EUROPEAN COMMISSION

Brussels, 9.11.2011
SEC(2011) 1322 final

COMMISSION STAFF WORKING PAPER

Impact assessment

Accompanying the document

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

{COM(2011) 709 final}
{SEC(2011) 1323 final}

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INTRODUCTION

In its Communication 'A Budget for Europe 2020'[1] the European Commission proposed an allocation of € 396 million for the period 2014-2020 for an expenditure programme in the area of health. This initial budgetary provision was to be followed up by a detailed legal proposal for a future Health Programme, to be adopted by the College by the end of 2011.

This report therefore has to be seen as a key milestone in this process. Its purpose is to describe the main challenges facing health in Europe to outline the framework for EU initiatives in this policy area, alongside the action taken by the Member States. It aims also to define the objectives and demonstrate the value of the proposed Health Programme and, finally, to assess different options for such a Programme, focusing on their expected impact.

This document therefore consists of the following sections:

- Section 1 describes the expectations for the future Programme, on the basis of previous evaluations, audits and consultations with other departments of the Commission and third parties (Member States and other stakeholders).
- Section 2 describes the policy context in which the Programme will operate and the main challenges common to all Member States creating incentives for action at EU level.
- Section 3 explains the objectives of the Programme.
- Section 4 discusses the right of the Union to act towards those objectives (subsidiarity, necessity and EU added value).
- Section 5 underlines the links of the proposed Programme with the Europe 2020 Strategy.
- Section 6 presents the policy options considered. They are each assessed against the objectives of the Programme, based on their expected impact, and are then compared with each other in order to conclude which one is the most suitable choice.
- Section 7 sums up the main factors and indicators for monitoring and evaluating the Programme.

Finally, seven annexes add further details:

- Annex 1: List of participants in the Steering Group for drafting this report.
- Annex 2: Timetable for drafting this report and further steps.
- Annex 3: Key points and executive summary, including recommendations from the final evaluation of the Public Health Programme for 2003-2007.
- Annex 4: Key points and executive summary, including recommendations from the mid-term evaluation of the Health Programme for 2008-2013.
- Annex 5: Summary of main points raised in the consultation with stakeholders and Member States.

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

- Annex 6: List of all the legislation that Programme will support in its implementation, application, evaluation and review.
- Annex 7: Seven case studies illustrating the intervention logic, EU added value, results and impact of action financed under the current and previous Health Programmes.

1. PROCEDURAL ISSUES AND CONSULTATIONS WITH THIRD PARTIES

1.1. Organisation and timing

Organisation

The Inter-Service Group (ISG) on Health Policy has served as the steering group for the mid-term evaluations of the current Health Strategy and Programme (till 2013) and also for the Impact Assessment (IA) on the new Programme post-2013. The first meeting of the Impact Assessment Steering Group (IASG) took place on 15 April, the second on 17 June and the third on 18 July 2011 (*see Annex 1 for the list of Commission Directorates-General invited*).

Timetable

See Annex 2.

Sources of data

- The *ex-post* evaluation of the Public Health Programme (PHP) for 2003-2007 and the mid-term evaluation of the Health Programme (HP) for 2008-2013.
- The Joint Report on Health Systems, Occasional Papers 74/December 2010, prepared by the European Commission and the Economic Policy Committee/Working Group on Ageing (AWG).
- The Court of Auditors special report No 2/2009 'The European Union's Public Health Programme (2003-2007): An effective way to improve health?'
- Other studies, in-depth surveys and impact assessments on legislative initiatives in the area of health.

1.2. Expertise and consultations

The new Health Programme (the 'Programme') should build on the results achieved by both the Public Health Programme (PHP) for 2003-2007 and the current Health Programme (HP) for 2008-2013. It should do so in line with the conclusions drawn and recommendations made in the different evaluations and audits performed on these programmes.

1.2.1. Main results of the *ex-post* evaluation of the Public Health Programme (2003-2007)[2] and the mid-term evaluation of the Health Programme (2008-2013)[3]

Originally, the first Public Health Programme (2003-2007) grew out of a small number of isolated, empirically managed activities in response to calls from the Council and the European Parliament, such as action on HIV/AIDS, health information, etc. Inevitably, the number of

2 See Executive summary under Annex 3.

3 See Executive summary under Annex 4.

priorities gradually increased, to meet the new expectations, until they reached a point well above what could be manageable and make a strong impact. Nevertheless, the evaluation of the PHP recognised its strong potential contribution to preparing, developing and implementing EU public health policies even if it tried to cover too broad spectrum of health priorities.

The 2nd Health Programme (2008-2013) followed similar design as the first one, facing similar difficulties (*this is discussed in details in section 2.2.1*.). The mid-term evaluation, however, concluded that even though the HP is relatively minor in terms of a magnitude, it has a significant impact on the work done by public health practitioners across the EU. It achieves certain, albeit modest, global resonance that is important for its recognition. The HP is instrumental in creating and maintaining a strong professional public health community at European level that finds it natural to exchange knowledge and experience. 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 Programmes.

Second, the HP made it possible to develop many 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.

Third, the current Programme has promoted important issues at EU level and on national political agendas, such as rare diseases and cancer-screening guidelines. It has also influenced policymaking and implementation at national level. In this context, dissemination of the results of the PHP and HP is seen as another field where there is room for improvement and is directly linked to the underlying logic. The outcomes of the financed actions targeting health policymaking at EU, national or regional levels are still not sufficiently known, so not always recognised and used by stakeholders and policymakers. However, this is essential to ensure the sustainability of the results and to help monitor the impact of actions under the new Programme.

At management level, there has been a significant improvement in delivery of the Programme, mainly due to outsourcing of the management to the Executive Agency for Health and Consumers. The procedure for selecting actions to be funded has been tightened up to make sure that the best applicants are selected. The new financial mechanisms introduced in the 2nd Programme have generally been positively received and widely used.

1.2.2. Main conclusions of the evaluations and indications for a new Health Programme

First: The post-2013 Health Programme should be much more focused and concentrate financial support on a smaller number of activities in key priority areas, bringing the biggest EU added value. It was underlined by the Court of Auditors in the report 'The European Union's Public Health Programme (2003-2007): an effective way to improve health?'[4]

Second: The post-2013 Programme should be able to serve and involve all EU Member States better, especially those with relatively low Gross National Income (GNI), where numerous cultural, procedural and financial barriers reduce the opportunities to participate. Emphasis should be placed on areas where Member States cannot act in isolation in a cost-effective manner, where there are clear cross-border or internal market issues or where there are significant advantages and efficiency gains from collaboration at EU level.

Third: The evaluators recommended adopting more tangible and specific, measurable, attainable, relevant and time-bound (SMART) objectives for the Programme, set in a better defined strategic framework with long-term targets. Limiting the number of activities to the ones that concern the

4 http://eca.europa.eu/portal/pls/portal/docs/1/2838313.PDF.

most Member States and where there is a real value in taking action at EU level could increase efficiency gains and maximise the impacts of the Programme. Action and results need to be built into a regular reporting system and shared more effectively within the Commission and with stakeholders and national policymakers.

1.2.3. Consultations with third parties

In line with the main recommendation of external evaluations, namely to reduce the number of priority areas of the Programme, the consultation was targeted at Member States' representatives, for instance national focal points, the Senior Working-Level Group and the informal Health Council. Additional expert advice was provided through the EU Health Policy Forum, by health professionals and patients associations. Other stakeholders, especially the beneficiaries, have expressed their views in recent evaluations.

Representatives of Member States and NGOs participating in the various consultations strongly supported the continuation of the Health Programme. While unanimously agreeing with this need, some Member States concurred with the view that it should be more focused, cost-efficient and supporting actions with proven EU added value. Others however were of the opinion that it should continue to support the existing objectives and a wide range of actions.

When expressing their views on the EU Health Strategy (in the context of its mid-term evaluation) the vast majority of Member States consider it as a framework or driver of best practice exchange at EU level and for cooperation with other Member States. In this context many mentioned the possibilities provided by the Health Programme, in particular **the joint actions, as very important for their national health policies**.

National focal points, designated by Member States' authorities, argued that the Programme should continue to support national policies by:

- providing best practices to follow at national level;
- sharing and exchanging practical experience, expertise and knowledge;
- giving support on health issues on the national political agendas.

The areas suggested by Member States to be tackled by the post-2013 Health Programme were:

- health systems sustainability and reform;
- health impact of demographic change (healthy ageing and dementia);
- health in all policies;
- cancer;
- major non-communicable diseases and chronic diseases;
- rare diseases;
- communicable diseases;
- prevention and action on major health determinants (alcohol, tobacco, etc.);
- mental health;
- health promotion, including promotion of a healthy life, nutrition and obesity;
- e-Health;

- other topics mentioned less frequently: health technology assessment, sexual health policy, health indicators, etc.

Furthermore, Member States and stakeholders alike stressed the need to engage all EU countries more actively in the Programme. They also emphasised that the Programme should be more closely linked to the Treaty, to the EU 2020 agenda and to the existing legislation.

Stakeholders gathered in the EU Health Policy Forum reasserted that it is **fundamental to have a new Programme,** especially **for patients**, and to support health literacy and the fight against health inequalities. According to them the current financial mechanisms for EU public health should be maintained.

The Forum stressed that strong emphasis should be put on health determinants and a patient centred focus. They also recommended that the Programme addresses the role of social determinants, thus making an impact on reducing health inequalities.

A **human rights approach** to support EU public health was advised - one that is equipped with adequate resources and that reflects non discrimination in healthcare provision. Several members of the Forum expressed **worries for the future of the Programme**, as they fear that less support might be provided to the work being done towards improved public health and its outcomes. **Prioritisation of projects** within the Programme should be **discussed with the stakeholders.** Moreover the Programme should have longer as well as short terms goals.

In addition **coordination between European and national programmes** could be a guarantee for greater involvement of Member States and a solution to avoid fragmentation of efforts deployed in multiple levels (national, local, European). The **difficulties to access** the Programme were raised by some members of the Forum, even if it was understood that there are strict rules for the use of EU funds. In the areas of funding, they argued, there is a **need to balance between the joint actions and core funding for project grants**.

Further contributions were received from health stakeholders and have been taken into account in this document and, beyond that, in drafting of the Programme. Overall 20 organisations have provided written contributions out of the 52 member organisations participating in the EU Health Policy Forum.

The details of consultations are provided in Annex 5.

1.3 Impact Assesment Board's comments:

The recommendations made by the Impact Assessment Board have been taken into account in the following way: a paragraph has been added to present the policy context and a table explains the link between identified challenges, MFF announcements, policy objectives and specific objectives; evaluation recommendations have been added to the problem definition, more explanation and evidence have been added about the necessity of the programme and the EU added value.

Regarding policy options, the baseline scenario has been strengthened, sub-options have been added to option 3the focus for each of the sub-options has been clarified and an overview of the planned budget allocations for the different areas of intervention has been provided. The assessment of the impact has been developed and examples have been added also from previous programme experience.

Regarding the indicators, we have explained that, the programme being a supporting programme for policies, it's main impact can only be measured at the level of Member States in their uptake of the guidelines, best practices, advices that will be developed under each specific objectives. Thus, output indicators can only measure the production of these best practices, tools, mechanisms, guidelines, that have been developed. And impact indicators can only be about the uptake of these best practices, mechanisms, guidelines by the end users. Thus, the success of the Programme can only be defined in terms of the rate of implementation, participation by Member States and take-up of the outcome in the different Member States and stakeholder groups, on top of the actual results achieved compared with predefined levels.

Finally, evaluations arrangements have been improved and more details have been provided on stakeholders views.

2. PROBLEM DEFINITION

In order to demonstrate the value of the proposed Programme, this section is structured around three key issues:

- the policy context;
- the key challenges for public health in Europe in the years ahead;
- the specific context for EU action in the area of health, with its inherent limitations.

2.1. Policy context

The points already included in the Commission's Communication of 29 June 2011 'A Budget for Europe 2020' are to be taken into account as the pre-defined overarching framework for the Programme. As stated in this Communication, "*Promoting good health is an integral part of the smart and inclusive growth objectives of Europe 2020. Keeping people healthy and active for longer has a positive impact on productivity and competitiveness. Innovation in healthcare helps take up the challenge of sustainability in the sector in the context of demographic change*" and action to reduce inequalities in health is important to achieve "*inclusive growth*".

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

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

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

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

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

Four particularly important factors for the design of the Programme are the general principles underpinning the overall budgetary proposal outlined by the Commission in the 2010 budget review:

- focus on delivering key policy priorities;
- focus on EU added value;
- focus on impact and results;
- deliver mutual benefits across the European Union.

The definition of the aim, objectives and the scope of the Programme, proposed below in Section 3, takes full account of these principles, in both the design and the implementation phases. In doing so, the proposed Programme is in line with the Commission's general statement on the budgetary proposal, i.e. that the EU budget expresses 'policy in numbers', in that the funding must go hand in hand with the existing regulatory environment and the policy priorities in the relevant areas.

As a consequence, in order to ensure that its output and impact push forward the key policy priorities of the EU, in line with the Europe 2020 Strategy, the Programme will concentrate on a limited number of high-profile priorities and activities where it can build up a critical mass, *inter alia* by exerting a leverage effect and complementing Member States' action.

2.2. Defining the problem and its causes and effects

In the area of health the challenges for Member States are serious while the expectations of the patients and stakeholders are high. Member States are under pressure to strike the right balance between providing universal access to high quality health services and respecting budgetary constraints.

