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# COMMISSION OF THE EUROPEAN COMMUNITIES



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# COMMISSION STAFF WORKING DOCUMENT

Accompanying document to the

### WHITE PAPER

"Together for Health: A Strategic Approach for the EU 2008 - 2013"

# SUMMARY OF THE IMPACT ASSESSMENT

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### 1. PROBLEM DEFINITION

The need for a new Strategy is based on growing and changing challenges that face the EU, and which can only be met effectively by a coordinated response at EU level involving all partners and stakeholders. These include the ageing of the population which is changing disease patterns and putting pressure on the sustainability of health systems and the wider economy in an enlarged EU. Health threats such as communicable disease pandemics and bioterrorism are a growing concern, while the health impact of climate change raises new threats. New technologies are revolutionising the way health is promoted and illness is predicted, prevented and treated, and globalisation continues to change the way we interact with the wider world.

## Enlarged EU with Greater Inequities in Health

In an EU of 27 Member States there are wide health inequities (inequalities that are avoidable and unfair) within and between countries. For example, in Italy, men live 71 Healthy Life Years (HLY) compared to 53 HLY for men in Hungary. The ageing population will put a strain on health systems and the wider economy. Commission projections have estimated that if HLY increase at the same rate as increasing life expectancy, health care costs due to ageing would be halved. Although action is already taking place in this area, the EU could add value by, for example, further encouraging the use of Regional Policy programmes for health and by sharing good practice in this and other areas.

# Current and Emerging Threats to Health

Protecting citizens against health threats such as communicable and non-communicable diseases, and improving safety and security are ongoing health challenges where the EU provides clear added value, because these are issues which cross boundaries and cannot be tackled effectively by individual Member States. A new Strategy can add value by providing new opportunities to share good practice and drive forward improvements in areas such as communicable disease surveillance where EU systems can be further developed, and patient safety, where currently as many as 10% of hospital patients suffer an adverse effect.

### Sustainable Health Systems

The sustainability of health systems in the future is a challenge where the EU can add value on cross border issues such as patient and health professional mobility, and in facilitating exchange of knowledge and good practice on issues such as demographic change and the appropriate use of new technologies. The new Strategy can add value through the Community Framework for Safe and Efficient Health Services which is one of the initiatives it will encompass.

## Globalisation and Health

In today's globalised world it is increasingly difficult to separate national or EU wide actions from global policy. Decisions affecting EU citizens directly are often made at global level, and EU's internal policy can have consequences outside the EU borders. The proposed Health Strategy can add value by putting a new focus on strengthening the EU's voice on global health issues on the international stage and on tackling issues such as the global shortage of health professionals and improving access to medicines and technologies.

### Good Governance

To be effective, a new Strategy needs to support the principles of good governance, meaning that the EU's response to these challenges would be coordinated, effective, transparent, and coherent.

A coherent framework for health policy at EU level would act as a driver for achieving objectives, and would help to rationalise and simplify existing structures. A Strategy at EU level would help strengthen health action at national level, and would guide the use of EU instruments and actions for health.

The proposed Strategy would have a focus on Health in All Policies, a concept which underpins the EU health action in the Treaty. A cross-sectoral approach is more effective than an approach which is limited to the health sector. The Strategy would encourage this approach at national as well as EU level.

A new Strategy would also make EU health action more visible to stakeholders including Member States, international organisations, NGOs, industry, academia and citizens.

#### 2. SUBSIDIARITY TEST

EU Member States have the prime responsibility for protecting and improving the health of their citizens. As part of that responsibility, it is for them to decide on the organisation and delivery of health services and medical care. However, the fundamental aims of the EU in terms of free movement of goods and services and working together on cross-border issues, necessarily have a health dimension. It is recognised that there are many areas relating to health where, to be effective, action needs to involve cooperation and coordination between countries. The prevention of major health scourges, pandemic preparedness, or movement of patients or health professionals are areas where Member States cannot act alone effectively, and where cooperative action at EU level is indispensable.

The EU can add value through a wide range of activities. These may include working to reach critical mass or obtain **economies of scale**, for example sharing information on rare diseases where only a small number people are affected in each Member State. It may mean working with Member States to enlarge the **internal market** and increasing the **international competitiveness** of health services. Added value can be found in health promotion **campaigns** such as the 'Help' tobacco campaign<sup>1</sup>, in devising **common standards** such as food labelling, in the support of pharmaceutical **research** and in e-health development and deployment. **Sharing best practice and benchmarking** activities in many areas can play a major role for the efficient and effective use of scarce resources and support future financial sustainability.

