting snus after surviving a heart attack can reduce the chance of mortality by 50 %. Acute effects of snus use include increased heart rate and increased blood pressure, and heart function may also be affected. There are indications that use of snus may be associated with an increased risk of heart failure.

There is also evidence to indicate that heavy use of snus may be linked to an increased risk of developing diabetes type 2, and evidence to suggest that snus use may be associated with an increased risk of weight gain and obesity. There are also indications that snus use may reduce fertility.

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<sup>20</sup> Institute of Public Health (2014), *Helserisiko ved snusbruk*: <http://www.fhi.no/dokumenter/35f7c1d9e4.pdf>

Use of snus may damage mucosal membranes in the mouth, causing the formation of white or red patches. These are known as snus-induced lesions. Some of these lesions have been classified as pre-cancerous, but most of them go away after the person quits using snus. There may be permanent local areas of receding gum tissue in the spot where the snus was placed. This may lead to exposed roots and nerve pain, and possibly loss of teeth in localised areas.

One important issue is whether snus use among young people increases the risk that they will later begin smoking. There are several studies on this issue, but so far results have been contradictory. There is a predominance of evidence to indicate that snus use increases the risk of later smoking behaviour.

The Ministry maintains that the health risks of snus use among young people should primarily not be compared with the health risks of smoking, but rather with not using tobacco at all.

### **3. STANDARDISED TOBACCO PACKAGING AND PRODUCTS**

#### **3.1 Existing law**

The Tobacco Control Act includes, inter alia, the following restrictions: a ban on tobacco advertising and sponsorship, a ban on free distribution of, and discounts on tobacco products, a ban on the visible display of tobacco products at points of sale, a ban on self-service, an age limit of 18 years for buying tobacco, a ban on the sale of packs of less than 20 cigarettes, a ban on the use of tobacco on schools grounds and during school hours for students, a normative provision on children's right to a smoke-free environment, and a complete ban on smoking in all buildings and transportation accessed by the public, including workplaces, entrances to health institutions and public offices.

The Act is supplemented by three regulations: Regulations no. 989 of 15 December 1995 on the prohibition of advertising of tobacco products (hereinafter the Advertising Regulations), Regulations 141 of 6 February 2003 on the contents and labelling of tobacco products (hereinafter the Labelling Regulations), and Regulations 1044 of 13 October 1989 on the prohibition of new tobacco and nicotine products.

The Tobacco Control Act, the advertising and labelling regulations all include specific provisions on the labelling of tobacco packaging. These are to a large extent an implementation of the current EU Tobacco Products Directive, 2001/37/EC.

The Tobacco Control Act, Section 30 states:

*“Section 30 Requirements concerning labelling of tobacco products*

It is prohibited to bring into Norway, sell or distribute tobacco products that are not labelled with a warning indicating the health risks of using these products. Cigarette packets shall similarly carry a declaration of their contents.

It is prohibited to bring into Norway, sell or distribute tobacco products which by their text, name, trademark, illustrations or other sign or symbol suggest that a particular tobacco product is less damaging to health than other tobacco products.

A manufacturer or vendor of tobacco products may not by means of symbols or text on packaging provide their own information on the health consequences of smoking.

The Ministry will issue more detailed regulations on labelling pursuant to this section.”

The Labelling Regulations, Section 17 states:

“Section 17. *Misleading product descriptions*

To ensure that consumers are not misled with regard to the damage to health caused by using tobacco products, it is prohibited to import into Norway, process, sell or transfer tobacco products which imply by text, name, trade mark, illustrations or other signs that a particular tobacco product is less harmful to health than others.”

The Advertising Regulations, Section 6 states:

“Section 6. *Prohibition of untraditional designs or appearance of tobacco product packets*

It is prohibited to sell tobacco product packets that may as a result of non-traditional design or appearance lead to an increase in sales. It is prohibited to design tobacco product packets with the aim of increasing sales among young people. This includes untraditional designs of tobacco product packets with respect to logos, colours, shape of packet or continually changing design which may encourage collecting.”

### 3.1.1 EU legislation

Norway is bound by two EU Directives relating to tobacco: Directive 2001/37/EC regarding the manufacture, display and sale of tobacco products, and Directive 2003/33/EC regarding tobacco advertising and sponsorship. The new Directive 2014/40/EU of 3 April 2014 regarding the manufacture, display and sale of tobacco and tobacco-related products replaces Directive 2001/37/EC, and will be implemented in all member states by 20 May 2016.<sup>21</sup> The Directive is EEA relevant and the process of incorporating this directive into the EEA agreement has begun.

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<sup>21</sup> The European Parliament and Council Directive 2014/40/EU of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, display and sale of tobacco and related products and repealing Directive 2001/37/EC: <http://eur-lex.europa.eu/legal-content/DA/TXT/HTML/?uri=CELEX:32014L0040&qid=1413455761491&from=EN>

Directive 2014/40/EU contains a number of new requirements which will apply to all tobacco and tobacco-related products in the EU, including, inter alia, larger health warnings and the regulation of additives. The Ministry will consult separately on the implementation of the Directive during 2015.

The Directive does not directly regulate standardised tobacco packaging, but Article 24 (2) specifies that the Directive does not prevent member states from introducing such legislation, provided that certain conditions are met. Article 24 (2) states:

“This Directive shall not affect the right of a Member State to maintain or introduce further requirements, applicable to all products placed on its market, in relation to the standardisation of the packaging of tobacco products, where it is justified on grounds of public health, taking into account the high level of protection of human health achieved through this Directive. Such measures shall be proportionate and may not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. Those measures shall be notified to the Commission together with the grounds for maintaining or introducing them.”

The right to introduce such legislation beyond the explicit provisions of the Directive are stated in the Directive’s preamble, number 53:

“Tobacco and related products which comply with this Directive should benefit from the free movement of goods. However, in light of the different degrees of harmonisation achieved by this Directive, the Member States should, under certain conditions, retain the power to impose further requirements in certain respects in order to protect public health. This is the case in relation to display and packaging, including colours, of tobacco products other than health warnings, for which this Directive provides a first set of basic common rules. Accordingly, Member States could, for example, introduce provisions providing for further standardisation of the packaging of tobacco products, provided that those provisions are compatible with the TFEU, with WTO obligations and do not affect the full application of this Directive.”

### *3.1.2 The Framework Convention on Tobacco Control*

The World Health Organization’s convention on tobacco control is a evidence-based, international, legally binding agreement.<sup>22</sup> The objective of the convention is presented in Article 3:

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<sup>22</sup> WHO Framework Convention on Tobacco Control (FCTC): <http://whqlibdoc.who.int/publications/2003/9241591013.pdf>, Norwegian translation: [http://www.helsedirektoratet.no/vp/multimedia/archive/00000/Rammekonvensjonen\\_om\\_f\\_603a.pdf](http://www.helsedirektoratet.no/vp/multimedia/archive/00000/Rammekonvensjonen_om_f_603a.pdf)

“The objective of this Convention and its protocols is to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke.”

The Convention currently has 180 Parties, and Norway was the first country to sign and ratify it. There is an ongoing effort to implement and elaborate on the obligations of the Convention, including the preparation of guidelines. Provisions of the Convention provide considerable freedom to the various parties in terms of forming their own legal provisions and measures based on the conditions in each country. Provisions of the Convention determine what must be regulated by the Parties, as well as the goals they must strive toward. However, the parties are often free to determine the manner in which these regulations will take shape. The guidelines are more detailed, and some provide explanations on the manner in which parties have agreed on the interpretation and implementation of Convention provisions. Other guidelines provide only suggestions for various measures and examples of best practice.

Guidelines under Article 11 of the Convention, regarding labelling and packaging of tobacco products, and guidelines under Article 13 regarding the ban on advertising, recommend that the Parties consider introducing standardised tobacco packaging. The guidelines for Article 11 refer to “plain packaging” in point 46:

“46. Parties should consider adopting measures to restrict or prohibit the use of logos, colours, brand images or promotional information on packaging other than brand names and product names displayed in a standard colour and font style (plain packaging). This may increase the noticeability and effectiveness of health warnings and messages, prevent the package from detracting attention from them, and address industry package design techniques that may suggest that some products are less harmful than others.”

The guidelines for Article 13 refer to “plain packaging” in points 15 to 17:

**“Packaging and product features**

15. Packaging is an important element of advertising and promotion. Tobacco packs or product features are used in various ways to attract consumers, to promote products and to cultivate and promote brand identity, for example by using logos, colours, fonts, pictures, shapes and materials on or in packs or on individual cigarettes or other tobacco products.

16. The effect of advertising or promotion on packaging can be eliminated by requiring plain packaging: black and white or two other contrasting colours, as prescribed by national authorities; nothing other than a brand name, a product name and/or manufacturer's name, contact details and the quantity of product in the packaging, without any logos or other features apart from health warnings, tax stamps and other government-mandated information or markings; prescribed font style and size; and standardized shape, size and materials. There should be no advertising or promotions inside or attached to the package or on individual cigarettes or other tobacco products.

17. If plain packaging is not yet mandated, the restriction should cover as many as possible of the design features that make tobacco products more attractive to consumers such as animal or other figures, "fun" phrases, coloured cigarette papers, attractive smells, novelty or seasonal packs.

### **Recommendation**

Packaging and product design are important elements of advertising and promotion. Parties should consider adopting plain packaging requirements to eliminate the effects of advertising or promotion on packaging. Packaging, individual cigarettes or other tobacco products should carry no advertising or promotion, including design features that make products attractive."

The proposals provided in this consultation paper will contribute toward enabling Norway to fulfil the obligations of the FCTC.

### **3.2 Objectives and justification**

The overarching objective of the proposal to introduce standardised tobacco packaging is to reduce the number of children and youngsters who begin smoking and using snus, in order to protect them from the harmful effects of tobacco use. More specifically the objective is to make tobacco products less appealing by limiting the advertising effect of the packaging, increasing the impact of the mandatory health warnings, as well as minimising the risk that the packaging design gives misleading information about the harmful health effects of tobacco. It is assumed that the measure will also contribute toward a moderate reduction in the use of tobacco among adults by helping people to quit smoking and using snus, and by helping to prevent relapse among those who have quit. It will also have the effect of denormalising tobacco products and tobacco use.

The Ministry believes that this measure may help to prevent today's children and young people from becoming the next generation of tobacco-dependent adults. The measure would also contribute toward fulfilling the long-term vision of a tobacco-free society.

Research has shown that packaging design may give the false impression that tobacco products are less harmful to one's health than is actually the case, especially to young people. In the preamble of the new EU Directive, point 27 states that certain types of tobacco packaging may give the impression that the product purports benefits in terms of weight loss, sex appeal, social status, or qualities such as femininity, masculinity or elegance. The packaging is designed to make the use of tobacco appear more attractive and appealing, especially among young people, and reduces the impact of the health warnings. Furthermore, it is well known that the appearance of various brands may have some importance as identity markers. It is therefore the opinion of the Ministry that standardised appearance and design of tobacco packaging may be a useful and effective preventative measure, especially with regard to young people.

Most people who start smoking are minors, and research shows that they tend to underestimate the risk of becoming addicted to tobacco.<sup>23</sup> The appearance of tobacco packaging is an important factor in attracting young users. A number of tobacco products with an untraditional design have appeared on the market over the last few years. Tobacco packaging design serves as advertising, with the greatest impact on young people. Older, more established tobacco users rarely switch brands.

More than half of smokers began smoking before they turned 18. Despite extensive tobacco control measures in Norway since the 1970s, the total percentage of smokers and snus users in the 16 to 24 age bracket remains high. It is therefore necessary to implement further measures if the goal of a tobacco-free generation is to be realised.

The proposal will only have consequences for the tobacco industry, as it will limit their opportunity to display trademarks on their products. The measure will not affect adults' opportunity to purchase and use tobacco.

It is well-documented that tobacco advertising affects tobacco use. This is a fundamental tenet of the FCTC. The preamble states that its parties are "seriously concerned about the impact of all forms of advertising, promotion and sponsorship aimed at encouraging the use of tobacco products." In Article 13, no. 1 it is stated that the parties "recognize that a comprehensive ban on advertising, promotion and sponsorship would reduce the consumption of tobacco products."

Norway, as many other countries, has introduced a number of restrictions on marketing and sponsorship of tobacco, and has a near total ban on advertising, including a display ban at points of sale. Due to these strict regulations, promotion through the product packaging is the only remaining legal form of advertising. The tobacco industry has therefore invested large sums in the development of packaging design and brand imaging.

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<sup>23</sup> Lund and Rise (2002), *Gjennomgang av forskningslitteraturen om tiltak for å redusere røyking blant ungdom*, Directorate for Health and Social Affairs, IS-1037, p. 22-23.

The tobacco industry itself has stated that tobacco packaging represents the company's "billboard".<sup>24</sup> One UK study found a significant development in product innovation following the introduction of a ban on tobacco advertising and sponsorship.<sup>25</sup> During this period, a high number of innovative packaging designs began to appear, and many had advanced design and packaging elements.