The financial crisis has further magnified the need to improve cost-effectiveness of national health systems. First and foremost it is up to Member States to take direct action at their level. The aim of EU Health policy, as stated in the Treaty, is to complement and support these national policies and encourage cooperation between Member States.

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

The Programme should provide possibilities to build and strengthen cooperation mechanisms and coordination processes between Member States with a view to identifying common tools and best practices that create synergies. It should bring the biggest EU added value and lead to economies of scale, thus supporting reforms under challenging circumstances.

2.2.1. The past experience and a new process leading to a better design of the Programme

According to the ex-post evaluation, the Public Health Programme lacked explicit intervention logic on the basis of clearly defined objectives linked to actions and corresponding performance indicators. As a result, the PHP had no strategic focus. For example, the programme's 'action areas' established in the annual work plans (AWPs) outnumbered the projects funded to address them and there was no sufficient competition between the proposed projects. The project

proposers were invited to apply for funding under very general headings. The multiplicity and diversity of project topics and target groups resulted in the dilution of inputs and led to fragmented results.

The 2nd Health Programme has similar objectives as the PHP. They are far reaching and encompass most areas of public health in Europe. As a consequence the implementation of the Programme faces similar difficulties caused by the lack of clear intervention logic. It is hard to demonstrate how actions lead to the achievement of HP's goals and how progress can be effectively measured. Additionally there is still not enough of prioritisation of actions in the Annual Work Plans, and there are problems to disseminate satisfactory results of the funded actions and to measure their impacts. Following the mid-term evaluations' recommendations some corrective measures are now being implemented but they cannot heal the root causes of the problems.

Recommendations[5] stemming from the report of the Court of Auditors in 2008 and the external evaluations of the previous and current programmes demonstrated that the problem lies in the design of the Programme itself. In all audits and evaluations similar recommendations were made (see comparative table with the highest ranked recommendations in annex 3bis) and stressed the need:

- to improve the concept and the design of the future Programme with an explicit intervention logic;
- to focus the Programme on SMART objectives, and reduce the number of priorities;
- To better take into consideration the real needs and what is achievable within the limited budget, and
- To support actions that will create proven EU added value.

The definition of well targeted Programme objectives starts with a horizon scanning of the most relevant health challenges that Member States are facing.. This is crucial in order to align the Programme to real needs and ensure that the expected outcomes will be used to improve national health policies. The Programme should support actions with proven EU added value and suggest solutions that cannot be found by each MS individually and so the leading role of EU makes sense.

2.2.2. Major challenges for the health in the EU

> *"Promoting good health is an integral part of the smart and inclusive growth objectives of Europe 2020. Keeping people healthy and active for longer has a positive impact on productivity and competitiveness. Innovation in healthcare helps take up the challenge of sustainability in the sector in the context of demographic change' and action to reduce inequalities in health is important to achieve "inclusive growth"*
>
> (Commission's Communication 'A Budget for Europe 2020')

Health is not just a value in itself - it is also a strong economic driver for growth. Health care expenditure accounts for nearly 10% of the EU's gross domestic product[6] and is one of the

[5] The main recommendations of Court of Auditors report, ex-post evaluation of PHP 2003-2008 and mid-term evaluation of HP 2008-2013 are presented in annex 4 pages 72-74.

6 Source: Source EC/EPC Joint Report on Health Systems, p.46. The average is 9.6 %. (http://ec.europa.eu/economy_finance/publications/occasional_paper/2010/pdf/ocp74_en.pdf)"

largest economic sectors in the EU. Moreover it is driven by innovation and a highly qualified workforce. The health care sector employs one in 10 workers in the EU[7] and among the most qualified, since it has a higher than average proportion of workers with tertiary-level education.[8] This weight gives the health care sector an important role to play in the economy in general and in contributing to the Europe 2020[9] Strategy. There is a strong evidence of the link between health and economic performance:[10] a population in good health is a *sine qua non* for attaining smart, sustainable and inclusive growth.

Good health is one of the most important factors for increasing individual productivity and consumer empowerment. An increase in the number of productive years as a result of better health has an immediate positive impact on collective productivity and competitiveness. Finally, investing in health can boost innovation, as health-related research and development has the potential to reach 0.3% of GDP. It creates new skills and jobs and addresses the challenges of an ageing society. The conclusions of the last Council meeting of Health Ministers made a point on this aspect of investment.[11]

Over the next 20 years, the number of Europeans aged over 65 is expected to rise by 45 %, from 85 million in 2008 to 123 million in 2030[12]. While the steady increase in life expectancy at birth is a major achievement of the recent past, living older does not necessarily mean doing so in good health. Issues arising in this context are related not only to protecting, promoting and improving the health status of the elderly, but also to financing the rising healthcare costs and to improving the healthcare offered, in response to higher expectations, and also access to it.

In order to ensure that the potential improvements reach citizens effectively, both as individuals and as members of an EU-wide community, major problems and challenges need to be overcome.

These problems are not necessarily new, but they are most often analysed separately, within the specific national or thematic context. It is, however, clear that they are strongly linked, that there is the European wide context that requires EU-wide collaboration and common responses, with due respect to the principle of subsidiarity and the ultimate responsibility of Member States.

A well designed and realistic Health Programme can contribute to and complement Member States' actions to increase the number of years Europeans live in good health through finding and applying innovative solutions for the improvement of quality and sustainability of health systems, putting the emphasis on human capital and exchange of best practices.

2.2.3. Financial sustainability of health systems

For several years now, Member States have been facing budget constraints with implications for the sustainability of their health budgets, which account for 15% of public expenditure.[13] They

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7 Source: Eurostat 'Employment in human health and social work activity'. 2008: 9.6 %; 2009: 10 %; 2010: 10.3 %.

7 43% compared with 25.5% for the average for the other economic sectors. Source: Factsheet of Eurofound, using data from the European Working Conditions Survey:
http://www.eurofound.europa.eu/pubdocs/2008/1423/en/1/EF081423EN.pdf (see page 2).

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

10 Several quantitative economic studies using methods such as multivariate analysis, along with more classical observational cohort studies, have produced strong evidence of the links between health and growth (BMJ 333: 1017, 9.11.2009, M.Suhrke et al.).

11 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:202:0010:0012:EN:PDF.

12."Ageing report 2009"
http://ec.europa.eu/economy_finance/publications/publication14992_en.pdf.

13 Source: Eurostat 'General expenditure by function — health compared to total'. 2009: 14.63 %.

are challenged by an ageing population, rising expectations for high-quality services and the emergence of new technologies. These constraints have increased with the curbs on public spending in the wake of the debt crisis.

Evidence[14] suggests that effective health system reforms show potential for containing 'excess cost growth', i.e. keeping health spending in line with GDP growth.

In this area, the EU intends to support Member States in achieving their 'budgetary' targets, while also ensuring that the impact of such reforms is not only assessed from a short-term budgetary perspective, but also seen in a broader social context to secure health system sustainability in the long term too.

Broadly speaking, the collaboration envisaged should cover a wide spectrum of issues related both to the supply side for health services and to the related costs. Planning, costing and reimbursement of healthcare services is one key area. In this context, the role of health technology assessment as a tool to be used across the EU and for achieving economies of scale by working closely with other Member States is a priority. A second key area is close collaboration on addressing the scarcity of resources, both human and financial.

Finally, building up their knowledge base about what works and what does not in health system organisation and reforms is another area where Member States can learn from sharing experience and practice, both positive and negative.

2.2.4. Health workforce shortages

Demographic developments in the EU will result in healthcare systems competing for a dwindling working-age population, with fewer and fewer potential healthcare workers. In parallel, with an ageing population and the availability of informal care in the family environment declining as a result of changing family structures, the demand for formal, professional care is increasing. Healthcare has also become more specialised and requires more intense work and longer training. These trends are currently challenging the traditional health workforce planning tools and policies of Member States.

Estimates show that, by 2020, one million health workers will be missing in the EU and 15% of the care needed will not be covered.[15] All Member States will face shortages of health workers (doctors, nurses, others professionals) and could therefore benefit from cooperating with each other. Health workforce shortages can increase regional health disparities and put at risk access to high-quality healthcare in some Member States. These structural shortages in the health workforce in Europe are accompanied by rural/urban disparities and the escalating brain and skills drain from poorer to richer and from new to old Member States of the EU.

Recent cases brought before the European Court of Justice shows that some Member States have resorted to measures that are in breach of the principle of free movement of persons, e.g. by limiting the number of foreign students in their medical faculties or halting emigration of freshly graduated health professionals. Efforts should be made to support Member States in addressing these challenges in collaboration and not in isolation, in particular their efforts on educating, recruiting and, especially, retaining young practitioners in all health professions, while reinvesting in the mature workforce.

2.2.5. Improvements necessary in patient safety

14 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).

15 Communication from the Commission 'An agenda for new skills and jobs', COM(2010) 682 final.

On average in western European countries, about 10% of patients suffer an adverse event,[16] which has consequences for them and the healthcare system. Data show that the confidence of patients in healthcare is not high. More than half of EU citizens are afraid of being harmed in the healthcare process.[17]

Estimates suggest that infections with bacteria resistant to medicinal products cause about 25 000 deaths and at least 1.5 billion euros in extra healthcare costs every year in the EU.[18] In addition, healthcare-associated infections (HCAI) hit 4.1 million patients and result in 37 000 deaths every year in the EU.[19] Although published scientific studies and reviews indicate that a reduction of 20 to 30% in healthcare-associated infections is highly cost-effective, evidence suggests that Member States are at different levels in developing and implementing effective strategies against HCAI.

2.2.6. Lack of sustained progress on control and prevention of chronic conditions

According to the latest Global Status Report of the World Health Organisation (WHO) on non-communicable diseases[20] (NCDs), the situation in the EU is worrying. In 2009, over 4 million deaths in Member States were attributable to such diseases, with nearly 50% being caused by cardiovascular diseases and diabetes, around 26% by cancer and 8% by chronic respiratory diseases. These numbers demonstrate that there is still much room for improvement in control and prevention of chronic conditions. This could, in turn, yield big gains in overall quality of life and save very large amounts of public and household expenditure.

For instance, the reduction of cancer mortality rates has been modest. Despite a decrease in the overall mortality rates,[21] the absolute number of cancers is unlikely to decline and gaps persist between old and new Member States. More worryingly, recent studies in transitional countries show that the downward trend in mortality due to cardiovascular diseases can, unfortunately, be reversed.

It is therefore crucial that Member States not only collaborate to develop and disseminate validated tools and approaches for prevention, but also work together in supporting large-scale and EU-wide implementation of the policies and practices that work.

2.2.7. Loss of best productive years in much of the population because of the slow increase in healthy life years (HLY)

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

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[16] Technical report 'Improving Patient Safety in the EU' prepared for the European Commission, published in 2008 by the RAND Cooperation.

[17] Special Eurobarometer 327. 'Patient safety and quality of healthcare'. April 2010: http://ec.europa.eu/public_opinion/archives/ebs/ebs_327_en.pdf.

[18] ECDC/EMA joint study 'The bacterial challenge: time to react', September 2009: http://www.ema.europa.eu/docs/en_GB/document_library/Report/2009/11/WC500008770.pdf.

[19] Impact Assessment on a proposal for a Council Recommendation on patient safety and quality of health services, including the prevention and control of healthcare-associated infections. SEC(2008) 3004, Annex 3, pp. 49-50: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2008:3004:FIN:EN:PDF.

[20] http://whqlibdoc.who.in/publications/2011/9789240686458_eng.pdf.

[21] Malevezzi et al., 'Advances in Oncology', OUP 2011 doi:10.1093, European cancer mortality predictions for 2011.

of HLY has been progressing at a much slower pace and was only 60.9 years for men and 62 years for women. Moreover this varies widely from one Member State to another.

In addition, a significant level of premature mortality or premature invalidity can be found in many places, with a very significant impact on the workforce. By way of illustration, in 2007 the number of deaths among people of working age totalled approximately 900 000, equivalent to about 19 % of all deaths that year.[22]

Also people with health problems show very low participation in the labour force[23] And it has not increased over the last decade. Consequently, the level of unemployment of such people is twice as high as that of people without a disability. Development of the human capital crucial for a knowledge-based economy is therefore greatly impaired.

The financial impact is significant: it is estimated that, on average, OECD countries spend 1.2 % of GDP on disability benefits and this figure rises to 2 % when including sickness benefits.[24] According to the latest figures, EU governments have been spending twice as much on illness and disability benefits as on unemployment benefits.

Solutions to these problems depend not so much on gaining better insights into the most cost-effective ways to reduce premature mortality, since the factors most to blame for modest HLY are known,[25] but more on understanding ways to implement large-scale measures covering entire populations. This will therefore be the focus of activities in this area to be covered by the Programme, as Member States stand to gain from EU-wide collaboration and exchanges on practices which aim at redressing the loss of the best years of productive life.

2.2.8. Increasing inequalities in health throughout Europe

Health inequalities have become a central concern of policymakers in many parts of the world and the EU offers a striking image in this respect. Population health varies enormously between different parts of the EU and between advantaged and disadvantaged groups. Life expectancy amongst males varied by 11.9 years between Member States in 2009 and 7.6 years for women. Health inequalities within Member States are also very large. The Eurostat has estimated that the difference in life expectancy between men with higher and lower levels of education varied between Member States from around 4 years up to nearly 20 years. Life expectancy for the Roma population is up to 10 years shorter than the general population.

