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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on
establishing a Health for Growth Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020

(Text with EEA relevance)

{SEC(2011) 1322 final}
{SEC(2011) 1323 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

Health is not just a value in itself - it is also a driver for growth. Only a healthy population can achieve its full economic potential. The health sector is driven by innovation and a highly qualified workforce. Health-related research and development has the potential to reach 0.3% of GDP. The healthcare sector is one of the largest in the EU: it accounts for approximately 10% of the EU's gross domestic product and employs one in ten workers, with a higher than average proportion of workers with tertiary-level education.

Health therefore plays an important role in the Europe 2020 agenda. In its Communication of 29 June 2011 'A budget for Europe 2020'[1] the Commission stressed that '*promoting good health is an integral part of the smart and inclusive growth objectives for 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*'.

The proposed third programme of EU action in the field of health (2014-2020), 'Health for Growth', strengthens and emphasises the links between economic growth and a healthy population to a greater extent than the previous programmes. The Programme is geared towards actions with clear EU added value, in line with the Europe 2020 objectives and current policy priorities.

The financial crisis has further highlighted the need to improve the cost-effectiveness of health systems. Member States are under pressure to strike the right balance between providing universal access to high-quality health services and respecting budgetary constraints. In this context, supporting Member States' efforts to improve the sustainability of their health systems is crucial to ensure their ability to provide high quality healthcare to all their citizens now and in the future. The Health for Growth Programme contributes to finding and applying innovative solutions for improving the quality, efficiency and sustainability of health systems, putting the emphasis on human capital and the exchange of good practices.

Key goals, set out in the "Europe 2020 – A strategy for smart, sustainable and inclusive growth"[2], all hinge on increasing innovation in healthcare as reflected in flagship initiatives such as the Innovation Union and the Digital Agenda. However, innovation is not just about technology and new products. It is also about innovating in how healthcare is organised and structured, how resources are used, how systems are financed.

As such, innovation in health has the potential to help reduce healthcare costs and improve the quality of care. Many areas of the proposed Health for Growth Programme, such as health technology assessment (HTA), medical devices, clinical trials and medicinal products, as well as the European Innovation Partnership on Active and Healthy Ageing, aim to strengthen the link between technological innovation and its uptake and commercialisation; while fostering security, quality and efficiency of healthcare. Other initiatives focus on promoting the uptake

[1] COM(2011)500 Final.
[2] COM(2010)2020 Final.

and interoperability of e-Health solutions, to improve for example cross-border use of patient registers.

The Programme will further support better forecasting, planning of needs and training of health professionals, which will contribute to both organisational innovation and inclusive growth. This is in line with the EU 2020 flagship initiative for New Skills and Jobs and its focus on flexibility and security, equipping people with the right skills for the jobs of today and tomorrow, better working conditions and improving job creation. As the population ages and demand for healthcare grows, the health sector has great potential to create new jobs.

Health problems are one of the major causes of absenteeism from work and early retirement. Keeping people healthy and active for longer has a positive impact on productivity and competitiveness. Increasing the number of healthy life years is a prerequisite if Europe is to succeed in employing 75% of 20-64 year-olds and avoiding early retirement due to illness. In addition, keeping people over 65 years of age healthy and active can impact on labour market participation and lead to potential important savings in healthcare budgets.

The general objectives of the Health for Growth Programme 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.

It focuses on four specific objectives with a strong potential for economic growth through better health:

(1) to develop common tools and mechanisms at EU level to address shortages of resources, both human and financial and to facilitate up-take of innovation in healthcare in order **to contribute to innovative and sustainable health systems**;

(2) to increase access to medical expertise and information for specific conditions also beyond national borders and to develop shared solutions and guidelines to improve healthcare quality and patient safety in order to **increase access to better and safer healthcare for EU citizens;**

(3) to identify, disseminate and promote 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 promote good health; and**

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

This proposed Regulation sets out the general provisions governing the Health for Growth Programme and repeals Decision (EC) No 1350/2007.

2. OBJECTIVES

The challenges outlined above first and foremost require Member States to take direct action at national 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 Programme provides 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, bring EU added value and lead to economies of scale, thus supporting reform under challenging circumstances.

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

For many years, Member States have been facing budget constraints with regard to the sustainability of their health budgets, which represent up to 15% of public expenditure in some Member States[3].

This is further compounded by an ageing population, rising expectations for high quality services and the emergence of new, more effective but more expensive technologies. The challenges have increased with curbs on public spending in the wake of the financial crisis. Evidence[4] suggests, however, that effective health system reforms have the potential to contain 'excess cost growth', i.e. keep health spending in line with GDP growth.

By supporting Member States' efforts to improve the efficiency and financial sustainability of health care, the programme aims to encourage a significant shift of resources in this sector towards 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. It also seeks to support innovation in how healthcare is organised, to foster for example a greater shift towards community care and integrated care. Health system reform must clearly consist of a mix of immediate efficiency gains and longer-term strategic action addressing key cost drivers. For example, European cooperation on health technology assessment will not only reduce duplication and pool expertise, but can also unlock the potential for sustainable innovation in health products and services.

Health-related investments under the Structural Funds can play a particularly important role in helping Member States reform their health systems at national and regional level, and in meeting the four specific objectives under this Programme, drawing from best practice and pilot project experience acquired through the Health for Growth Programme. As such, co-operation and synergies between the Health for Growth programme and the Structural Funds will be reinforced.

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[3] Source: extracted from Eurostat online database in July 2011 'General expenditure by function - health compared to total'. 2009: 14.63 %; http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=gov_a_exp&lang=en .

[4] IMF 2011 and Joumard et al., 2010, i.e. the rise in public health spending over GDP in excess of what is due to population ageing (this excess cost growth is estimated at an average of about 1 % for the OECD).

With an ageing population and changing family structures, the demand for formal, professionalized care is increasing as the availability of informal care in the family environment is declining. Healthcare has also become more specialised and requires more intense work and longer training. By 2020 there will be a shortage of one million health workers in the EU and, should no action be taken, 15% of necessary care will not be covered. If successfully addressed, however, this would create significant employment and growth opportunities.

To achieve this, the Programme will 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, tools and models. Successful implementation of such solutions will also require overcoming barriers such as public procurement and lack of user involvement in innovation.

In this context, actions planned under this objective aim for example to foster European cooperation on Health Technology Assessment (HTA) and explore the potential of e-Health and ICT for Health, including a dedicated e-Health network and cooperation among electronic patient registries, as part of the implementation of the Directive on patients' rights in cross border healthcare[5]**.** Actions will also address shortages in the health workforce and assist Member States in reforming their health systems through the pooling and strengthening of expertise on technical evaluation of policy action.

They will also support measures setting high standards of safety, quality and efficacy for devices for medical use required by or contributing to the objectives of EU legislation in this field, as well as contributing to provisions on e-Health and HTA of the above mentioned Directive.

The programme may also provide support, under its different objectives, to specific actions under the European Innovation Partnership on Active and Healthy Ageing in its three themes: innovation in awareness, prevention and early diagnosis; innovation in cure and care and innovation for active ageing and independent living.

2.2. 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 for all citizens regardless of income, social status, location and nationality is 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. Poor health status often has a substantial impact on accessibility to effective healthcare and the possibilities of citizens to act on health information. People with low income, the socially excluded and those living in depressed or micro regions can experience specific difficulties in accessing healthcare. Action under all the objectives of the programme should help contribute to bridging such inequalities by addressing various factors that give rise to and increase

[5] Directive 2011/24/EU of the European Parliament and the Council of 9 March 2011

inequalities, as well as complement action under other programmes aimed at 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 specialised European centres of reference accessible to all citizens across the EU.

In addition, to help Member States further improve the quality and safety of healthcare, the programme will consolidate and continue on-going action to identify, exchange and disseminate good practices in this area. The programme will increase access to medical expertise by supporting the establishment and setting up of a system of European reference networks defining their criteria and conditions and by developing shared solutions and guidelines for healthcare quality and patient safety across the EU, tackling a range of issues including antimicrobial resistance.

Actions under this objective will also support measures setting high standards of safety, quality and efficacy of blood, organs, tissues and cells, of pharmaceutical products and patients' rights in cross border health care required by or contributing to the objectives of EU legislation in these fields.

2.3. 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 promote good health

Life expectancy has been progressing over the last decades in an unprecedented way and was 76.4 years for men and 82.4 years for women in the EU in 2008. By contrast, the average number of healthy life years has been progressing at a much slower pace and was 60.9 years for men and 62 years for women.

This means that a greater part of a longer life is being spent in ill health, which is one of the factors driving spiralling health costs and hampering participation in the labour market. Ill health adversely affects the development of human capital, which is crucial for developing a knowledge-based economy.

Chronic diseases are the main cause of death and poor quality of life in Europe. Over 4 million people in the European Union die every year because of chronic diseases, which represent 87% of premature mortality in the EU. Chronic diseases also represent a huge economic burden through loss of people’s capacity to work in the prime of their lives. The programme includes action to support the efforts of Member States aimed at prolonging the healthy and productive life years of their population by preventing chronic diseases.

Many chronic diseases are preventable. They are often the result of smoking, harmful alcohol consumption, poor diet and insufficient physical activity. These risk factors are further compounded by underlying socio-economic factors as well as environment factors.

This is not just a major health challenge, but also a substantial economic opportunity. The right investments will lead not only 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

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

The programme will address the challenges in these areas by fostering best practice in health promotion and cost-effective prevention targeting key health determinants namely smoking, abuse of alcohol and obesity, as well as HIV/AIDS, with a focus on cross border issues. It will support European cooperation and networking on preventing chronic diseases, including guidelines on quality cancer screening. Actions under this objective will also support measures which have as their direct objective the protection of public health regarding tobacco products and advertisement required by or contributing to the objectives of EU legislation in this field.

2.4. Developing common approaches and demonstrating 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 coordinating preparedness for and response to serious cross-border health threats is enshrined in the Lisbon Treaty. By their very nature, such health threats are not confined to national borders and cannot be effectively addressed by any Member State or by the Union alone. The EU needs to be well prepared against these threats, which can have a heavy impact not just on the health and life of citizens, but also on the economy.

Actions planned under this objective will help develop common approaches to prepare for possible health emergencies, to co-ordinate a response to such health emergencies at European level, and to support national capacity building in preparedness and management of health crises taking into account international initiatives. The aim is to support preparedness planning, including for pandemic influenza, address gaps in risk assessment capacities between Member States and support capacity building against health threats in Member States as well as promoting the capacity at global level to respond to health treats.