The fact that packaging serves as advertising was also noted by the Directorate of Health in a report from 1 November 2006 regarding a tobacco display ban at points of sale. In this report, the Directorate referred to research which, with reference to previous internal documents from the American tobacco industry, revealed that tobacco packaging design is an integral part of the industry's marketing strategy, intended to serve two purposes: Packaging should attract attention in a shop display of tobacco, and it should communicate a message about image. In a later research report by Sirius, it was noted that packaging is a communication medium which has grown in importance, since an increasing number of countries are placing restrictions on ordinary tobacco advertising.<sup>26</sup> This is also the conclusion from several other international studies. The guidelines of Article 13 of the FCTC states that "packaging and product design features are important elements of advertising and promotion". Briefly summarised, the general opinion of the research literature is that tobacco packaging marked with a logo and the manufacturer's own design brand constitutes one of the last remaining influential channels by which tobacco manufacturers can reach consumers.<sup>27</sup>

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<sup>24</sup> Article in WIPO Magazine, February 2013, *Cigarettes will kill you: The High Court of Australia & plain packaging of tobacco products*: [http://www.wipo.int/wipo\\_magazine/en/2013/01/article\\_0005.html](http://www.wipo.int/wipo_magazine/en/2013/01/article_0005.html)

<sup>25</sup> Cancer Research UK (2012), *The packaging of tobacco products*: [http://www.cancerresearchuk.org/—prod\\_consump/groups/cr\\_common/@nre/@new/@pre/documents/generalcontent/cr\\_086687.pdf](http://www.cancerresearchuk.org/—prod_consump/groups/cr_common/@nre/@new/@pre/documents/generalcontent/cr_086687.pdf)

<sup>26</sup> Lund and Rise, *Kunnskapsgrunnlag for forslaget om et forbud mot synlig oppstilling av tobakksvarer*, Sirius-Skrifter 1/2008 (hereafter Lund & Rise 2008): [http://www.sirus.no/filestore/Import\\_vedlegg/siruskrifter1.08.pdf](http://www.sirus.no/filestore/Import_vedlegg/siruskrifter1.08.pdf)

<sup>27</sup> See Lavik and Scheffels, *Evaluering av forbud mot synlig oppstilling av tobakksvarer*, Report no. 2-2011, Sirius (hereafter Lavik & Scheffels, 2011); Cancer Council Victoria, Australia, *Plain packaging of cigarettes: a review of the evidence*, 2011, p. 6-10; Moodie and Hastings (2010), *Tobacco Packaging as promotion*: <http://tobaccocontrol.bmj.com/content/19/2/168.full>; Scollo and Freeman (2012), *Packaging as Promotion*: <http://tobaccocontrol.bmj.com/content/19/2/168.full>; Moodie et al, *Plain Tobacco Packaging: A Systematic Review* (hereafter Moodie 1): [http://phrc.lshtm.ac.uk/papers/PHRC\\_006\\_Final\\_Report.pdf](http://phrc.lshtm.ac.uk/papers/PHRC_006_Final_Report.pdf); as well as updates (hereafter Moodie 2): <http://www.stir.ac.uk/media/schools/management/documents/Plain%20Packaging%20Studies%20Update.pdf>; Chantler, *Standardised packaging of tobacco*, UK (hereafter Chantler): [http://www.kcl.ac.uk/health/10035-TSO-2901853-Chantler-Review-ACCESSIBLE.PDF?utm\\_source=rss&utm\\_medium=rss&utm\\_campaign=standardised-packaging-of-tobacco-report-of-the-independent-review-undertaken-by-sir-cyril-chantler-pdf](http://www.kcl.ac.uk/health/10035-TSO-2901853-Chantler-Review-ACCESSIBLE.PDF?utm_source=rss&utm_medium=rss&utm_campaign=standardised-packaging-of-tobacco-report-of-the-independent-review-undertaken-by-sir-cyril-chantler-pdf); Hammond, *Standardized packaging of tobacco products, Evidence Review*, Ireland: <http://health.gov.ie/wp-content/uploads/2013/12/2014-Ireland-Plain-Pack-Main-Report-Final-Report-July-26.pdf>

With the introduction of the display ban, tobacco packaging no longer has any advertising impact in retail outlets. After purchase, however, tobacco packaging is still visible, and continues to have an advertising effect while the product is being used. An Australian study showed that 81 % of ordinary cigarette packages were displayed in such a way that the brand was visible after purchase (in cafes, restaurants, etc.), so that the effect of advertising was significant also after the sale of the package.<sup>28</sup> A person who smokes a packet of 20 cigarettes per day is exposed to this packaging more than 7000 times a year.<sup>29</sup> Snus boxes are also very visible in social settings.

Children are repeatedly taught about the dangers and addictive qualities of tobacco products, that tobacco should never be used, and that it is illegal to sell tobacco products to children and youngsters under the age of 18. Yet children are often exposed to tobacco products with appealing packaging, colours and designs. Adults can more easily deal with these mixed messages due to the government's comprehensive health warnings, but children are not able to sort out mixed messages in the same manner. It is the Ministry's opinion that the measure clearly has the potential for reducing tobacco use.

### **3.3 Regulations in other countries**

The introduction of standardised tobacco packaging has currently been implemented in Australia, adopted in Ireland and United Kingdom, and considered introduced in France, New Zealand, Sweden and Finland among others.

#### *3.3.1 Australia*

Australia was the first country in the world to introduce mandatory standardised tobacco packaging, effective from 1 December 2012. Australia's goal is to reduce the prevalence of smoking to 10 % by 2018, and the measure is a means to achieve this goal. The measure is meant to encourage the population to quit smoking and reduce its use of tobacco, and to make it easier for people who are trying to quit or have quit using tobacco, as well as reduce the public's exposure to tobacco smoke. The specific purpose of the regulation of tobacco packaging, its appearance and design, is to reduce the appeal of tobacco products, especially for children and young people, as well as to increase the impact of health warnings, reduce the opportunity for tobacco packaging to provide misleading information about the harmful effects of tobacco use, and in the long term, along with other tobacco control measures, contribute toward reducing the number of tobacco users. The provisions of the law state that the measure also will contribute toward fulfilling Australia's commitments under the FCTC.

Australia has a long history of comprehensive tobacco control policy, including a ban on advertising, on display, and on smoking in public areas, in addition to comprehensive smoking cessation campaigns.

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<sup>28</sup> Wakefield et al, *The silent salesman: an observational study of personal tobacco pack display at outdoor café strips in Australia*, *Tob Control*. 2014 Jul;23(4):339-44: <http://www.ncbi.nlm.nih.gov/pubmed/23427292>

<sup>29</sup> Department of Health, England, Impact Assessment, 5.3.2012: [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/170569/dh\\_133576.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170569/dh_133576.pdf), see page 10.

Standardised tobacco packaging is a knowledge-based measure, and Australian authorities based the introduction of the measure on extensive studies.<sup>30</sup>

In summary, Australia found evidence to support the claim that standardised packaging led to more effective health warnings, minimised misconceptions about the risks associated with the various brands, and reduced the appeal associated with tobacco use. For further details on these studies and the effects of the measure, see point 3.4 below.

Shortly after the introduction of the measure, Australia was sued by several tobacco companies in domestic courts. The main issue of the case was whether the measure could be considered legitimate, based on the provisions of the country's constitution. The government won the case. Philip Morris Asia then brought a case before an arbitration court on 21 November 2011, based on a bilateral investment agreement with Hong Kong. The case has not yet been decided. Five countries have initiated dispute settlement cases against Australia in the WTO system. The tobacco industry is covering court costs for several of them. It is expected that the cases will be decided sometime between 2016 and 2017. Norway is a third party in these cases.

### 3.3.2 *United Kingdom*

The United Kingdom adopted primary legislation providing for the introduction of mandatory standardised tobacco packaging on 13 March 2014. Supplementary regulations for England were approved in the House of Commons on 11 March 2015.

The purpose of this measure is to prevent the use of tobacco by reducing the appeal of tobacco products to consumers, increasing the effectiveness of health warnings on the packaging of tobacco products, reducing the ability of tobacco packaging to mislead consumers about the harmful effects of smoking, and having a positive effect on smoking-related attitudes, beliefs, intentions and behaviours, particularly among children and young people. The measure only covers cigarettes and hand-rolling tobacco, since these products are the most prevalent among young people in England.

Two evidence reviews were carried out, along with one independent study of the effects of the measure. All three concluded that the measure is likely to have a positive effect on the population's health, especially with regard to children and young people.<sup>31</sup> In the conclusion of the final report it is stated:

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<sup>30</sup> Quit, Cancer Council Victoria, *Plain packaging of cigarettes: a review of the evidence*, April 2011: <http://www.cancervic.org.au/plainfacts/browse.asp?ContainerID=plainfacts-evidence>

<sup>31</sup> First knowledge review, Moodie 1: [http://phrc.lshtm.ac.uk/papers/PHRC\\_006\\_Final\\_Report.pdf](http://phrc.lshtm.ac.uk/papers/PHRC_006_Final_Report.pdf); Updated version of first knowledge review, Moodie 2: <http://www.stir.ac.uk/media/schools/management/documents/Plain%20Packaging%20Studies%20Update.pdf>; Chantler review: [http://www.kcl.ac.uk/health/10035-TSO-2901853-Chantler-Review-ACCESSIBLE.PDF?utm\\_source=rss&utm\\_medium=rss&utm\\_campaign=standardised-packaging-of-tobacco-report-of-the-independent-review-undertaken-by-sir-cyril-chantler-pdf](http://www.kcl.ac.uk/health/10035-TSO-2901853-Chantler-Review-ACCESSIBLE.PDF?utm_source=rss&utm_medium=rss&utm_campaign=standardised-packaging-of-tobacco-report-of-the-independent-review-undertaken-by-sir-cyril-chantler-pdf)

“In conclusion, research cannot prove conclusively that a single intervention such as standardised packaging of tobacco products will reduce smoking prevalence. For various reasons, as cited, it is not possible to carry out a randomised, controlled trial. Even if it was possible, it would be extremely difficult to control for all the various confounding factors which are known to affect smoking. However, after a careful review of all of the relevant evidence before me, I am satisfied *there is sufficient evidence derived from independent sources that the introduction of standardised packaging, as part of a comprehensive policy of tobacco control measures, would be very likely, over time, to contribute to a modest but important reduction in smoking prevalence, especially in children and young adults.* Given the dangers of smoking, the suffering that it causes, the highly addictive nature of nicotine, the fact that most smokers become addicted when they are children or young adults and the overall cost to society, the importance of such a reduction should not be underestimated.” (our italics).

### 3.3.3 Ireland

In 2013, Ireland adopted a strategy to reduce the prevalence of tobacco use to less than 5 % by 2025. One measure aimed at achieving this objective was the introduction of standardised tobacco packaging on 3 March 2015. Irish authorities specify that this measure is one of many intended to reduce the use of tobacco in the population. The purpose of the legislation is to reduce the appeal of tobacco products, increase the effect of health warnings, and minimise misconceptions about the risks of tobacco use. It is also noted that the legislation will contribute toward fulfilling Ireland’s obligations under the FCTC. The legislation applies to all tobacco products.

An Irish evidence review concludes that the measure is appropriate for achieving these objectives.<sup>32</sup> The review contains an analysis of studies from a number of disciplines, such as marketing directed toward young people, and the causal relationship between marketing and use of tobacco, health warnings, understanding of risks, consumer behaviour, choice of colour, and studies on the effect of the measure in Australia.

The report also indicates that Western countries are very similar in terms of the conditions that influence smoking uptake, patterns of use, as well as cessation. The tobacco industry’s practice with regard to the design and use of tobacco packaging as promotion is also similar across countries. Results of research on packaging from other Western nations may therefore reasonably be applied to Ireland. Findings from the various countries are consistent, and they support the conclusion that studies and results from other countries may be transferred to, and used as a foundation for the introduction of standardised tobacco packaging in Ireland. The measure is widely supported by the public. According to a European study from 2012, 81 % of the Irish population supported the proposal.<sup>33</sup>

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<sup>32</sup> Hammond (2014), *Standardized packaging of tobacco products – Evidence Review*: <http://health.gov.ie/wp-content/uploads/2013/12/2014-Ireland-Plain-Pack-Main-Report-Final-Report-July-26.pdf>

<sup>33</sup> [http://ec.europa.eu/health/tobacco/docs/eurobaro\\_attitudes\\_towards\\_tobacco\\_2012\\_en.pdf](http://ec.europa.eu/health/tobacco/docs/eurobaro_attitudes_towards_tobacco_2012_en.pdf)

### 3.3.4 New Zealand

In 2011, the government adopted the goal to make New Zealand a smoke-free nation by 2025. In 2012, a proposal to introduce standardised tobacco packaging was sent on public consultation.. With this proposal, New Zealand wished to establish regulations that were to a large extent aligned with the Australian legislation. A legislative proposal was presented to the parliament on 17 December 2013. The objective of the proposal was to reduce the appeal of tobacco products, particularly among children and young people, denormalise the social acceptance of tobacco products in the population, raise awareness and increase the impact of health warnings, and reduce misconceptions about health risks caused by tobacco packaging.

### 3.3.5 France

France presented a bill regarding standardised tobacco packaging to its parliament on 27 October 2014. The purpose of the legislation was to discourage the use of tobacco among children and young people.

### 3.3.6 Sweden

A Swedish public committee has been given the task of assessing the possible introduction of standardised tobacco packaging in Sweden. The committee report will be presented by 1 March 2016.<sup>34</sup>

### 3.3.7 Finland

Finland adopted a new tobacco strategy in 2014, where the long-term goal is to reduce the prevalence of tobacco use to less than 2 % by 2040. One of the measures in the strategy is the introduction of standardised tobacco packaging. The goal is to reduce the use of tobacco, particularly among children and young people, by reducing the appeal of tobacco products.

## 3.4 Research on the effects of standardised tobacco packaging

Preliminary findings from Australia indicate that the measure has been effective, and that in time it will help to ensure that tobacco use in younger generations is gradually phased out. All countries that have introduced or that have begun to introduce standardised tobacco packaging have carried out evidence reviews. Major reviews and reports carried out in Europe include the following:

- United Kingdom:
  - Moodie et.al. (2011), *Plain Tobacco Packaging: A systematic Review*, University of Stirling.<sup>35</sup>
  - Moodie et.al. (2013), *Plain Tobacco Packaging Research: An Update*, University of Stirling.<sup>36</sup>
  - Chantler (2014), *Standardised packaging of tobacco products. Report of the independent review undertaken by Sir Cyril Chantler.*<sup>37</sup>

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<sup>34</sup> Socialdepartementet, Kommittédirektiv 2015:16, Tilläggsdirektiv till Utredningen om genomförande av EU:s tobaksproduktdirektiv (p. 2014:16): [https://www.riksdagen.se/sv/Dokument-Lagar/Utredningar/Kommittedirektiv/Tillaggsdirektiv-till-Utrednin\\_H3B116/](https://www.riksdagen.se/sv/Dokument-Lagar/Utredningar/Kommittedirektiv/Tillaggsdirektiv-till-Utrednin_H3B116/)

<sup>35</sup> [http://phrc.lshtm.ac.uk/papers/PHRC\\_006\\_Final\\_Report.pdf](http://phrc.lshtm.ac.uk/papers/PHRC_006_Final_Report.pdf)

<sup>36</sup> <http://www.stir.ac.uk/media/schools/management/documents/Plain%20Packaging%20Studies%20Update.pdf>

- Ireland: Hammond (2014), *Standardised Packaging of Tobacco Products. Evidence Review*, University of Waterloo.<sup>38</sup>
- Norway: Sirius (2015), *Oppdatering av kunnskapsgrunnlaget om standardiserte tobakkspakninger* (Update of the knowledge base for standardised tobacco packaging)<sup>39</sup>

New Zealand and Australia have also carried out studies and evidence reviews.<sup>40,41</sup>

On 11 February 2015, Sirius presented an updated review on standardised tobacco packaging. Sirius reports that the extent of experimental studies of the measure have risen significantly since the previous knowledge review in 2012. The Sirius report confirms that the research is sufficient to draw conclusions on the effect of the measure, in terms of the level of recruitment of young people to tobacco.

Evidence reviews include descriptions and analyses of studies which apply to various aspects of standardised tobacco packaging, with particular focus on the three main goals of the measure. Several studies have also looked at the measure's effect on attitudes and behaviour related to tobacco use, as well as illicit trade of tobacco products.

#### *Less appealing tobacco packaging*

One of the key findings from all studies focusing on appeal and attractiveness is that standardised packaging was ranked as less appealing than equivalent packaging with logos or brand designs (ordinary packages). Standardised packaging was also perceived to contain a product with poorer quality and taste. The positive impression of smoker identity and personality characteristics associated with specific tobacco brands was weakened or erased completely with standardised packages. Another consistent finding was that non-smokers and younger people reacted more negatively to standardised packaging than smokers and older people.