The main causes of these inequalities in health are systematic difference in determinants of health experienced by different populations, including social, economic, environment and behavioural factors. The persistence of such inequalities is by no means a fatality. A number of Member States have built up experience of successfully reducing inequalities at a rapid pace, for instance in Germany following reunification,[26] while there is also value to be gained from working together on unsuccessful experience and learning from each others' mistakes.[27]

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[22] Oortwijn, W., Nelissen, E., Adamini, S., Van den Heuvel, S., Geukens, G., Burdof, L., Social determinants state of the art reviews — Health of People of Working Age — Full report (2011), European Commission Directorate-General for Health and Consumers. Luxembourg. ISBN 978-92-79-18526-7. Point 3.5.1, page 81.

[23] Sickness, disability and work. Keeping on track in the economic downturn. Background paper. High-Level Forum: Stockholm (14-15 May 2009), pp. 11 to 13, Organisation for Economic Cooperation and Development (OECD) 2009: http://www.oecd.org/dataoecd/42/15/42699911.pdf.

[24] Idem, footnote 12.

[25] See The Lancet on the forthcoming UN conference on non-communicable diseases.

[26] Report on Health in Germany 20 years after reunification, Robert Koch Institut, Berlin, 2010.

[27] Mackenbach article in The Lancet on UK experience

Although, clearly, part of the link between the causes and effects of health inequalities could lie outside the health policy area, primarily in social inequalities, there is sufficient ground for fostering the collaboration between Member States to address, jointly, differences in access to healthcare, especially in the context of application of the Cross-border Healthcare Directive.

2.2.9. Global and cross-border threats

After the industrialised world was close to eradicating the most serious infectious diseases in the late 1970s, the rapid social and economic changes triggered by globalisation have brought new factors that are driving the return of old pathogens and the rise of new ones.

The Treaty gives the European Union specific responsibility for averting cross-border health threats, i.e. events caused by communicable diseases or by biological, chemical, or environmental agents or of unknown origin.

The great value of improving crisis preparedness and management to safeguard against the very severe consequences of such threats to public health has been amply demonstrated over the last decade. Opinion polls also show the value that most stakeholders see in the past and present action by the Commission in this area. Cooperation at EU level not only allows multi-sectoral aspects to be made an integral part of crisis preparedness and management. It is also structured in a way that takes the interests and needs of smaller Member States into account while, at the same time, keeping the internal market functioning and the borders in the EU open.

3. THE POLICY OBJECTIVES

The challenges identified in section 2 are not at all new. The need to face them together by all Member States, with the modest support the EU Health Programme can offer, has become however even more urgent in face of the current financial crisis. The Programme can offer the biggest EU added value by focusing its intervention on four key policy objectives, covering five specific objectives for actions described below in this section.

> *"The new Health for Growth Programme will be oriented towards actions with clear EU added-value, in line with the Europe 2020 objectives and new legal obligations. The principal aim is:*
> *- to work with Member states to protect citizens from cross-border health threats,*
> *- to increase the sustainability of health services,*
> *- to improve the health of the population, whilst encouraging innovation in health".*
>
> (Commission's Communication 'A Budget for Europe 2020')

3.1. Policy objective 1: Contributing to innovativeand sustainable health systems

By supporting Member States' efforts to improve the efficiency and financial sustainability of health care, the EU Health Programme aims at encouraging a shift of significant resources in this sector on the most innovative and valuable products and services which at the same time offer the best market potential and cost savings in the longer term. Health system reform must clearly consist of a mix of immediate efficiency gains with longer term strategic action addressing key cost drivers. This is the only way if countries are to ensure universal access and equity in health, health financing and use of the system. As an example, European cooperation on **health**

technology assessments will not only reduce duplication and pool expertise but can unlock the potential for sustainable innovation in health products and services.

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

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

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

To achieve this, the Programme will:

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

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

3.1.1. Health technology assessment

Health technology assessment (HTA) can provide decision-makers with an evidence-based, transparent basis for decisions on taking up and phasing out health technologies, thereby making the best use of health budgets and providing the best treatment to patients. In the increasingly difficult context of constrained financial resources, the impact of HTA could be increased if it were commonly used throughout the EU (see case study in Annex 7).

By 2014, an EU-wide voluntary network on HTA will be established, with a common methodological basis and tools for interaction. In addition, by the same date a number of pilot schemes will have been launched to test the tools already developed and explore specific cooperation models for joint assessments of new medicinal products and other health technologies. The outcomes of these pilot schemes, to be completed in 2015, will provide useful insights into how effective EU cooperation on health technology assessment could be organised towards 2020 onwards. The Programme will continue to lend support to EU cooperation on HTA in order to address the challenges identified by:

- supporting further development of common methods for evaluating new health technologies, in order to avoid duplication of work, to help identify cost-effective health intervention at national/regional levels and thus obtain economies of scale;

- supporting capacity-building measures on rational use of HTA for health administrators at national level. This is particularly relevant for those Member States with limited experience of use of HTA so far;
- establishing common guidelines for submissions by the industry on pricing and reimbursement of new medicines and medical devices, so that the industry can improve the quality of data from its clinical trials submitted to the assessment bodies;
- establishing effective ways of liaising with the industry in order to speed up assessments conducted after market authorisation is given.

3.1.2. Health innovation and e-Health

Mobility of patients across Europe also requires interoperable e-Health solutions for emergency care and continuity of care. After substantial support for large-scale projects to develop such interoperable tools, there is now a clear need for Member States and stakeholders to take some tangible decisions in order to achieve effective interoperability. Otherwise, the risk of making massive e-Health investments suitable for local solutions only will increase and will prevent patients from having access to cross-border care. In addition, the Directive provides for drawing up guidelines on use of e-Health solutions as a way to collect epidemiological data across borders in order to obtain better feedback on the effectiveness of treatments.

This would be done by:

- adopting guidelines after consultation of the e-Health network;
- establishing a non-exhaustive list of data that are to be included in patients' records;
- developing effective methods for allowing use of medical information for public health purposes and research, including patient registers.

Such solutions will enable policymakers and health professionals to make better informed decisions on the appropriate treatment. This would also serve HTA, clinical trials and quality of care. In addition, e-Health can be considered a domain for technical solutions to strengthen healthcare, for example by increasing efficiency and promoting safety and quality. A common approach in the EU is needed for topics which call for interoperability of systems and data and to optimise the development of technical solutions.

3.1.3. Health workforce

To address the predicted shortage of 1 million health professionals in 2020, a series of measures are needed at both EU and Member State levels. The aims would be to develop effective health workforce planning, in terms of numbers and skills, to monitor mobility (within the EU) and migration of health professionals, to develop efficient recruitment and retention strategies and to build capacity. This action could include:

- Continuing the work on the EU platform for Member States, to be initiated in 2012, to collaborate on forecasting health workforce needs, workforce planning methods and mobility trends. The platform would tell policymakers that valid and reliable information is available. It would also make it easier to transfer successful solutions between countries.
- Supporting implementation by Member States of the WHO Code of Practice on the international recruitment of health personnel in the EU-specific context of free mobility of persons and services. The recently adopted Code aims at ensuring that international recruitment of health professionals does not weaken already fragile health systems.

- Promoting successful strategies for professional recruitment to the health sector and retention of health workers in their jobs.
- Encouraging cross-border education and training by implementing exchange programmes for health professionals as part of their curricula; bilateral agreements on sharing training capacity or use of ICT solutions for distance-learning to increase the flexibility of the health workforce on the labour market.

3.1.4. Better decision making on Health systems

There is a political momentum for health system reform in Member States. Furthermore, there is a demonstrated need, in the light of the EU 2020 headline targets, to conduct a broad-spectrum assessment of all wider societal effects of health system reforms. This is crucial in order to secure the long-term sustainability of Member States' health systems. To avoid duplication of assessments at Member State level and to speed up execution and increase the success rate of health system reforms, the Commission should be able to reply to requests from Member States for advice on how to organise and manage their health systems better and effectively foster sharing of best practice between Member States.

A mechanism for pooling existing expertise at EU level will be initiated in 2012. The planned advice from the Commission will take the form of technical evaluation of the consequences of policy action or of analysis of the expected outcomes of different and possibly conflicting policies, in order to provide Member States with relevant information to take into account in their decisions. Provision of such advice will be all the more necessary in the current context and over the years ahead and should therefore be continued after 2013.

3.1.5. European Innovation Partnership on Active and Healthy Ageing

Announced in October 2010 as part of the Commission's "Innovation Union" strategy, the pilot European Innovation Partnership on Active and Healthy Ageing represents a new, stakeholder-driven approach to research and innovation. The ambition is to connect diverse actors and programmes in order to improve the conditions for innovation and bridge gaps between research and market, whilst ultimately benefit the final users – the older people, care providers and health professionals and other carers.

The Partnership offers a coordinated framework for existing instruments and tools across the entire innovation chain in health and ageing, thus aiming to build synergies and align these tools to optimise their use and efficiency.

The Partnership focuses on three broader themes:

- Innovation in awareness, prevention & early diagnosis i.e., exploring actions on: health literacy, adherence and compliance, older people's functionality, early diagnosis & screening, coordination of research, lifestyle management and nutrition, home monitoring.
- Innovation in cure and care i.e. identifying actions on: continuum of care/integrated care inc. e-health, HTA and evidence (cost-effectiveness and efficiency), innovative ways for management of multiple chronic conditions, cohesion funds and community care, training of care professionals.
- Innovation in environment for active and independent living i.e. focusing on actions related to: social inclusion, working conditions for older people, older people's participation in the labour market, independent living in an age-friendly environment.

The Health Programme may provide support to specific actions under the Partnership.

3.2. Policy objective 2: Increasing access to better and safer healthcare for EU citizens

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

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

To achieve this, the Programme will:

Specific objective 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**

Scarce knowledge can be shared and resources combined as efficiently as possible across the EU, as can be seen, for instance, in the case of rare diseases.[28] Under specific objective 2, this sharing of resources is to be expanded to other areas of health requiring a particular concentration of resources or expertise to look at various clinical conditions. The main goal here is to pool medical expertise and knowledge in order to improve access to diagnosis and provision for all patients requiring highly specialised care for a specific disease or group of diseases.

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

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

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

3.2.1. Setting up accreditation and support of European Reference Networks

[28] See Annex 7 for case studies on European reference networks for rare diseases and ORPHANET.

European reference networks (ERNs), to be set up as provided for by the Cross-border Healthcare Directive[29], will provide the general context by setting the criteria for designating centres of reference and for establishing, managing and evaluating the ERNs. Once the period for transposition of the Directive ends, in October 2013, the operations and logistics related to the actual launch of the ERNs will start, in particular with the development of methods to identify and designate the centres and manage the networks on a permanent basis. This would imply:

- launching the process for identifying and designating centres of reference which meet the criteria to be set out in the delegated act;
- launching, managing and evaluating the European reference networks system, as provided for in the legal acts implementing the Directive;
- designing and setting up a permanent mechanism for running the network satisfactorily (means, structure and human and material resources should be decided);
- accrediting and supporting a number of European reference networks in order to enable the mobility of medical expertise.

These ERNs already exist: eleven pilot ERNs for rare diseases have been funded by the former Health Programmes, but following the same logic as the ERNs that will be put in place in the context of the Cross-border Healthcare Directive. The aim is:

- to put in place an improved coding and classification system for rare diseases, as part of the ongoing revision of the International Classification of Diseases (ICD) to be adopted by the WHO in 2014, and contribute this to a WHO-based global approach, in collaboration with other international partners;
- to continue developing ORPHANET, the central European database on rare diseases, to extend its treatment facilities and its scientific, language and health system coverage to all rare diseases as far as technically possible;
- to continue providing more support to Member States in developing their national strategies: the Council Recommendation on action on rare diseases commits Member States to developing national plans, including common European elements, to facilitate cooperation, but this is technically challenging for any country;
- building on the EUROPLAN project, to provide technical support and assistance to Member States and neighbouring countries in developing and implementing their plans and strategies and provide practical links between them to maximise European cooperation and efficient use of resources.

3.2.2. Strengthening collaboration on patient safety and quality of care

The Programme will strengthen the EU collaboration on patient safety and quality of care initiated by the joint action in 2011 with two goals: implementation of the Council Recommendation on patient safety and structured exchanges of knowledge about quality assurance systems. The ultimate aim is that by 2020 Member States will have jointly developed and implemented a selected set of guidelines and tools to promote patient safety and healthcare quality.

[29] Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare

The position of the patient can be strengthened in order to achieve better healthcare outcomes. Patients can be empowered to manage their health and, partly, their healthcare. For this, the transparency of healthcare activities and systems and the availability of information to patients should be optimised and healthcare practices should learn from the feedback from and inter-communication with patients.

3.2.3. Improving the prudent use of antimicrobial agents in human medicine

The Programme will strengthen the EU coordination in the form of supporting, in close cooperation with the food safety and animal health authorities, implementation of the Council Recommendation on prudent use of antimicrobial agents, to allow better alignment of the national strategies against antimicrobial resistance and increase the positive impact which these national measures are expected to have on the spread and burden of antimicrobial resistance.

It will offer EU support to facilitate exchanges of best practice and information and to enhance implementation of the Council Recommendation on patient safety, including HCAI, to increase the cost-effectiveness and impact of the national measures against HCAI.