Actions will also support measures designed to protect and improve human health against communicable diseases, major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health required by or contributing to the objectives of EU legislation in these fields.

Under all four objectives mentioned above, the Programme will support actions on Health information and knowledge to contribute to evidence-based decision making, including collecting and analysing health data and wide-ranging dissemination of the results of the Programme. It will also support the activities of the Scientific Committees set up in accordance with Commission Decision 2008/721/EC.

3. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENTS

3.1. Consultation and expert advice

The consultation targeted in particular Member States' representatives, National Focal Points, the Council working party on Public health at Senior Level and the informal Health Council. Additional expert advice was provided through the EU Health Policy Forum, health

professionals and patients associations. Other programme stakeholders, especially beneficiaries, have expressed their views in the recent programme evaluations.

All participants in the various consultations strongly supported the Health Programme. Some Member States concurred with the view that it should be more focused, cost-efficient and based on action with proven EU added value, whereas others were of the opinion that it should continue to support the existing objectives and a wide range of actions.

National Focal Points designated by Member States' authorities mentioned that the programme could help to shape national policies by (a) providing best practices, (b) sharing and exchanging practical experience, expertise and knowledge and (c) giving support on health issues on the national political agenda. The EU Health Policy Forum argued that strong emphasis should be put on health determinants and a patient-centred focus. It also recommended that the programme address the role of social determinants.

Furthermore, Member States and stakeholders alike mentioned the need for more active participation in the programme by all EU Member States and emphasised that the programme should be more closely linked to the Treaty on the Functioning of the European Union, to the Europe 2020 agenda and to the existing legislation.

3.2. Impact Assessment

The Impact Assessment report analysed various options for the programme. It identified the preferred option, from a cost/benefit point of view, as corresponding to a well structured programme, with specific, measurable, attainable, relevant and time-bound (SMART) objectives, prioritised actions, creating EU added value and with better monitoring of outcomes and impacts. The programme will focus on:

- contributing to facilitate the up-take of innovative solutions for improving the quality, efficiency and sustainability of health systems and increasing access to better and safer healthcare;
- promoting good health and preventing diseases at EU level by helping and complementing Member States' efforts to increase their citizens' number of healthy life years;
- supporting solutions for cross-border health threats;
- supporting actions required by the current EU legal obligations.

The budget under this option is approximately 57 million euro annually (in 2011 prices), which is in line with the proposed budget allocation for the Health for Growth Programme in the Communication 'A Budget for Europe 2020' of June 2011.

3.3. Delivering European added value

As stated in Article 168 of the Treaty on the Functioning of the European Union, EU action must complement national policies and encourage cooperation between Member States. The programme should contribute only where Member States can not act individually or where coordination is the best way to move forward.

The programme puts forward actions in areas where there is evidence of EU added-value on the basis of the following criteria: 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 relating 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; improving economies of scale by avoiding waste due to duplication and optimising the use of financial resources.

3.4. Increasing the performance of the programme

The Programme builds on the results of the first Public Health Programme (2003-2008) and the second Health Programme (2008-2013), in line with the conclusions and recommendations made in the different evaluations and audits performed on these programmes.

The new programme aims to focus on fewer actions, of proven EU added value, that deliver concrete results, and respond to identified needs or gaps. The programme seeks to improve the way Member States cooperate in the area of health and to provide leverage for reform of national health policies.

Activities over the seven years period and annual work plans should be based on multi-annual programming of a limited number of actions per year. In addition, building on lessons learnt and the results of various evaluations, the programme introduces a number of new elements:

- progress indicators to measure and monitor the objectives and the impact of the programme;
- EU added value as a key determinant in setting the priorities for the annual work plans;
- better dissemination and communication of the results of the projects to policy makers;
- incentives to encourage greater participation of Member States with lower Gross National Income (GNI) in the programme. This will include a higher co-financing rate for those Member States.

Simplification

The revision of the Financial Regulation will contribute to facilitate participation in EU programmes, for example by simplifying rules, reducing the costs of participation, accelerating award procedures and providing a "one-stop shop" to make it easier for beneficiaries to access EU funding. The Programme will make a maximum use of the provisions of the revised EU Financial Regulation, in particular by further simplifying reporting requirements, including a more extensive use of online reporting.

The design of the new programme involves simplifying its implementation and management:

1. The level of Union co-financing for grants for actions, actions co-financed by the competent authorities of the Member States or third countries, or by non-governmental bodies

mandated by these authorities and operating grants will be harmonised at 60% of eligible costs and up to 80% in cases of exceptional utility.

2. The long-term programming of strategic actions under the programme will help reduce their overall number per year and avoid repetitive work in application, evaluation, negotiation and contracting procedures. In addition, this will allow greater focus on the priority areas and better use of human and financial resources. The funding process will be simplified in particular through the use of framework contracts for operating grants, and the possibility of using lump sums will be examined whenever possible so as to reduce the administrative burden.

3. The new monitoring and evaluation indicators rely on effective dissemination of Programme results and will trace their use in Member States with the assistance of the National Focal Points network. It is therefore expected to have a simplified approach to Programme outcomes; their uptake from the end-users should increase the visibility and impact of the Programme.

4. In accordance with the Council Regulation (EC) No 58/2003 of 19 December 2002 laying down the statute for Executive Agencies to be entrusted with certain tasks in the management of Community programmes, the Commission has entrusted the Executive Agency for Health and Consumers with implementation tasks for the management of the Programme of Community Action in the field of Health since 2005. The Commission may use, on the basis of a cost-benefit analysis, an existing executive agency for the implementation of the Health for Growth Programme.

4. LEGAL ELEMENTS OF THE PROPOSAL

EU action is justified on the grounds both of the objectives laid down in Article 168 of the Treaty and the subsidiarity principle. 'Union action shall complement the national policies and the Member States' action.' The Union can also 'lend support to their action'.

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*'; and the third paragraph stipulates 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 designed to protect and improve human health.

5. BUDGETARY IMPLICATION

The financial appropriations for implementing the programme over the period from 1 January 2014 to 31 December 2020 will amount to 446 million euro (in current prices). This corresponds to the proposed budget allocation for the Health Programme in the Communication 'A Budget for Europe 2020' of June 2011.

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(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article168 (5) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee[6],

Having regard to the opinion of the Committee of the Regions[7],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) A high level of health protection should be ensured in the definition and implementation of all Union policies and activities, in accordance with Article 168 of the Treaty. The Union shall complement and support national health policies, encourage the cooperation between Member States and promote the coordination between their programmes, in full respect of the responsibilities of the national authorities for shaping their health policies and organising and delivering health services and medical care.

(2) Continued effort is required in order to meet the requirements set out in Article 168 of the Treaty. Promoting good health at EU level is an integral part of the 'Europe 2020: A European Strategy for smart, sustainable and inclusive growth'[8]. Keeping people healthy and active for longer will have positive overall health effects, and a positive impact on productivity and competitiveness, while reducing pressures on national budgets. Innovation in health helps take up the challenge of sustainability in the sector in the context of demographic

6 OJ C , , p. .
7 OJ C , , p. .
8 Communication from the Commission, COM (2010) 2020 final

change, and action to reduce inequalities in health is important to achieve 'inclusive growth'. It is appropriate in this context to establish a 'Health for Growth' Programme, the third programme of EU action on health (2014-2020) (hereinafter referred to as 'the Programme').

(3) The previous programmes of Community action in the field of public health (2003-2008) and in the field of health (2008-2013), adopted respectively by Decisions Nos 1786/2002/EC[9] and 1350/2007/EC of the European Parliament and of the Council[10], have been positively assessed as delivering a number of important developments and improvements. The new programme should build on the achievements of the previous ones. It should also take into account the recommendations of the external audits and evaluations carried out, in particular recommendations of the Court of Auditors[11], according to which "for the period after 2013, the European Parliament, the Council and the Commission should reconsider the scope for EU public health activities and the approach of EU funding in this area. This should be done bearing in mind the budgetary means available and the existence of other cooperation mechanisms (…) as a means of facilitating collaboration and the exchange of information among stakeholders throughout Europe".

(4) In line with the objectives of the Europe 2020 Strategy, the Programme should focus on a set of well defined objectives and actions with clear, proven EU added value, and concentrate support on a smaller number of activities in priority areas. The emphasis will be placed in accordance with the principle of subsidiarity, on areas where Member States cannot act in isolation in a cost-effective manner, where there are clear cross-border or internal market issues at stake, or where there are significant advantages and efficiency gains from collaboration at EU level.

(5) The programme shall put forward actions in areas where there is evidence of EU added-value on the basis of the following criteria: 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 relating 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 to allow informed decision-making at European level; improving economies of scale by avoiding waste due to duplication and optimising the use of financial resources.

(6) The World Health Organisation (WHO) European Health Report 2009 identifies scope for increasing investment in public health and health systems. In this regard, Member States are encouraged to identify health improvement as a priority in their national programmes and to benefit from better awareness of the possibilities of EU funding for health. Therefore, the Programme should facilitate the uptake of its results into the national health policies.

(7) Innovation in health in terms of products and services, and the organisation and provision of care, has the potential to enhance the quality of care to patients and respond to unmet needs, while also improving the cost-efficiency and sustainability of care. Therefore, the Programme should facilitate the uptake of innovation in healthcare.

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9 OJ L 271, 9.10.2002, p. 1-12

10 OJ L 301, 20.11.2007, p. 3-13

11 Court of Auditor's Special Report n°212009 of 5.3.2009, "The European Union's Public Health Programme (2003-2007): an effective way to improve health?"

(8) The programme should contribute to addressing health inequalities through action under the different objectives and by encouraging and facilitating the exchange of good practices to tackle them.

(9) The position of the patient should be strengthened to achieve better and safer health outcomes. Patients need to be empowered to manage their health and their healthcare more pro-actively. The transparency of healthcare activities and systems and the availability of information to patients should be optimised. Healthcare practices should be informed by feedback from and communication with patients. Support for Member States, patient organisations and stakeholders is essential and should be coordinated at EU level in order to effectively help patients and in particular those affected by rare diseases to benefit from cross border healthcare.