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<sup>37</sup> [http://www.kcl.ac.uk/health/10035-TSO-2901853-Chantler-Review-ACCESSIBLE.PDF?utm\\_source=rss&utm\\_medium=rss&utm\\_campaign=standardised-packaging-of-tobacco-report-of-the-independent-review-undertaken-by-sir-cyril-chantler-pdf](http://www.kcl.ac.uk/health/10035-TSO-2901853-Chantler-Review-ACCESSIBLE.PDF?utm_source=rss&utm_medium=rss&utm_campaign=standardised-packaging-of-tobacco-report-of-the-independent-review-undertaken-by-sir-cyril-chantler-pdf)

<sup>38</sup> <http://health.gov.ie/wp-content/uploads/2014/06/2014-Ireland-Plain-Pack-Main-Report-Final-Report-July-26.pdf>

<sup>39</sup> <http://www.sirus.no/kunnskapsopsummering-om-standardiserte-tobakkspakninger/> (updated knowledge review from 2012)

<sup>40</sup> <http://www.health.govt.nz/publication/proposal-introduce-plain-packaging-tobacco-products-new-zealand>

<sup>41</sup> <http://www.health.gov.au/internet/preventativehealth/publishing.nsf/Content/home-1>

### *More visible health warnings*

Several of the studies have looked at the relationship between standardised packaging and perceptions of the prominence of health warnings on the packages. The majority of the studies concluded that the health warnings were more visible on standardised packages than on ordinary packages, and participants remembered the warnings more often after observing them on standardised packages. Results from qualitative studies on the topic indicate that standardised packages emphasise health warnings to a greater extent because these packages are less “busy”. There is less of a visual impression to interfere with the message, and drab packages are seen to emphasise the seriousness and credibility of the health warnings.

### *Reduced misconceptions about health risks*

Other studies examined perceptions regarding health risks and harmful effects. A review of these indicates that standardised packaging may reduce misconceptions about the general harmful effects of various brands of tobacco. Studies also found that the use of terms such as “gold” or “smooth” on standardised cigarette packets may potentially give the consumers the wrong impression of harmful effects, much as ordinary packages do.

### *Increase in negative attitudes toward tobacco use*

Other studies have focused on the possible impact of standardised packaging on smoking-related attitudes and smoking behaviour. These studies primarily found that standardised packaging appears to increase negative attitudes toward smoking, and that general perceptions of standardised packaging may help to discourage young people from starting smoking, and established smokers to quit. These perceptions were most common among non-smokers, those who smoke fewer cigarettes, and younger people.

### *Norwegian studies – with particular focus on snus*

Sirus has also carried out studies in Norway.<sup>42</sup> The main conclusion from these studies was that standardised packaging appeared less attractive, especially to young people. Furthermore, the health warnings on these packages had a stronger impact and received more attention. Most of the smokers did not believe that standardised tobacco packets would make them stop smoking, but they did think that standardised packages might prevent someone else from starting.

One study from Norway showed that standardised snus packs were perceived by young people as being less appealing.<sup>43</sup> The study indicates that the design of a snus pack is important for the product's appeal to young people between the ages of 14 and 18. Packaging design and snus brands communicate social identity, while design, colour and use of materials all influence young people's perception of the snus products. Brands had a clear social significance for young people, through their interactions with others. Brands also had a greater symbolic significance, since they were used to express social identity and affiliation. Participants described snus products on the market as identity markers, the reason being that the packages were so different. Packaging design was also important for young people's perception of health risks. Light-coloured tins with flavouring were perceived as less harmful than other brands. Other tins were perceived as containing something other than tobacco, especially the light-coloured or colourful tins with flavouring. These made people think of candy, cosmetics or chewing gum. Several of the participants mentioned that new products with smaller and thinner snus portions were especially appealing to young people. In summary, the study showed that packaging design for snus, like cigarettes, is important to young people, and it may represent identity markers and carry social significance when young people interact. Furthermore, packaging design and product development is important for the recruitment of young and new snus users.

### *Key findings from Australia*

A number of studies have been carried out in Australia following the introduction of the measure. Key findings include the following:

- Standardised packaging may have an impact on attitudes toward smoking.
- The measure does not appear to have had any negative impact on general sales and purchases in shops or on the preference for larger or smaller retail outlets. Neither do they appear to have had any impact on illicit trade.
- Smokers perceive standardised packaging as less attractive.

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<sup>42</sup> Scheffels & Sæbø (2013), [Perceptions of Plain and Branded Cigarette Packaging Among Norwegian Youth and Adults: A Focus Group Study](#), *Nicotine & Tobacco Research* 15(2): 450-456; Lund & Scheffels (2013), [Young smokers and non-smokers perceptions of typical users of plain vs. branded cigarette packs: a between-subjects experimental survey](#), *BMC Public Health* 13(1): 1005; Scheffels & Lund (2013), [The impact of cigarette branding and plain packaging on perceptions of product appeal and risk among young adults in Norway: A between-subjects experimental survey.](#), *BMJ Open* 3(12).

<sup>43</sup> Sirus (2015), [Oppdatering av kunnskapsgrunnlaget om standardiserte tobakspakninger](#)

- Cigarette packages have become less visible in public places – a 15 % decline in comparison with the period prior to the introduction of standardised packaging. This decline is sharper in places where young people tend to gather.
- There has been an increase in the number of people calling the quitline, and an increase in the number of those expressing an intent to quit.
- Support for standardised packaging among smokers rose from 28 % prior to introduction of the measure, to 49 % after the introduction of the measure.
- After the measure was introduced, there has also been a reduction in the percentage of smokers in Australia, from 15.1 % in 2010 to 12.8 % in 2013.<sup>44</sup> This is the largest decline since surveys began in 1991. The percentage of young people between the ages of 18 to 24 who reported that they had never smoked rose from 72 % in 2010 to 77 % in 2013.

The Ministry emphasises that the effects of the measure will primarily occur in the long term, particularly when it comes to decline in tobacco use. However, the abovementioned studies indicate that the measure has already been effective in Australia.<sup>45</sup>

### 3.4.1 Choice of colours

Several studies have looked at packaging colours and their impact on relevant outcomes. Results from these studies consistently show that darker colours are perceived as significantly less appealing.<sup>46</sup> A UK study found that brown packets were perceived as less appealing than white packets, and the former was also associated with the perception of more severe health risks.<sup>47</sup> Another UK study found that brown packs with a dull finish were perceived as containing a higher level of tar and greater health risks, and that this colour made the health warnings more visible.<sup>48</sup> Qualitative studies among young smokers in Scotland found that dark brown packs were perceived as less appealing than light brown and light grey packs in all focus groups.<sup>49</sup> In Australia, a number of studies concluded that darker colours were associated with higher risk, less appeal and judged to be more effective in discouraging tobacco use.<sup>50</sup> These studies are consistent with results from other research, including research carried out by the tobacco industry, which found that white and light colours are

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<sup>44</sup> Australian Department of Health website, Key facts and figures on tobacco sales, consumption and prevalence: <http://www.health.gov.au/internet/main/publishing.nsf/Content/tobacco-kff>

<sup>45</sup> Sirus (2015), *Oppdatering av kunnskapsgrunnlaget om standardiserte tobakkspakninger*

<sup>46</sup> Centre for Health Promotion (1993). *Effects of plain packaging on the image of tobacco products among youth*. Centre for Health Promotion, University of Toronto.

<sup>47</sup> Hammond et al (2009), *Cigarette pack design and perceptions of risk among UK adults and youth*. *Eur J Public Health* 2009; 6:631-637.

<sup>48</sup> Hammond et al (2013), *The perceptions of UK youth of branded and standardized, 'plain' cigarette packaging*. *Eur J Public Health* 2013; 1-7.

<sup>49</sup> Moodie and Ford (2011), *Young adult smokers' perceptions of cigarette pack innovation, pack colour and plain packaging*. *Australasian Marketing Journal*. 2011; 3:174-180.

<sup>50</sup> Parr et al, *Market research on determine effective plain packaging of tobacco products – Study 2: Consumer perceptions of plain pack colour*, Australian Government Department of Health and Ageing, 2011; Parr et al, *Market research on determine effective plain packaging of tobacco products – Study 4: Consumer perceptions of plain pack colour with brand elements*, Australian Government Department of Health and Ageing, 2011; Parr et al, *Market research on determine effective plain packaging of tobacco products – Study 5: Face-to-face: consumer appraisal of plain packs with new health warnings using prototype packs*, Australian Government Department of Health and Ageing, 2011.

perceived as “healthier” and “cleaner”.<sup>51</sup> Since the purpose of the measure is to reduce misconceptions about risks, and to make tobacco products less appealing, it is the opinion of the Ministry that dark colours on tobacco packaging would contribute to this objective.

### **3.5 Regulation regarding smokeless tobacco**

The Ministry proposes that the legislation on standardisation should apply to all tobacco products. Even if smokeless tobacco, especially snus, is not as harmful to health as combustible tobacco, the Ministry would like to emphasise that use of smokeless tobacco also presents serious health risks, see more detailed information in point 2.2 above. In order to protect younger generations from the adverse health effects of tobacco, the Ministry believes that the proposals described in this consultation paper should apply to all tobacco products.

If only combustible tobacco were to be included in this measure, it may be perceived as though there are no health risks associated with the use of smokeless tobacco. It would be unfortunate if children and young people were to get this impression.

The Ministry is particularly concerned about the increased use of snus among young people, and it is the Ministry’s stated objective to stop this development. A number of tobacco products with untraditional designs have appeared on the market over the last few years. This is particularly the case in the snus market. In 2014, the Directorate of Health received reports about the Norwegian tobacco market from tobacco importers. This information covered what tobacco brands were sold in Norway, as well as their shape, weight, size and a description of sales volume for each of the products. This survey indicates that there are 97 brands of snus on the Norwegian market. In comparison, there are a reported 42 brands of cigarettes. Among the various types of snus, there are 11 brands of loose-weight snus and 86 brands with portion bags, including 77 brands with normal portion bags and 9 with mini-portions. Many of the snus tins have design and colours that are meant to make the product more attractive. In 2013, the Norwegian Design Council gave one snus brand an award for “best design” for their snus pack in the “packaging” category. This tin was designed with younger users in mind. In their impact assessment of the new tobacco product directive, the European Commission states that there has been a significant development of the snus segment.<sup>52</sup> In 2002, Swedish Match had 22 types of snus, in 2008 this number had risen to 180.

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<sup>51</sup> U.S. Department of Health and Human Services (2012), *Preventing tobacco use among youth and young adults: A report of the Surgeon General*, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, Atlanta, GA;

<sup>52</sup> [http://ec.europa.eu/health/tobacco/docs/com\\_2012\\_788\\_ia\\_en.pdf](http://ec.europa.eu/health/tobacco/docs/com_2012_788_ia_en.pdf) , see pages 10 and 11

One of the objectives of the proposal for standardised tobacco packaging is to facilitate the denormalisation of tobacco products and tobacco use. In November 2014, Sirus published a report about Norwegian newspaper coverage on the topic of snus from 2002 to 2011.<sup>53</sup> The report notes the following: “The content of the newspaper articles illustrates the tendency toward a normalisation of snus in Norwegian society. Even though several of the articles had a neutral or even negative tone, they may still play a significant role in the promotion of snus in a country such as Norway, where tobacco advertising is prohibited.” It is the opinion of the Ministry that the proposed regulations should also apply to snus.

The rise in snus use among young woman has also led to a growing problem with the use of snus during pregnancy. The adverse health effects of snus use among members of this group is one of the topics highlighted by the Institute for Public Health in their health risk assessment from 2014.

Although snus involves fewer health risks than combustible tobacco, the Ministry is of the opinion that the health risks of snus use, especially among young people, should not primarily be compared with the health risks of smoking, but rather with the level of risk of using no tobacco. Information about tobacco products and the various health risks should be supplied through channels other than the introduction of differentiated regulations with regard to standardised tobacco packaging.

Since the proposed regulations do not prohibit the sale of tobacco, various tobacco products will still be available on the market. Tobacco customers will continue to have the opportunity to choose whatever tobacco product they wish, and are free to consider the risks associated with their choices. The Ministry is of the opinion that arguments for differentiating between products are not sufficiently strong, and propose that the legislation should apply to all tobacco products. This is also in accordance with the FCTC, which states that parties must implement measures to discourage people from starting to use tobacco, to encourage and assist people in quitting, and to reduce the consumption of all types of tobacco.

To ensure effective implementation and supervision of the proposed regulation, it is important that it should apply to all tobacco products. Uniform regulation will also facilitate supervision, avoiding problems of distinguishing between, for instance, cigarettes, cigars and cigarillos, and other tobacco products.

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<sup>53</sup> Sæbø and Tokle (2014), *Norske avisers dekning av snus 2002–2011 – En innholdsanalyse*, Sirus report no. 2/2014: <http://www.sirus.no/wp-content/uploads/2014/12/sirusrap.2.14.pdf>

### 3.6 Public opinion

In December 2014 and January 2015, Sirus carried out an opinion survey commissioned by the Ministry, focusing on public support for various tobacco regulations.<sup>54</sup> As indicated by the survey, about one-third of the population supports standardised tobacco packaging (37 % for combustible tobacco and 33 % for snus). Opposition is greatest among tobacco users. It is important to remember that the survey was carried out prior to the public proposal of the measure. The reasoning behind the measure had not yet been debated in public and was therefore not well known.

Furthermore, the survey indicates that many people agree that the design of the tobacco packets have most likely been developed for the purpose of appealing to young people. This applies more to snus packs than to cigarette packs (37 % for cigarettes and 49 % for snus). Many people agree with the claim that the tobacco industry attempts to circumvent the advertising ban by using product placement. Nearly half of the population believes this to be the case (49 %).

Experience has shown that support for tobacco control policies tends to increase over time. In 2003, before the smoke-free legislation in bars and restaurants was introduced, only 23 % of daily smokers supported the initiative. This support rose to 69 % by 2010. Public support for the measure has now reached 90 %. In 2010, just after the display ban was introduced, 50 % of the public supported the display ban, including 22 % of daily smokers. By 2014 this support had risen to 67 % of the public, including 36 % of daily smokers.

Opinion polls from England indicate that support for standardised tobacco packaging has increased from 42 % in 2008 to 72 % by 2015.<sup>55,56</sup>

In Australia, 28 % of smokers supported the initiative before the law was passed, and two years later support had risen to 49 %.<sup>57</sup>

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<sup>54</sup> Sirus, *Befolkningens oppslutning om eksisterende og potensielle tobakkspolitiske reguleringer, med særlig vekt på tiltak for nøytral innpakking*, report to the Ministry of Health and Care Services, 3 February 2015. The survey was carried out by IPSOS MMI, sample size 5543 people, ages 15–90.

<sup>55</sup> ICM survey commissioned by the UK Department of Health, carried out in October 2008. Sample size was 2606 people over the age of 18, in England. They were asked: 'if there is evidence that each of the following will discourage young people from starting to smoke, to what extent would you support or oppose each of the following: Selling cigarettes in plain packets with no logos or colours'.