3.3. Policy objective 3: Promoting good health and preventing diseases to improve citizens' health

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

The right investments will not only lead to better health, but also to longer and more productive lives and lower labour shortages. If Europeans live in better health, they will be able to continue contributing to the economy as they grow older - as workers, volunteers and consumers. The expertise of the elderly will also be needed even more in a population with low birth rates and lack of skilled labour.

To achieve this, the Programme will:

Specific objective 3: **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**

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

3.3.1 Cost-effective promotion and prevention measures addressing risk factors and underlying health determinants

There is considerable evidence on the most accessible and effective measures that can be promoted in this context to reduce the impact of major health determinants such as alcohol, smoking, diet and behavioural factors. These risk factors can only be effectively addressed across

society if, at the same time, underlying socio-economic factors, such as health inequalities, mental health and well-being, and environmental factors are also taken into account.

Addressing nutrition, obesity, poor diet and alcohol-related harm; increasing the rates of participation in physical activity for children and adults; reducing exposure to tobacco smoke and developing platforms on prevention against smoking (to replace the ongoing anti-tobacco campaign); and ongoing support on effective prevention of HIV/AIDS.

The aim is to help develop the contribution made by policies and activities at EU, Member State and local levels and the activities of key stakeholders — including employers, non-governmental organisations, economic operators and other interest groups — into more comprehensive and effective efforts to prevent diseases and promote health.

Finally, the goal will be to support and accelerate the take-up of best practices by Member States and allow further large-scale preventive measures by:

- supporting EU strategies in these areas;
- fostering effective cooperation between Member States;
- establishing a validation mechanism, at EU level, that will show how practices and community-based intervention can be assessed with a view to sustainable implementation at the level of whole populations;
- supporting adequate dissemination and evaluation methods.

3.3.2. Chronic diseases

The Programme will provide support for studies and models of good practice addressing the key issues identified in the Council Conclusions on innovative approaches for chronic diseases in public health and health care systems. These include: health promotion and prevention, healthcare – including the development and dissemination of innovative chronic care models, information and research.

It will also support with the aim of establishing standards on good practices for treatment of dementia and other neurological impairments, including care models, increasing attention to dignity, autonomy, rights and social inclusion.

3.3.3. Cancer

The action will be concentrated on the development of high-quality population-based organised screening programmes for breast, cervical and colorectal cancer aiming at very high population coverage. It is set out in the Council Recommendation on cancer screening.

The Programme will also support the update/revision of the EU cancer-screening guidelines and the development of further, science-based European guidelines for scaled-up cancer prevention.

3.4. Policy objective 4: Protecting citizens from cross-border health threats

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

To achieve this, the Programme will:

Specific objective 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 treats**

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

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

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

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

3.5. Horizontal activities

In addition, the Programme will support two horizontal activities that cut across the policy objectives described above and contribute to the main aim of the Programme, although they can also run independently of the existence of the future Health Programme.

3.5.1. Actions required by or contributing to the objectives of EU legislation

All the legal obligations deriving from existing legislation and legislation currently under revision have been regrouped under this specific chapter. Often, implementation of this legislation can also help to achieve one or more of the objectives described above. But, contrary to other action financed by the Programme, in this case the Commission is under legal obligation to take these measures. (see Annex 6 for the indicative list of legislation).

Following various meetings with DG BUDG and SEC GEN, these activities have been split between the 4 objectives listed above. They are grouped per these objectives in the following section.

SPECIFIC OBJECTIVE 1:

Medical devices[30]

The objective is:

- To manage, implement and develop the legislation on medical devices for human use, including *in vitro* diagnostics in order to to ensure the safety and clinical performance of medical devices placed on the EU market.

The existing directives are currently being fundamentally revised with the aims to ensure EU-wide, uniform high level of protection of human health and safety, to provide a regulatory framework which supports innovation and the competitiveness of the European 'medtech' industry, to enhance the transparency of the regulatory system and to ensure the smooth functioning of the internal market for medical devices.

In addition, synergies can be created between implementation of the legislation in this area and other activities within the Programme which would contribute to specific objective 1 by supporting the development of medical technologies which could contribute to mitigating the shortage of healthcare professionals and to the sustainability of healthcare systems.[31]

SPECIFIC OBJECTIVE 2:

(a) Substances of human origin (blood, tissues, cells and organs)

The objectives are:

- To monitor and support Member States with implementation of the current EU legislation on the safety and quality of substances of human origin (SoHO).
- To follow up innovative scientific and technological developments/new medical applications in the field of SoHO in order to update the legislation on quality and safety.
- To support Member States in their efforts to improve donation, vigilance and surveillance, to identify and share best practices in the field of SoHO and to increase access for European patients to SoHO therapies.

In addition, synergies can be created between implementation of the legislation and other activities within the Programme which would contribute to specific objective 3, healthcare quality and patient safety, by providing guidance to Member States on good implementation of legislation, including technical details.

(b) Patients' rights in cross-border healthcare

The objectives are:

- To monitor and support Member States with implementation of the new EU legislation on the application of patients' rights in cross-border healthcare in order to avoid further litigation on the issue of patient mobility by clarifying patients' rights to access to cross-border healthcare and to be reimbursed for it.
- To enhance cooperation between MS in the areas of recognition of prescriptions, e-Health, European reference networks, health technology assessment, standards on quality and safety of care and cross-border healthcare provision in border regions.

[30] Corresponding costs are financed under the 'Internal market for goods and sectoral policies' until 2013.

[31] See Council conclusions on innovation in the medical device sector, adopted on 6 June 2011 (point 3, third indent), OJ C 202, 8.7.2011, p. 7

(c) Medicinal products[32]

The objectives are:

- To meet its obligations in the medicinal products field, the Commission will be required to manage, maintain and implement the legislation on medicinal products for human and veterinary use, including proposals for future legislation, in order to ensure a high level of public health protection across the EU, based on high scientific expertise.

Examples of action to be taken include:

1. developing and adopting the measures for implementing newly adopted legislation on pharmaco-vigilance and falsified medicines;
2. establishing the list of non-EU countries whose manufacturing standards are equivalent to the EU standards, i.e. that may export active ingredients for medicinal products to the EU;
3. securing the development of quality standards and control methods for medicinal products by funding the specific activities undertaken by the European Directorate for the Quality of Medicines (EDQM) of the Council of Europe;
4. getting involved at international level in establishing public health standards to minimise the risk of unsafe products being placed on the EU market and to maintain the competitiveness of the EU pharmaceuticals industry;
5. intervening on the specific public health concerns related to antimicrobial resistance.

- To manage the decision-making process for EU authorisation of medicinal products for human and veterinary use, within the strict deadlines laid down in the legislation.
- To implement the transparency requirements of the EU pharmaceuticals legislation, as illustrated by setting up and managing the EU register of medicinal products.

Moreover, the implementation of legislation on medicinal products would contribute to attaining the Programme's specific objective 3 on patient safety, as illustrated by the new legislation on pharmaco-vigilance (adopted in 2010) and on falsified medicines (adopted in 2011).

SPECIFIC OBJECTIVE 3:

Tobacco Product directive and Tobacco Advertising Directive

The objectives are:

- To monitor and support Member States with implementation of the current EU legislation on tobacco product and tobacco advertising.
- To regulate the marketing of tobacco products for public health reasons and to ensure appropriate consumer information and harmonised standards.
- To follow up innovations and developments in tobacco products and its advertising in order to update the legislation.

In addition, synergies can be created between implementation of the legislation and other activities within the Programme which would contribute to specific objective 4, on prevention measures, by providing guidance to Member States on good implementation of legislation.

[32] Corresponding costs are financed under the 'Internal market for goods and sectoral policies' until 2013.

SPECIFIC OBJECTIVE 4:

(c) Health Security Initiative

The objective is:

- To improve public health pandemic and generic preparedness and response following lessons learned from past events, including the 2009 pandemic.

3.5.2. 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

Following various meetings with DG BUDG and SEC GEN, these activities have been split between the 4 objectives listed above in proportion to their contribution to the objectives.

A fully operating European health monitoring system can provide added value in the form of information allowing comparisons, which can in turn support identification, dissemination and application of best practices while also highlighting critical areas to be improved. This also helps the EU, the Member States and other regional players to support health systems not only by highlighting critical areas to be improved but also by detecting health-related obstacles to growth.

Harmonised collection of comparable data also helps to reduce the administrative and economic burden on Member States by reducing multiplication of data provision. Only a system operating at European level will be able to identify differences in health outcomes as a result of circumstances created by national policies, at both geographical and socio-economic levels, and therefore to tackle them effectively. Also, the EU is the leading player able to enforce data collection effectively at national level. Ideally, a health monitoring system will also provide a means to measure the impact of future health initiatives at EU level.

This objective could be met by mobilising internet platforms, developing and regularly updating sets of health policy-relevant indicators, harmonised with the WHO and OECD, which implies working on defining, constructing and disseminating these indicators on health status, health systems, social determinants of health and health promotion. Such action could also include releasing reports and *ad-hoc* analyses on specific issues of political, economic and social relevance involving scientific networks and advice groups.

Data and evidence to be produced will be linked to and depend on the broad overarching policy objectives of the Commission in the area of health, with particular attention to support for the sustainability of health systems. Within these objectives, priority will be given to information and evidence in areas where (a) the greatest EU added value can be demonstrated and (b) a real lack of EU-level data is making it difficult to set or achieve specific policy objectives.

In addition, results of the planned assessment of the use of health indicators at EU level will be taken into account in setting priorities.

Also, there is a need for independent, high-quality scientific advice on health and environmental risks in order to support relevant policymaking, identify research priorities and provide monitoring and guidance on new and emerging health and environmental issues. This is currently being done by the Commission's Scientific Committees and will be continued in the next Programme. The objective is to be a centre of scientific excellence for the EU and internationally.

Wider dissemination of the results of the EU Health Programmes, in particular targeting policy makers, stakeholders and health professionals, was identified in diverse evaluation as an important area for improvement. This can be done via development of the dedicated IT tools, like

the EU Health Portal, as well as through dedicated actions (publications, brochures, road shows etc.) and information campaigns in close cooperation with Member States themselves.

3.6. Context of the Programme

The proposed Programme can contribute to addressing the above-mentioned policy objectives only to the extent that it offers financial opportunities to build and launch cooperation mechanisms and coordination processes between Member States with a view to identifying common tools and best practices that would create synergies, bring EU added value and lead to economies of scale. It is therefore important to underline the framework within which the EU action can take place effectively and provide an account of its inherent limitations.

First of all, 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 problems outlined will, for the most part, have to be tackled directly by Member States.

Second, the **EU has to remain within the subsidiarity principle**. Thus, the Programme can 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 EU 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.

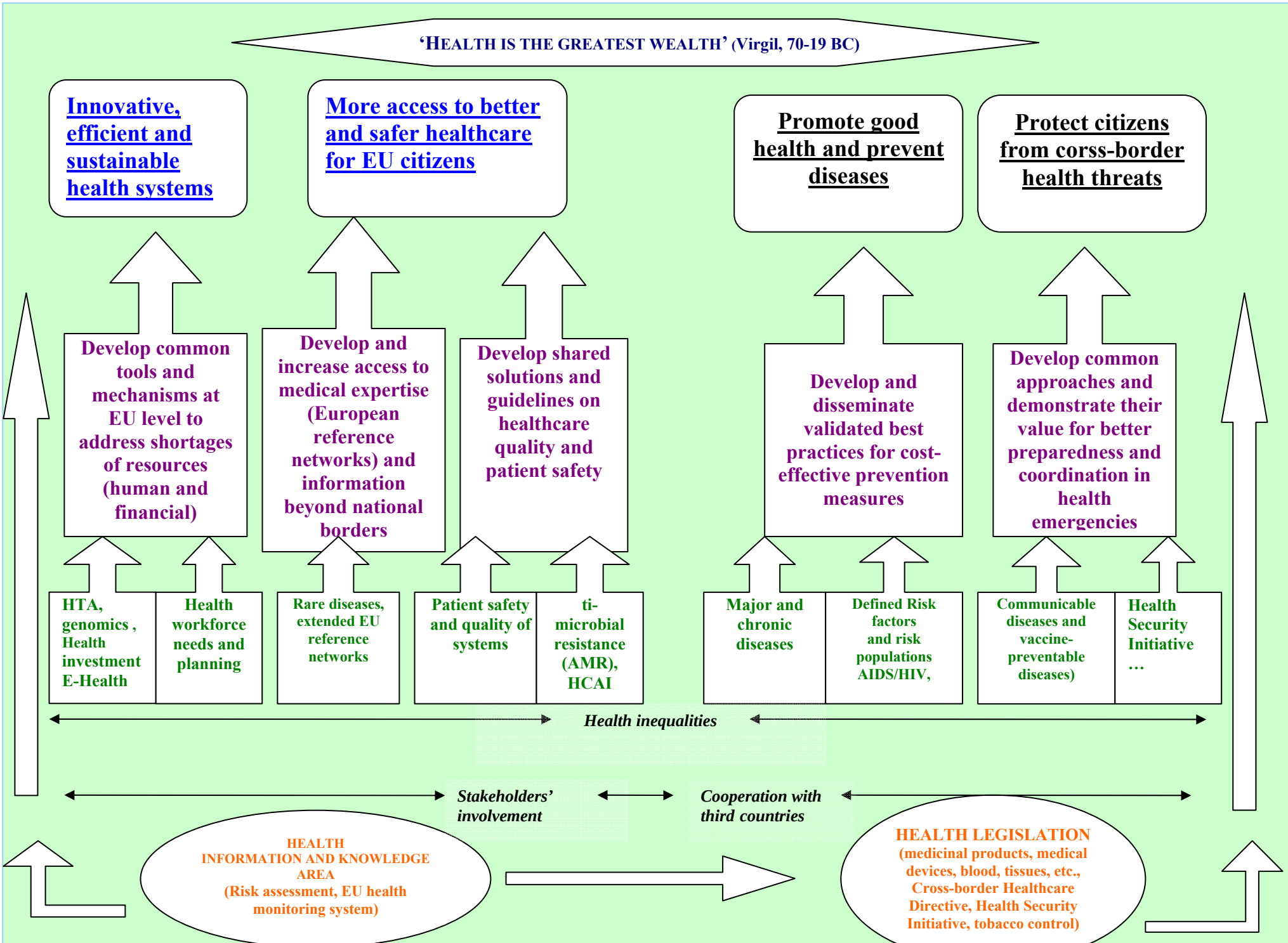
Third, as explained in the section on the policy context, the Commission is committed to **delivering on Europe 2020 goals**. This implies that the Programme also has to contribute to achieving these goals. Still in line with the EU 2020 objectives, the action taken in the Programme must prove to have real EU added value and a measurable impact.

