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**Executive summary of impact assessment
Accompanying the document
Health for growth programme of EU action in the field of health for the period 2014-
2020**

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Disclaimer

This Impact Assessment report commits only the Commission's services involved in its preparation and the text is prepared as a basis for comments and does not prejudge the final form of any decision to be taken by the Commission.

1. PROBLEM DEFINITION

‘Health for Growth’ the third EU Programme in the area of Health for the period 2014-2020 (hereinafter the ‘Programme’), will seek to build on the results achieved by both the first Public Health Programme (PHP) for 2003-2007 and the current, second Health Programme (HP) for 2008-2013.

However, in line with the objectives of ‘Europe 2020: A European strategy for smart, sustainable and inclusive growth’¹ and based on the conclusions drawn and recommendations made in the different evaluations and audit exercises performed on the previous programmes, the new Programme will also introduce a new approach in certain respects. It will be a more focused programme, concentrating on a more limited number of high-profile priorities and activities where it can build up a critical mass, *inter alia* by exerting a leverage effect, complementing Member States' policies and encouraging cooperation in the area of health, in accordance with Article 168 of the Treaty on the Functioning of the European Union.

Lessons learnt from the previous programmes and their evaluations were unequivocal:

a) The new Programme should contain less and have more focused objectives and concentrate its financial support on a smaller number of activities in key priority areas, bringing the greatest EU added value. It should increase efficiency gains and maximise the impact of the Programme;

b) The Programme should better involve all participating countries, especially those EU Member States with relatively low Gross National Income (GNI). The emphasis should be placed on areas where they cannot act in isolation in a cost-effective manner, where there are clear cross-border or internal market issues or where there are significant advantages and efficiency gains from collaboration at EU level.

c) The results need to be built into a regular reporting system and shared/spread more efficiently between Commission departments and with stakeholders and national policymakers.

As stated in the European Commission's Communication of 29 June 2011 ‘A budget for Europe 2020’² ‘Promoting good health is an integral part of the smart and inclusive growth objectives of Europe 2020. Keeping people healthy and active for longer has a positive impact on productivity and competitiveness. Innovation in healthcare helps take up the challenge of sustainability in the sector in the context of demographic change and action to reduce inequalities in health is important to achieve ‘inclusive growth’.

More particularly in the related policy fiche on Health of the Multi-annual Financial Framework (MFF) Communication it is stated:

¹ Communication from the Commission: ‘Europe 2020 — A strategy for smart, sustainable and inclusive growth’ COM(2010) 2020 final.

² ‘A Budget for Europe 2020’ — Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions — COM(2011) 500 final.

"The new Health for Growth Programme will be oriented towards actions with clear EU added-value, in line with the Europe 2020 objectives and new legal obligations. The principal aim is:

- *to work with Member states to **protect citizens from cross-border health threats,***
- *to **increase the sustainability of health services,***
- *to **improve the health of the population, whilst encouraging innovation in health.***

For example, the programme will support health policy by developing best practices and guidelines for the diagnosis and treatment of rare diseases, supporting European reference networks on diseases, developing best practices and guidelines for scanner screening and developing a common EU approach to health technology assessments and e-Health.

[In the same time] Research and innovation actions in the area of health will be supported under the Common Strategic Framework for Research and Innovation".

In this Communication the Commission proposed an allocation of 396 million euros (in 2011 prices; or 446 million euros in current prices) for the period 2014-2020 for a dedicated expenditure programme in the area of health. In budgetary terms this is undeniably a small to medium size programme, especially when taking into account that health care expenditure accounts for nearly 10% of the EU's gross domestic product and is one of the largest economic sectors in the EU.

Health is not just a value in itself - it is also a strong economic driver for growth. The healthcare sector employs one in ten workers in the EU who are among the most qualified because there is a higher than average proportion of workers with tertiary-level education. This weight gives the healthcare sector an important role to play in the economy in general and in contributing to the Europe 2020 Strategy. There is strong evidence of the link between health and economic performance: a population in good health is a *sine qua non* for attaining smart, sustainable and inclusive growth.