The EU's legal right and obligation to take action on cross-border health issues, and its demonstration of success in taking relevant and effective action on health, while respecting Member States' prerogative, and the ability of the EU to add value to work done by Member States in the field of health are clearly demonstrated.

http://ec.europa.eu/health/ph\_determinants/life\_style/Tobacco/help\_en.htm

### 3. OBJECTIVES

The broad objectives of the Strategy are to address the key health challenges faced in the coming decade, through protecting citizens from health threats, supporting healthy ageing, supporting sustainability of health systems and the wider economy, increasing the focus on global health, working to reduce inequities in health, and supporting a Health In All Policies approach. More detailed specific actions would be defined in the follow-up to the Strategy.

### 4. POLICY OPTIONS

Four options were analysed.

Option 1: to continue the status quo.

Option 2: to put in place a Health Strategy with an enhanced Health In All Policies approach at EU level but no new mechanisms with Member States or other stakeholders

Option 3: to put in place a Health Strategy with an enhanced Health In All Policies approach at EU level and a new Structured Cooperation implementation mechanism to engage Member States and other stakeholders

Option 4: to put in place the same measures as in Option 3, with the addition of legislation to set binding targets for key objectives in the Strategy

### 5. ANALYSIS OF IMPACTS

## **Economic Impacts**

There is a clear link between a healthy population and economic prosperity. Under Option 1, the full potential for enhancing support for the wider economy through health improvements would not be achieved. Under Option 2, enhanced development of cross-sectoral synergies could lead to a positive impact on the economy through better understanding of, for example, the impact of health on the labour force and the impact of innovation on health systems. However, without the full engagement of Member States these gains would be limited. Under Options 3 and 4, a stronger positive impact would be expected as a new Structured Cooperation mechanism would allow Member States to share knowledge and good practice in relation to, for example, investments in health. Through a visible new Strategy, the link between health and economic prosperity would be better understood, supporting sustainable health systems and economic gains in the long term.

### Social Impacts

Positive social impacts would continue from ongoing health actions under the Status Quo option, but this would ignore the potential for improvements through a new strategic framework. Option 2 would build on existing cross-sectoral synergies which could lead to a positive social impact particularly in fields like employment and health, and health education. However, this impact would be likely to be limited without the full engagement of Member States and other stakeholders. Under Option 3, positive social impacts would be expected through the new strategic focus and Structured Cooperation mechanism. A risk of binding

legislative targets under Option 4 could be that this would oversimplify complex issues, leading to less 'across the board' improvement than in Option 3.

## **Environmental Impacts**

Ongoing work on environmental health issues would mean some positive impacts under the Status Quo option. Option 2 could offer further benefits through increasing cross-sectoral cooperation in fields such as climate change, and by building on existing work. Option 3 would offer the greatest potential for improvement through increasing opportunities for Member States and other stakeholders to share knowledge and experience on environmental health issues, including global issues. Option 4 would offer similar outcomes to Option 3, but could be seen as unnecessarily burdensome.

# **Comparing the Options**

Option	Impact for Health Objectives	Impact for Governance Objectives
Option 1: Status Quo	Option 1 would lead to benefits based on continuing action to protect and improve people's health, including sharing knowledge and best practice.	Effective work would continue, including work with other sectors.
	However, the lack of a coherent strategic direction may mean that potential for improvement would not be fully exploited. New health challenges, including those linked to the enlargement to 27 Member States from 15 in 2004, may not be adequately addressed. Economic benefits of a more targeted approach to health systems issues could be lost.	However, a clear, strategic vision for the future would not be achieved, and there would not be a focus on addressing key new challenges and fully exploiting synergies between sectors at all levels.  Without a well defined Strategy, presenting a clear direction of travel that stakeholders and citizens could engage with would be difficult.
Option 2: Health Strategy with Enhanced Intersectoral Action	Through a more strategic approach to the many varied actions across the EU that impact on health, Option 2 could lead to benefits, for example a stronger focus on supporting healthy lifestyles, or further clarification of issues relating to the use of new technologies within health systems.	Option 2 would set strategic objectives which would help to strengthen HIAP cooperation across sectors by offering a clear, strategic framework and direction of travel.
	However, without full engagement by Member States the added value and actual outcomes under this Option would be limited.	However, it is likely that the new framework would not become widely recognised by Member States and other stakeholders, and that progress towards the objectives would therefore be limited. Option 2 would be unlikely to adequately fulfil the objective of greater visibility and understanding of work on health at