<sup>56</sup> YouGov survey, commissioned by the Cancer Research UK, utført januar 2015. Utvalgsstørrelse 1834 personer over 18 år; [https://d25d2506sfb94s.cloudfront.net/cumulus/uploads/document/w3wqzsegsk/CancerResearchResults\\_150114\\_smoking\\_Website.pdf](https://d25d2506sfb94s.cloudfront.net/cumulus/uploads/document/w3wqzsegsk/CancerResearchResults_150114_smoking_Website.pdf)

<sup>57</sup> Swift et al, *Australian smokers' support for plain or standardised packs before and after implementation: findings from the ITC Four Country Survey*, Tob Control doi:10.1136/tobaccocontrol-2014-051880: <http://tobaccocontrol.bmj.com/content/early/2014/10/27/tobaccocontrol-2014-051880>

### **3.7 Norway's international legal obligations in the area of trade law, trademark and design law, the Norwegian Constitution and the ECHR**

#### *3.7.1 EEA and EU law*

The EU Tobacco Products Directive 2014/40/EU does not regulate standardised tobacco packaging directly, but Article 24 (2), cf. preamble point 53, specifies that the Directive does not prevent member states from introducing such a measure where it is justified on grounds of public health, is proportionate with regard to the objective, and does not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. Questions have been raised regarding the interpretation of the Article 24 (2), but it is the opinion of the Ministry that the Directive does not restrict the introduction of national legislation on standardised tobacco packaging. The legality hinges on the health impacts of the measure, specifically whether or not it can be justified on grounds of public health and if it is proportionate to the objective.

These conditions mentioned in Article 24 (2) must be understood in light of the principle of free movement of goods, and the restrictions on movement of goods that may be appropriate or necessary in the interest of public health, according to Articles 11 and 13 of the EEA Agreement.

The EEA Agreement includes prohibitions on measures that prevent or restrict free movement of goods. The introduction of standardised tobacco packaging and tobacco products constitutes a product requirement, and the Ministry considers this proposal to fall under Article 11 of the EEA Agreement, which prohibits quantitative restrictions on import and all measures having equivalent effect.

The question is then whether the measure is legitimate according to Article 13 of the EEA Agreement. The purpose of standardised tobacco packaging is to make all tobacco products less appealing to young people, to increase the impact of health warnings and to denormalise the use of tobacco. It is therefore justified on grounds of public health, which is a legitimate objective under Article 13. The measure must in addition be considered both proportionate and necessary in order to achieve the established objectives.

The Ministry finds that the measure is appropriate for reducing the adverse health effects caused by the use of tobacco, especially by reducing the number of young people recruited into tobacco use. The objective of standardised tobacco packaging is to make tobacco products less appealing by limiting the advertising effects, increasing the impact of health warnings, and by minimising the risk that package designs lead to misconceptions about the risks of tobacco use. It is assumed that the measure will have a moderate effect on smoking among adults, and that the measure will contribute toward denormalising the use of tobacco and tobacco products. The Ministry refers to the evidence base for the proposal, discussed in point 3.4 above. In light of this, the Ministry finds that the measure is appropriate for achieving these objectives.

The next question is whether standardised tobacco packaging is necessary in order to reach the objectives, or whether they can be achieved just as effectively with less restrictive measures.

In this regard, it must be emphasised that Norway for decades has had a particularly high level of protection in the area of tobacco control, with comprehensive tobacco control legislation, in addition to other measures, but so far there has been very little focus on the regulation of the tobacco packaging or products themselves. The Tobacco Control Act states that the long-term goal for Norway's tobacco policies is to achieve a tobacco-free society, cf. Section 1.

The Ministry finds that the proposal for standardised tobacco packaging is an important element in a comprehensive set of measures whereby the objective is to reduce and prevent the harmful effects of tobacco use. This proposal must not be viewed as an alternative to other tobacco control measures, but rather as a supplement to these. The measures are meant to complement one another and achieve long term objectives over time.

A key objective for the government is to ensure that as few young people as possible begin smoking or using snus, thereby preventing future tobacco addiction. This measure is specifically targeted at tobacco packaging as a means of advertising after the packet has been sold, cf. how often cigarette packets are visible after sale, in the second to the last paragraph in point 3.2 above. Reducing the advertising effect of tobacco packaging will be a central issue, with regard to the absence of advertising and as a part of a denormalisation process. This will also increase the impact of health warnings. The Ministry finds that there are no other measures which would have an equivalent impact on all the objectives that justify standardised tobacco packaging.

### *3.7.2 WTO Agreements*

The World Trade Organization (WTO) is the only global organisation that regulates trade between nations. Norway has been a member of the organisation since its establishment in 1995, and membership involves an obligation to follow contractual obligations regarding trade across national borders. These obligations come in addition to the obligation to ensure free movement of goods within the EEA. A breach of these regulations may lead to countermeasures from other members through a dispute settlement body.

The WTO agreements cover goods, services and intellectual property. The provisions to be considered with regard to standardised tobacco packaging include the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)<sup>58</sup> and the Agreement in Technical Barriers to Trade (TBT)<sup>59</sup>. Five countries (Cuba, the Dominican Republic, Indonesia, Honduras and Ukraine) have brought complaints against Australia's plain packaging measure before the WTO's dispute settlement body, citing breach of various provisions in the WTO agreements. Norway is a third party in these cases.

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<sup>58</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS): [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips\\_01\\_e.htm](http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm).

<sup>59</sup> Agreement on Technical Barriers to Trade (TBT): [http://www.wto.org/english/docs\\_e/legal\\_e/17-tbt\\_e.htm](http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm).

Following an assessment of the relevant provisions, the Ministry finds that the proposal is not in violation of any WTO agreements.

### 3.7.3 *Trademark and design legislation*

The proposal for standardised tobacco packaging will have an impact on tobacco manufacturers' opportunities to use individual trademarks, logos, symbols, and other pictures or colours on their product packaging. This may be an aspect of manufacturers' intellectual property, and the proposal must therefore be assessed in light of Norway's obligations in the area of trademarks and design.

One of the primary objections to the introduction of standardised tobacco packaging has been that it interferes with the tobacco manufacturers' rights to use their trademarks or designs on the packaging of the tobacco products. This type of argumentation presupposes that trademark and design law grant the right holders a positive right to use their trademarks or designs. Another objection has been that standardised tobacco packaging may weaken the key objective of using trademarks as a guarantee for a product's commercial origin (the so-called "essential function").

In Norway, trademarks are regulated in the Trademarks Act of 26 March 2010, no. 8. Section 1 defines a trademark right as an "exclusive right to use a trademark as a distinctive sign for goods or services in an industrial or commercial undertaking". The Trademarks Act implements the Trademark Directive 2008/95/EC. Article 5 of the Directive, which is implemented in Section 4 of the Trademarks Act, grants the trademark owner the exclusive right to prevent third parties from using a sign which is identical to or that might be confused with the trademark. This provision grants the trademark owner a so-called negative right, in the sense that he on certain conditions can prohibit others from carrying out certain actions which may infringe the trademark right. The Ministry finds it clear that the trademark owner thus has a civil right to be the *only* one to use the trademark, and not a positive right to use the mark in any desired circumstance.

Article 5, Section 1 of the Trademarks Directive and Section 4 of the Trademarks Act are parallel to Article 16, No. 1 of TRIPS. According to these provisions, the trademark owner's rights are limited to a negative right. The Ministry therefore finds that neither the Trademarks Directive nor TRIPS grants the trademark owner a positive right which may be infringed by the introduction of national regulations on standardised tobacco packaging.

As for design rights, they are in Norway regulated by the Designs Act of 14 March 2003 No. 15, which also implements the Design Directive 98/71/EC. Article 12 of the directive, which is implemented in Section 9 of the Designs Act states that a design right entails that no third party is permitted to use the design without the permission of the right holder. A right to a design, similar to the right to a trademark, is a civil prohibitory right: the right holder can deny others the right to use his design in specific ways. The rights secured by a designer according to Article 26 of TRIPS, is also limited to the right to prevent third parties from using the design, making it a negative right.

Even if national regulations on standardised tobacco packaging do not have a direct impact on trademark owners' rights as a result of trademark registration, the measure may undermine the primary purpose of the use of a trademark: to guarantee that the consumer will know the product's commercial origins.

In this case, this undermining would follow from the possible risk that standardised tobacco packaging may create confusion, as the standardisation of both packaging and display of trademarks and brands would make it more difficult to distinguish between products. This may then lead to a breach of the essential function, cf. also Article 5, no. 1b of the Trademarks Directive and Section 4, first paragraph, litra b of the Trademarks Act, whereby it is stated that a trademark owner is entitled to prohibit the use of any sign that is identical or similar to the trademark on similar goods or services if there exists a likelihood of confusion.

Standardised tobacco packaging implies that the origin of the goods will no longer be displayed with a trademark. Nevertheless, the consumer will still be informed of the product's origin because this information will be printed on the package. As long as the manufacturer and product name is on the packaging, it will not be difficult to see from where the various products originate.

Article I 10bis of the Paris Convention has a similar rule, where the purpose is to prevent unfair competition between business enterprises. The proposed regulations will apply on equal terms to everyone, and will therefore cause no imbalance in the tobacco manufacturers' opportunities for competition, or in the relationships between competitors.

In light of this, it is the opinion of the Ministry that the potential risk of confusion as a result of the manufacturers being unable to use their trademark on the tobacco packaging is not of such a nature that the regulations raise questions regarding the purpose of trademark law or the essential function, nor regarding the ban on unfair competition between business enterprises.

#### *3.7.4 The Norwegian Constitution and the ECHR*

The Ministry has also assessed the proposal for standardised tobacco packaging in relation to the Norwegian Constitution and the European Convention on Human Rights (ECHR).

Section 97 of the Constitution ensures a certain level of protection against a retroactive effect of new legislation on established rights. It could be asserted that standardised tobacco packaging interferes with the tobacco manufacturers' established trademark rights. A right holder must however in principle accept interference by the legislative branch. The Supreme Court has declared that it is only in cases where interference with established rights has a "clearly unreasonable or unfair" effect that interference is prohibited under Section 97 of the Constitution, cf. Case 1996 p. 1415 *Borthen*. Constitutional protection hinges on a balancing of the consideration for those who are affected by the interference and those societal considerations underlying the measure. It must also be considered whether the measure is necessary and justifiable in protecting the relevant interests of society. The proposal for standardised tobacco packaging is grounded in the need to protect particularly strong and legitimate societal interests of protecting public health. These provisions are introduced in an area with already extensive regulations and where further measures must be expected, and where the expectations of right holders and consideration for their needs is therefore somewhat restricted. The Ministry finds that the possible retroactive aspect of the proposed legislation is not "clearly unreasonable or unfair" and therefore not in conflict with Section 97 of the Constitution.

Section 105 of the Constitution states that a person who is forced to surrender his "property" may claim "full compensation" for the financial loss suffered as a consequence of this surrender. It is clear that the imposition of standardised tobacco packaging does not constitute a surrender of property as described in Section 105 of the Constitution, since it only entails governmental *limitations* on the use of the trademark.

There may be an issue of whether intellectual property rights fall within the concept of "property" in Article 1 Protocol 1 of the ECHR, which provides protection for property rights. The Ministry finds that should the proposed limitations in the use of trademarks be viewed as interference under the provisions, it would still be deemed lawful since it has a legitimate objective and fulfils the requirements of proportionality, as it does not involve a disproportionate intervention.

Section 100 of the Constitution states the right to freedom of expression. The Ministry has assessed whether standardised tobacco packaging would conflict with this provision, since it restricts tobacco manufacturers' right to freedom of commercial expression.

Commercial expression is considered falling outside the core area of the provision on freedom of expression. In practice, the legislators may limit commercial expression if there are compelling societal interests which make this necessary. This includes the existing prohibitions on tobacco and alcohol advertising. The underlying premise is that commercial expression in the form of advertising for goods and services which have been viewed as harmful to society, does not deserve the same constitutional protection as political, religious, moral and cultural expression.

Section 100 of the Constitution, second and third paragraph, states that an assessment of the various interests is essential. The purpose of the interference must be able to justify the interference. The interests of the tobacco industry in advertising their products cannot be considered as important as the objective of reducing the use of tobacco among young people, thereby preventing adverse health effects from tobacco use. In this assessment, consideration for public health weighs more heavily than consideration for the interests of the industry in increasing its revenue from an exceptionally harmful product. The Ministry therefore finds that standardised tobacco packaging does not conflict with Section 100 of the Constitution. A similar assessment will apply under Article 10, no. 2 of the ECHR.

### **3.8 The Ministry's proposals**

The Ministry proposes the introduction of standardised tobacco packaging, as well as other changes to labelling and design of tobacco packets, tobacco products, surrogate tobacco products and smoking accessories. These proposals are grounded in the necessity to discourage the use of tobacco, first and foremost among young people, by making tobacco products less appealing.

The Ministry finds it unacceptable that such a high number of children and young people begin using tobacco. If we are to achieve our goal of a tobacco-free generation, and in the long term, a tobacco-free society, it is absolutely essential to limit the appeal of tobacco products to children and young people.

The Ministry finds it appropriate that the primary legislation and regulations to a large extent are aligned to the regulation in the United Kingdom and Ireland. The Ministry asks for input on the suggested legislation. The Ministry has evaluated the extensive consumer surveys which formed the basis for the colour choice for the tobacco packaging in Australia (Pantone 448 C), and finds that there is sufficient documentation to indicate that the chosen colour will contribute toward achieving the established objectives. We therefore propose that this same colour be used in Norway. England and Ireland have also chosen this colour.

A new provision is proposed in the Tobacco Control Act Section 30, first paragraph, while the more detailed regulations are proposed to be included in the Labelling Regulations. Section 30 of the Act would provide a legal basis for the standardisation of tobacco packaging and tobacco products with regard to colour, shape, size, material, labelling, opening mechanisms and other elements of design. The Ministry proposes that the new provision should apply to all tobacco products. There are important tobacco control policy reasons for this and it is essential if we are to achieve the long-term objective of a tobacco-free society.

Recommendations on standardised tobacco packaging in the FCTC Article 11 and 13 guidelines also apply to all tobacco products. The draft regulations will also apply to tobacco products in any sales area, including tax-free sales and specialised tobacco shops.

It is also proposed pursuant to Article 30, first paragraph, last sentence, a statutory authority for the Ministry to introduce regulations on the standardisation of labelling and packaging for tobacco surrogates and smoking accessories, including herbal cigarettes, filters, and casings for use with hand-rolling tobacco. Regulations are not proposed for tobacco surrogates at this time, since there is a need for further evaluations before such regulation is proposed.

It is proposed that the existing Section 30, second and third paragraph, should be repealed. The provision includes the ban on tobacco labelling which suggest that one product may be less hazardous than another, as well as the prohibition on providing information about health risks by the producer. The Ministry finds these provisions to be superfluous as a result of the new standardisation regulations. The existing second paragraph is replaced by the Labelling Regulations draft Section 24, first paragraph, litra b.