Not only is good health one of the most important factors for increasing individual productivity and citizen empowerment, but also an increase in the number of productive years as a result of better health would have an immediate positive impact on collective productivity and competitiveness. In addition, health is a strong economic driver of growth, both by sustaining household demand and by increasing savings, as well as by creating high quality jobs, stimulating innovation and providing a basis for a strong European industry.

Finally, investing in health can also help address the challenges as well as better exploit the opportunities offered by an ageing society (over the next 20 years, the number of Europeans aged over 65 is expected to rise by 45%, from 85 million in 2008 to 123 million in 2030). Issues arising in this context are related not only to protecting, promoting and improving the health status of the elderly, but also to financing the rising healthcare costs and to improving the healthcare offered, in response to higher and different expectations, and also ensuring access to it.

In the area of health the Member States are under pressure to strike the right balance between providing universal access to high quality health services and respecting budgetary constraints. These problems are not necessarily new, but the need to tackle them has become more and more urgent, particularly in the current economic climate. The financial crisis has further magnified the need to improve cost-effectiveness of national health systems. First and foremost it is up to Member States to take direct action at their level. The aim of EU Health policy, as stated in the Treaty, is to complement and support these national policies and encourage cooperation between Member States.

The challenge is to build an EU Health Programme that serves the best the interests of Member States and other stakeholders within a limited budget. It is therefore necessary to prioritise needs in such a manner that results of the Programme are used and create a leverage effect to support and develop health policies at European, national and local level.

The Programme should provide possibilities to build and strengthen cooperation mechanisms and coordination processes between Member States with a view to identifying common tools and best practices that create synergies. It should bring the biggest EU added value and lead to economies of scale, thus supporting reforms under challenging circumstances. There are several challenges that Member States and the EU as a whole are facing from the 2020 perspective and beyond:

- A. Financial sustainability of health systems;**
- B. Health workforce shortages;**
- C. Improvements necessary in patient safety;**
- D. Lack of sustained progress on control and prevention of chronic conditions;**
- E. Loss of best productive years in much of the population because of the slow increase in healthy life years;**
- F. Increasing inequalities in health throughout Europe and in its neighbourhood;**
- G. Global and cross-border threats.**

The Programme can contribute to addressing the above-mentioned challenges only to the extent that it offers financial opportunities to build and strengthen cooperation mechanisms and coordination processes between Member States with a view to identifying common tools and best practices that would create synergies, bring EU added value and lead to economies of scale, while fully respecting the principle of subsidiarity and recognizing the ultimate responsibility of Member States to take decisions most suited to their specific situations

Thus, the Programme will contribute only where Member States could not act individually or where coordination is clearly the best way to move forward. In line with the EU 2020 objectives, the action taken in the Programme must prove to have real EU added value and a measurable impact.

Also other better resourced EU funding programmes will contribute to improving public health in the EU, most notably the public health component of the Research Programme and of the Structural Funds. However, the Health Programme is the only one aiming specifically at addressing the challenges and concerns in the health policy field, while also enabling further achievement of the policy goals in this area. It can therefore address issues that are out of the scope of other funding programmes. Its success can nonetheless be amplified by forging the necessary links and clear synergies with other spending programmes.

2. SUBSIDIARITY TEST – THE RIGHT OF THE EUROPEAN UNION TO ACT

Article 168 of the Treaty on the Functioning of the European Union (TFEU) strongly asserts the **principle of subsidiarity in public health**. It says that ‘Union action ... shall **complement** the national policies’ and then that ‘Union action shall **complement** the Member States’ action.’ The Union can also ‘**lend support** to their action’.

The main areas where this complementary action has to be taken are also mentioned:

- improving public health,
- preventing physical and mental illness and diseases,
- obviating sources of danger to physical and mental health,
- fighting against the major health scourges,
- reducing drugs-related health damage, including information and prevention, and
- improving the complementarity of the Member States' health services in cross-border areas.

The same article also indicates ways to contribute to the fight against major health scourges:

- promoting research into their causes, their transmission and their prevention,
- promoting health information and education,
- monitoring, early warning of and combating serious cross-border threats to health,
- encouraging cooperation between the Member States. In particular, the second subparagraph of Article 168(2) states that 'The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation.'