Fourth factor is related to the fact that **EU financial intervention is limited by the size of the Programme**: in budgetary terms, this is undeniably a small to medium-sized programme, although, at the same time, other funding programmes also contribute to improving public health in the EU, most notably the public health component of the Research Programme and of the Structural Funds. However, the Health Programme is the only one aiming specifically at addressing the challenges and concerns in the health policy field, while also enabling further achievement of the policy goals in this area. Its success can be magnified by forging the necessary links and clear synergies with other spending programmes.

Finally, the Programme should meet the needs and expectations expressed by the Member States and stakeholders, as long as they also fit into the framework outlined above.

3.7. Link between health challenges, MFF announcements, policy objectives, specific objectives and Programme actions

The table below summarises these links.


'HEALTH IS THE GREATEST WEALTH' (Virgil, 70-19 BC)
Innovative, efficient and sustainable health systems
More access to better and safer healthcare for EU citizens
Promote good health and prevent diseases
Protect citizens from corss-border health threats
Develop common tools and mechanisms at EU level to address shortages of resources (human and financial)
Develop and increase access to medical expertise (European reference networks) and information beyond national borders
Develop shared solutions and guidelines on healthcare quality and patient safety
Develop and disseminate validated best practices for cost-effective prevention measures
Develop common approaches and demonstrate their value for better preparedness and coordination in health emergencies
HTA, genomics , Health investment E-Health
Health workforce needs and planning
Rare diseases, extended EU reference networks
Patient safety and quality of systems
ti-microbial resistance (AMR), HCAI
Major and chronic diseases
Defined Risk factors and risk populations AIDS/HIV,
Communicable diseases and vaccine-preventable diseases)
Health Security Initiative …
Health inequalities
Stakeholders' involvement
Cooperation with third countries
HEALTH INFORMATION AND KNOWLEDGE AREA (Risk assessment, EU health monitoring system)
HEALTH LEGISLATION (medicinal products, medical devices, blood, tissues, etc., Cross-border Healthcare Directive, Health Security Initiative, tobacco control)

Policy objectives	Specific objectives		The overall health challenges	The announcements in the MFF
Contributing to innovative, efficient and sustainable health systems	To develop **common tools and mechanisms** at EU level to address shortages of resources, both human and financial and facilitate the up-take of innovation in healthcare. Actions: *1. Health Technology assessment* *2. Health innovation and e-Health* *3. Health Workforce* *4. Better decision making on health systems reforms* *5. Support to the European Innovation Partnership on Active and Healthy Ageing*		Financial sustainability of health systems	**sustainability of health services while encouraging health innovation** ***- a common EU approach to health technology assessment (HTA)***
			Health workforce shortages	**sustainability of health services while encouraging innovation in health**
Increasing access to better and safer healthcare for EU citizens	To develop and increase access to medical expertise (**European Reference networks**) and information beyond borders and to develop shared **solutions and guidelines to improve public health, healthcare quality and patient safety** *Actions:* *1. Setting up accreditation and support of European Reference Networks* *2.Strengthening collaboration on patient safety and quality of care* *3. Improve the prudent use of antimicrobial agents in medicine*		Improvements necessary in patient safety	**sustainability of health services while encouraging health innovation** ***- Rare diseases*** ***- supporting European reference networks on diseases*** **increase the sustainability of health services**
Promoting good health and preventing diseases to improve citizens' health	To identify, disseminate and promote the up-take of validated **best practices for cost-effective prevention** measures; *1. Cost-effective promotion and prevention measures addressing risk factors and underlying health determinants and health promotion* *2. Chronic diseases* *3. Cancer*		Lack of sustained progress on control and prevention of chronic conditions Loss of best productive years (slow increase in HLY)	**to improve the health of the population**<br***(cancer as an example in MFF)*** **increase the sustainability of health services**
No policy objective	No specific objective *No actions*		(Increasing inequalities) *Addressed only partially as side effect of the specific objectives*	**Not in the MFF**

Protecting citizens from cross-border health threats	To develop **common approaches** and demonstrate their value or **better preparedness and coordination in health emergencies** *Actions:* *1. Preparedness and response for serious cross-border health threats* *2. Risk assessment capacity* *3. Support capacity building against health threats in Member States*		Global and cross-border threats	**to protect citizens from cross-border health threats**

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

4.1. Legal basis

Article 168 of the Treaty strongly reasserts the **principle of subsidiarity in public health.** It says that 'Union action … shall **complement** the national policies' and then that 'Union action shall **complement** the Member States' action.' The Union can also '**lend support** to their action'.

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

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

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

- promoting research into their causes, their transmission and their prevention,
- promoting health information and education,
- monitoring, early warning of and combating serious cross-border threats to health,
- encouraging cooperation between the Member States.

In particular, the second subparagraph of Article 168(2) states that '*The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation.*'

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

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

4.2. Necessity test

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

The Programme will, in particular, fund action that cannot be carried out as effectively by Member States themselves but depends greatly on cooperation at EU level.

Here are some examples of such actions:

✓Under specific objective 1. **Health Technology Assessment (HTA):**

Improving cost-effectiveness of health systems is a key intervention area in order to ensure overall sustainability of health expenditure in an environment of reduced resources and capital. In this framework, Health Technology Assessment can, y identifying resource-effective, safe aand effective intrventions, provide health decision-makers with an evidence-based and transparent basis for decisions on the uptake and phase-out of health technologies, optimizing use of health budgets and providing best treatment to patients. HTA is a important tool but unfortunately related resources, knowledge and expertise are unevenly spread in Europe. EU action in this area could provide economies of scale, insofar common methodological standards for the assessment of different health technologies lead to simplified sharig and re-use of HTA information generated.

✓Under specific objective 2. **European Reference Networks (ERNs) in the area of rare Diseases:**

There is a high overall burden of rare Diseases, in terms of significant morbidity, premature mortality, loss of quality of Life, with extended impact beyond patients, to the socioeconomic potential of family members (often acting as fisrt line carers) and wide community, due to costly management. Low prevalence, as well as low number of patients by diseases and per Member State leads to large variance in access to diagnosis, to quality care and ultimately, to treatment for lack of available information on and training about the diseases. The limited number of patient and scarcity of knowledge and expertise at member sattse level gives high potential added value to Eu level action. The Programme could support generation, translation, validation and dissemination of knowledge and information in this area.

✓Under specific objective 3. **Revision of the EU cancer-screening guidelines for high-quality screening programmes for breast, cervical and colorectal cancer33 and treatment:**
In the fight against cancer, EU cooperation has already proven its added value. A study in 2003 showed a reduction of 9 % in expected cancer deaths and of 10.5 % in the risk of cancer death between 1985 and 2000 and concluded that the 'Europe Against Cancer' Programme (1987–2000) had contributed to these results. The Commission has therefore decided to continue to support Member States in this area: one of the objectives set in its 2009 Communication on 'Action Against Cancer: European partnership'34 is to reduce cancer incidence by 15 % by 2020.

✓Under specific objective 4: **Reference Laboratories for highly pathogenic agents:**

Europe is facing continuous threats related to emergent communication diseases, with natural or intentional release as illustrated by several events caused by highly pathogenic agents in the recent past (H5N1, Chikungunya, H1N1, E.coli etc). Such threats will by definition not stop at borders and preparedness and response depends on timely and accurate identification of the specific agent. The laboratory preparedness among EU Member states is heterogeneous, with some laboratories using well-established methods for the identification of highly pathogenic bacteria and virus (Bio-safety group 3 and 4).

The development of the European laboratories of reference network with individual laboratories covering more than one Member State has increased the return on investment, while the cost of creating such highly specialised laboratories at individual EU Member sate level was prohibitive.

[34] COM(2009) 291 final of 24 June 2009:
http://ec.europa.eu/health/archive/ph_information/dissemination/diseases/docs/com_2009_291.en.pdf.

More examples can be found in Annex 7.

By definition, as previous experience has demonstrated, Member States do not have always the possibility, neither financially nor scientifically, to act on their own in these areas. In addition, some health issues have an increasing cross-border dimension which can only be addressed at EU level.

The first line of beneficiaries of the Programme will be health policymakers and health professionals, patients' organisations and other civil society organisations. EU citizens will be the ultimate beneficiaries. Given the broad spectrum of stakeholders, it is crucial that the Programme involves all of them and supports not only public bodies but also the non-governmental organisations at EU and national levels which, during the crisis, are facing particular challenges. Emphasis should be given to stakeholders from Member States with low GNI who remained inactive during the previous Health Programmes and to small entities facing language problems and other barriers.

The common nature of the challenges and the opportunities for growth as a result of better health make the Programme increasingly important. Its own particular value is as a unique bridge between technological innovation, social policy and practice. Its specific objectives aim to have a catalytic effect and help the parties involved find the most suitable and effective solutions. The Programme will provide a significant complement to national programmes together with other EU Programmes and policies such as the Structural Funds and the Research Framework Programme. In particular, the Programme will offer significant scope for connecting research to policy, practice and implementation and developing innovative knowledge transfer throughout Europe, including possibly neighbouring and other non-EU countries. For the above-mentioned reasons, the outcome of the Programme will be unique and should be disseminated strategically.

4.3. EU added value

European added value is the value that EU action adds to the value that would otherwise have been created by Member States acting alone or by action contributing to objectives more specific to the Commission. The concept of European added value plays a key role in the assessment of subsidiarity where, in the areas which do not fall within its exclusive competence, the Union has to justify its action in terms of the additional value it might have over action by individual Member States.[35]

The value of investing in preparedness, prevention and coordination of measures on health threats and communicable diseases at EU level was clearly demonstrated by the H1N1 outbreak in 2009. Strengthening the capacity to manage serious cross-border health threats, along with joint procurement of vaccines against pandemics, is another area where significant EU added value can be obtained. The EU can also deliver significant benefits on cross-border issues such as cross-border healthcare and health inequalities and by developing strategies to counter growing antimicrobial resistance, along with cost-effective health technologies and innovative healthcare, and promoting healthy ageing with the aid of a European Innovation Partnership.

Action under the Health Programme complements and adds value to Member States' action on health promotion and prevention of illness (including work on, for example, nutrition and smoking and on reducing inequalities in healthcare), protection of citizens against health threats,

[35] While there is no Treaty obligation to assess the European added value in those areas falling under the Union's exclusive powers, the Commission is nevertheless also striving to maximise the effectiveness and efficiency of its action in these fields.

in particular pandemic preparedness, the safety of medical products, blood, tissues, cells and organs, and cooperation between health systems.

Some examples of actions with the proven EU added value:

- Understanding rare diseases and developing innovative treatment for them requires pooling patient populations in European registers across several countries; many such measures depend critically on the Health Programme if they are to take place.
- Cooperating on cross-border diseases such as H1N1 flu also cannot be undertaken by individual Member States, but depends on initiatives and funding at EU level. In the area of health threats, the EU's role, beyond coordinating the response to these threats, is also to enhance the capacity of the Member States and of non-EU countries to respond to these threats. Providing a rapid and coordinated answer to global health threats is also the EU's role.
- The Health Programme has developed and strengthened networks between European health specialists, national and regional health authorities and other stakeholders who greatly contribute to sharing knowledge and building health capacity in the EU. It has also built consortia, partnerships and other ways to interchange information and practices across Europe, thus boosting cooperation and the pace of research. The outcome of the projects and action funded by the Public Health Programme is the most effective, if not the only, way to build the evidence base for defining much broader regulatory policies (for instance, on cancer, Alzheimer's, rare diseases and health inequalities).

In the context of the mid-term evaluation of the 2nd Health Programme and based on the in-depth analysis of the case studies (see more in Annex 7) most of the following EU added value criteria were developed on the basis of the subsidiarity principle and Article 168 of the Treaty and tested regarding concrete funded actions:

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

It is intended to extend the use of these EU added value criteria in both prioritising the actions to be funded in the new Programme and in the selection process for the annual calls for proposals and to use them *a posteriori* as well.

The table set out below sums up the EU added value expected in relation to the objectives of the Health for Growth Programme.