(10) In the context of an ageing society, well-directed investments to promote health and prevent diseases can increase the number of 'healthy life years' and thus enable the elderly to continue working as they grow older. Chronic diseases are responsible for over 80% of premature mortality in the EU. By identifying, disseminating and promoting the up-take of validated best practices for cost-effective prevention measures focused on the key risk factors, namely smoking, abuse of alcohol and obesity, as well as on HIV/AIDS, the Programme will contribute to prevent diseases and promote good health, also bearing in mind underlying factors of a social and environmental nature.

(11) To minimise the public health consequences of cross-border health threats which could range from mass contamination caused by chemical incidents to pandemics, like those unleashed recently by E coli, influenza strain H1N1 or SARS (severe acute respiratory syndrome), the Programme should contribute to the creation and maintenance of robust mechanisms and tools to detect, assess and manage major cross-border health threats.. Due to the nature of these threats, the Programme should support coordinated public health measures at EU level to address different aspects, building on preparedness and response planning, robust and reliable risk assessment and a strong risk and crisis management framework. In this context, it is important that the programme should benefit from complementarity with the work programme of the European Centre for Disease Prevention and Control[12] in the fight against communicable diseases and the activities supported under the Unions programmes for research and innovation. Special efforts should be undertaken to ensure coherence and synergies between the Programme and global health work carried out under other Community programmes and instruments that address in particular the areas of influenza, HIV/AIDS, tuberculosis and other cross-border health threats in third countries. Action under the programme may also cover cross-border threats to health caused by biological and chemical incidents, environment and climate change. As stated in the Commission's Communication "A Budget for Europe 2020", the Commission has committed to mainstreaming climate change into overall Union spending programmes and to direct at least 20% of the Union budget to climate-related objectives. Spending in the Health for Growth Programme under objective 4 will contribute in a general manner to this objective by addressing health threats associated to climate change. The Commission will provide information on climate change expenditure within the Health for Growth Programme.

[12] The European Centre for Disease Prevention and Control was established by Regulation (EC) 851/2004 of the European Parliament and of the Council.

(12) In accordance with art 114 of the Treaty, a high level of health protection should be ensured in the legislation adopted by the Union for the establishment and the functioning of the Internal Market. In line with this objective, the Programme should undertake special efforts to support actions required by and contributing to the aims of EU legislation in the fields of medicinal products, medical devices, human tissues and cells, blood, human organs, communicable diseases and other health threats, patients' rights in cross-border healthcare and tobacco products and advertisement.

(13) The Programme should contribute to evidence based decision making by fostering a health information and knowledge system. The later would consist in, inter alia, collecting and analysing health data, supporting the scientific Committees[13] and participating in the wide dissemination of the results of the Programme.

(14) The Programme should focus mainly on cooperation with national health competent authorities and provide incentives for wide participation of all Member States. In particular, participation of Members States with Gross National Income (GNI) lower than 90% of the Union average should be actively encouraged.

(15) Non-governmental bodies and health stakeholders, in particular patients' organisations and health professionals' associations, play an important role in providing the Commission the information and advice necessary to implement the programme. In playing this role, they may require contributions from the Programme to enable them to function. That is why the programme shall be accessible to representative NGOs and patient organisations working in the public health area, which play an effective role in civil dialogue processes at EU level, such as for example participation in consultative groups, and in that way contribute to pursuing the Programme's specific objectives.

(16) The programme should promote synergies while avoiding duplication with related Union programmes and actions. Appropriate use should be made of other Union funds and programmes, in particular the current and future Union framework programmes for research and innovation and their outcomes, the Structural Funds, the Programme for social change and innovation, the European Solidarity Fund, the European strategy for health at work, the Competitiveness and Innovation Programme, the Framework Programme for Environment and Climate action (LIFE), the programme of Union action in the field of consumer policy (2014-2020)[14], the Justice programme (2014-2020), the Ambient Assisted Living Joint Programme, (the Education Europe Programme) and the Union Statistical Programme within their respective activities.

(17) According to Article 168 of the Treaty, the Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health. The programme should therefore be open to the participation of third countries, in particular of acceding countries, candidate countries and potential candidates benefiting from a pre-accession strategy, EFTA/EEA countries, neighbouring countries and the countries to which the European Neighbourhood Policy (ENP) applies and other countries in accordance with the conditions laid down by a relevant bilateral or multilateral agreement.

(18) Appropriate relations with third countries not participating in the programme should be facilitated to help achieve the objectives of the programme, taking account of any relevant

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[13] The Scientific Committees were set up in accordance with Commission Decision 2008/721/EC, OJ reference

[14] OJ L, ,p.

agreements between those countries and the Union. This may involve EU organised health events or third countries taking forward complementary activities to those financed through the programme on areas of mutual interest, but should not involve a financial contribution under the Programme.

(19) To maximise the effectiveness and efficiency of actions at Union and international level, cooperation should be developed with relevant international organisations such as the United Nations and its specialised agencies, in particular the World Health Organisation, as well as with the Council of Europe and the Organisation for Economic Cooperation and Development, with a view to implementing the Programme.

(20) The programme should run for a period of seven years to align its duration with that of the Multi-annual Financial Framework as set out in [Article 1] of the Council Regulation laying down the multiannual financial framework for the year 2014-2020. This Regulation lays down, for the entire duration of the Programme, a financial envelope constituting the prime reference within the meaning of point (17) of the Inter-institutional Agreement of XX/YY/201Z between the European Parliament, the Council and the Commission on budgetary discipline and sound financial management [link], for the budgetary authority during the annual budgetary procedure.

(21) In accordance with Article 49 of Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities[15], this Regulation provides the legal basis for the action and for the implementation of the Health for Growth Programme.

(22) In order to ensure uniform conditions for the implementation of this Regulation by means of annual work programmes, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers[16].

(23) The Programme should be implemented in full respect of the principle of transparency and with a reasonable balance between its different objectives. Appropriate actions covered by the programme's specific objectives and with a clear EU added value should be selected and funded by the Programme. The annual work programmes should set out, in particular, the essential selection criteria applicable to the potential beneficiaries, in accordance with the Financial Regulation, in order to ensure they have the financial and operational capacity to undertake activities financed under the Programme, and, where appropriate, the evidence required to demonstrate their independence.

(24) The value and impact of the Programme should be regularly monitored and evaluated. Its evaluation should take into account the fact that the achievement of the Programme's objectives may require a longer time period than its duration.

(25) The cooperation of national authorities is essential in sharing information with potential applicants to allow equitable participation in the Programme, and knowledge produced by the programme with the different national health sector stakeholders. Moreover, their

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15 OJ L 248, 16.9.2002, p. 1.

16 OJ L 55, 28.2.2011, p 13.

involvement in tracing the impacts generated by the Programme at national level is considered of major importance. Thus, National Focal Points should be designated by the Member States in order to support the above mentioned activities.

(26) The financial interests of the European Union should be protected through proportionate measures throughout the expenditure cycle, including the prevention, detection and investigation of irregularities, the recovery of funds lost, wrongly paid or incorrectly used and, where appropriate, penalties.

(27) A transition should be ensured between the new programme and the previous programme it replaces, in particular regarding the continuation of multi-annual arrangements for its management, such as the financing of technical and administrative assistance. As of 1 January 2021, the technical and administrative assistance appropriations should cover, if necessary, the expenditure related to the management of actions not yet completed by the end of 2020.

(28) This Regulation replaces Decision No 1350/2007/EC. That Decision should therefore be repealed,

HAVE ADOPTED THIS REGULATION:

Chapter I

General provisions

Article 1

Establishment of the Programme

This Regulation establishes a third multi-annual programme of Union action in the field of health, called Health for Growth Programme, covering the period from 1 January 2014 to 31 December 2020 (hereinafter referred to as "the Programme").

Article 2

General objectives

The general objectives of the Health for Growth Programme shall be to work with the 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.

Chapter II

Objectives and actions

Article 3

Specific objectives and indicators

The general objectives referred to in Article 2 shall be pursued through the following specific objectives:

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

This objective will be measured in particular through the increase of number of Member States using the developed tools and mechanisms and pieces of advice.

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

This objective will be measured in particular through the increase of number of health professionals using the expertise gathered through the European Reference Networks in the context of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (hereinafter referred to as "the European Reference Networks"); the increase of number of patients using these networks; and the increase of number of Member States using the developed guidelines.

(3) To identify, disseminate and promote the up-take of validated best practices for cost-effective prevention measure 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 promote good health.

This objective will be measured in particular through the increase of number of Member States involved in promoting good health and preventing diseases, using the validated best practices.

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

This objective will be measured in particular through the increase of number of Member States integrating the developed common approaches in the design of their preparedness plans.

Article 4

Eligible actions

The objectives referred to in Article 3 shall be achieved through the actions listed below and according to the priorities set out in the work programme referred to in Article 11 of this Regulation.

(1) Contributing to innovative and sustainable health systems:

– 1.1. Develop EU cooperation on Health Technology Assessment in the context of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare;

– 1.2. Promote the uptake of health innovation and e-Health by increasing the interoperability of e-Health applications;

– 1.3. Support the sustainability of EU health workforce by promoting effective forecasting and planning and efficient recruitment and retention strategies;

– 1.4. Provide expertise to assist Member States undertaking health systems reforms;

– 1.5 Support to the European Innovation Partnership on Active and Healthy Ageing, a pilot project under Europe 2020 flagship initiative Innovation Union[17];

– 1.6 Actions required by or contributing to the objectives of EU legislation in the fields of medical devices as well as e-Health and Health Technology Assessment provisions in legislation on cross border healthcare;

– 1.7 Foster a health knowledge system, including Scientific Committees, to contribute to evidence-based decision making.

(2) Increasing access to better and safer healthcare for citizens:

– 2.1. Set up accreditation and support European Reference Networks;

– 2.2. Support action on rare diseases including creation of European Reference Networks (in accordance with 2.1), information and registries based on the common criteria for accreditation;

– 2.3. Strengthen collaboration on patient safety and quality of healthcare, by increasing the availability of information to patients, exchange of best practices and development of guidelines; support action on chronic diseases care and research including development of European guidelines;

– 2.4. Develop guidelines to improve the prudent use of antimicrobials in human medicine and reduce the practices that increase antimicrobial resistance;

– 2.5. Actions required by or contributing to the objectives of EU legislation in the fields of tissues and cells, blood, organs, patients' rights in cross-border healthcare and medicinal products;

– 2.6. Foster a health knowledge system, to contribute to evidence-based decision making.