It is furthermore proposed that the Labelling Regulations Section 9, second and third point, regarding an exception to mandatory labelling and standardisation for duty-free import quota, travel baggage and gifts be moved to the Tobacco Control Act Section 30, new third paragraph. This is purely a technical alteration.

The new draft provisions of the Labelling Regulations contain detailed specifications on permitted colour and finish for packaging of all tobacco products, as well as the regulation of surfaces, linings, packing material, inserts, tab and seal, barcodes, calibration marks and packaging elements that change after sale, see Chapter IV. Furthermore, specific requirements are proposed for the use of material, size, shape and opening mechanisms for certain tobacco packets, see Chapter V, as well as regulations for the permitted text for brand name and variant name as well as text which gives details about the producer, see Chapter VI.

Regulation on the labelling of the content and weight of tobacco packaging is further proposed in chapter VII, and certain tobacco products are to be standardised to a certain extent in terms of paper, colour and labelling of brand and variant name, cf. the draft Labelling Regulations chapter VIII. Text stating the brand and variant name on cigarettes is permitted in the UK but not in Australia. The Ministry has proposed the same regulations as in the UK, but asks for feedback on the issue.

The Ministry further proposes implementation of two of the provisions in the new Tobacco Products Directive 2014/40/EU (hereafter TPD), as these are closely linked to the regulation of standardised tobacco packaging. TPD Article 13 covers certain aspects of product presentation and a ban on misleading elements and it is proposed to implement this article in draft Section 24 of the Labelling Regulations. Research indicates that tobacco products or their packaging may mislead consumers, particularly young people, to think that some products are less harmful. This is the case, for instance, with the use of certain terms or features, including ‘low-tar’, ‘light’, ‘mild’, ‘natural’, ‘organic’, ‘without additives’ or ‘slim’, or with the use of certain names, images, and signs. Other misleading elements might include inserts or other additional material such as adhesive stickers, scratch-offs and sleeves, or the shape of the tobacco product itself. The Directive also states that certain packaging may also mislead consumers by giving the impression that the product provides benefits such as weight loss, sex appeal, social status, social life or qualities such as femininity, masculinity or elegance. Such design is intended to make tobacco use appear more attractive and appealing, especially to young people, and reduces the impact of the health warnings.

The Ministry proposes to repeal the current Section 6 in the Tobacco Advertising Regulations. This provision involves a ban on untraditional design or appearance of tobacco packaging and is considered superfluous. The same applies to the Labelling Regulations Section 17 concerning the ban on misleading product descriptions, which is a repetition of the Tobacco Control Act Section 30 Paragraph 3. It is furthermore proposed to repeal Section 20 of the Labelling Regulations, regarding permission for the Directorate of Health to grant dispensations from the regulations. As far as the Ministry is aware, this provision has never been used, and since many of the regulatory requirements are based on the TPD, the Ministry does not consider such a dispensation provision appropriate.

TPD Article 14 regulates the appearance and content of unit packets of cigarettes and hand-rolled tobacco, and determines that cigarette packets shall have a cuboid shape and shall contain at least 20 cigarettes, and also specifies the material and opening mechanism of the packet. The ban on cigarette packets that contain less than 20 cigarettes is currently regulated by the Tobacco Control Act Section 33 Paragraph 1, but it is proposed that this be moved to the Labelling Regulations draft Section 33 Paragraph 1. This is a purely technical amendment. It is further proposed that the requirements concerning material, shape and opening mechanism for cigarettes is implemented in the Labelling Regulations draft Section 26. TPD Article 14 also regulates shape and minimum weight for unit packets of hand-rolled tobacco. This is proposed implemented in the Labelling Regulations draft Section 27 Paragraph 1 (shape and size) and draft Section 33 Paragraph 2 (minimum weight).

Furthermore, TPD Article 9, no. 3, third paragraph concerning the minimum size of the lateral surfaces for shoulder boxes with a hinged lid is proposed implemented in the Labelling Regulations draft Section 26 Paragraph 3, and for hand-rolled tobacco in draft Section 27 Paragraph 2. The Ministry will return with a separate consultation paper in 2015 on the implementation of the other parts of the TPD.

The Ministry proposes that the snus tins shall be standardised in terms of shape and material, cf. the draft regulations Section 28. A number of snus products with untraditional design have been put on the market in recent years, which has contributed to an increased appeal among young people. The Ministry has therefore determined that standardised packaging is particularly essential for these products. The Ministry proposes that snus tins shall have a uniform, flat lid, which means it will no longer be permitted to place a lid on top of the snus tin lid, or include other design elements intended to increase the appeal to young people.

There are also snus boxes and snus portion bags in various sizes and types, including slim, long, mini, max, pre-baked etc. We request input on whether there is a need for further standardisation of the snus tins, as well as the size of the snus portions. We also request input on whether there is a need to regulate the boxes further, for instance, whether straight edges should be mandatory.

We also request input on whether other types of tobacco should be standardised in terms of shape and material, and if so, in what manner, including cigarillos, cigar tubes, pipe tobacco, chewing tobacco, dry snus and other smokeless tobacco. We also request input on whether cigars should be requested to be sold in cigar tubes if they are sold individually, cf. the draft regulations Section 33 Paragraph 3.

Regulations on the labelling of the number of units in cigarette packages, cigarillos and cigars is further proposed in the draft regulations Section 34, as well as labelling of weight in grams and content for hand-rolled tobacco, snus, chewing tobacco and pipe tobacco in draft Section 35, including the labelling on packaging that describes the tobacco type, e.g. “snus” and “hand rolled tobacco”. The Ministry asks for input on the potential need for other types of labelling, e.g. “bulk snus”, “portion snus”, “mini portion”, “dry snus”, “best before”, “keep refrigerated” etc. We also ask for input on whether there are other types of tobacco that should be regulated similarly.

The Ministry considers that a transitional period of one year from entry into force will allow the tobacco industry sufficient time to adapt to the new requirements. In the United Kingdom and Ireland, the proposed entry into force is 20 May 2016 with a transitional period from 20 May 2016 to 20 May 2017 to sell out tobacco products that are labelled in accordance with current legislation. The Ministry considers it advantageous if the standardisation provisions enter into force at the same time as legislation to implement the other parts of the TPD. The Ministry requests input on the transitional period.

The Ministry is of the opinion that the proposals are not in violation of Norway’s obligations under EEA/EU law or the WTO agreements. Since the purpose of the proposal is to reduce tobacco prevalence, the Ministry finds the proposal to be in accordance with our legal obligations under the various trade agreements.

### **3.9 Supervision and sanctions**

Currently, the Directorate of Health supervises compliance with the ban on advertising and the rules concerning labelling, cf. the Tobacco Control Act Section 35. The Ministry proposes that the Directorate of Health should continue this general supervisory task in relation to the new provisions on standardised packaging. However, the Ministry is working on proposals for a new municipal licencing system for the sale of tobacco products. It would therefore be appropriate to grant municipalities a local supervisory authority to ensure compliance with packaging provisions. The Ministry will return with more detailed information on this question in a future consultation.

The Directorate has a legal basis in Section 36 of the Tobacco Control Act to impose correctional sanctions and establish compulsory fines in the event of breaches of *inter alia* the advertising ban and the labelling provisions. Similar sanctions may be imposed in the event of breaches of the standardised packaging requirements.

### **3.10 Authority for seizure and destruction**

The Tobacco Control Act currently lacks the authority for confiscation and destruction of illegally imported tobacco products etc.

In the event of illegal import, the customs authorities currently have two optional procedures. One is confiscation and reporting to the police in accordance with the Customs Act Section 16-13, which gives customs a legal basis to confiscate goods that may be subject to seizure, but only when there are reasonable grounds to suspect a criminal violation of the Customs Act with regulations. The other is a return of the goods to the country of origin. The first option is cumbersome and demands significant resources, and often results in the case being dropped by the police. The other option is procedurally simple, but result in the goods being returned to the sender, who can subsequently re-send the goods to the buyer or to other buyers in Norway. Confiscation and destruction will prevent goods from being illegally imported to Norway a second time.

On this basis, the Ministry proposes a new provision in the Tobacco Control Act Section 41A with a legal basis for confiscation and destruction of illegally imported tobacco products, smoking accessories and tobacco surrogates, which would not require reporting to the police. This would be an administrative alternative to reporting to the police and confiscation according to the Customs Act Section 16-13. A legal basis in the Tobacco Control Act for the confiscation and destruction of such goods, without requiring the involvement of the police, would make it significantly easier for customs to ensure that these goods are taken out of circulation.

Confiscation and destruction will occur in accordance with the Public Administration Act's provisions. The legal requirement for prior notice, reporting and disclosure obligations, right of access, requirement for written and justified decisions, reversal of complaints and procedural costs will apply as usual. An exception is proposed for cases in which the importer does not respond to the notice that the goods may be confiscated and destroyed, whereby exceptions to the requirements could be made regarding written, justified individual decisions, as well as the requirement of informing the party about the decision.

Subsequent to the proposal for a new Section 41A Paragraph 4, the King may issue regulations concerning withholding, confiscation and destruction of illegally imported tobacco products etc. In such regulations, concrete deadlines for responding to the prior notice may be established. According to the last paragraph of the provision, the King may issue exceptions from the right of appeal concerning decisions made pursuant to this provision. The legal basis may be utilised in the event of a particularly high volume of complaints. The detailed scope for the exception must be established based on the inconvenience of a decision of confiscation and destruction to the private party.

## **4. ARTICLE 5.3 OF THE FRAMEWORK CONVENTION ON TOBACCO CONTROL**

### **4.1 Background**

Norway is a party to the World Health Organisation's Framework Convention on Tobacco Control (FCTC). The Convention is a knowledge-based, legally binding international agreement and currently has 180 State Parties. A fundamental provision of the FCTC is Article 5.3, which states that parties must protect tobacco policies from commercial and other vested interests of the tobacco industry. The tobacco industry is in an exceptional position, as no other industries are regulated in this manner.

The basis for this exceptional regulation is the vast documentation that shows that the tobacco industry has for years attempted – and often succeeded – in undermining tobacco control efforts of both national authorities and the WHO.

In the preamble to the FCTC, the Parties recognise “the need to be alert to any efforts by the tobacco industry to undermine or subvert tobacco control efforts and the need to be informed of activities of the tobacco industry that have a negative impact on tobacco control efforts”.

The political declaration of 16 September 2011 from the UN's High-level Meeting on the Prevention and Control of Non-communicable Diseases recognises that there is a fundamental and irreconcilable conflict of interest between the tobacco industry and public health.<sup>60</sup>

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<sup>60</sup> [http://www.who.int/nmh/events/un\\_ncd\\_summit2011/political\\_declaration\\_en.pdf](http://www.who.int/nmh/events/un_ncd_summit2011/political_declaration_en.pdf), see point 38

According to the WHO, the tobacco industry represents a serious threat to the achievement of the FCTC's goals and objectives, since the tobacco industry's tactics and interference with public policy-making are aimed at increasing tobacco consumption and thus detrimental to public health.<sup>61</sup>

## 4.2 Tobacco industry tactics

Knowledge of the industry's methods has largely been uncovered through lawsuits in the United States. The first lawsuits took place in the 1990s, whereby American courts ordered tobacco companies in the United States and England to publicise a large amount of internal documentation.<sup>62</sup> State lawsuits were grounded in the discovery that the tobacco companies had long had in-depth knowledge of the health risks associated with smoking, but kept this a secret from the public. It was also documented that the companies had experimented with various additives to increase the nicotine's addictive effect. Access to the tobacco industry's internal research archives indicated that tobacco products were more dangerous than previously assumed and that the public health costs of treating tobacco-related illnesses were higher than what had previously been assumed.<sup>63</sup>

In more recent cases, the industry has been ordered to hand over various types of documents. Moreover, there have been leaks of internal documents from the tobacco industry and their PR agencies. Examples of this will be discussed in more detail below.

The WHO<sup>64</sup> has surveyed the industry's methods globally, and found that the same tactics are repeated in most countries and over time:

### 1) Interference in political and legislative processes

In the report "Tobacco Industry Interference with Tobacco Control" from 2008, the WHO writes that there are many examples of the tobacco industry's attempts to influence legislative processes by "blocking, delaying and diluting evidence-based national tobacco legislation".<sup>65</sup>

This is done, *inter alia*, through massive lobbying. According to the Tobacco Atlas, the tobacco company Phillip Morris is the second most active lobbying organisation in the USA. Between 1998 and 2004, they spent approximately NOK 770 million on lobbying the U.S. Congress. In 2010, 19 companies with tobacco interests spent NOK 126 million

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<sup>61</sup> WHO (2012), *Technical resource for country implementation of WHO framework convention on tobacco control article 5.3*: [http://whqlibdoc.who.int/publications/2012/9789241503730\\_eng.pdf?ua=1](http://whqlibdoc.who.int/publications/2012/9789241503730_eng.pdf?ua=1), page 4

<sup>62</sup> NOU 2000:16 Tobakksindustriens erstatningsansvar, page 281 et seq: <http://www.regjeringen.no/Rpub/NOU/20002000/016/PDFA/NOU200020000016000DDDPDFA.pdf>

<sup>63</sup> NOU 2000:16 Tobakksindustriens erstatningsansvar, page 276 et seq.

<sup>64</sup> WHO (2012), *Technical resource for country implementation of WHO framework convention on tobacco control article 5.3*: [http://whqlibdoc.who.int/publications/2012/9789241503730\\_eng.pdf?ua=1](http://whqlibdoc.who.int/publications/2012/9789241503730_eng.pdf?ua=1)

<sup>65</sup> WHO (2008), *Tobacco industry interference with tobacco control*, [http://whqlibdoc.who.int/publications/2008/9789241597340\\_eng.pdf?ua=1](http://whqlibdoc.who.int/publications/2008/9789241597340_eng.pdf?ua=1), page 4 (hereinafter WHO 2008)

and used 168 lobbyists in an attempt to influence the political decision-making in the United States.<sup>66</sup>

The tobacco industry also lobbied during the revision of the EU Tobacco Products Directive (TPD). There were a record number of submissions to the Commission's consultation, mainly from the tobacco industry and their front groups (80 000 in total). Leaked documents from the tobacco industry indicate that their strategy was precisely to delay and dilute the directive.<sup>67</sup> The leaked documents also contained detailed strategies for lobbying activities. Phillip Morris alone had 161 employees and consultants (not full-time) who worked on lobbying against the directive, and in the first six months of 2012, they had spent almost NOK 11 million on lobby activities. Furthermore, the strategy involved influencing sections of the Commission other than DG Sanco (the EU's health ministry), by arguing that the proposed directive would result in an increase of illicit trade, in addition to establishing front groups consisting of small vendors and others with greater credibility than the industry itself.