Specific objectives	**Develop common tools and mechanisms at EU level to address shortages of resources (human and financial) and facilitate the up-take of innovation in healthcare**	**Develop and increase access to medical expertise (EU reference networks) and information beyond national borders**	**Develop shared solutions and guidelines to improve healthcare quality and patient safety**	**Identify, disseminate and promote the up-take of validated best practices for cost-effective prevention measures**	**Develop common approaches and demonstrate their value for better preparedness and coordination in health emergencies**		
EU added value	Addressing certain issues relating to the **internal market** where EU has substantial legitimacy to ensure high-quality solutions across EU Member States; unlocking the **potential in innovation** in health; provide high-value services while achieving **economies of scale** and avoiding waste due to duplication, with the aid of common HTA at EU level.	**Stronger knowledge base networking** Pooling resources and expertise to address issues (e.g. rare diseases) which Member States cannot deal with individually in a cost-effective manner. Unlocking the **potential in innovation** in health. Reference networks are sure to bring **economies of scale** by means of	**Stronger knowledge base networking Economies of scale** Issues are often similar in all countries, but resources are limited. The process can be better staffed at EU level (for resources and statistical reasons). Unlocking the **potential in innovation** in health. **Benchmarking for decision-making** There is great potential for Member States to learn from each other's good practice and implementation strategies. By doing so, there is a chance of	**Promotion of best practice** Demonstrate the value of action taken at the level of various large populations in order to provide more evidence on practices and ways to implement action.	**Cross-border threats** This area has high added value. The objective is to reduce the risks and mitigate the consequences of health threats that develop across borders in a multi-interdependent EU. Individual threats also determine the targets. Increases in performance will be measured by assessing preparedness and evaluating performance during crises.		

		concentration of skills and knowledge.	reducing health inequalities between EU Member States				

5. LINKS BETWEEN THE HEALTH FOR GROWTH PROGRAMME AND THE EU 2020 STRATEGY

Promoting health is an integral part of the **smart and inclusive growth** objectives of Europe 2020 agenda. The objectives set for the Programme are tailored to the needs of Member States in order to make progress against specific targets.[36]

5.1. Provide innovative solutions for improving the quality and sustainability of health systems

According to the Joint Report on Health Systems prepared by the European Commission and the Economic Policy Committee/Working Group on Ageing (AWG),[37] health systems need to be monitored rigorously and, where needed, reformed to ensure greater cost-efficiency and sustainability, especially considering demographic ageing. By investing in innovative solutions for improving the quality and sustainability of health systems, the Programme supports take-up by Member States of reforms in the health sector which are necessary to ensure its sustainability and contribute to economic recovery. In addition, health systems are also a driving force for economic growth and innovation by improving the health of the population and by virtue of their role as major employers and users of new technologies.

Innovation in health is crucial to Europe. Key European goals, set out in the Europe 2020 Strategy, on economic growth and development, European competitiveness, job creation, healthcare and quality of life, all hinge on continued and increasing innovation in healthcare in Europe. However, innovation is not just about technology and new products,[38] but also about people, management of expectations and improving organisational efficiency.

Innovation in health has unique potential, not only as a possibly powerful driver of socio-economic development, economic growth and high-value jobs, but also in terms of reducing healthcare costs and increasing the quality of care to patients. Many areas of the Programme, such as health technology assessment, medical devices and medicinal products or public health genomics, aim to strengthen the link between technological innovation and commercialisation, while ensuring security, quality and efficiency. Other initiatives are focusing on e-Health solutions and fostering interoperability at EU level in order to increase for example cross-border use of patient registers. They also serve HTA, clinical trials and quality of care.

Finally, the contribution made by the Programme to better planning of needs and training of the health workforce also contributes to both organisational innovation and inclusive growth. The expected benefits fit in with the Agenda for new skills and jobs (flexibility and security; equipping people with the right skills for the jobs of today and tomorrow; improving the quality of jobs; ensuring better working conditions; and improving the conditions for job creation).

5.2. Support and complement the efforts of Member States to increase the number of healthy life years of the EU population

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 2020 is to succeed in employing 75% of the working-age population (20-64 years) and avoiding early retirement due to severe illness or invalidity. Keeping even the more elderly population (for instance, those between 64 and 74 years) healthy and active provides a crucial boost to the economy, with an impact on the labour market. While it has long been recognised that increased

[36] Member States have agreed on a new EU-level economic governance structure, the 'European semester', which helps them to coordinate their macro-economic, budgetary and structural reform policies.

[37] December 2010: http://ec.europa.eu/economy_finance/publications/occasional_paper/2010/pdf/ocp74_en.pdf.

[38] See Council conclusions on innovation in the medical device sector, adopted on 6 June 2011, OJ C 202, 8.7.2011, p. 7

national wealth is associated with improved health, only more recently has the contribution which better health makes to economic growth been recognised.

Lacking the proper facilities to improve the health of the population, to prevent and treat diseases and injuries and to reintegrate people who suffered poor health back into the labour market is an obstacle to economic prosperity. In its report '*The contribution of health to the economy in the European Union*[39]' the Commission on Macroeconomics and Health emphasised the role played by health and healthcare in generating social cohesion, a productive workforce, employment and, hence, economic growth.

6. POLICY OPTIONS

6.1. Options considered

The ***option involving no resources at all*** was not considered. After all, without credits the Commission would simply not be able to fulfil its obligations stemming from the Treaty and existing legislation. This action cannot be funded from credits secured under specific budget lines. Until 2013, it will be financed under the current Health Programme and the 'Internal market for goods and sectoral policies'.

For instance, the EU pharmaceuticals legislation provides for the Commission to adopt decisions on marketing authorisations for medicinal products for human and veterinary use (Regulation (EC) No 726/2004).[40] In addition, the transparency requirements of the EU pharmaceuticals legislation require establishment and management of a Union's register of medicinal products. These decisions are prepared on the basis of the scientific evaluations by the European Medicines Agency, using a database. In 2010 alone, the Commission adopted 1279 decisions in this area. Given the number of decisions and their voluminous scientific annexes, the Commission would not be able to fulfil its obligations without a system for electronic management of the decisions. This cannot be put in place and operated without funding.

Moreover, the Commission has also set up a European databank on medical devices (Eudamed)[41] in accordance with Directive 93/42/EEC. All Member States are required to upload certain data regarding manufacturers, medical devices, vigilance reports and clinical investigations in this databank, so that the information can be shared between the national authorities. Eudamed will be further developed to establish it as the central and publicly accessible EU registration and listing database for economic operators and medical devices, integrating a function for tracing medical devices by means of a unique device identification (UDI). The future Eudamed will thus ensure a high level of transparency in the field of medical devices placed on the EU market, but significant financial resources will be required to develop the necessary IT infrastructure.

The Impact Assessment report analyses the following options for the future Programme:

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

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[39] http://ec.europa.eu/health/ph_overview/Documents/health_economy_en.pdf.

[40] EU pharmaceuticals legislation also provides for the Commission to adopt decisions on subsequent amendments to these authorisations (Regulation (EC) No 1234/2008), decisions addressed to the Member States on action to be taken as regards medicinal products for human and veterinary use authorised by the national authorities (Directives 2001/82/EC and 2001/83/EC) and regulations on maximum residue limits for veterinary medicines in food of animal origin (Regulation (EC) No 470/2009).

[41] See Commission Decision 2010/227/EU on the European Databank on Medical Devices (Eudamed)

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

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

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

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

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

Sub-option 3, sub-option C corresponds to a programme limited to supporting actions required by the current EU health related legislation and to supporting solutions for cross border health threats. In addition, there would be some dissemination of the results of the current Health Programme (2008–2013) in order to take into account the conclusions of previous evaluations,

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

6.2 Option 1

The first option would be to focus exclusively on support based on a strict interpretation of the current obligations of the Commission, which are: implementation of the health and internal market legislation plus dissemination of the results of the current Health Programme (2008–2013) in order to take into account the recommendations made by previous evaluations.

In this case, the Commission would concentrate on actions required by or contributing to the objectives of EU legislation already existing or currently being prepared or revised on:

- medicinal products;
- medical devices;
- substances of human origin (blood, tissues, cells and organs);
- patients' rights in cross-border healthcare;
- tobacco product and tobacco advertising directives;
- the Health Security Initiative.

6.2.1. Consistency with the announcements of the MFF communication

The announcements, which predefine the scope of the new Health Programme, state that "*the programme will support health policy by developing best practices and guidelines for the diagnosis and treatment of rare diseases, supporting European reference networks on diseases, developing best practices and guidelines for cancer screening and developing a common EU approach to health technology assessments and e-Health*."

Under this option, none of these actions would be undertaken.

6.2.2. Contribution to the EU 2020 strategy

Under this option, the Programme would not be contributing to:

- the smart growth objective, as it would not be supporting the implementation of innovative solutions and techniques in the area of health;

- the sustainable growth objective by not supporting MS in finding sustainable solutions for healthcare systems, including prevention;

- the inclusive growth objective by not working on the health workforce shortage problem.

6.2.3. Improvement of the design and monitoring of the Programme as recommended in the evaluations

The implementation of the recommendations made would be of a limited magnitude as these recommendations are mainly about the design of the Programme, and this option means that there is no more programme, only very punctual individual actions, mainly dissemination of past results and support for the actions required by or contributing to the objectives of EU legislation.

This would of course not prevent from having indicators and a monitoring system to be able to measure achievements made in the implementation of the legislation.

6.2.4. Achievement of objectives, thus of the programme

(a) Loss of investments made in previous Programmes:

The inability to upgrade dissemination of the results of the current Health Programme will lead to the situation where most of them would actually be lost. For instance, common guidelines for cancer have been developed thanks to the Programme and are now being applied at national level. Failing to update them at regular intervals on the basis of scientific developments and assessments would deprive Member States and health practitioners of this benefit.

(b) Possibility of a regression in areas where MS cannot tackle issues alone:

Under this option, actions that cannot be taken effectively by Member States alone but depends greatly on cooperation funded at EU level would not be funded anymore. One example can be the area of cross-border health threats. Fast-spreading communicable diseases do not stop at political borders. In such, possibly very dramatic situations, it is important that Member States are well-prepared in advance and are accustomed to cooperate as much as possible. In the absence of common training and exercises, guidelines and compatibility among Member States' procedures, there is a serious risk that diseases will spread quicker and wider, causing more human casualties and greater disruption for the EU economy.

Another example can be rare diseases. Because of the low numbers of patients in each Member State alone and isolated centres of expertise (sometimes just three or four across the whole EU), it is impossible for all Member States to provide equally high-quality expertise and care to patients with rare diseases. The pooling of expertise across the Union, which makes much more efficient use of the limited resources in this area, is likely to be abandoned in the absence of continuous funding from the EU budget, denying many European citizens with rare diseases access to proper care if they happen to live in a country where little, if any, expertise is available.

(c)No leverage for MS health policies:

In this option, no support would be given to the Member States, in the form of cooperation, sharing knowledge, exchange of best practices etc. Thus probably the degree of importance to do things in certain areas would decrease in Member States, which would, in turn, have a negative incidence on the sustainability of health systems.

The EU Health Programme as such could not be used as an example or source of inspiration for Member States own public health programmes. Longer term goals in the public health would loose importance to some short term fixes, especially as many Member States budgets need to be reduced due to the financial crisis.

In addition, under this option None of Member States' and stakeholders' concerns will be taken into account.

6.2.5. Implementation of Commission's legal obligations and synergies between the actions undertaken for the implementation of legislation and actions undertaken in order to achieve different objectives

These obligations would be fully fulfilled however no synergies could be developed as there would be no programme.

6.2.6. Impact of the simplification measures

The implementation of the simplification measures would be of a limited magnitude as these measures are mainly about the implementation of actions (and not support to the implementation of legislation) which is not foreseen under this option.

This would of course not prevent the limitation of activities to be funded and their size.

6.2.7. Compatibility with the available resources

This option would be compatible with the available resources as the amount of allocations would be lower as the amount in the MFF communication.

6.3 Option 2

This option is the baseline scenario. It corresponds to continuing the programme in its present form with 3 main objectives as described in the decision for the programme[42]:

- improve citizens' health security;

- promote health,

- generate and disseminate health information and knowledge.

For each of these broad and general objectives, there is a long and broad list of actions in the annex to the decision which are not prioritised. No indicators have been provided and none can be found for such objectives that would allow to measure achievements against objectives and thus measure the impact of the programme.

This option implies that none or very little of the recommendations made or conclusions drawn in the different evaluations and audits would be fully taken into account. Indeed, some steps have already been taken in order to answer these recommendations: the number of projects to be financed annually has been decreased significantly, priority areas are set internally and proposed funding is set against these priorities. This prioritisation process is now being further improved so as to avoid criticisms made by Programme Committee Members and stakeholders in the mid-term evaluation about the lack of transparency. Nevertheless the root causes of the problems would not be healed.

[42] See Annex to Decision n°1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008 – 2013), OJ L 301 p 3 of 20.11.2007.

6.3.1. Consistency with the announcements of the MFF communication

Under this option, the programme's objectives would not be aligned to these announcements. There would be a lack of focus on actions that contribute to encouraging innovation in health such as Health Technology Assessment or e-Health.

6.3.2. Contribution to the EU 2020 strategy

Indeed, implementing the future programme in the same way as the current one would imply that objectives, dating back to 2007, would not take into account Commission's political priorities as formulated in the EU 2020 strategy.