(3) Promoting good health and preventing diseases:

– 3.1 Exchange best practices on key health issues such as smoking prevention, abuse of alcohol and obesity;

[17] COM (2010) 546 final

– 3.2. Supporting the prevention of chronic diseases including cancer, by sharing knowledge and best practice and developing joint activities;

– 3.3. Actions required by or contributing to the objectives of EU legislation in the fields of tobacco products and advertisement;

– 3.4. Foster a health knowledge system, to contribute to evidence-based decision making.

(4) Protecting citizens from cross border health threats:

– 4.1. Strengthen preparedness and response for serious cross border health threats;

– 4.2. Improve risk assessment capacity by providing additional capacities for scientific expertise and map existing assessments;

– 4.3. Support capacity building against health threats in Member States by *inter alia* developing preparedness and response planning and coordination, common approaches to vaccination, developing guidelines and mechanisms for joint procurement of medical countermeasures;

– 4.4. Actions required by or contributing to the objectives of EU legislation in the fields of communicable diseases and other health threats;

– 4.5. Foster a health knowledge system to contribute to evidence-based decision making.

A more detailed description of the content those actions may have is included in Annex I. An indicative list of the relevant legislation is provided in Annex II to this Regulation.

Chapter III

Financial provisions

Article 5

Funding

1. The financial allocation for the implementation of the Programme for the period from 1 January 2014 to 31 December 2020 is hereby set at EUR 446 000 000 in current prices.

Article 6

Participation of third countries

1. The Programme shall be open on a cost basis, to the participation of third countries, in particular of:

(a) acceding countries, candidate countries and potential candidates benefiting from a pre-accession strategy, in accordance with the general principles and general terms and conditions

for their participation in Union programmes established in the respective Framework Agreements, Association Council Decisions or similar Agreements;

(b) EFTA/EEA countries in accordance with the conditions established in the EEA Agreement;

(c) neighbouring countries and the countries to which the European Neighbourhood Policy (ENP) applies in accordance with the conditions laid down by a relevant bilateral or multilateral agreement;

(d) other countries in accordance with the conditions laid down by a relevant bilateral or multilateral agreement.

Article 7

Types of intervention

1. In accordance with the Financial Regulation, financial contributions by the Union may take the form of either grants or public procurement or any other interventions necessary for achieving the objectives of the Programme.

2. Grants may be awarded to fund:

(a) actions having a clear EU added value co-financed by the competent authorities of the Member States responsible for Public Health or the third countries participating pursuant to Article 6, or by non-governmental bodies mandated by these competent authorities;

(b) actions having a clear EU added value co-financed by other public or private bodies, as referred to in article 8 (1), including international organisations active in the area of health and for the latter, where appropriate without previous call for proposal, duly justified in the annual work programmes;

(c) the functioning of non governmental bodies as referred to in article 8(2) where financial support is necessary to the pursuit of one or more of the specific objectives of the Programme.

3. Grants paid by the Union shall not exceed the following levels:

(a) 60 % of eligible costs for an action aimed at an objective of the Programme. In cases of exceptional utility, the contribution by the Union may be up to 80% of eligible costs;

(b) 60 % of eligible costs for the functioning of a non-governmental body. In cases of exceptional utility such bodies may benefit from a financial contribution up to a maximum of 80% of eligible costs;

(c) 60 % of eligible costs for actions referred to in point (a) of paragraph 2 except for Member States whose gross national income per inhabitant is less than 90 % of the Union average, which shall benefit from a financial contribution up to a maximum of 80 % of eligible costs. In cases of exceptional utility, the financial contribution for actions referred to in point (a) of paragraph 2 may be up to a maximum of 80% of eligible costs for competent authorities of all Member States or third countries participating in the Programme.

4. Grants may be paid in the form of lump sums, standard scales of unit costs or flat-rate financing where this is suited to the nature of the actions concerned.

Article 8

Beneficiaries eligible for grants

1. The grants for actions referred to under Article 7 (2) (a) and (b) may be awarded to legally established organisations, public authorities, public sector bodies, in particular research and health institutions, universities and higher education establishments and undertakings.

2. The grants for the functioning of bodies referred to under Article 7 (2) (c) may be awarded to the bodies which comply with all the following criteria:

(a) They are non-governmental, non-profit-making, independent of industry, commercial and business or other conflicting interests;

(b) They are working in the public health area, playing an effective role in civil dialogue processes at EU level and pursuing at least one of the specific objectives of the Programme as referred to in article 3;

(c) They are active at the Union level and in at least half of the Member States, and have a balanced geographical coverage of the Union.

Article 9

Administrative and technical assistance

The financial allocation for the Programme may also cover expenses pertaining to preparatory, monitoring, control, audit and evaluation activities required directly for the management of the Programme and the achievement of its objectives, in particular studies, meetings, information and communication actions, including corporate communication of the political priorities of the European Union as far as they are related to the general objectives of this Regulation, expenses linked to IT networks focusing on information exchange, as well as all other technical and administrative assistance expense incurred by the Commission for the management of the Programme.

Chapter IV

Implementation

Article 10

Methods of implementation

The Commission shall be responsible for the implementation of the Programme in compliance with the management modes set out in the Financial Regulation.

Article 11

Annual Work programmes

1. The Commission shall implement the Programme by establishing annual work programmes setting out the elements provided in the Financial Regulation and in particular:

(a) the priorities and the actions to be undertaken, including the allocation of financial resources;

(b) detailed eligibility criteria for the beneficiaries in compliance with Article 8;

(c) the criteria for the percentage of the financial contribution of the Union, including criteria for assessing whether or not exceptional utility applies, and the applicable rate of the co-financing;

(d) the essential selection and award criteria to be used to select the proposals receiving financial contributions;

(e) the time schedule of the planned calls for the tenders and calls for proposals;

(f) where appropriate, the authorisation to use lump sums, standard scales of unit costs or flat-rate financing in line with the Financial Regulation;

(g) the actions co-financed by international organisations active in the area of health without previous call for proposal duly justified.

2. The working programme referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 16(2).

3. In implementing the Programme, the Commission, together with the Member States, shall ensure compliance with all relevant legal provisions regarding personal data protection and, where appropriate, the introduction of mechanisms to ensure the confidentiality and safety of such data.

Article 12

Consistency and complementarity with other policies

The Commission shall, in cooperation with the Member States, ensure overall consistency and complementarity between the Programme and other policies, instruments and actions of the Union.

Article 13

Monitoring, evaluation and dissemination of results

1. The Commission shall, in close cooperation with the Member States, monitor the implementation of the actions under the programme in the light of its objectives and indicators, including information on the amount of climate related expenditure. It shall report thereon to the committee referred to in Article 13, and shall keep the European Parliament and the Council informed.

2. At the request of the Commission, which shall avoid causing any disproportionate increase in the administrative burden on the Member States, Member States shall submit any available information on the implementation and impact of the Programme.

3. No later then mid-2018, an evaluation report shall be established by the Commission on the achievement of the objectives of all the measures (at the level of results and impacts), the efficiency of the use of resources and its European added value, in view of a decision on the renewal, modification or suspension of the measures. The evaluation shall additionally address the scope for simplification, its internal and external coherence, the continued relevance of all objectives, as well as the contribution of the measures to the Union priorities of smart, sustainable and inclusive growth. It shall take into account evaluation results on the long-term impact of the predecessor programme.

The longer-term impacts and the sustainability of effects of the Health for Growth Programme should be evaluated with a view to feeding into a decision on a possible renewal, modification or suspension of a subsequent programme.

4. The Commission shall make the results of actions undertaken pursuant to this Regulation publicly available and shall ensure they are widely disseminated.

Article 14

National Focal Points

Member States shall designate National Focal Points which shall assist the Commission in the promotion of the Programme, the dissemination of the results of the Programme and the information on impacts generated by the Programme in their respective countries.

Article 15

Protection of the financial interests of the European Union

1. The Commission shall take appropriate measures ensuring that, when actions financed under this Regulation are implemented, the financial interests of the European Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportionate and deterrent penalties.

2. The Commission or its representatives and the Court of Auditors shall have the power of audit, on the basis of documents and on-the spot, over all grant beneficiaries, contractors and subcontractors who have received Union funds.

The European Anti-fraud Office (OLAF) may carry out on-the-spot checks and inspections on economic operators concerned directly or indirectly by such funding in accordance with the procedures laid down in Regulation (Euratom, EC) No 2185/96 with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the European Union in connection with a grant agreement or grant decision or a contract concerning Union funding.

Without prejudice to the first and second subparagraphs, cooperation agreements with third countries and international organisations and grant agreements and grant decisions and contracts resulting from the implementation of this Regulation shall expressly empower the Commission, the Court of Auditors and OLAF to conduct such audits, on-the-spot checks and inspections.

Chapter V

Procedural provisions

Article 16

Committee procedure

1. The Commission shall be assisted by a committee within the meaning of Regulation (EU) No. 182/2011.

2. Where reference is made to the first paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

3. Where the opinion of the committee is to be obtained by the written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

Chapter VI

Transitional and final provisions

Article 17

Transitional provisions

1. The financial allocation for the Programme may also cover technical and administrative assistance expenses necessary to ensure the transition between the Programme and the measures adopted under Decision No 1350/2007/EC.

2. If necessary, appropriations may be entered in the budget beyond 2020 to cover the expenses provided for in Article 9, to enable the management of actions not completed by 31 December 2020.

Article 18

Repeal provisions

Decision No 1350/2007/EC shall be repealed with effect from 1 January 2014.

Article 19

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*. This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX I

Types of actions

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

1.1. Health technology assessment: support European cooperation on Health Technology Assessment (HTA) under the European voluntary network on Health Technology Assessment set up by the Directive 2011/24/EU of the European Parliament and of the Council[18]. Facilitate the uptake of the results streaming from research projects supported under 7th Framework Programme and the in the longer term the activities which will be undertaken in the forthcoming research and innovation programmes 2014-2020 (Horizon 2020).

1.2. Health innovation and e-Health: increasing the interoperability of patient registers and other e-Health solutions; support European cooperation on e-Health, notably on registries and uptake by health professionals. This will serve the European voluntary network on e-Health set up by the Directive 2011/24/EU of the European Parliament and of the Council.