It was also uncovered that politicians and employees of the Commission held meetings with the tobacco industry, but did not disclose this. Nor did they disclose the minutes from the meetings. Only DG Sanco has guidelines for such disclosure of meetings with the industry. The EU's Ombudsman is now investigating the matter, due to complaints that the Commission has not fulfilled its obligations under the FCTC Art. 5.3. An article from February 2015, which has reviewed the tobacco industry's lobbying activities against the TPD, concludes that the tobacco industry's influence probably resulted in the removal of two of the original proposals (standardised packaging and points of sale display ban) and repeated delays in the legislative process.<sup>68</sup> Another finding in the article is that the tobacco industry is making increasing use of third parties as their mouthpiece. The researchers identified 137 organisations and 34 companies that supported the tobacco industry's positions, and leaked documents have revealed that 12 of these were part of a third-party coalition with Phillip Morris.

Another example is the implementation of plain packaging in Australia. The tobacco industry initiated various measures to prevent the implementation of the measure. For instance, a front group was established that appeared to be a grassroots organisation representing the retail industry. Leaked documents showed that the group received funding from several tobacco companies.<sup>69</sup>

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<sup>66</sup> Eriksen et al (2012), *The Tobacco Atlas*. Fourth Ed, American Cancer Society, World Lung Foundation: [http://tobaccoatlas.org/uploads/Files/pdfs/industry/influence/influence\\_pdf.pdf](http://tobaccoatlas.org/uploads/Files/pdfs/industry/influence/influence_pdf.pdf)

<sup>67</sup> Various newspaper articles: <http://www.theguardian.com/business/2013/sep/07/tobacco-philip-morris-millions-delay-eu-legislation?view=mobile>; <http://www.spiegel.de/wirtschaft/unternehmen/zigarettenhersteller-philip-morris-legt-liste-von-abgeordneten-an-a-924220.html>; <http://corporateeurope.org/power-lobbies/2014/05/looking-back-tobacco-lobbying-battle-philip-morris-allies-european-parliament>

<sup>68</sup> Peeters et al. Tob Control Published Online First: 24 February 2015, doi:10.1136/tobaccocontrol-2014-051919

<sup>69</sup> [http://www.tobaccotactics.org/index.php/Alliance\\_of\\_Australian\\_Retailers](http://www.tobaccotactics.org/index.php/Alliance_of_Australian_Retailers)

Several media campaigns against plain packaging were run. A leaked memo showed that counter campaigns by the industry were to:

- contain elements that lead to concern among decision makers,
- utilise trustworthy third parties to achieve success in the media debate,
- create a database of journalists who are broadly sympathetic either specifically to the cause of smokers, or who are pre-disposed to anti nanny-state arguments,
- argue that the measure is ineffective and will result in an increase in illicit trade in tobacco products, increased costs to retail industry, and an increased number of violations of international trade agreements and attacks on individual freedom.<sup>70</sup>

Several mass media campaigns with these arguments were run in various media.

## **2) Exaggerations of the economic importance of the industry**

The tobacco industry often claims that the implementation of effective tobacco control measures will result in serious negative financial consequences for various industries and workplaces. When plain packaging was introduced in Australia, it was claimed that the measure would lead to a 30 % reduction in tobacco sales in the first year and a further 30 % in the following year.<sup>71</sup> This has not happened, and the Ministry notes that no individual tobacco control measure has ever resulted in such an immediate reduction in tobacco sales. Based on experiences from other measures, this measure is expected to have a gradual effect in the long term.

Similar statements have been made with regard to smoke-free legislation, when the tobacco industry claimed that such regulation would result in a 30 % reduction in income.<sup>72</sup> Evaluations from several countries that introduced smoke-free legislation indicate that the effect is neutral, as in Norway, or that the revenue of the restaurant industry has increased. The tobacco industry's estimations are often far higher than the numbers suggest, and the Ministry points out that tobacco use results in large negative costs to society.

## **3) Manipulating the public to create the impression that the industry is responsible and credible**

The tobacco industry conducts so-called socially responsible activities (Corporate Social Responsibility) to distance itself from the serious health damage caused by the products they manufacture, and to undermine development and implementation of tobacco control measures. Such activities often function as both advertising and as PR strategy, and are covered by the FCTC's ban on advertising and sponsorship. CSR activities is according to the WHO a contradiction, as the industry's core business activities directly contradict the objectives of tobacco control policies.<sup>73</sup>

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<sup>70</sup> <http://legacy.library.ucsf.edu/tid/kte92i00/pdf>

<sup>71</sup> Simon Chapman (2014), *Removing the emperor's clothes*: <http://ses.library.usyd.edu.au/handle/2123/12257>

<sup>72</sup> Alamar, Glantz (2007), *Effect of Smoke-Free Laws on Bar Value and Profits*, Am J Public Health: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1931474/>

<sup>73</sup> WHO (2004), *Tobacco industry and corporate social responsibility – an inherent contradiction*

In its report from 2008, the WHO notes that the industry increasingly promotes its companies through participation in, or support for, events and projects with socially responsible objectives.<sup>74</sup> The companies thereby attempt to create a positive image of their business and present themselves as socially responsible actors, to restore the trust of the public. However, the report shows that the intention behind these measures is to block, delay and dilute tobacco regulation.

Another report shows that such socially responsible projects are described by the tobacco industry as “*air cover from criticism*” and “*a degree of publicly endorsed amnesty*”.<sup>75</sup> The same report documents that the industry contributes to health care systems, housing for homeless persons, arts and education, all of which are considered important investments in gaining trust, distracting from the industry’s core business activities and, over time, gaining political influence.

In its 2008 report, the WHO writes that tobacco companies are known to initiate so-called smoking prevention programmes for youth. Here too, the intention is to delay and undermine further regulation, and give the impression that the industry is a responsible actor.<sup>76</sup> In internal documents from Phillip Morris from 1993, the following is stated about the industry’s youth campaigns:

“Taking into consideration the emerging adverse legislative climate in the [Latin American] region, we have an opportunity to create good will for the tobacco industry by going public with a campaign to discourage juvenile smoking. Our objective is to communicate that the tobacco industry is not interested in having young people smoke and to position the industry as ‘a concerned corporate citizen’ in an effort to ward off further attacks by the anti-tobacco movement.”<sup>77</sup>

Another example is found in the minutes from an internal industry meeting in Hong Kong regarding tobacco advertising on TV and radio. Here it is stated:

“This is one of the proposals that we shall initiate to show that we as an industry are doing something about discouraging young people to smoke. This of course is a phony way of showing sincerity as we all well know.”<sup>78</sup>

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<sup>74</sup> WHO (2008), *Tobacco industry interference with tobacco control*, [http://whqlibdoc.who.int/publications/2008/9789241597340\\_eng.pdf?ua=1](http://whqlibdoc.who.int/publications/2008/9789241597340_eng.pdf?ua=1), page 15 med videre henvisninger

<sup>75</sup> Action on Smoking and Health, *BAT in its own words*: [http://www.ash.org.uk/files/documents/ASH\\_371.pdf](http://www.ash.org.uk/files/documents/ASH_371.pdf), page 13

<sup>76</sup> WHO 2008, page 14 med videre henvisninger

<sup>77</sup> Leiber C. Corporate (1993), Youth campaign for Latin America: <http://legacy.library.ucsf.edu/tid/ehq19e00>

<sup>78</sup> Philip Morris (1973), Corporate smoking and health meeting: <http://legacy.library.ucsf.edu/tid/owq24e00>

It is well documented that the industry has conducted youth campaigns in many countries and that these are not effective in preventing youth smoking.<sup>79</sup> Many of the campaigns do not focus on health damage caused by tobacco consumption. On the contrary, these campaigns can contribute to increasing the attractiveness of tobacco amongst young people. We have also seen examples of such campaigns in Norway, the most recent in 2013, when Swedish Match conducted a campaign on the age limit for snus. The campaign was to be conducted at a number of festivals, and on social media and the target group for the campaign was teenagers. It was also announced with full-page newspaper ads with text such as “You know you are #18 when you can go to the Hove Music Festival without asking for permission”, and the campaign encouraged youth to share “their best and funniest tips on how vendors can tell if you are 18”. The Directorate of Health ordered the company to stop the campaign as they considered the campaign clearly in breach of the ban on tobacco advertising. Swedish Match stated that the background for the campaign was the wish to direct attention to the age limit and show that they are responsible. The Directorate of Health noted that none of the campaign elements were targeted towards the tobacco vendors who are responsible for enforcing the age limit. They further concluded that it is well-documented that such campaigns serve as indirect advertisement for tobacco.

Moreover, the tobacco industry has – contrary to its own claims – conducted widespread research related to marketing and product development which targets children and youth. See the detailed discussion of this in point 3.2 above.

#### **4) Establishment of front groups to give the impression of substantial support for the industry**

It is common for the tobacco industry to establish and finance front groups, and to associate themselves with organisations and projects that are used to influence the public, politicians and other decision makers.<sup>80</sup>

A front group is an organisation which appears to represent a stated agenda, while in reality it promotes and is sponsored by, most often, a clandestine interest. The tobacco industry is known for its use of front groups to promote its financial and political interests, including undermining the knowledge of the health risks of tobacco use. The clandestine manner in which such groups operate often makes it difficult to know which interests are actually being represented by the organisation. These front groups are often organised by PR agencies. The tobacco industry uses front groups to give the impression of broad support for their views on various matters, among seemingly independent third parties.

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<sup>79</sup> WHO 2008, page 13 et seq. med videre henvisninger

<sup>80</sup> WHO 2008, page 5 et seq. videre henvisninger

When plain packaging was introduced in Australia, a front group was established, which seemingly only represented the retail industry.<sup>81</sup> Internal documentation about this group and other counter measures on the part of the industry were leaked to the media, revealing that the group was receiving support from several tobacco companies.

When smoking bans became more prevalent, the tobacco industry created and financed a number of organisations and groups that appeared to campaign for the rights of smokers. The objective was to block, delay and dilute the smoking bans that were to protect against second-hand smoke. A report prepared by the WHO EURO shows that 13 front groups were created in Europe, pretending to represent smokers' rights in the region.<sup>82</sup>

In internal documents from the tobacco industry, it was stated that “smoking groups have no commercial interests and are a more credible voice than the tobacco industry.” The function of these groups was to feed the debate about health damage related to second-hand smoke, contribute to delays in legislation on smoking restrictions, and create doubts about the harmful effects of smoking.

Another type of front group have a sociological aspect, such as Associates for Research into the Science of Enjoyment (ARISE), which was active in Europe from 1988 to 1999. ARISE claimed that stress-reducing activities such as shopping, drinking tea, eating chocolate and smoking cigarettes (the latter was always grouped with less harmful activities) were key to maintaining good health.

In a judgement from the USA against Phillip Morris et al. the tobacco industry's network of researchers and front groups were described as follows:

“the intricate, interlocking, and overlapping web of national and international organizations, committees, affiliations, conferences, research laboratories, funding mechanisms, and repositories for smoking and health information which Defendants established, staffed, and funded in order to accomplish the following goals: counter the growing scientific evidence that smoking causes cancer and other illnesses, avoid liability verdicts in the growing number of plaintiffs' personal injury lawsuits against Defendants, and ensure the future economic viability of the industry.”<sup>83</sup>

The WHO explains that the objective of such groups is purposefully to use science or pseudoscience to defeat legitimate scientific enquiry into the harm caused by tobacco.<sup>84</sup>

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<sup>81</sup> <https://www.australianretailers.com.au/>; Chapman, *Removing the emperor's clothes*, 2014: <http://ses.library.usyd.edu.au/handle/2123/12257>

<sup>82</sup> WHO (2012), *Tobacco industry interference in the WHO European Region*: [http://www.euro.who.int/data/assets/pdf\\_file/0005/166748/Tobacco-Industry-Interference-In-the-WHO-European-Region.pdf](http://www.euro.who.int/data/assets/pdf_file/0005/166748/Tobacco-Industry-Interference-In-the-WHO-European-Region.pdf)

<sup>83</sup> Kessler G. Final opinion: United States of America versus Philip Morris. Civil action No 99-2496 (GK), 2006. [https://www.tobaccofreekids.org/content/what we do/industry watch/doj/FinalOpinion.pdf](https://www.tobaccofreekids.org/content/what_we_do/industry_watch/doj/FinalOpinion.pdf)

<sup>84</sup> WHO 2008, page 11 med further references

## 5) Undermining scientific documentation

In addition to the fact that the tobacco industry has kept research results with negative implications to themselves, they have played an active role in disseminating studies that are favourable to the industry – often studies they have financed. The tobacco industry’s strategy is to sow seeds of doubt about research that documents the health damage and/or the beneficial effect of tobacco control measures. Paid researchers often attack the methodology and basis of such reports, something we also experienced in Norway in connection with Phillip Morris’ lawsuit against the display ban in 2010.

There have been several examples of industry-financed research being used to delay and attack the implementation of effective tobacco control measures. With regard to the implementation of plain packaging in Australia, several tobacco industry-financed reports concerning the measures’ alleged effect on illicit trade have been published (approx. 10 reports from KPMG, Deloitte and PWC, respectively).<sup>85</sup> So far, no increase in illicit trade in Australia has been proven and Australian researchers, health and customs authorities and international researchers have refuted several of the reports.<sup>86</sup> When the proposal for standardised tobacco packaging was publicly announced in Norway, the tobacco industry also claimed that the measure would lead to a rise in illicit trade, with reference to, *inter alia*, the industry financed reports from Australia.

For decades, the tobacco industry has attempted to undermine scientific documentation of the health damages related to first and second-hand smoking. The industry has also created and financed biomedical research groups for the purpose of publicising scientific articles about tobacco which either question or refute the harmful effects of passive or second-hand smoking.<sup>87</sup>

In 1999, the U.S. Department of Justice sued Phillip Morris and other tobacco companies with claims of violations of the Racketeer Influenced and Corrupt Organizations Act (a law concerning fraud and organised crime). In 2006 Phillip Morris et al. (and upon appeal in 2009) was found guilty of fraud. *Inter alia*, the court found that Phillip Morris et al. had:

- conspired to minimise, distort and confuse the public about the harmful effects of smoking,
- publically denied, but internally recognised, that second-hand smoking is harmful, and
- destroyed relevant documents tied to the lawsuit.<sup>88</sup>

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<sup>85</sup> Chapman (2014), *Removing the Emperor’s Clothes*, page 70 et seq:

<http://ses.library.usyd.edu.au/handle/2123/12257>

<sup>86</sup> <http://www.cancervic.org.au/plainfacts/browse.asp?ContainerID=illicittobacco>

<sup>87</sup> WHO 2012, page 8

<sup>88</sup> <http://publichealthlawcenter.org/sites/default/files/resources/doj-final-opinion.pdf>

The Court further found that the tobacco companies had systematically worked to undermine and discredit the scientific consensus that smoking causes diseases, particularly by referring to research results by paid consultants. The companies were later ordered to disclose information in various media, on the company's websites and on cigarette packages, stating that they had disseminated misleading information and defrauded the public with regard to tobacco use and adverse health effects, addiction, adverse health effects associated with "light" cigarettes, manipulation of cigarette design to ensure maximum nicotine intake, as well as adverse health effects related to second-hand smoking.<sup>89</sup> Parts of the case are still ongoing in the legal system.