In addition, except for the implementation of legislation, the repartition of budget between the objectives (should be towards an equal split) would make it much more difficult to finance all the actions on HTA, health workforce, e-health, sustainability of health systems etc. and thus to participate significantly (on the programme's scale) in the smart, sustainable and inclusive growth objectives.

6.3.3. Improvement of the design and monitoring of the Programme as recommended in the evaluations

This option would mean that none or very little of the recommendations made or conclusions drawn in the different evaluations and audits would be fully taken into account. Indeed, some steps have already been taken in order to answer the recommendations made by the Court of Auditors and in the external evaluations (number of projects to be financed annually has been recently significantly decreased, prioritisation is being somehow improved).

But in order to fully implement these recommendations, it’s the whole design of the programme that needs to be reviewed. It can only be done while preparing a new Programme.

The main results would be:

- insufficient focus: a long list of items would have to be addressed with little or no prioritisation and time limits;
- insufficient logic of intervention, leaving no possibility to demonstrate that the action taken is converging towards a given aim;
- a lack of smart objectives and indicators, meaning that again, the level of achievement of the objectives would be very difficult to monitor, and it would not be possible to demonstrate the impact of the Programme.

6.3.4. Achievement of objectives, thus of the programme:

The objectives of the current programme are neither result oriented, nor focused. A big variety of actions can be undertaken while not necessary corresponding to the real needs. Without the strengthening of the dissemination the results of many of the projects would be lost.

As a consequence the programme would not sufficiently contribute to support Member States in their efforts to find solutions for the challenges they are facing.

The leverage would exist, as it currently exists according to the findings of the evaluations. However, the lack of focus and prioritisation of the objectives and actions would weaken the level of incidence on national policies.

Finally, Member States' and stakeholders' concerns would be taken into account only to some extend.

6.3.5. Implementation of Commission's legal obligations and synergies between the actions undertaken for the implementation of legislation and actions undertaken in order to achieve different objectives

These obligations would not be fully fulfilled as the obligations related to medical devices and medicinal products would not be taken into account.

6.3.6. Impact of simplification measures

Under this option, no simplification is foreseen other than steps already taken in order to answer the recommendations made in the latest evaluations and audits. These steps may indeed result in a lesser burden on administrative costs.

6.3.7. Compatibility with the available resources

This option would be compatible with the available resources as the amount of allocations would be the same as the amount in the MFF communication.

6.4 Option 3

Option 3 follows strictly the recommendations made by evaluations of the previous and current Health programmes as well as the recommendations stemming from the report of the Court of Auditors in 2008 (see above point **2.2.1)**. The highest ranked recommendations stressed the need:

- to improve the concept and the design of the future Programme with an explicit intervention logic;
- to focus the Programme on SMART objectives, and reduce the number of priorities
- To better take into consideration the real needs and what is achievable within the limited budget, and
- to support actions that will create proven EU added value.

This option corresponds to a well structured programme, with SMART objectives, prioritised actions, creating EU added value and with better monitoring of outcomes and impacts.

An idea which clearly underpins option 3 is to learn the lessons from the previous Health Programmes. Although this option may be equivalent to option 2 in budgetary terms it differs significantly regarding the design and monitoring of the programme. Under this option, the new Programme would address the main criticisms made by the Court of Auditors in its report and in the external evaluations.

a) Intervention logic of the programme, focused and smart objectives

Specific objectives (described under point 4) have been determined in accordance with the review of the challenges and policy objectives. There is a clear link between them and MFF announcements (as shown in the table under point 3.7).

The specific objectives underpinning the logic of the Programme are all outcome-oriented and put the emphasis on the practical results and their up-take by Member States in their national programmes and health policies. This will be measured by means of appropriate SMART indicators in the extensive evaluation and monitoring. The activities supported by the Programme will be compatible with the overarching aims of the EU health policy that is to improve the performance of health systems and render them more equitable, sustainable and compatible with EU 2020 objectives. Initiatives supported by the Programme are expected to produce specific outcomes. Without a valid outcome they will not be continued.

In line with MFF announcements the priority specific objectives are the one defined in the section 3, namely:

Objective 1: **develop common tools and mechanisms at EU level to address shortages of resources, both human and financial, and facilitate up-take of innovation in healthcare in order to contribute to innovate and sustainable health system** Objective 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

Objective 3: **identify, disseminate and promote the up-take of validated best practices for cost-effective prevention measures, in particular 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**;

Objective 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 treats**.

b) Prioritisation of actions

The prioritising of areas of intervention and of concrete actions for fundingwill be based on: a) legal obligations for the Commission; b) the potentiality to create the largest European added value according to the determined criterias (as described in the point 4.3), c) direct links with the challenges/real needs and policy objectives, d) past experience and the results of the evaluations; e) the level of importance for Member States policies and stakeholders activities; f) size of the population that might be impacted, and g) what may be achievable within the modest budget.

As a result, some of the activities from the past and current programmes will not be continued or their financing will be significantly reduced. Other policy areas and actions will witness their budget increased. Last but not least a limited number of new actions will be also added taking into account the overall need for reduction of priorities.

In the preferred option (see below option 3a), the total number of actions is reduced to 22 and the total number of outputs is estimated to 210.

In line with the policy objectives the following actions will not be carried out in comparison to the current and previous programme: incidence of environment on health, actions on prevention of injuries. These actions can be more effectively supported by other EU policies and programmes than the modest Health Programme.

Following objectives and horizontal activities will have their budget reduced: promotion of good health and health information and knowledge. The examples of concrete action to be reduced are: the action on mental health or health crisis preparedness. This is because these activities can be supported by other EU programmes, or the Commission will concentrate on putting forward the legislation (Health Security Initiative), or/and much was achieved up to now and actions can focus more on networking or exchange of best practices which are simply less costly. Promotion of health nevertheless remains an important part of the programme as it contributes to the prevention of diseases, such as cancer and chronic diseases and it is one of the action's which is the most requested by our stakeholders, especially NGOs. The decrease of support in the area of health evidence and knowledge is related to the de-prioritisation of this activity, especially regarding the work on the definition of adequate and pertinent health indicators. An evaluation on the use of relevant EU indicators in the context of a comprehensive European health monitoring system is ongoing. The acquisition, validation and dissemination of data can provide added value in the form of information allowing for benchmarking for informed decision-making. In addition, a harmonised collection of comparable data may help reduce the administrative and economic burden on Member States by reducing multiplication of such tasks.

A number of actions from the previous programme are continued in the new one with the same range of funding. They are maintained either :

because of their recognised high level of EU added value (cancer, chronic diseases); because of the impossibility for Member States to act alone (rare diseases and cross border health threats) or

because there is additional ground work to be carried out in view of further developments of existing legislation (patient safety for patients rights in cross border healthcare).

These actions address to great extend the real needs, challenges and expectations of end-users of the Programme as expressed in the consultations.

A number of actions that are now emerging in the current programme will be further developed in the next programme. They have been deemed to have a high EU added value in that guidelines, best practices and advices developed with the support of the Programme could contribute to the sustainability and efficiency of health systems in Member States implementing them (on topics of health workforce, better decision making on health systems reforms, cross border health care). The other reason is because they deal with innovative solutions (health technology assessment or health innovation and e-Health). HTA for example has a recognised potential for generating important economies of scale, notably because of the size of the population that they may affect.

In addition, these are also political priorities of the Member States and the Commission, they are fully in line with EU 2020 agenda to support innovation in health and inclusive and sustainable growth. As they are relatively new they are also more costly for Member States than for example an exchange of best practices within already well established network.

New actions under the new Health Programme are the one under support for the EU legislation on medicinal products and medical devices (transferred from Internal Market budget lines) and all other obligations stemming from the legislation under preparation. Regarding medical devices, it will be with a much increased funding compared to the years prior to 2014 as the directive is currently begin revised and it is one of the tools that will be used to unlock the potential of innovation in health.

Option 3 has been divided into 3 sub-options in order to take into account different levels of contribution to the main strategic goals, also taking into account possible trade-offs

6.4.1. Option 3 sub-option A

In this option, the Programme comprises full set of policy objectives and horizontal activities described under point 3.

The repartition of credits per policy objectives and in comparison with the current programme in this option would be as follows:

Evolution of allocations between old and new programme per specific objective:

	Average per year		
Specific objectives	**2014 – 2020 (sub-option 3A)**	**2014 – 2020 (sub-option 3 B)**	**difference**
1) develop common tools and mechanisms at EU level to address shortages of resources, both human and financial, and facilitate up-take of innovation in healthcare in order to contribute to innovate and sustainable health system			
Sub-total	**9**	**24.3**	**15.3**

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 citizen			
Sub-total	**9.8**	**11.3**	**1.5**
3) 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			
Sub-total	**21.1**	**10.9**	**-10.5**
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 treats			
Sub-total	**7.5**	**4.6**	**-2.9**
TOTAL	**47.4**	**51.1**	**3.7**

6.4.1.1. Consistency with the announcements of the MFF communication

Under this option, the Programme's objectives would be aligned to these announcements as it would imply working with Member States:

- "to protect citizens from cross border health threats," as described under policy objective 4 and also by implementing the future legislation on Health Security;

- "to increase the sustainability of health services", as described within policy objective 1 and also, indirectly, under policy objective 3 with prevention aspects;

- "to improve the health of the population "as described under policy objectives 2 and 3 and also by implementing EU health related legislation;

- "whilst encouraging innovation in health" as described under objective 1 with HTA and e-health and also by implementing the legislation on medical devices, on medicinal products, on substances of human origin.

6.4.1.2. Contribution to the EU 2020 strategy

This option would allow the Commission to contribute to these objectives:

- Smart growth - by supporting the implementation of innovative solutions and techniques in the area of health;
- Sustainable growth - by contributing to find sustainable solutions for healthcare systems, including prevention;
- Inclusive growth - by working on the health workforce shortage problem .

6.4.1.3. Improvement of the design and monitoring of the Programme as recommended in the evaluations

Under this option, the new Programme proposed would address the main criticisms made by the external evaluations and in the Court of Auditors report. It would have:

- An intervention logic for its actions;
- SMART, realistic objectives;

- Prioritised actions;
- A set of indicators for measuring the outcomes and the impact.

Thus, it would be possible to measure achievements, to adjust priorities, indicators, to act if achievements are not in line with the milestones established and to determine the impact of the programme.

6.4.1.4. Achievement of objectives, thus of the programme

Objective1 (example: HTA)

At Programme's level, it is expected to have the highest number of Member States (through their policy makers, health professionals, health institutions) using the developed tools, mechanisms and advices

At policy level, these items will support Member States, policy makers, health professionals, health institutions in reaching an adequate supply of health professionals in MS, reaching a cost-effective use of medical technologies and improving decision-making, organisational management and performance of the health systems.

For instance, with HTA, the projects funded until now have supported the establishment of a European HTA network, the development of common methodological basis for assessing health technologies (so called "core HTA model"), the testing of this core model on selected methodologies (medicine and screening devices) and the development of tools supporting and enlarging EU cooperation. This will be continued in the coming years to gain better insight on the feasibility of cooperation models, to establish scientific guidelines for users (health related industries) and to organise trainings in MS for stakeholders on the use of the core HTA model.

The availability of core model should help reduce the duplication of work and result in economies of scale. The standardisation, at EU level, of data and information requirements from industry should have positive effects on transparency and quality of decision making

Objective 2 (example: reference networks for rare diseases)

At Programme's level, it is expected to have the highest number of health professionals using the expertise gathered through the European Reference Networks put in place and functioning, and to have the highest number of Member States (through their policy makers, health professionals, health institutions) using the developed guidelines on patient safety.

At policy level, these items will support MS in improving access to diagnosis and provision for all patients requiring highly specialised care for a specific disease or group of diseases and to support MS reducing morbidity and mortality related to healthcare quality and increasing patients/citizens confidence in the health care system.

For instance, the pilot European reference Networks (ERNs) in the area of Rare Diseases (RD), aims at supporting the policies and initiatives of MS in the following areas: recognition of RD, research, development of national plans and strategies, knowledge production and dissemination, empowerment of patient organizations; setup of pilot European Reference Networks.

Analysis of networks previously and currently funded show that the most valuable outcomes developed by the pilot networks are:

- Shared databases/ registries;
- Shared tools for expertise in diagnosis and treatment, including tele-expertise;
- Guidelines for clinical care and for biological diagnosis and disease-specific information;
- Training tools and sessions, both for healthcare professionals and patients;

Taking into account that knowledge and resources in the area of Rare Diseases are extremely scarce, the mere collection of information and existence of shared tools for exchange of

knowledge and expertise, are more than simple outputs. They effectively represent an increase in access to available information both for healthcare professionals and other experts and patients and their families that should lead to improved quality of care and improved quality of life for patients.

But in order to ensure a long lasting impact and the expansion to new members, the update of information/knowledge and the maintenance and further development of tools put in place in the initial phases have to be continued.

Objective 3 (example: cancer)

At Programme's level, it is expected to have the highest number of Member States, through their policy makers, health professionals, health institutions and stakeholders from bodies involved in good health and prevention of diseases, using the validated best practices in order to, at policy level, support Member States in their efforts to reduce risk factors for diseases.

For instance, under the previous current Health Programme, the aim of the projects funded under the action for cancer is to contribute to the reduction of cancer's burden in the EU by:

(i). providing a framework for identifying and sharing information, capacity and expertise in cancer prevention and control,

(ii). involving relevant stakeholders across the EU in a collective effort.