1.3. Health workforce: develop effective health workforce forecasting and planning in terms of numbers, scope of practice and skills, monitor mobility (within the Union) and migration of health professionals, establish efficient recruitment and retention strategies and capacity development.

1.4. Decision making on health systems reforms: set up a mechanism for pooling expertise at Union level, to provide sound and evidence-based advice on effective and efficient investment in public health and health systems. Facilitate the uptake of the results streaming from research projects supported under the 7th Framework Programme and the in the longer term the activities which will be undertaken in the forthcoming research and innovation programme 2014-2020 (Horizon 2020).

1.5. Support for the European Innovation Partnership on Active and Healthy Ageing in its three themes: innovation in awareness, prevention and early diagnosis; innovation in cure and care and innovation for active ageing and independent living.

1.6. Actions required by or contributing to the implementation of Union legislation in the field of medical devices and cross border healthcare (e-Health and HTA). Such action may include activities aimed at ensuring the implementation, application, monitoring and review of that legislation.

1.7. Fostering a health knowledge system to contribute to evidence-based decision making including collecting and analysing health data and wide-dissemination of the results of the Programme and including support to the Scientific Committees set up in accordance with Commission Decision 2008/721/EC.

2. Increase access to medical expertise and information for specific conditions also beyond national borders and developing shared solutions and guidelines to improve

[18] OJ L 88, 4.4.2011, p. 45.

healthcare quality and patient safety in order to increase access to better and safer healthcare for EU citizens

2.1. Access: support the establishment of a system of European Reference Networks to enable *inter alia* the mobility of medical expertise for patients with conditions requiring highly specialised care and a particular concentration of resources or expertise, like in the case of rare diseases, on the basis of criteria to be set under Directive on the application of patients' rights in cross-border healthcare (Directive 2011/24/EU)[19].

2.2 Rare diseases: support Member States, patient organisations and stakeholders by coordinated action at Union level in order to effectively help patients affected by rare diseases. This includes creation of reference networks (in compliance with point 2.1), information and registries for rare diseases based on the common criteria of accreditation.

2.3. Quality and safety: strengthen collaboration on patient safety and quality of healthcare, through, *inter alia*, implementing the Council Recommendation on patient safety and the prevention and control of healthcare-associated infections; exchange best practice on quality assurance systems; develop guidelines and tools to promote patient safety and quality; increase the availability of information to patients on safety and quality, improve feedback and interaction between health providers and patients; support action to exchange knowledge and best practice on chronic diseases care, the response of health systems and research including development of European guidelines.

2.4. Safety: improve the prudent use of antimicrobial agents in medicinal products and reduce the practices that increase antimicrobial resistance; reduce the burden of resistant infections and healthcare-associated infections and secure the availability of effective antimicrobials.

2.5. Actions required by or contributing to the implementation of Union legislation in the fields of tissues and cells, blood, organs, medicinal products use and patients' rights in cross-border healthcare. Such action may include activities aimed at ensuring the implementation, application, monitoring and review of that legislation.

2.6. Fostering a health knowledge system to contribute to evidence-based decision making including collecting and analysing health data and wide dissemination of the results of the Programme.

3. Identifying, disseminating and promoting up-take of validated best practices for cost-effective prevention measure 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 promote good health

3.1. Cost-effective promotion and prevention measures: this will include actions towards the setting up of pan-European networks and partnerships engaging wide range of actors in communication and awareness raising actions on key health issues such as smoking prevention, abuse of alcohol, addressing obesity with a focus on the cross-border dimension and on Member States with no or little action on these issues.

3.2. Chronic diseases: support European cooperation and networking on preventing and improving the response to chronic diseases including cancer, by sharing knowledge, good practice and developing joint activities on prevention. Cancer: follow-up work already

[19] OJ L 88, 4.4.2011, p. 45.

undertaken; set up a European cancer information system with comparable data; support cancer screening, including voluntary accreditation mechanisms; support the development of European guidelines for prevention where major inequalities exist.

3.3. Actions required by or contributing to the implementation of Union legislation in the fields of tobacco products and advertisement. Such action may include activities aimed at ensuring the implementation, application, monitoring and review of that legislation.

3.4. Fostering a health knowledge system to contribute to evidence-based decision making including collecting and analysing health data and wide dissemination of the results of the Programme.

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

4.1. Preparedness to and response for serious cross border health threats taking into account and coordinating with global initiatives: put in place common components of generic and specific preparedness planning, including for pandemic influenza, and report regularly on implementation of preparedness plans.

4.2. Risk assessment capacity: close gaps in risk assessment capacities by providing additional capacities for scientific expertise and map existing assessments to improve coherence at Union level.

4.3. Support capacity building against health threats in Member States: develop preparedness and response planning, public health response coordination, common approaches on vaccination; develop guidelines on protective measures in an emergency situation, guidelines on information and guides to good practice; set up a new mechanism for joint procurement of medical countermeasures; develop common communication strategies.

4.4. Actions required by or contributing to the implementation of Union legislation in the fields of communicable diseases and other health threats, including those caused by biological, and chemical incidents, environment and climate change. Such action may include activities aimed at ensuring the implementation, application, monitoring and review of that legislation.

4.5. Fostering a health knowledge system to contribute to evidence-based decision making including collecting and analysing health data and wide- dissemination of the results of the Programme.

This list might be completed with additional actions of similar type and impact pursuing the specific objectives mentioned in Article 3.

ANNEX II

Indicative list of the relevant legislation referred to in Article 4 and Annex I

1. Blood, organs, tissues and cells

1.1. Directive 2002/98/EC of the European Parliament and the Council of 27January 2003,

setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30).

1.2. Directive 2010/45/EU of the European Parliament and the Council of 7 July 2010,

on standards of quality and safety of human organs intended for transplantation (OJ L 207, 6.8.2010, p. 14).

1.3. Directive 2004/23/EC of the European Parliament and the Council of 31 March 2004,

on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p. 48).

Only important basic legislation has been listed here; for other legislation relating to blood, organs, tissues and cells please see:
http://ec.europa.eu/health/blood_tissues_organs/key_documents/index_en.htm#anchor3

2. Communicable diseases

2.1. Decision N° 2011/98/EC of the European Parliament and the Council of 24 September 1998,

setting up a network for the epidemiological surveillance and control of communicable diseases in the Community (OJ L 268, 3.10.1998, p. 1).

2.2. Regulation (EC) No851/2004 of the European Parliament and of the Council of 21 April 2004,

establishing a European Centre for Disease and Prevention and Control (OJ L 142, 30.4.2004, p. 1).

Only important basic legislation has listed here; for other legislation relating to diseases please see:
http://ec.europa.eu/health/communicable_diseases/key_documents/index_en.htm#anchor1

3. Tobacco products and advertisement

3.1. Directive 2001/37/EC of the European Parliament and the Council of 5 June 2001,

on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products (OJ L 194, 18.7.2001, p. 26).

3.2. Directive 2003/33/EC of the European Parliament and the Council of 26 May 2003,

on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products (OJ L 152, 20.6.2003, p. 16).

Only important basic legislation has been listed here; for other legislation relating to tobacco please see: http://ec.europa.eu/health/tobacco/law/index_en.htm

4. Patients' rights in cross border health care

4.1. Directive 2011/24/EU of the European Parliament and the Council of 9 March 2011,

on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

5. Pharmaceutical products

5.1. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004,

laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

5.2. Council Regulation (EC) No 297/95 of 10 February 1995,

on fees payable to the European Agency for the Evaluation of Medicinal Products (OJ L 35, 15.2.1995, p. 1).

5.3. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001,

on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

5.4. Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999,

on orphan medicinal products (OJ L 18, 22.1.2000, p. 1).

5.5. Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006,

on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).

5.6. Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007,

on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).

5.7. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001,

on the approximation of the laws, regulations and administrative provisions of the Members States relating to the implementation of good clinical practice in the conduct of clinical trials on the medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

5.8. Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001,

on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p.1).

5.9. Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009,

laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

Only important basic legislation has been listed here; for other legislation relating to pharmaceutical products, please see:
Products for human use: http://ec.europa.eu/health/documents/eudralex/vol-1/index_en.htm
Products for veterinary use: http://ec.europa.eu/health/documents/eudralex/vol-5/index_en.htm

6. Medical devices

6.1. Directive 90/385/EC of the European Parliament and of the Council of 20 June 1990,

on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

6.2. Directive 93/42/EC of the European Parliament and of the Council of 14 June 1993,

concerning medical devices (OJ L 169, 12.7.1993, p. 1).

6.3. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998

on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

Only important basic legislation has been listed here; for other legislation relating to medical devices please see: http://ec.europa.eu/health/medical-devices/documents/index_en.htm

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

1.2. Policy area(s) concerned in the ABM/ABB structure

1.3. Nature of the proposal/initiative

1.4. Objective(s)

1.5. Grounds for the proposal/initiative

1.6. Duration and financial impact

1.7. Management method(s) envisaged

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

2.2. Management and control system

2.3. Measures to prevent fraud and irregularities

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

3.2.2. Estimated impact on operational appropriations

3.2.3. Estimated impact on appropriations of an administrative nature

3.2.4. Compatibility with the current multiannual financial framework

3.2.5. Third-party participation in financing

3.3. Estimated impact on revenue

LEGISLATIVE FINANCIAL STATEMENT

6. FRAMEWORK OF THE PROPOSAL/INITIATIVE

6.1. Title of the proposal/initiative

HEALTH FOR GROWTH PROGRAMME (2014 – 2020)

6.2. Policy area(s) concerned in the ABM/ABB structure

PUBLIC HEALTH

6.3. Nature of the proposal/initiative

☐ The proposal/initiative relates to **a new action**

☐ The proposal/initiative relates to **a new action following a pilot project/preparatory action**[20]

☑ The proposal/initiative relates to **the extension of an existing action**

☐ The proposal/initiative relates to **an action redirected towards a new action**

6.4. Objectives

6.4.1. The Commission's multiannual strategic objective(s) targeted by the proposal/initiative

The Health for Growth Programme would seek to contribute to the two main strategic objectives/goals below:

INNOVATION:

where the Programme would seek **to facilitate the uptake by policymakers and public-health practitioners of innovative solutions, technological and organisational, for improving the quality and sustainability of health systems and increasing access to better and safer healthcare.**

PREVENTION:

where the Programme would seek **to promote good health and preventing diseases at EU level by helping and complementing Member States' efforts to increase their citizens' number of healthy life years.**

The programme will support the general objectives of the future public health policy**.**

6.4.2. Specific objective(s) and ABM/ABB activity(ies) concerned

Specific objective No 1:

[20] As referred to in Article 49(6)(a) or (b) of the Financial Regulation.