Paragraph 3 of the same article then goes on to say that 'The Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.'

Against this background, Article 168(5) TFEU empowers the European Parliament and the Council to adopt incentive measures to protect and improve human health.

Necessity test

While Member States as sovereign entities have to tackle the above-mentioned problems and decide on their national health policies, in a number of cases they can only take action after coordination at EU level. For many countries, the cooperation between Member States is very beneficial and is far more cost-effective. There is also a better chance of solving global issues and common concerns by mobilising efforts at EU level and establishing common values and principles.

The Programme will therefore primarily fund actions that cannot be carried out as effectively by Member States on their own but depend greatly on cooperation at EU level.

3. EU ADDED VALUE

Experience from past programmes has provided a number of examples where action at EU level can provide clear added value that has been recognised by the Member States (cf. case studies annexed to the Impact Assessment).

The value of investing in preparedness, prevention and coordination of measures on health threats and communicable diseases at EU level was clearly demonstrated recently by the H1N1 outbreak in 2009. Strengthening the capacity to manage serious cross-border health threats, along with joint procurement of vaccines against pandemics, is another area where significant EU added value can be obtained. Cooperating on cross-border diseases such as

H1N1 flu also cannot be undertaken by individual Member States, but depends on initiatives and funding at EU level. In the area of health threats, the EU's role, beyond coordinating the response to these threats, is also to enhance the capacity of Member States and non-EU countries to respond to them. Providing a rapid and coordinated answer to global health threats is also the EU's role.

The EU can also deliver significant benefits on issues such as cross-border health care and health inequalities and by developing strategies to counter growing antimicrobial resistance, along with cost-effective health technologies and innovative healthcare, and promoting healthy ageing with the aid of a European Innovation Partnership. Action under the Health Programme complements and adds value to Member States' action on health promotion and prevention of illness (including work on, for example, nutrition and smoking and on reducing inequalities in healthcare), protection of citizens against health threats, in particular pandemic preparedness, the safety of medical products, blood, tissues, cells and organs, and cooperation between health systems. Understanding rare diseases and developing innovative treatment for them requires pooling of patient populations in European registers across several countries; many such measures depend critically on the Health Programme.

The Health Programme has developed and strengthened networks between European health specialists, national and regional health authorities and other stakeholders who greatly contribute to sharing knowledge and building health capacity in the EU. It has also built consortia, partnerships and other ways to exchange information and practices across Europe, thus boosting cooperation and the pace of research. The outcome of the projects and action funded by the Health Programme constitute the most effective, if not the only, way to build the evidence base for defining much broader regulatory policies (for instance, on cancer, Alzheimer's, rare diseases and health inequalities).

In the context of the mid-term evaluation of the 2nd Health Programme and based on the in-depth analysis of the case studies following EU added value criteria were developed and tested regarding concrete funded actions:

- Fostering **best practice exchange** between Member States;
- Supporting **networks** for knowledge sharing or mutual learning;
- Addressing **cross-border threats** to reduce risks and mitigate their consequences;
- Addressing certain issues related to the **internal market** where the EU has substantial legitimacy to ensure high-quality solutions across Member States;
- Unlocking the **potential of innovation** in health;
- Actions that could lead to a system for **benchmarking** for decision-making;
- Improving **economies of scale** by avoiding waste due to duplication and optimising use of financial resources.

4. OBJECTIVES OF THE PROGRAMME

Taking into consideration the problems and context described above, as well as limited financial resources in the coming years, the 'Health for Growth' Programme general objectives shall be to work with Member States to encourage innovation in healthcare and increase the sustainability of health systems, to improve the health of the EU citizens and protect them from cross-border health threats.