		EU level.
Option 3: Health Strategy with  Enhanced Intersectoral Action and  Structured Cooperation with Stakeholders	Option 3 would be likely to lead to positive impacts by engaging all Member States through a Structured Cooperation system, including measuring progress against indicators, to focus attention on tackling new challenges, such as protecting health, reducing inequities, supporting healthy lifestyles, addressing the future sustainability of health systems, and supporting the consideration of global issues in health policy at all levels.	Option 3 would put in place a system of Structured Cooperation with Member States and stakeholders to support work towards objectives and open up new opportunities for sharing knowledge and information.  It would go beyond Options 1 and 2 by supporting greater recognition of the importance of intersectoral working at national, regional and local levels across the EU, and greater involvement of non-traditional stakeholders as partners to achieve health aims.  Option 3 would be more likely than Options 1 and 2 to fulfil the objective of improved visibility of work on health at EU level.
Option 4: Health Strategy with  Enhanced Intersectoral Action,  Structured Cooperation with Stakeholders and  Binding Targets	Option 4, like Option 3, would be likely to have a positive outcome through putting in place a new Structured Cooperation mechanism to help focus attention on key challenges. The impact might be greater than in Option 3 due to the imposing of binding legislative targets.  However, this may be seen as disproportionately burdensome to Member States and may reduce their flexibility in addressing problems at national level.	Option 4 would be likely to be slightly more effective than Option 3 as it would enforce Member States to work toward the objectives through binding targets, rather than relying on the cooperation process alone.  Similarly, it might be slightly more effective in improving visibility of work done at the EU level, as setting binding targets may mean that more policymakers at national, regional and local levels are required to consider EU health objectives.
		This Option, however, could be seen as disproportionately burdensome to Member States.

Option 3 uses the powers given to the EU in the Treaty to go a step further than Option 2, by putting in place a new implementation system. This Option would ensure that the new strategy is not just a paper exercise, but that it drives real change. At the same time it does not go too far in placing a burden on Member States and respects the subsidiarity and proportionality principles. This Option is therefore the preferred Option.

# Monitoring and Evaluation

Monitoring and evaluation will be on the basis of measurement against the seven objectives. The three 'good governance' objectives can be measured by the following indicators:

- Process indicator that a framework with objectives has been put in place (objective 5)
- Quantitative indicator awareness of the new strategy among policymakers, professionals, academia and the public
- Qualitative indicator that HIAP is more common practice at all levels

Setting the parameters for monitoring and evaluation of the four health objectives of the Strategy are outside the scope of the White Paper and will need to be decided with Member States following adoption of the Strategy. The recommendation to take forward Option 3 means that a new implementation mechanism of Structured Cooperation will be agreed and set up by and with Member States. One of the first tasks of this new Cooperation process will be to set indicators for monitoring the Strategy, target values for those indicators, and how frequently data will be collected.

The Strategy will have a mid-term evaluation and a final evaluation and will cover a period of 10 years.

## **Consultation of Interested Parties**

Two consultation processes took place in relation to the proposed Strategy. The first was in 2004 where the document 'Enabling Good Health for All – A Reflection Process for a new EU Health Strategy' generated a broad debate among stakeholders. 193 responses were received, which supported a focus on mainstreaming health into other policy areas, reducing health inequalities within and between Member States, health promotion, a stronger role for the EU in global health issues, and tackling key issues including those with a cross-border impact.

The second consultation was launched on 11 December 2006 and ended on 12 February 2007. 156 responses were received including responses from 16 Member States. Responses reflected the previous consultation and expressed general support for the Strategy. Inter alia, responses called for a focus on tackling health threats, reducing health inequalities, promoting healthy lifestyles, and improving the availability of comparable data across the EU. There was also broad support for an implementation mechanism similar to the Open Method of Coordination that is used for achieving progress towards the goals of the Lisbon agenda.