Such revelations are one of the reasons why a series of research publications have introduced a policy of no longer publishing studies that are in whole or in part financed by the tobacco industry. The editors of the respected British Medical Journal have justified this with the following statement:

"The tobacco industry, far from advancing knowledge, has used research to deliberately produce ignorance and to advance its ultimate goal of selling its deadly products while shoring up its damaged legitimacy. We now know, from extensive research drawing on the tobacco industry's own internal documents, that for decades the industry sought to create both scientific and popular ignorance or "doubt." At first this doubt related to the fact that smoking caused lung cancer; later, it related to the harmful effects of secondhand smoke on non-smokers and the true effects of using so called light or reduced tar cigarettes on smokers' health. (...)

Back in 2003, the editor of the BMJ defended publication of a study with tobacco industry funding saying "The BMJ is passionately antitobacco, but we are also passionately prodebate and proscience. A ban would be antiscience." But it is time to cease supporting the now discredited notion that tobacco industry funded research is just like any other research. Refusing to publish research funded by the tobacco industry affirms our fundamental commitment not to allow our journals to be used in the service of an industry that continues to perpetuate the most deadly disease epidemic of our times."<sup>90</sup>

## **6) Threats of lawsuits against governments**

The tobacco industry's use of lawsuits or threats of lawsuits has been a growing trend in recent years, to which Norway has also been exposed. In 2010, Norwegian authorities were sued by Phillip Morris with a claim that the points of sale tobacco display ban was in violation of the EEA Trade Agreement. The government won the case. The intention of such lawsuits is to delay the introduction of effective tobacco control measures.

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<sup>89</sup> [http://www.tobaccofreekids.org/what\\_we\\_do/industry\\_watch/doj\\_lawsuit/corrective\\_statements](http://www.tobaccofreekids.org/what_we_do/industry_watch/doj_lawsuit/corrective_statements)

<sup>90</sup> Journal policy on research funded by the tobacco industry, BMJ 2013;347:f5193

In 2010, Phillip Morris sued Uruguay based on a bilateral investment agreement from 1991, between Uruguay and Switzerland. The reason was that Uruguay had adopted the use of larger health warnings (from 50 % to 80 % in size) on cigarette packets, as well as a requirement that only one type of cigarette could be sold per label, to prevent tobacco producers from circumvented the ban on “light” cigarettes with the use of colour codes.

The tobacco industry’s use of legal action is especially clear when looking at their various lawsuits against Australia for introducing plain packaging in 2012, cf. point 3.3.1 above. In the noted cases against Australia in the WTO system, it is known that Phillip Morris covers legal costs of the Dominican Republic and that British American Tobacco does the same for the Ukraine and Honduras.

It is important to remember that the tobacco industry has enormous financial resources. In 2013, the five largest global tobacco companies controlled 83 % of the world’s tobacco production<sup>91</sup> and in 2010, the six largest had a turnover of approx. NOK 2630 billion and a profit of approx. 267 billion, which is the equivalent of the combined profits of Coca-Cola, Microsoft and McDonalds in the same year.<sup>92</sup>

The value of the global tobacco production is currently estimated at between NOK 4500 and 5300 billion. The world’s leading tobacco company is Phillip Morris International, which in 2012 generated revenue of NOK 235 billion.<sup>93</sup>

### **4.3 Applicable laws**

The Framework Convention on Tobacco Control states in Article 5.3:

“In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law”

This provision is by many described as the most important and most fundamental provision in the entire FCTC, as lacking implementation thereof can prevent the introduction of, and compliance with the Convention’s other provisions on various effective tobacco control measures. The provision is a legally binding obligation, and parties are obligated to implement it domestically.

The obligations of Article 5.3 must also be seen in relation to FCTC Article 12 regarding the right of the public to information about health risks associated with tobacco use, and regarding the tobacco industry and its methods, in addition to FCTC Article 13 regarding a ban on tobacco advertising.

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<sup>91</sup> Euromonitor International 2013, [http://global.tobaccofreekids.org/files/pdfs/en/Global\\_Cigarette\\_Industry\\_pdf.pdf](http://global.tobaccofreekids.org/files/pdfs/en/Global_Cigarette_Industry_pdf.pdf)

<sup>92</sup> Tobacco Atlas: [http://www.tobaccoatlas.org/industry/tobacco\\_companies/profits/](http://www.tobaccoatlas.org/industry/tobacco_companies/profits/)

<sup>93</sup> Statista: <http://www.statista.com/topics/1593/tobacco/>

FCTC Article 5.3, with guidelines, are not directly regulated in the Tobacco Control Act. However, the Act has a general legal basis for requiring information about the Norwegian tobacco market, cf. Section 38. The provision also provides a legal basis for requiring companies to report the contents of tobacco products. This duty to report is pursuant to the EU Tobacco Products Directive 2001/37/EF. The Tobacco Control Act Section 38 is formulated as follows:

*“Duty of disclosure etc.*

All persons shall, when ordered to do so by the Directorate, provide such information as is necessary to prevent damage to health entailed by the use of tobacco or to carry out tasks under this Act.

The Directorate may require a manufacturer or importer of tobacco products to provide information about the content of the products. The Ministry may lay down regulations detailing the information requirement in the first sentence.

The Directorate may require a manufacturer or importer of tobacco products to produce a representative sample of a product or to perform such tests as are necessary to assess the product’s characteristics or effects. The costs of such tests shall be borne by the manufacturer or importer in question. The Directorate may decide that the costs shall entirely or in part be covered by the government.

The Directorate may initiate such tests itself, and may order the manufacturer or importer to cover the costs of the tests. The costs may be recovered by execution proceedings.”

#### **4.4 FCTC Article 5.3 Guidelines**

Guidelines have been adopted under Article 5.3. The guidelines were adopted by consensus by the Conference of the Parties to the FCTC and are instrumental to the interpretation of the provision. The guidelines provide recommendations for how the Parties can fulfil their obligations in accordance with the provision. Below, the Ministry will review the guidelines with a special emphasis on the measures that may be relevant for consideration in Norway.

##### *4.4.1 Purpose and scope*

The purpose of the guidelines is to ensure that efforts to protect tobacco control from commercial and other vested interests of the tobacco industry are both comprehensive and effective. The measures should be implemented in all branches of government that may have an interest in, or the capacity to, affect public health policies with respect to tobacco control. The aim of the guidelines is to assist Parties in meeting their legal obligations under FCTC Article 5.3. The guidelines draw on the best available scientific evidence and the experience of Parties in addressing tobacco industry interference.

The guidelines apply to setting and implementing of policies with respect to tobacco control. They also apply to persons, bodies or entities that contribute to, or might contribute to, the formulation, implementation, administration or enforcement of those policies.

The guidelines apply to government officials, representatives and employees, and to any persons acting on their behalf. Any government branch responsible for setting and implementing tobacco control policies and for protecting those policies against tobacco industry interests should, according to the guidelines, be held accountable.

The broad array of strategies and tactics used by the tobacco industry to interfere with the setting and implementing of tobacco control measures, such as those that Parties to the Convention are required to implement, is documented by a vast body of evidence. The measures recommended in these guidelines are aimed at protecting against interference not only by the tobacco industry itself but also by organisations and individuals that are working to further the interests of the tobacco industry.

#### *4.4.2 Overarching principles*

The guidelines list four overarching principles:

- 1) *There is a fundamental and irreconcilable conflict between the interests of the tobacco industry and public health policy interests.*

The tobacco industry produces and promotes a product that is scientifically proven to be addictive, to cause disease and death and to lead to a variety of social ills, including increased poverty. Therefore, Parties should protect the formulation and implementation of public health policies for tobacco control from the tobacco industry to the greatest extent possible.

- 2) *Parties, when dealing with the tobacco industry or those working to further its interests, should be accountable and transparent.*

- 3) *Parties shall require the tobacco industry and those working to further its interests to operate and act in a manner that is accountable and transparent.*

The tobacco industry should be required to provide Parties with information necessary for the effective implementation of these guidelines.

- 4) *Because their products are lethal, the tobacco industry should not be granted incentives to establish or run their businesses.*

Any preferential treatment of the tobacco industry will be in conflict with tobacco control policies.

#### *4.4.3 Primary recommendations of the guidelines*

The guidelines list eight primary recommendations to address tobacco industry interference in public health policies. Parties are explicitly encouraged to go beyond the recommendations provided by the guidelines.

- 1) **Raise awareness in all branches of government and the public about the addictive and harmful nature of tobacco products, the need to protect public health policies for tobacco control from commercial and other vested interests of the tobacco industry and the strategies and tactics used to undermine tobacco control**

Parties should, in addition, raise awareness about the tobacco industry's practice of using individuals, front groups and affiliated organisations to act, openly or covertly, on their behalf or to take action to further the interests of the tobacco industry.

**2) Establish measures to limit interactions with the tobacco industry and ensure the transparency of the interactions that take place**

Interaction with the tobacco industry should only occur in the extent that it is strictly necessary for the effective regulation of the tobacco industry and tobacco products. There must be full transparency about the meetings and the content thereof. Several institutions and politicians in other countries have on this basis introduced a procedure of publicising the reason for, and minutes from, such meetings, online.

**3) Reject partnerships and agreements with the tobacco industry**

The tobacco industry should not be a partner in any initiative linked to setting or implementing public health policies, given that its interests are in direct conflict with the goals of public health.

**4) Avoid conflicts of interest**

- Parties should mandate a policy on the disclosure and management of conflicts of interest that applies to all persons involved in setting and implementing public health policies with respect to tobacco control, including government officials, employees, consultants and other relevant parties
- Parties should formulate, adopt and implement a code of conduct for public officials, prescribing the standards with which they should comply in their dealings with the tobacco industry
- Parties should not award contracts for assignments related to tobacco control measures to anyone who has a conflict of interests with established tobacco control policies.
- Parties should develop clear guidelines on quarantine periods for public office holders, who have or have had a role in setting and implementing public health policies with respect to tobacco control.
- Parties should develop clear policies that require applicants for public office positions which have a role in setting and implementing public health policies with respect to tobacco control to declare any current or previous activity with any tobacco industry.
- Parties should require government officials to declare and divest themselves of direct interests in the tobacco industry.
- Government institutions and their bodies should not have any financial interest in the tobacco industry.
- Parties should not allow any person employed by the tobacco industry or any entity working to further its interests to hold public offices or positions that set or implement tobacco control or public health policy.
- Persons employed by the tobacco industry or any entity working to further its interests should not participate in the meetings of the Conference of the Parties to the FCTC.
- Parties should not allow any official or employee of government to accept payments, gifts or services from the tobacco industry.

- Taking into account national law and constitutional principles, Parties should have effective measures to prohibit contributions from the tobacco industry or any entity working to further its interests to political parties, candidates or campaigns, or to require full disclosure of such contributions.

**5) Require that information provided by the tobacco industry is transparent and accurate**

- Parties should introduce and apply measures to ensure that all operations and activities of the tobacco industry are transparent.
- Parties should require the tobacco industry and those working to further its interests to periodically submit information on tobacco production, manufacture, market share, marketing expenditures, revenues and any other activity, including lobbying, philanthropy, political contributions and all other activities not prohibited or not yet prohibited under the ban on advertising/sponsorship.
- Parties should require rules for the disclosure or registration of the tobacco industry entities, affiliated organisations and individuals acting on their behalf, including lobbyists.
- Parties should impose mandatory penalties on the tobacco industry in case of the provision of false or misleading information.
- Parties should adopt and implement effective measures to ensure public access to a wide range of information on tobacco industry activities.

**6) Denormalise and, to the extent possible, regulate activities described as “socially responsible” by the tobacco industry**

- Parties should ensure that all branches of government and the public are informed and made aware of the true purpose and scope of CSR activities conducted by the tobacco industry.
- Parties should not endorse, support or form partnerships with the CSR activities of the tobacco industry.
- Parties should not allow public disclosure by the tobacco industry or any other person acting on its behalf of CSR activities or of the expenditures made for these activities, except when legally required to report on such expenditures.
- Parties should not allow any branch of government or the public sector to accept political, social, financial, educational, or other contributions from the tobacco industry or from those working to further its interests, except for compensations due to legal settlements or mandated by law or legally binding and enforceable agreements.

**7) Do not give preferential treatment to the tobacco industry**

- Parties should not grant incentives, privileges or benefits to the tobacco industry to establish or run their businesses, e.g. subsidies, investments or facilitation for the tobacco industry.

- Parties that do not have a State-owned tobacco industry should not invest in the tobacco industry and related ventures. Parties should not provide any preferential tax exemption to the tobacco industry

## **8) Treat State-owned tobacco industry in the same manner as any other tobacco industry**

### *4.4.4 Enforcement and monitoring*

According to the guidelines, Parties should put in place enforcement mechanisms in order to fulfil their obligations under FCTC Article 5.3 and its guidelines. Monitoring implementation of Article 5.3 and of these guidelines is considered essential for ensuring the introduction and implementation of efficient tobacco control policies. This includes monitoring of the tobacco industry. According to the guidelines, non-governmental organisations and other members of civil society play an essential role in monitoring the activities of the tobacco industry. It is further recommended that codes of conduct or staff regulations for all branches of governments should include a “whistleblower function”, with adequate protection of whistleblowers. In addition, the Parties should establish an enforcement mechanism to ensure compliance, offering the opportunity to bring an action to court, and to use complaint procedures such as an ombudsman system.

### **4.5 The WHO’s assessment of Norwegian tobacco control work**

The WHO’s assessment of Norwegian tobacco control efforts in 2010 concluded that the tobacco industry’s marketing strategies are not well-known in Norway. Despite the fact that the industry sued Norwegian authorities for the display ban, the general impression was that the tobacco industry was inactive and did not require monitoring. Although there has been no tobacco manufacturing in Norway since 2008, major international actors have nonetheless established offices in Norway (British American Tobacco, Philip Morris, Imperial Tobacco and Swedish Match), in addition to major importers such as Langgaard, owned by Thon.

The WHO report<sup>94</sup> emphasises that monitoring of the tobacco industry is necessary in order to effectively implement the FCTC, and that Norway should introduce additional measures to implement Article 5.3. They made the following key findings:

**“Tobacco industry marketing tactics and strategies in Norway are barely known**

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<sup>94</sup> [https://www.regjeringen.no/globalassets/upload/hod/dokumenter-fha/tobakk/who\\_rapport\\_norsk.pdf](https://www.regjeringen.no/globalassets/upload/hod/dokumenter-fha/tobakk/who_rapport_norsk.pdf)

Despite an ongoing legal action contesting tobacco control measures filed against the government by the tobacco industry, there is a wide impression in both governmental and nongovernmental circles that the tobacco industry is inactive and that there is no need to monitor it. However, global experience has shown that, while the industry's work may not be obvious, it is omnipresent, monitoring what health authorities are doing and finding opportunities to influence policy and activities that are to its advantage. The tobacco market and the tobacco industry's marketing strategies in Norway are not well known and there is no mechanism for monitoring the industry's activities at either national or international level. In this regard, the WHO FCTC Article 5.3 which protects against undue interference from the tobacco industry and the Article 13 guidelines on tobacco advertising, promotion and sponsorship are not being appropriately implemented unless there is monitoring to prevent the activities of the tobacco industry from undermining tobacco control.”