The specific objectives underpinning the logic of the Programme are all outcome-oriented and

put the emphasis on the practical results and their up-take by Member States in their national programmes and health policies in order to exert leverage on health action and across other policies and other EU funding programmes:

1. Developing common tools and mechanisms at EU level to address shortages of resources, both human and financial, and to facilitating up-take of innovation in healthcare in order to contribute to innovative and sustainable health systems

By supporting Member States' efforts to improve the efficiency and financial sustainability of health care, EU Health Programme aims at encouraging a shift of significant resources in this sector on the most innovative and valuable products and services which at the same time offer the best market potential and cost savings in the longer term. Health system reform must clearly consist of a mix of immediate efficiency gains with longer term strategic action addressing key cost drivers. This is the only way if countries are to ensure universal access and equity in health, health financing and use of the system. As an example, European cooperation on **health technology assessments** will not only reduce duplication and pool expertise but can unlock the potential for sustainable innovation in health products and services.

It is of utmost importance to develop common tools and mechanisms at EU level to help national health systems deliver more care with fewer resources. Innovative solutions are needed to tackle workforce shortages and to maximise the efficiency of health systems through the use of innovative products, services and tools.

The EU 2020 strategy identifies innovation as a key to creating smart growth. There is a huge "smart growth" potential in health which can lead to increased efficiency and the creation of new health interventions and products adapting to our society. Innovation responds to the sustainability challenge facing health systems both by fostering completely novel solutions to answer unmet needs and by deploying more efficiently what is already available and creating the right conditions for future innovation. Innovation should be seen not only as technology-based but also as organisational and social, centred on the human factor, so that it can bring genuine benefits in a cost-effective way.

The recent economic crisis has rendered the need to improve the cost-effectiveness of health systems even more pressing and has turned it into a top policy priority that is likely to remain on the agenda for many years to come. Member States will have to balance the need to provide access for all against the increasing demand for quality health services at a time of constrained resources.

The cost-effective use of medical technologies, including the upcoming therapies based on genomic science, an adequate supply of health professionals, expertise necessary to improve decision-making, as well as support for the European Innovation Partnership on Active and Healthy Ageing are the areas where the Programme could play an important role under this policy objective by taking a very pragmatic approach.

2. Increasing access to medical expertise and information for specific conditions also beyond national borders, and developing shared solutions and guidelines to improve healthcare quality and patient safety, in order to increase access to better and safer healthcare for EU citizens

Improving access to healthcare to all citizens regardless of income, social status, location and nationality is a key to bridging the current substantial inequalities in health. All EU citizens should have access to safe and high quality healthcare regardless of their circumstances.

However, in reality, access to healthcare still varies significantly in the EU. It is also recognized that health is a key driver of inequalities, as poor health status often has a substantial impact on accessibility to effective health care and the possibilities of individual citizens to act on health information disseminated at national and European level. Action under all the objectives of the programme should help contribute to bridging such inequalities by addressing various health factors that give rise to and increase inequalities, as well as complement action under other programmes specifically addressing social and regional differences within the EU.

To improve access to healthcare, in particular for specific conditions where national capacity is scarce, there is clear added value in fostering the networking of European centres of reference accessible to all citizens across the EU.

Scarce knowledge can be shared and resources combined as efficiently as possible across the EU, as can be seen, for instance, in the case of rare diseases.³ Under specific objective 2, this sharing of resources is to be expanded to other areas of health requiring a particular concentration of resources or expertise to look at various clinical conditions. The main goal here is to pool medical expertise and knowledge in order to improve access to diagnosis and provision for all patients requiring highly specialised care for a specific disease or group of diseases.

Such networks would add to the already substantial expertise and capacity for specific complex/high-tech diagnostic or treatment services of the centres participating, offering significant added value in the form of improved quality and cost-effectiveness spread throughout the continuum of care.

The ultimate aim would be to improve patients' health by increasing cross-border possibilities. This would also help Member States with empowering patients, by increasing the availability of information and transparency on care delivery which, in turn, would help to achieve better healthcare outcomes.

Specific actions under this policy objective would include setting up accreditation and support of European reference networks, strengthening collaboration on patient safety and quality of care and improve the prudent use of antimicrobial agents in human medicine.