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

Specific objective No 2:

Increase access to medical expertise (European reference networks) and information for specific conditions and beyond national borders and develop shared solutions and guidelines to improve healthcare quality and patient safety in order to increase access to better and safer healthcare for EU citizens.

Specific objective No 3:

Identify, disseminate and promote up-take of validated best practices for cost-effective prevention measure by addressing 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 promote good health.

Specific objective No 4:

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

ABM/ABB activity concerned

PUBLIC HEALTH POLICY for all the specific objectives listed above.

6.4.3. Expected result(s) and impact

Specific objective No 1:

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

Effects at the programme's level:

Have the highest number of Member States (through their policy makers, health professionals, health institutions) using the developed tools, mechanisms and guidelines /pieces of advice.

Effects at policy level:

Member States (Policy makers, health professionals, health institutions) are provided with effective support in:

* Implementing innovation in health in their health systems.
* Reaching an adequate supply of health professionals in MS.
* Reaching a cost-effective use of medical technologies.
* Improving decision-making, organisational management and performance of the health systems.

Beneficiaries:

Member States through Health policy makers, health professionals and health institutions.

Specific objective No 2:

Increase access to medical expertise (European reference networks) and information for specific areas and beyond national borders and develop shared solutions and guidelines to improve healthcare quality and patient safety in order to increase access to better and safer healthcare for EU citizens.

Effects at the programme's level:

Have the highest number of health professionals using the expertise gathered through the European Reference Networks put in place and operating.

Have the highest number of Member States (through their policy makers, health professionals, health institutions) using the developed guidelines.

Effects at policy level:

Member States are provided with support in improving access to diagnosis and provision for all patients requiring highly specialised care for a specific disease or group of diseases.

Member States are provided with support in reducing morbidity and mortality related to healthcare quality and increasing patients / citizens confidence in the health care system.

Beneficiaries:

Member States through Health policy makers and health professionals and ultimately patients and citizens.

Specific objective No 3:

Identify, disseminate and promote up-take of validated best practices for cost-effective prevention measure 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 promote good health.

Effects at the programme's level:

Have the highest number of Member States, through their policy makers, health professionals, health institutions and stakeholders from bodies involved in lifestyles, using the validated best practices.

Effects at policy level:

Member States are provided with support in their efforts to reduce risk factors for chronic diseases

Beneficiaries:

Member States through Health policy makers, health professionals, health institutions; NGOs committed in the promotion of health, and ultimately citizens.

Specific objective No 4:

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

Effects at the programme's level:

Have the highest number of Member States, through their policy makers, health professionals, health institutions, integrating the developed common approaches in the design of their preparedness plans.

Effects at policy level:

Support MS putting in place a strong set of coordinated public health measures at EU level to help minimise the public health consequences of cross-border health threats (which could range from mass contamination caused by chemical incidents to epidemics or pandemics).

Beneficiaries:

Member States through Health authorities, health professionals, health institutions and other competent bodies involved in interior affairs and civil protection.

6.4.4. Indicators of results and impact

Specific objective No 1

Outcome indicators:

Number of tools and mechanisms developed by 2017, 2020 and 2023.

Number of guidelines/recommendations/pieces of advice given as from 2015 and then every year.

Impact indicators:

Number of Member States (through their policy makers, health professionals, health institutions) using the developed tools and mechanisms and pieces of advice by 2018, 2021 and 2024.

Specific objective No 2

Outcome indicators:

Number of operating European Reference Networks by 2017, 2020 and 2023.

Number of guidelines developed by 2017, 2020 and 2023

Impact indicators:

Number of health professionals using the expertise gathered through the European Reference Networks put in place and operating by 2018, 2021 and 2024.

Number of Member States (through their policy makers, health professionals, health institutions) using the developed guidelines by 2018, 2021 and 2024.

Number of patients using European Reference Networks (in other Member State than the state where they live)

Specific objective No 3

Outcome indicators:

Number of validated best practices developed by 2017, 2020 and 2023.

Increase in number of up-takes of cancer screening guidelines by the health professionals.

Impact indicators:

Number of Member States, through their policy makers, health professionals, health institutions and stakeholders from bodies involved in promoting good health and preventing diseases, using the validated best practices by 2018, 2021 and 2024.

Specific objective No 4

Outcome indicators:

Number of common approaches developed by 2017, 2020 and 2013.

Impact indicators:

Number of Member States, through their health authorities, health professionals, health institutions, and other competent bodies involved in interior affairs and civil protection, integrating the developed common approaches in the design of their preparedness plans by 2018, 2021 and 2024.

6.5. Grounds for the proposal/initiative

6.5.1. Requirement(s) to be met in the short or long term

The post 2013 "Health for Growth" programme will support the implementation of the Commission's actions in the field of Public Health policy from 2014 onwards. The new programme will build on the results achieved through the current (2008 – 2013) programme, taking also into account the recommendations of the ex-post evaluation of the programme 2003 – 2007 and of the mid-term evaluation of the programme 2008 – 2013.

The Programme will seek to support the Commission, Member States and key stakeholders in designing, coordinating and implementing effective policies which will aim at tackling the following long term challenges:

* financial sustainability of the health systems in Europe as a result of an ageing population, and taking into account the current situation of public finances in the MS;

* health workforce shortages as a result of a dwindling working-age population and an increase in demand for such workforce;

* need for improvement in patient safety and quality of healthcare as more than half of EU citizens are afraid of being harmed in the healthcare process;

* lack of sustained progress on control and prevention of chronic conditions which results in the loss of best productive years

* increasing health inequalities in health throughout Europe

* to be prepared to face global and 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).

In the short term, the programme will also be taking the following actions:

* support for implementation of legislation in health and fulfilling Commission's obligations for medicinal products and medical devices;

* a need for EU wide sound, comparable and accessible evidence, statistics and indicators.

6.5.2. Added value of EU involvement

The proposed Programme offers financial opportunities to build and launch cooperation mechanisms and coordination processes between Member States with the view to identifying common tools and best practices that could create synergies, bring EU added value and lead to economies of scale. The Programme cannot replace Member States' action. Instead, as stated in Article 168 of the Treaty on the Functioning of the European Union, EU action must complement national policies and encourage cooperation between Member States. Thus, the programme should contribute only where Member States could not act individually or where coordination is the best way to move forward. It is acknowledged that health problems vary from one Member State to another and that Member States' capacity to solve them might not necessarily be equal. From this perspective, cooperation might not always be a process that is self-organising and natural. The Programme will therefore intervene, preferably, where it can promote and steer this coordination at European level, while also serving the interests of the Member States and of the wider public health agenda.

The objectives of the proposed Programmes reflect the areas in which it has clearly attested and verified that the Programme provides EU added value. These are: 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 relating to the internal market where 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; improving economies of scale by avoiding waste due to duplication and optimising use of financial resources.

6.5.3. Lessons learned from similar experiences in the past

Summary of the ex-post evaluation of the Public Health Programme for 2003-2007and the mid-term evaluation of the Health Programme for 2008-2013:

The evaluations of the Health Programme recognise its strong potential contribution to preparing, developing and implementing EU public health policies.

Even though the Health Programme is relatively minor in terms of magnitude, it is instrumental in creating and maintaining a strong professional public health community at European level that exchanges knowledge and experience. It has a significant impact on the work done by public health practitioners across the EU, achieving a certain, albeit modest, global resonance that is important for its overall recognition. As a matter of fact, the presently modest yet laudable efforts on data collection and exchanges between Member States would not have taken place without the support of the Health Programme.

Support from the Health Programme made it possible to develop activities, for example on health determinants and comparable health data, in new Member States, where the economic situation and budget restrictions would not have allowed them to be made a priority.

The current Health Programme has promoted important issues at EU level and on national political agendas, such as rare diseases and cancer-screening guidelines, and has influenced policymaking and implementation at national level.

At management level, there has been a significant improvement in delivery of the Programme following the first five-year cycle, mainly due to outsourcing management to the Executive Agency for Health and Consumers. The procedure for selecting the action to be funded has been tightened up to make sure that the right applicants are selected for funding. The new financial mechanisms have generally been received positively and have all been used.

However, stakeholders as well as programme committee members think that the objectives are too broad to the extent of being sometimes unclear and that there are too many priorities in the annual work plans. The evaluations recommended to refine the objectives of the Health Programme for them to be more tangible and focussed on certain public health issues, especially those that are difficult for Member States to reach individually.

The evaluations also recommended to reduce the number of priority areas in the annual work plans and to base them on the needs and their EU added value.

The case studies illustrate a clear linkage between the objectives of the Health Programme and the projects funded on one hand and how these projects may contribute to the achievements of the objectives of the Programme on the other hand. However, the assessment of achievement of objectives is hampered by lack of clear performance indicators.

It was also recommended to define clear performance indicators to facilitate the follow-up and evaluation of the achievements and that progress can be measured in terms of the achievement of the objectives. And, to ensure an effective implementation of the Health Programme, it was recommended to develop a plan for long-term targets to be achieved by the Programme. In conjunction with other policy implementation tools, appropriate priority actions could then be set, financing mechanisms selected and an appropriate spread among the objectives and priorities ensured.

The dissemination of the results of the Health Programme is seen as another field where there is room for improvement and is directly linked to the underlying logic: the outcomes of the action financed targeting health policymaking at EU level, and also at national or regional levels, are not sufficiently known and not recognised by national stakeholders and policymakers. However, this is essential to ensure the sustainability of the results and to help monitor the impact of the action under the Programme.

Thus both evaluations recommend that more effort is put in the dissemination of the results obtained through different channels.

Summary of the Recommendations of the Court of Auditors:

These recommendations were in line with the findings of the evaluations summarised above, they pointed out the following needs:

* Any successor programme should be assigned **better targeted programme objectives** which are in line with its budgetary means.

* The underlying **intervention logic should be stated in an explicit manner,** setting out SMART objectives at policy and programme level, illustrating the links between them and defining indicators to measure their achievement.

* **Mapping exercise** in order to gain an overview of projects undertaken and their results **to identify the existing overlaps and any remaining gaps** in its portfolio.