Based on these findings, the WHO made the following recommendations in its report:

**“The activities of the tobacco industry that influence the internal market should be monitored nationally and internationally.**

The tobacco industry – importers, distributors and front groups in Norway and producers and exporters internationally – must not be underestimated. Keeping up to date with the changes in the country's tobacco market, and knowing existing products, brands and the tobacco industry's presence are crucial in anticipating opposition to new tobacco control policies. Understanding the tobacco industry's marketing strategies nationally and internationally can be an invaluable help in guiding tobacco control policies and protecting the government proactively against attacks. This includes price promotions, new publicity tactics, packaging and product manipulations, and placement strategies to increase profits and reach new customers. Furthermore, studies on the files of tobacco industry documents released as part of the US Master Settlement Agreement can be an important source of information for the country.

In this regard, the mission recommends the establishment of a tobacco industry monitoring system. This can be undertaken either by a research body in the government or by a civil society organization, or by both to ensure complementarity. Such a system would also allow Norway to comply with WHO FCTC Article 5.3 guidelines.”

#### **4.6 Status of implementation of Article 5.3 in Norway**

The Norwegian Pension Fund (SPU) withdrew from the tobacco industry in 2009, and the FCTC was then used as an argument for amendments to the ethical guidelines. Beyond this, there have been no special measures for the implementation of Article 5.3 in Norway, as the WHO points out. There exist no national guidelines for how authorities, government employees or politicians are to deal with the tobacco industry.

The Ministry of Health and Care Services and the Directorate of Health on principle do not interact with the tobacco industry beyond recorded communications. However, there is no defined policy on this matter. There is currently no reporting on the part of the tobacco industry concerning production, market shares, income, lobbying activities, CSR activities, organising, use of third parties etc.

In the Directorate of Health's report "Norwegian Implementation of the Framework Convention on Tobacco Control" of December 2013, the following status update for the implementation of Art. 5.3 is provided:

"As far as the Directorate of Health is aware, no extraordinary measures have been taken, such as conveying special information to all relevant branches of government about the need to protect tobacco control from commercial interests or information about the tobacco industry's tactics to interfere in the policies.

The Directorate has, and has had very limited interaction with the tobacco industry beyond recorded communications. The tobacco industry is a consulted party in matters that concern them (e.g. amendments to the Tobacco Control Act). There are no settlements or voluntary/self-policing arrangements in tobacco control policy. We are not aware of any defined policy that prevents persons with ties to the tobacco industry from working for government bodies, committees, advisory groups and the like, concerning tobacco control or public health. (...) At this point, we are also not aware of any established measures to limit interaction between branches of government and the tobacco industry beyond what is necessary to ensure proper regulation of tobacco products and the tobacco industry. There are no guidelines for how government employees should deal with the tobacco industry, nor is there any specific system for declaring potential conflicts of interest. However, several general rules for government employees are applicable. (...)

No reporting from the tobacco industry is required with respect to production, market shares, income, lobbying activities, contributions to political parties, socially responsible activities, organising, actors, etc.(...)

Influence from the tobacco industry has probably been an underestimated topic in Norwegian tobacco control, but there has been a conscious decision to focus more attention on the public than on the industry. There was a gradual decline in production in Norwegian soil, and the last factory finally moved out of the country in 2008. The tobacco industry has in this sense become less visible and flown under the radar."

#### **4.7 Proposal by the Norwegian Directorate of Health**

In its 2013 report, the Directorate of Health made the following recommendations for how obligations under Article 5.3 can be implemented in Norway:

“WHO’s assessment from 2010 noted a certain degree of naivety towards the tobacco industry’s presence and influence in Norway. The Directorate frequently comes up short with regard to knowledge of the Norwegian tobacco market, whether in terms of reporting or regulation of the market. In addition to snus and smoking tobacco/cigarettes, e-cigarettes are now included in this selection of products, and this development must be followed closely.

- Gain a better overview of Norwegian actors by:
  - compiling already available information (web search queries, newspaper searches, registers and the like)
  - expand the duty of disclosure for ingredients to include an overview of the labels, sales figures, revenue, market shares, marketing budgets, income, CSR/social responsibility and other activities
  - introduce licensing systems for actors that produce, import, distribute or sell tobacco products, to assist in eliminating illegal trade in tobacco products and to achieve a better overview of the Norwegian market
  
- A review of article 5.3 and assessment of the need for an advisor on the relationship between Norwegian authorities and the tobacco industry
  
- Consider measures to involve the voluntary sector in the monitoring of the tobacco industry and actors working to promote its interests

Even if separate rules for politicians, government employees etc. are not necessarily developed in terms of potential relations with actors in the tobacco industry, information regarding the methods used by the tobacco industry, knowledge of lobbying activities and PR work etc. would contribute to becoming more cautious and critical in matters where potential exertion of influence are attempted. The WHO has guidelines for how the WHO is to respond to requests for meetings from the tobacco industry, and the manner in which such potential meetings should be conducted. The tobacco strategy proposes a review of Article 5.3 and an assessment of the need for an advisor on the relationship between Norwegian authorities and the tobacco industry.

We currently have little information about the actors and products on the Norwegian tobacco market. Some countries practice registration of actors and products in order to obtain permits to sell goods. This should also be considered in Norway. It would ensure a continually updated overview of the products existing on the Norwegian market. In the protocol to the FTCT article 15 concerning illicit trade, the parties are asked to introduce a licensing system for actors that manufacture, import, distribute or sell tobacco products, in order to eliminate illicit trade in tobacco products. In proposition Prp 55 L (p. 88), reference is made to further consideration of a separate duty of registration for importers and manufacturers. Tobacco manufacturers, suppliers, importers, etc., are already obligated to disclose information about the contents of the products. New legal and regulatory amendments should assess whether the duty of disclosure should be extended to apply to all labels, including revenue, market shares etc. (...)

An assessment should be made of whether it is appropriate to allocate time for a report or the like, based at least on the information available by way of open web search queries, newspaper searches, media events, registers and the like, and thereafter keep it regularly updated. Based on experience, these are tasks which are outside of what the Directorate of Health considers core tasks in the area of tobacco control. This is mechanisms to strengthen civil society tobacco-control efforts should be considered. Such mechanisms may include cooperation, partnership, or grants.”

#### **4.8 The Ministry’s proposals and assessments**

The National Strategy for Tobacco Control 2013-2016 states that the Ministry will review the guidelines for Article 5.3 and assess the manner in which Norway can fulfil its obligations under the provision. The Ministry has determined that there is a need for various types of measures, which are discussed below.

To make it clear that Article 5.3 is a cross-sectorial obligation, one option may be to include a provision in the Tobacco Control Act concerning the government branches’ contact with and handling of the tobacco industry. Legislation would raise awareness of the tobacco industry’s interference and their methods in all branches of government. A legal provision could be worded similarly to the FCTC Article 5.3:

“In setting and implementing public health policies with respect to tobacco control, all branches of government shall act to protect these policies from the commercial and other vested interests of the tobacco industry.”

For the time being, the Ministry does not suggest detailed regulations on protective measures, but is instead requesting input on what measures would be appropriate in a Norwegian context. Examples of measures that have been implemented in other countries include guidelines for public authorities, guidelines for contact between public employees and the industry, as well as a lobby registry to ensure transparency about contact between the industry and various branches of the public sector.

The Ministry has also noted that authorities are in need of a better overview of the tobacco market and of the industry's activities. Tobacco manufacturers and importers already have an obligation to annually submit information about ingredients to the Directorate of Health. This reporting obligation has been expanded in the new Tobacco Products Directive.

The Ministry is of the opinion that the duty of disclosure should be expanded to include not only the duty to report ingredients, but also an overview of the industry's revenue and market shares, marketing budgets, expenses and other information linked with lobbying activity, total income, research activities etc. Such reporting obligations have been introduced *inter alia* in Canada. However, the Ministry has determined that such a proposal should be coordinated with the necessary legal amendments related to the implementation of the new Tobacco Products Directive, and will therefore return to this question in a later consultation.

Certain countries have introduced a mandatory registration of actors and products for the permission to sell tobacco products. This would contribute to an improved overview of the market. Several large tobacco manufacturers are entering the e-cigarette market and the authorities also need to track this development. In accordance with the FCTC's Protocol on illicit trade, the Parties shall introduce a licensing system for actors that manufacture, import and distribute tobacco products. The Ministry will consider this in relation to a possible ratification of the Protocol.

The Ministry is requesting input on the need for measures such as the examples provided above, and whether some of the noted measures may be relevant in a Norwegian context.

## **5. FINANCIAL AND ADMINISTRATIVE CONSEQUENCES**

The Directorate of Health has estimated that smoking costs approximately NOK 80 billion a year, if we consider the costs to society as a whole.<sup>95</sup> The costs of health services alone amount to NOK 8 billion a year. This estimate is based on the scale of smoking over the past 10 to 30 years. It is the financial valuation of welfare benefits in the form of lost years of life that has the greatest impact on the calculation of the socioeconomic costs.

The Directorate of Health have further estimated that the potential socioeconomic benefits of the decline in the number of daily smokers over the last 20 years amounts to NOK 26 billion per year, and the potential benefits of a further decline in the number of daily smokers may have an annual social value of approx. NOK 2-3 billion per percentage point. However, it is important to remember that it may take time before we see the effects of measures aimed at the smoking population, and that the most widespread smoking-related diseases generally do not appear until several decades later. The time factor and problems with isolating effects also

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<sup>95</sup> Directorate of Health (2010), *Samfunnsøkonomiske kostnader av røyking – En vurdering av metodikk og kostnadenes størrelsesorden*, IS-1825: [http://www.helsedirektoratet.no/vp/multimedia/archive/00312/IS-1825\\_Samfunns\\_ko\\_312409a.pdf](http://www.helsedirektoratet.no/vp/multimedia/archive/00312/IS-1825_Samfunns_ko_312409a.pdf)

complicate the evaluation of individual measures. Moreover, implementation of several measures produce synergies that are difficult to measure.

## **5.1 Standardised tobacco packaging**

### *Consequences for the tobacco industry*

Mandatory standardisation of tobacco packaging will in the long term result in reduced sales for the tobacco industry. This is precisely the purpose of the measure.

No substantial decline in the sale of tobacco products can be expected in the short term. In the long term, however, the percentage of children and young people who begin to smoke and use snus is likely to decline. Lost revenue must be weighed against the health benefits this measure will entail, both for individuals and for society as a whole.

The tobacco manufacturers will have to expect one-time costs associated with new labelling regulations. The Ministry emphasises that the industry already has considerable costs in this respect, since the packaging is frequently being altered. The Commission's impact assessment notes that the tobacco industry's costs related to the labelling of packaging will be reduced significantly over time, since regulations on standardised packaging will remove the need for frequent new designs on the packages.<sup>96</sup> Moreover, reference is made to the fact that standardised packaging is less expensive and uses far fewer colours.

### *Consequences for retailers*

It is not expected that the introduction of standardised packaging will have financial consequences for retailers. Most adult smokers are addicted to tobacco, have established a preferred tobacco product and will continue to purchase it. However, changes in revenue are expected in the long term as the percentage of children and young people who begin using tobacco will decline.

The Ministry submits that the proposal will not have significant administrative consequences for the retailers. The industry has claimed (*inter alia* in Australia and England) that the introduction of standardised tobacco packaging will increase costs for the retail industry, as it presumably takes longer to serve customers who purchase tobacco because the packages have identical designs. Experience from other countries has shown that costs related to the sales situation have been manageable for retailers. Potential consequences are considered to be short term. Studies from Australia indicated that retailers quickly became accustomed to the new packaging design, and that after a short period of time, it no longer took longer to serve customers than before.

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<sup>96</sup> [http://ec.europa.eu/health/tobacco/docs/com\\_2012\\_788\\_ia\\_en.pdf](http://ec.europa.eu/health/tobacco/docs/com_2012_788_ia_en.pdf), see page 92

The Ministry is of the opinion that it is important that the proposed regulations apply equally to all tobacco retailers. Tobacco sold in specialty shops shall therefore also be sold in standardised packaging. An exemption for specialised shops would lead to a growth in such establishments and thereby undermine the intention and effect of the proposal.

#### *Consequences for supervisory authorities*

The proposal could entail the need for increased resources for supervisory authorities in the first period following the introduction of the new provisions. The Ministry will return to this in a consultation document with proposals for implementation of the general provisions of the new Tobacco Products Directive.

#### *Consequences for illicit trade in tobacco products*

The Ministry is aware that several industry-financed reports claim that standardised tobacco packaging will result in an increase in illicit trade in tobacco goods, *inter alia* because the packaging will be easier to forge. It is already very easy to forge tobacco packaging, meaning that forgery of standardised tobacco packing will be neither easier nor more difficult than forgery of ordinary packaging. Tobacco companies have previously stated that complicated tax stamps with holograms, special ink and complication design elements can be quickly and easily be copied.<sup>97</sup> The Ministry is of the opinion that the proposed regulations will not result in a rise in illicit tobacco products.

In Australia, the measure does not appear to have led to an increase in illicit trade. Industry-financed reports claiming anything to the contrary have been thoroughly analysed and refuted by Australian researchers.

The Ministry refers to the Chantler report from the UK, which has specifically investigated whether standardised packaging will lead to increased tobacco consumption due to lower tobacco prices (due to competition), or to an increase in use of cheap and illicit tobacco. The report states:

“It is my view that the risks of price effects undermining the objectives of a standardised packaging policy are small and that the impacts could be readily mitigated through taxation if, nevertheless, they were to materialise. I am not convinced by the tobacco industry’s argument that standardised packaging would increase the illicit market, especially in counterfeit cigarettes. It seems to me that the solution to illicit use is instead, to have an effective enforcement regime, and the enforcement agencies in the UK have already demonstrated that an effective enforcement regime and appropriate sanctions can keep illicit [tobacco products] to low levels, even in a relatively high tax jurisdiction.”

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<sup>97</sup> Smuggling – the Tobacco Industry and Plain Packs, 2012; [http://www.cancerresearchuk.org/prod\\_consump/groups/cr\\_common/@nre/@pol/documents/generalcontent/smuggling\\_fullreport.pdf](http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/generalcontent/smuggling_fullreport.pdf), page 6.

This issue has also been considered by the Commission in their impact assessment. They are of the opinion that there is no documentation to suggest that standardised tobacco packaging will lead to increased sales of counterfeit tobacco products. Furthermore, they write that the argument is counterintuitive as manufacturers of counterfeit tobacco products try to exploit the reputation and recognition tied to the tobacco manufacturers' brand names. This is currently possible, but will not be possible with standardised packaging.

Either way, the most important measure to counter illicit trade is good control routines and regional and international cooperation. The Ministry notes that the new Tobacco Products Directive contains rules designed to improve such control and will discuss this in more detail in the upcoming consultation on implementation of the directive. Moreover, Norway has signed a protocol against illicit trade in tobacco under the FCTC.