3. Identifying, disseminating and promoting the up-take of validated best practices for cost-effective prevention measures by addressing the key risk factors, namely smoking, abuse of alcohol and obesity, as well as HIV/AIDS, with a focus on the cross-border dimension, in order to prevent diseases and promoting good health

Prevention of diseases and promotion of health contribute to increasing the number of 'healthy life years' or years in good health. Apart from the fact that health is the greatest wealth and a goal *per se*, healthy citizens contribute to economic prosperity by virtue of their higher labour market participation and productivity. Well-directed investment to promote health and prevent diseases is one of the most cost-effective means of stimulating growth in gross domestic product. This is becoming extremely crucial in the context of an ageing society and longer working lives.

The right investments will not only lead to better health, but also to longer and more productive lives and lower labour shortages. If Europeans live in better health, they will be able to continue contributing to the economy as they grow older - as workers, volunteers and

³ See Annex 7 for case studies on European reference networks for rare diseases and ORPHANET.

consumers. The expertise of the elderly will also be needed even more in a population with low birth rates and lack of skilled labour.

The Programme foresees action to support the efforts of Member States aimed at prolonging the healthy and productive life years in the areas of cost-effective promotion and prevention measures addressing risk factors and underlying health determinants, chronic diseases and cancer.

4. Developing common approaches and demonstrate their value for better preparedness and coordination in health emergencies in order to protect citizens from cross-border health threats

In the recent past, the EU has faced several major cross-border threats to health, such as pandemic influenza or SARS. EU competence as regards co-ordinating the preparedness and response for serious cross border health threats is enshrined in the Treaty. By their very nature, such health threats are not confined to national borders and cannot be effectively addressed by any Member State alone. The EU needs to be well prepared against these threats which can have a high impact not just on the health and life of citizens, but also on the economy.

In order to minimise the public health consequences of cross-border health threats which could range from mass contamination caused by chemical incidents to epidemics or pandemics, like those unleashed recently by *E coli*, H1N1 or SARS (severe acute respiratory syndrome), robust mechanisms and tools to detect, assess and manage major cross-border health threats need to be established or reinforced. Due to the nature of these threats, coordinated public health measures at EU level are needed to address different aspects, building on preparedness and response planning, robust and reliable risk assessment and on a strong risk and crisis management framework.

The overriding aim is to tighten up the monitoring, the early warning system and the fight against serious cross-border health threats, also in the light of the ‘one health’ concept and with a view to the comprehensive framework on health security that is currently being developed.

In this context, the future Health for Growth Programme would support implementation of the EU legislation on health threats and EU action in the field of public health crisis management. All the components of crisis management will be addressed: preparedness and response planning, risk and crisis communication, capacity-building for risk assessment and training, exchanges of experience and best practice in handling health emergencies. The action envisaged ranges from supporting development of Member States’ core capacity and standards for preparedness to response planning.

This capacity-building covers surveillance, detection and risk assessment for major health scourges, on the basis of the legislation being reviewed and developed, together with multinational, cross-sectoral training activities and initiatives for prevention and control of communicable diseases, antimicrobial resistance and hospital-acquired infections, plus improvements in vaccination policies and strategies at EU level.

5. POLICY OPTIONS

Option 1 corresponds to the absolute minimum of actions resulting from the legal obligations imposed by the Treaty and the existing EU *acquis* in the field of medicinal products, medical devices, substances of human origin, patients rights in cross border healthcare, Health security (cross border health threats) and tobacco.

Option 2 corresponds to the baseline scenario. It implies continuing the programme in its present form with no changes consequently to the findings of the evaluations, in addition to the direct legal obligations.

Option 3, sub-option A corresponds to a well structured programme, with SMART objectives, prioritised actions, creating EU added value and with better monitoring of outcomes and impacts. It will be focused on:

- supporting actions required by the current EU health and internal market legislation,
- supporting the up-take of innovative solutions for improving specific points concerning the quality, efficiency and sustainability of health systems,
- prevention of diseases at EU level by helping and complementing Member States' efforts to increase their citizens' number of healthy life years (HLY), including the aspect of reduction of health inequalities but mainly by other means than the resources of the Programme and limited to development of working methods and policy evaluation;
- supporting and complementing Member States efforts in protecting citizens from cross border health threats.