* The number of **annual "actions areas" should be significantly reduced and focused on strategic priorities.**

***** Commission to address weaknesses in project design and implementation by:

- **bringing project objectives into line with programme objectives and the refocused "annual priorities"** recommended above;

- Grant agreements should **establish not only which activities are to be undertaken, but also the desired results of those activities, the target groups and how the results will be used in a sustainable manner** after project completion;

- setting quantified targets and performance indicators wherever possible in order to facilitate monitoring of progress towards objectives;

- evaluating projects ex-post in order to improve the design of forthcoming projects (and putative successor programmes) by applying "lessons learnt".

* The Commission should fully exploit the existing Health Programme (2008-2013) financial mechanisms for networks (i.e. **operating grants**) since they are more suitable for such activities and **service contracts** to carry out activities contributing to policy development. However this requires more **rigorous definition of Terms of Reference** than in call for proposals.

* The Court also recommends that *"for the period after 2013, the European Parliament, the Council and the Commission should reconsider the scope for EU public health activities and the approach of EU funding in this area. This should be done bearing in mind the budgetary means available and the existence of other cooperation mechanisms (such as the open method of coordination) as a means of facilitating collaboration and the exchange of information among stakeholder throughout Europe".*

6.5.4. Coherence and possible synergy with other relevant instruments

The Programme will promote synergies while avoiding duplication with related Union programmes and actions. Appropriate use will be made of other Union funds and programmes, in particular:

* the current and future Union framework programmes for research and innovation and their outcomes,

* the Structural Funds,

* the Programme for Social Change and Innovation

* the European Solidarity Fund,

* the European strategy for health at work,

* the Competitiveness and Innovation Programme,

* the Framework Programme for Environment and Climate Action (LIFE)

* the programme of Union action in the field of consumer policy (2014-2020)

* the Justice programme (2014-2020),

* the Union Statistical Programme within its respective activities,

* the Ambient Assisted Living (AAL) Joint Programme.

* the Education Europe Programme.

6.6. Duration and financial impact

☒ Proposal/initiative of **limited duration**

– ☒ Proposal/initiative in effect from 01/01/2014 to 31/12/2020

– ☒ Financial impact from 2014 to 2023 in payment appropriations only

☐ Proposal/initiative of **unlimited duration**

– Implementation with a start-up period from YYYY to YYYY,

– followed by full-scale operation.

6.7. Management mode(s) envisaged[21]

☒ **Centralised direct management** by the Commission

☒ **Centralised indirect management** with the delegation of implementation tasks to:

– ☒ executive agencies

– ☐ bodies set up by the Communities[22]

– ☐ national public-sector bodies/bodies with public-service mission

[21] Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html

[22] As referred to in Article 185 of the Financial Regulation.

– ☐ persons entrusted with the implementation of specific actions pursuant to Title V of the Treaty on European Union and identified in the relevant basic act within the meaning of Article 49 of the Financial Regulation

☐ **Shared management** with the Member States

☐ **Decentralised management** with third countries

☒ **Joint management** with international organisations ***(to be specified)***

Comments

Executive Agency for Health and Consumers (EAHC): In accordance with Council Regulation (EC) No 58/2003 of 19 December 2002 laying down the statute for Executive Agencies to be entrusted with certain tasks in the management of Community programmes[23], the Commission has entrusted[24] the Executive Agency for Health and Consumers with implementation tasks for the management of the second programme of Community Action in the field of health for 2008-2013. The Commission may therefore decide to entrust an executive agency also with implementation tasks for the management of the "Health for Growth programme 2014-2020".

Joint management with international organisations:

Envisaged to develop cooperation with relevant international organisations such as the United Nations and its specialised agencies, in particular the WHO, as well as with the Council of Europe and the Organisation for Economic Cooperation and Development, with a view to implementing the Programme through maximising the effectiveness and efficiency of actions relating to health at Union and international level, taking into account the particular capacities and roles of the different organisations.

7. MANAGEMENT MEASURES

7.1. Monitoring and reporting rules

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.

The Programme will be subject to mid-term term and ex-post evaluation. A mid-term evaluation will aim at measuring progress made in meeting the Programme objectives, determining whether its resources have been used efficiently and assessing its European added value.

The ex-post evaluation of the current programme (2008 – 2013), which is foreseen before the end of 2015, will also provide useful elements for the implementation of the programme 2014 – 2020.

[23] OJ L 11, 16.1.2003, p. 1.

[24] Commission Decision C(2008)4943 of 9 September 2008.

Specific information on the amount of climate related expenditure, calculated in accordance with the Rio markers based methodology, as specified in the June 2011 MFF Communication, will be included throughout the annual work programmes, as well as within the evaluations at all levels and in the annual, mid-term and ex-post reports.

7.2. Management and control system

7.2.1. Risk(s) identified

The budget implementation focuses on the attribution of grants and service contracts.

The service contracts will be concluded in areas such as studies, data collection, evaluation contracts, training, information campaigns, IT and communication services, facilities management etc. The contractors are mainly health institutions, laboratories, consultancy firms and other private companies of which many SMEs. The average annual budget for contracts is estimated at some EUR 14 million for approximately 30 contracts per year.

Grants will mainly be awarded for support activities to non-governmental organisations, national agencies, universities etc. The period of execution of the subsidised projects is usually between one and three years. The average annual budget for grants is estimated at some EUR 37 million for approximately 50 grants per year.

The main risks are the following:

* Risk of poor quality of selected projects and poor technical implementation of the project, reducing the programmes' impact; due to inadequate selection procedures, lack of expertise or insufficient monitoring;

* Risk of inefficient or non-economic use of funds awarded, both for grants (complexity of reimbursing actual eligible costs coupled with limited possibilities to check eligible costs at the desk) and for procurement (sometimes limited number of economic providers with the required specialist knowledge entailing insufficient possibilities to compare price offers);

* Reputational risk for the Commission, if fraud or criminal activities are discovered; only partial assurance can be drawn from the third parties' internal control systems due to the rather large number of heterogeneous contractors and beneficiaries, each operating their own control system, often rather small in size.

7.2.2. Control method(s) envisaged

The budget will be implemented by centralised direct management, though parts of the implementation tasks of the programme might be delegated to the existing executive agency EAHC. This agency set up its own internal control system, is supervised by DG SANCO, and audited by the Commission's internal auditor as well as the Court of Auditors.

DG SANCO and the EAHC alike put in place internal procedures that aim at covering the risks identified above. The internal procedures are in full compliance with the financial regulation and include cost-benefit considerations. Within this framework, SANCO continues

to explore possibilities to enhance the management and to increase simplification. Main features of the control framework are the following:

Characteristics of the selection process of projects: each call for proposals/tender is based on the annual Work Programme adopted by the Commission. In each call, the exclusion, selection and award criteria for selecting proposals/offers are published. Against these criteria, an evaluation committee, possibly assisted by external experts, evaluates each proposal/offer observing the principles of independence, transparency, proportionality, equal treatment and non-discrimination. An Inter-service Consultation on the selected proposals is carried out within the Commission to prevent double funding.

External Communication strategy: DG SANCO has a well developed communication strategy that seeks to ensure the contractors'/beneficiaries' full understanding of the contractual requirements and provisions. Following means are being used: EUROPA Programme website, "frequently asked questions", a help desk, extensive guidance notes as well as information meetings with beneficiaries/contractors.

*** Controls before and during the implementation of the projects:**

- DG SANCO and the EAHC alike, use the model grant agreements and service contracts recommended by the Commission. They provide for a number of control provisions such as audit certificates, financial guarantees, on-site audits as well as inspections by OLAF. The rules governing the eligibility of costs will be simplified, for example, by using lump sums in a limited number of cost categories. This will also help to better concentrate the checks and controls. Partnership agreements are expected to improve the working relations with the beneficiaries and to enhance the understanding of the eligibility rules.

- All staff signs the code of good administrative behaviour. Staff who are involved in the selection procedure or in the management of the grant agreements/contracts also sign a declaration of absence of a conflict of interest. Staff is regularly trained and uses networks to exchange best practices.

- Technical implementation of a project is checked at regular intervals at the desk on the basis of technical progress reports of the contractor; in addition contractors' meetings and on-site-visits are foreseen on a case by case basis.

- Both SANCO's and EAHC's financial procedures are supported by the Commission's IT tools and have a high degree of segregation of duties: all financial transactions related to contracts/grant agreements are verified by two independent persons before they are signed by the authorising officers responsible for the activity. Operational initiation and verification is carried out by different members of staff of the policy areas. Payments are made on the basis of a number of pre-defined supporting documents such as approved technical reports as well as verified cost claims and invoices. For a sample of transactions, the central financial cell performs second-level ex-ante desk verification; on a case by case basis, also an ex-ante on-site financial control can be carried out prior to final payment.

*** Controls at the end of the project:**

Both DG SANCO and the EAHC have centralised audit teams who verify on-the-spot the eligibility of cost claims. The aim of these controls is to prevent, detect and correct material errors related to the legality and regularity of financial transactions. With a view to achieving a high control impact, the selection of contractors to be audited foresees to (a) combine a risk based selection with a random sampling, and (b) pay attention to operational aspects whenever possible during the on-site audit.

*** Costs and benefits of controls:**

The programme's management and control measures are designed on the basis of past experience: in the past three years, the established internal control system ensured an average residual error rate of less than 2% as well as compliance with the grant and procurement procedures laid down in the financial regulation. These are the two main "control objectives" of both the previous and the new public health programme.

As the main design features of the new programme are not significantly different from the previous programme, the risks related to programme implementation are considered to remain relatively stable. Thus, the established management and control measures are planned to be continued; nevertheless, further simplifications that might become possible under the new financial regulation will be taken up as soon and as far as possible.

The total management costs included in the Financial Statement (part 3.2.3) amount to EUR 45,4 million for EUR 446,0 million of funds managed from 2014 to 2020; this leads to a ratio "management costs to managed funds" of about 10.2 %, which should be viewed in the context of a policy area which is not as spending-oriented as other EU policies.

Thanks to the combination of grants and procurement, risk based ex-ante and ex-post controls as well as desk checks and on-site audits, the "control objectives" will be achieved at a reasonable cost level. The benefits of achieving an average residual error rate of less than 2% and compliance with the provisions of the financial regulation are assessed as sufficiently important to justify the chosen management and control measures.

7.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures.