Sub-option 3, sub-option B corresponds to a well structured programme but dealing only with one of the general objectives as a trade off. This programme would be focused on:

- supporting actions required by the current EU health and internal market legislation,
- supporting the up-take of innovative solutions for improving specific points concerning the quality, efficiency and sustainability of health,
- supporting and complementing Member States efforts in protecting citizens from cross border health threats.

Sub-option 3, sub-option C corresponds to a programme limited to supporting actions required by the current EU health and internal market related legislation and to support and complementing Member States efforts in protecting citizens from cross border health threats. In addition, there would be some dissemination of the results of the current Health Programme in order to take into account the conclusions of previous evaluations,

Option 4 corresponds to a well-structured programme focusing on the same issues as option 3 a) but adding a specific objective for addressing wider, social and economic, causes of health inequalities by appropriate financial means. This option would imply a significant increase of the envelope for the Programme.

6. COMPARISON OF THE OPTIONS

The *option involving no resources at all* was not considered. Without credits the Commission would simply not be able to fulfil its obligations stemming from the existing legislation.

Option 1 would cause a reduction of EU support to Public Health policy, as well as contravene the conclusions of the evaluation of the current Health programme and the requests for a continuation of the programme made by the EU Health ministers and other stakeholders. It would fail to guarantee an adequate support to the future Public Health policy.

Option 2 would allow taking into account to a certain degree concerns of Member States and stakeholders' and it would have leverage on national health policies. However, in the absence

of intervention logic, lack of SMART, realistic objectives, with a large number of actions not prioritised and no precise indicators to measure the achievements, any kind of impact would first be very difficult to assess and then very limited, because not part of a logic. This type of programme would not allow to achieve the objectives and it would not take into account the recommendations stemming from the past evaluations and audits.

Option 3, sub-option A will allow the specific objectives to be achieved through the actions defined and prioritised in this impact assessment. The Commission's legal obligations would be fulfilled. The proposed Programme would address the main criticisms made by the external evaluations and in the Court of Auditors report. It would have intervention logic, well defined policy objectives, SMART, realistic, outcome oriented and pragmatic specific objectives, actions to be carried out would be prioritised with the help of specific EU added value criteria and a set of indicators would be defined for measuring the outcomes and up-take of Programme results by Member States. Thus, it would be possible to measure achievements and to act if they are not in line with milestones established and, finally, to determine the impact of the Programme.

Option 3, sub-option B corresponds to a lower budget than the current programme and the allocation foreseen in the MFF Communication. This option would not allow addressing satisfactorily the challenges faced in public health as the synergies between promotion of good health and chronic diseases would be lost, especially regarding citizens' exposure to chronic diseases. The programme would not respond to the expectations of Member States and other stakeholders.

Option 3, sub-option C corresponds merely to option 1 but with the specific objective on health threats. While Commission's legal obligations would be fulfilled and while actions on health threats would be carried out, all the other actions at EU level would be discontinued. This would cause a reduction of EU support to Public Health policy, as well as contravene the conclusions of the evaluation of the current Health programme and the request for a continuation of the programme made by the stakeholders and the MS. It would fail to guarantee an adequate support to the future Public Health policy currently under preparation.

Option 4 means a substantial increase of the Public Health budget which is not realistic.

The result of the comparison of the option was unequivocal: the option 3A is by far the one preferred.

7. MONITORING AND EVALUATION

The Programme will be monitored on an annual basis in order to both assess headway towards the achievement of its specific objectives against its outcome and impact indicators and allow for any necessary adjustments of the policy and funding priorities.

At the request of the Commission, without disproportionate increase in the administrative burden, the Member States should submit any available information on the implementation and impact of the Programme.

The proposal is to set up an indicative internal multi-annual work programme - it would serve as a guideline for the annual work plans.

A wide range of financial mechanisms will be used in the Programme: calls for proposals, grants for actions with Member States, grants for international organisations, operating grants and public procurement contracts. As said in the evaluations, the experience gained from their

introduction in the current Health Programme was positive and considered as an improvement over the system for the previous Public Health Programme. The Programme will be subject to mid-term term and ex-post evaluation. The mid-term evaluation will serve the impact assessment exercise for eventual follow-up programme in the area of health post-2020.