In addition to the application of all regulatory control mechanisms, DG SANCO will devise an anti-fraud strategy in line with the Commission's new anti-fraud strategy (CAFS) adopted on 24 June 2011 in order to ensure inter alia that its internal anti-fraud related controls are fully aligned with the CAFS and that its fraud risk management approach is geared to identify fraud risk areas and adequate responses. Where necessary, networking groups and adequate IT tools dedicated to analysing fraud cases related to the public health programme will be set up in particular a series of measures such as:

- decisions, agreements and contracts resulting from the implementation of the Health Programme will expressly entitle the Commission, including OLAF, and the Court of Auditors to conduct audits, on-the-spot checks and inspections;

- during the evaluation phase of a call for proposals/tender, the proposers and tenderers are checked against the published exclusion criteria based on declarations and the Early Warning System (EWS);

- the rules governing the eligibility of costs will be simplified in accordance with the provisions of the Financial Regulation;

- regular training on issues related to fraud and irregularities is given to all staff involved in contract management as well as to auditors and controllers who verify the beneficiaries' declarations on the spot.

8. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

8.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing expenditure budget lines

In the order of multiannual financial framework headings and budget lines:

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./non-diff (25)	from EFTA[26] countries	from candidate countries[27]	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
3: security and citizenship	17 03 06 EU action in the field of health	Diff.	YES	YES	NO	NO
3: security and citizenship	17 01 04 Programme of European Union action in the field of Health – expenditure on administrative management	Non-diff.	YES	YES	NO	NO

No new budget lines requested.

25 Diff. = Differentiated appropriations / Non-Diff. = Non-differentiated appropriations

26 EFTA: European Free Trade Association.

27 Candidate countries and, where applicable, potential candidate countries from the Western Balkans.

8.2. Estimated impact on expenditure

8.2.1. Summary of estimated impact on expenditure

EUR million (to 3 decimal places) in current pric

Heading of multiannual financial framework:	Number 3	Security and citizenship

DG: SANCO			**Year 2014**	**Year 2015**	**Year 2016**	**Year 2017**	**Year 2018**	**Year 2019**	**Year 2020**	**Subsequent years**	**TOTAL**
Operational appropriations											
17 03 06	Commitments	(1)	54.465	56.281	57.188	58.096	59.004	60.819	59.004		**404.857**
	Payments	(2)	5.000	16.000	32.000	49.000	54.000	57.000	57.000	**134.857**	**404.857**
Appropriations of an administrative nature financed from the envelope for specific programmes[28]											
17 01 04		(3)	5.535	5.719	5.812	5.904	5.996	6.181	5.996		**41.143**
TOTAL appropriations for DG SANCO	Commitments	=1+1a +3	60.000	62.000	63.000	64.000	65.000	67.000	65.000		**446.000**
	Payments	=2+2a +3	10.535	21.719	37.812	54.904	59.996	63.181	62.996	**134.857**	**446.000**

• TOTAL operational appropriations	Commitments	(4)	54.465	56.281	57.188	58.096	59.004	60.819	59.004		**404.857**
	Payments	(5)	5.000	16.000	32.000	49.000	54.000	57.000	57.000	**134.857**	**404.857**
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	5.535	5.719	5.812	5.904	5.996	6.181	5.996		**41.143**
TOTAL appropriations under HEADING 3 Security and citizenship	Commitments	=4+ 6	60.000	62.000	63.000	64.000	65.000	67.000	65.000		**446.000**
	Payments	=5+ 6	10.535	21.719	37.812	54.904	59.996	63.181	62.996	**134.857**	**446.000**

[28] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, dire research.

The Commission could envisage externalising the implementation of the Health for Growth programme to an executive agency. Amounts and breakdown c
estimated costs may have to be adjusted according to the degree of externalisation finally retained.

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EUR million (to 3 decimal places) in current pric

Heading of multiannual financial framework:	**5**	**" Administrative expenditure "**

		Year 2014	**Year 2015**	**Year 2016**	**Year 2017**	**Year 2018**	**Year 2019**	**Year 2020**	**TOTAL**
DG: SANCO									
• Human resources SANCO (17 01 01)		1.088	1.110	1.132	1.155	1.178	1.202	1.226	**8.091**
DG: SANCO									
• Other administrative expenditure (17 01 02 11)		2.125	2.168	2.211	2.255	2.300	2.346	2.300	**15.705**
TOTAL DG SANCO	Appropriations	**3.213**	**3.278**	**3.343**	**3.410**	**3.478**	**3.548**	**3.526**	**23.796**
TOTAL appropriations under HEADING 5 of the MFF	(Total commitments = Total payments)	**3.213**	**3.278**	**3.343**	**3.410**	**3.478**	**3.548**	**3.526**	**23.796**

		Year 2014	**Year 2015**	**Year 2016**	**Year 2017**	**Year 2018**	**Year 2019**	**Year 2020**	**TOTAL**
TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework	Commitments	63.213	65.278	66.343	67.410	68.478	70.548	68.526	**469.796**
	Payments	13.748	24.997	41.155	58.314	63.475	66.729	66.522	**334.939**

8.2.2. Estimated impact on operational appropriations

– ☐ The proposal/initiative does not require the use of operational appropriations

– ☒ The proposal/initiative requires the use of operational appropriations, as explained below:

– *Commitment appropriations in EUR million in current prices (to 3 decimal places)*

Indicate objectives and outputs			**Year 2014**		**Year 2015**		**Year 2016**		**Year 2017**		**Year 2018**		**Year 2019**		**Year 2020**		**TOTAL**	
	OUTPUTS																	
⇩	Type of output		Nb of outputs	Cost	Nb of outputs	Cost	Nb of outputs	Cost	Nb of outputs	Cost	Nb of outputs	Cost	Nb of outputs	Cost	Nb of outputs	Cost	Total number of outputs	**Total cost**
SPECIFIC OBJECTIVE No 1			3	26.143	7	27.015	11	27.450	11	27.886	11	28.322	11	29.193	11	28.322	65	194.331
SPECIFIC OBJECTIVE No 2			2	11.982	4	12.382	6	12.581	6	12.871	6	12.981	6	13.380	6	12.981	36	89.069
SPECIFIC OBJECTIVE No 3			2	11.438	5	11.819	8	12.010	8	12.200	8	12.391	8	12.772	8	12.391	47	85.020
SPECIFIC OBJECTIVE No 4			1	4.902	3	5.065	5	5.147	5	5.229	5	5.310	5	5.474	5	5.310	29	36.437
TOTAL COST			**9**	**54.174**	**19**	**55.980**	**30**	**56.882**	**30**	**57.785**	**30**	**58.688**	**30**	**60.494**	**30**	**58.688**	**178**	**404.857**

Outputs expected in 2021 and 2022: objective 1: 12; objective 2: 6; objective 3: 9; objective 4: 6 thus 32 for the whole programme. In total, in indicative total of 210 outputs are expected.

Outputs consist in:

specific objective 1: number of tools and mechanisms developed;

specific objective 2: number of functioning European Reference Networks and number of guidelines developed;

specific objective 3: number of validated best practices for cost effective prevention measures identified and disseminated;

specific objective 4: number of common approaches (towards cross border health threats) developed.

The split per year is an average and is purely indicative as it is the split for the total envelope that is more significant for the programme. Indeed, it may well be that one year more efforts are put on one specific objective than the other. Orientations for annual spending will be given in a multi-annual strategic programming. The final decision will be taken when preparing the annual work programme.

8.2.3. Estimated impact on appropriations of an administrative nature

8.2.3.1. Summary

– ☐ The proposal/initiative does not require the use of administrative appropriations

– ☒ The proposal/initiative requires the use of administrative appropriations, as explained below:

*EUR million **in 2011 prices** (to 3 decimal places)*

	2014	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**TOTAL**
HEADING 5 of MFF								
Human resources (BL 17 01 01)	1.026	1.026	1.026	1.026	1.026	1.026	1.026	**7.182**
Other administrative expenditure (BL 17 01 02 11)	2.025	2.025	2.025	2.025	2.025	2.025	2.025	**14.175**
Subtotal HEADING 5 of the MFF	**3.051**	**3.051**	**3.051**	**3.051**	**3.051**	**3.051**	**3.051**	**21.357**

Outside HEADING 5 of the MFF								
Administrative expenditure in support of the programme (BL 17 01 04)	5.320	5.320	5.320	5.320	5.320	5.320	5.320	**37.240**
Subtotal outside HEADING 5 of the MFF	**5.320**	**5.320**	**5.320**	**5.320**	**5.320**	**5.320**	**5.320**	**37.240**

TOTAL	**8.371**	**8.371**	**8.371**	**8.371**	**8.371**	**8.371**	**8.371**	**58.597**

8.2.3.2. Estimated requirements of human resources

– ☐ The proposal/initiative does not require the use of human resources

– ☒ The proposal/initiative requires the use of human resources, as explained below:

Number of posts in FTEs

	2014	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
• Establishment Plan Posts (officials and temporary agents) SANCO							
17 01 01 01 - at headquarters and in Commission representation offices in Member States (AD &AST)	5.7	5.7	5.7	5.7	5.7	5.7	5.7
	2.375	2.375	2.375	2.375	2.375	2.375	2.375
Total establishment plan posts SANCO	***8.075***	***8.075***	***8.075***	***8.075***	***8.075***	***8.075***	***8.075***
TOTAL	***8.075***	***8.075***	***8.075***	***8.075***	***8.075***	***8.075***	***8.075***

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

Officials and temporary agents	***In SANCO:*** Elaboration of programme, multi-annual work programme, annual work programmes, follow-up of implementation of the programme, evaluation, audits, etc. Coordination with the executive agency if an externalisation of the management of the Programme is eventually decided.

8.2.4. Compatibility with the current multiannual financial framework

– ☒ Proposal/initiative is compatible with the 2014–2020 multiannual financial framework as proposed in Commission's Communication COM(2011)500.

– ☐ Proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

– ☐ Proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework[29].

8.2.5. Third-party contributions

– ☒ The proposal/initiative does not provide for co-financing by third parties

– ☐ The proposal/initiative provides for the co-financing estimated below:

8.3. Estimated impact on expenditure

– ☒ Proposal/initiative has no financial impact on revenue.

– ☐ Proposal/initiative has the following financial impact:

[29] See points 19 and 24 of the Interinstitutional Agreement.