As of today, the main results are:

- screening guidelines for colorectal and breast cancer;
- the support of EU-wide promotion/prevention activities: European week against cancer, EU code against cancer, AURORA project for screening of cervical cancer, EPIDERM project for skin cancers, conferences such as Europa Donna Breast cancer, ECPC cancer summit, etc;
- the support of a cancer network;
- the standardisation of data in relation with the European Community Health Indicators system;
- the support of the European Network of Cancer Registries

It is difficult to differentiate the impact of EU funded actions from MS action. The impact of the first programmes against cancer (1985-2000) has been evaluated via a study comparing the actual rate of mortality reduction (10%) to the pre-defined rate (15%). But the difficulty lies in identifying the exact role of the programme in this decrease. It is almost impossible to differentiate action at EU level and action at MS level. Which also demonstrates the need for indicators at the right level of incidence of the programme (see also point 6.4.3 and point 7.1).

Objective 4 (example: health threats)

At Programme's level, it is expected to 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.

At policy level, the uptake of the outcomes of these actions will 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).

Leverage for Member States' health policies: In this option, support would be given to the Member States, in the form of cooperation, sharing knowledge, etc in areas falling under the specific objectives. Thus probably the degree of importance to do things in these areas could be increased in MS which would, in turn, take them into consideration in their own policies.

For instance, to support the acquisition by Member States of the core capacities for the implementation of the International Health Regulation, the Health Programme has funded several actions (SHIPSAN, SHIPSAN II, REACT, Episouth, Episouth+) to develop a framework to identify and exchange good practice in all preparedness activities, including their transferability and procedures for travel related contact tracing. The following outcomes were obtained:

- a European Manual for hygiene standards and Communicable Disease surveillance on passenger ships (SHIPSAN project);
- training tools and models addressing generic preparedness and response for the international spread of infectious disease at European level (REACT project);
- reports and concept for future collaboration in Cross-border epidemic intelligence, Vaccine preventable diseases and migrants, Cross-border emerging zoonoses and Training in applied epidemiology, and developing the Mediterranean network (Episouth project);
- establishment of the Mediterranean regional laboratories network, development of generic preparedness plan and risk management procedures (EpiSouth+; currently ongoing).

The impact from SHIPSAN projects will be the most visible as the application of common standards in hygiene inspections are expected to have a significant contribution to the reduction of food borne and waterborne diseases in ships, as already demonstrated by US Vessel Sanitation Programme (VST). Additionally, experience acquired with SHIPSAN will be useful for the development of the cargo ships manual and inspection programme.

For other actions, the networking and exchange of experience could lead to the strengthening of core capacities and the development of a coordinated public health culture of risk assessment and risk management of hazards events.

6.4.1.5. Implementation of Commission's legal obligations and synergies between the actions undertaken for the implementation of legislation and actions undertaken in order to achieve different objectives

These obligations would be fully fulfilled and synergies could be developed with actions undertaken in view of achieving the objectives of the programme.

6.4.1.6. Impact of simplification measures

On one hand side, the multi-annual programming of the implementation of the programme as well as the reduction of the number of actions and also the increase of the size of the projects will contribute to limit the burden related to the management of the programme. This means that the overall increase of allocation, in comparison to the current programme, will not be applied to the administrative costs.

Other simplification measures are directed both at beneficiaries and also at reducing the burden related to the management of the programme (electronic submission of projects proposals, simplification of the evaluation criteria, etc.).

Thanks to these simplifications, it will be possible that administrative costs remain at the same level as in the current programme.

6.4.1.7. Compatibility with the available resources

This option would be compatible with the available resources as the amount of allocations would be the same as the amount in the MFF communication.

6.4.5. Option 3, sub-option B

This option corresponds to a well structured programme dealing only with the same set of objectives and horizontal activities but, as a trade off, action on promoting health would not be

impact is very difficult to measure and where it can only be measured on the long term.

The repartition of credits per policy objectives and in comparison with sub-option 3a would be as follows:

	Average per year		
Policy objectives	**2014 – 2020 (sub-option 3A)**	**2014 – 2020 (sub-option 3 B)**	**difference**
1) develop common tools and mechanisms at EU level to address shortages of resources, both human and financial, and facilitate up-take of innovation in healthcare in order to contribute to innovate and sustainable health system	24.3	24.3	0
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 citizen	11.3	11.3	0
3) identify, disseminate and promote the up-take of validated best practices for cost-effective prevention measures, in particular 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	10.9	5.9	-5
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 treats	4.6	4.6	0
TOTAL	**51.1**	**46.1**	**-5**

The total budget for the option 3 B would be EUR 43,9 million.

Under this sub-option, the impact of the programme would be comparable to that of sub-option 3a with the following exceptions.

6.4.5.1. Consistency with the announcements of the MFF communication

Under this option, the programme's objectives would be mostly aligned to these announcements but with a reduced contribution "to improve the health of the population" and also "to increase the sustainability of health services" as there would be no promotion of good health and health determinants anymore.

6.4.5.2. Contribution to the EU 2020 strategy

This option would also allow the Commission to contribute to these objectives but to a lesser extent than option 3 A as the objective on promotion of good health would not contribute to sustainable growth anymore.

6.4.5.3. Improvement of the design and monitoring of the Programme as recommended in the evaluations

As in option 3 A.

6.4.5.4. Achievement of objectives, thus of the programme

Objective 3 would be reduced to actions on cancer and chronic diseases which would mean that promotion of good health would remain at the sole level of the Member States. Thus the Programme would not be a source of inspiration or/and example for their own national polices. In the same time, prevention and promotion of good health are two of the areas that are very much demanded by Member States when they are consulted. This is also area of high importance for various NGOs.

Finally, prevention is probably one of the cheapest ways to ensure the sustainability of health systems, assuming that it prevents people from becoming ill. Commission thus ought to participate, generate, support work in this are as it also serves the first objective of this programme, even if indirectly.

6.4.5.5. Implementation of Commission's legal obligations and synergies between the actions undertaken for the implementation of legislation and actions undertaken in order to achieve different objectives

These obligations would be fully fulfilled and synergies could be developed with actions undertaken in view of achieving the objectives of the programme.

6.4.5.6. Impact of simplification measures

As in 3 A.

6.4.5.7 Compatibility with the available resources

This option would be compatible with the available resources as the amount of allocations would be lower as the amount in the MFF communication.

6.4.6. Option 3, sub-option C

This option corresponds to a programme limited to:

- the financing of Commission’s obligations for implementing the current health legislation, the tobacco directives, and the legislation on medicinal products and medical devices;

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

In addition, there would be some dissemination of the results of the current Health Programme (2008–2013) in order to take into account the conclusions of previous evaluations.

Protecting citizens from cross-border health threats would be retained for funding first because it is stipulated under the article 168 of the Treaty. Furthermore, the EU added value of this objective is clearly established, mainly in relation to the cross border criteria, as well as its legitimacy: it is considered of crucial importance to have well prepared Member States and an adequate EU coordination in order to be able to face such events. And by definition, Member States cannot act efficiently alone on this.

The repartition of credits per objectives command comparison with Option 3 A would be as follows:

	Average per year		
Policy objectives	**2014 – 2020 (sub-option 3A)**	**2014 – 2020 (sub-option 3 C)**	**difference**
1) develop common tools and mechanisms at EU level to address shortages of resources, both human and financial, and facilitate up-take of innovation in healthcare in order to contribute to innovate and sustainable health system	24.3	10.2	14.1
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 citizen	11.3	4.5	6.8
3) identify, disseminate and promote the up-take of validated best practices for cost-effective prevention measures, in particular 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	10.9	0.5	-10.4
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 treats	4.6	2	-2.6

Total	**51.1**	**17.2**	**-33.9**

The total budget for the option 3 C would be EUR 24.4 million

6.4.6.1. Consistency with the announcements of the MFF communication

Under this option actions undertaken would be reduced to the protection from cross border health threats and nearly nothing else.

6.4.6.2. Contribution to the EU 2020 strategy

Under this option, the programme would not be contributing to:

- the smart growth objective, as it would not be supporting the implementation of innovative solutions and techniques in the area of health;

- the sustainable growth objective by not supporting MS in finding sustainable solutions for healthcare systems, including prevention;

- the inclusive growth objective by not working on the health workforce shortage problem.

6.4.6.3. Improvement of the design and monitoring of the Programme as recommended in the evaluations

Under this option, the design of the programme would be very much limited as there would only be one objective left. However, prioritisation of actions and use of indicators under this objective would still be necessary.

6.4.6.4. Achievement of specific objectives, thus of the programme

In this option, none of the objectives would be achieved except for specific objective 4. In addition, this option would result in a loss of the investments made in previous programmes. It could even imply a regression in areas where MS cannot tackle issues alone (see rare diseases in option 1).

In addition, most of the concerns of the Member States would not be taken into account.

Finally, the leverage on member States policies would be limited to the protection of citizens from cross border health threats an nothing else.

6.4.6.5. Implementation of Commission's legal obligations and synergies between the actions undertaken for the implementation of legislation and actions undertaken in order to achieve different objectives

These obligations would be fully fulfilled but synergies could only be developed with the Health Security legislation (assuming that it is adopted).

6.4.6.6. Impact of simplification measures

The implementation of the simplification measures would be of a limited magnitude as these measures are mainly about the implementation of actions outside implementation of legislation and under this option there are only actions under the protection of citizens from cross border health threats. This would of course not prevent the limitation of projects to be funded and their size.

6.4.6.7. Compatibility with the available resources

This option would be compatible with the available resources as the amount of allocations would be significantly lower as the amount foreseen in the MFF communication.

6.5. Option 4

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

This would entail giving support to action taken by Member States - with a focus on countries and regions where health status and health inequalities are particularly negative - on:

- implementing and evaluating evidence-based plans to address inequalities by means of public health action, across the health system and in coordination across relevant policy fields;
- developing innovative approaches, by providing funding for specific pilot cooperation projects between Member States and stakeholders to develop joint work to reduce inequalities. This could include specific measures such as adapting health services to improve access; targeting services and improving the quality of the services offered; linking health, social and employment services; developing and implementing targeted health promotion measures; or helping with measures in other policy areas, for example to improve access to high-quality food or better housing;
- addressing the specific needs of vulnerable groups by taking forward coordinated action on specific priority work which would contribute to addressing inequalities, such as access to ARV treatment and prevention, good practice on migrant health or similar areas where EU support can help build added value.

Work would complement national policies to improve public health, prevent physical and mental illness and obviate sources of danger to physical and mental health. This would also cover support for a validation mechanism and for cooperation between Member States to coordinate their policies and programmes on public health. This would include organising exchanges of good practice, drafting and establishing guidelines and indicators and monitoring and evaluation activities.

It would also include stronger mechanisms to engage other relevant European players in the health sector, including regions and stakeholders, and cooperation with the relevant international organisations responsible for public health.

Given the challenges identified in the Commission Communication on health inequalities (COM(2009) 567), the Communication on Europe 2020 (COM(2010) 2020), the European Parliament resolution of 8 March 2011 on reducing health inequalities in the EU and the Council conclusions of June 2010 on equity and health in all policies, this option would require a considerable increase in investment from current levels.

Under this sub-option, the impact of the programme would be comparable to that of sub-option 3a with a developed action on health inequalities. However, this option would imply a much higher amount in funding than even sub-option 3a and thus is would not be consistent with the amount foreseen in the MFF communication.

6.6. Comparison and assessment of the options

Option 1:

This option corresponds to maintaining the minimum level of intervention imposed by the legislation and discontinuing all other actions at EU level. This would cause a reduction of EU support to Public Health policy, as well as contravene the conclusions of the evaluation of the current Health programme and the requests for a continuation of the programme made by the EU

Health ministers and other stakeholders. It would fail to guarantee an adequate support to the future Public Health policy.

Option 2:

Under this option, Member States and stakeholders' concerns would indeed be taken into account to a certain degree and it would have leverage on national health policies. However, in the absence of intervention logic, lack of SMART, focused and realistic objectives, with a large number of actions not prioritised and no indicators to measure the achievements or indicators geared towards an hypothetic impact on citizens, which a programme supporting policies cannot have, any kind of impact would first be very difficult to measure and then very limited, because not part of a logic. This type of programme would not allow to achieve the objectives defined in this impact assessment and it would not take into account the recommendations stemming from the past evaluations and audits.

Option 3 A:

Under this option, the specific objectives would be achieved through the actions defined and prioritised in this impact assessment. The Commission's legal obligations would be fulfilled.

The proposed Programme would address the main criticisms made by the external evaluations and in the Court of Auditors report. It would have an intervention logic, well defined policy objectives, SMART, realistic, outcome oriented and pragmatic specific objectives, actions to be carried out would be prioritised and a set of indicators would be defined for measuring the outcomes and the impact.

Thus, it would be possible to measure achievements and to act if they are not in line with milestones established and finally to determine the impact of the programme.

Option 3 B:

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

Option 3 C:

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

3 out of 4 of the specific objectives defined in this impact assessment would not be achieved. Such a programme would not respond to the expectations of Member States and other stakeholders.

Option 4:

This option corresponds to a substantial increase of the Public Health budget which is simply not realistic.

RESULT: Option 3a is thus, by far, the preferred one

This can be summarised in the table below:

	Options					
Regarding achievement of the objectives of the Programme						
Impact/output	**1**	**2**	**3a**	**3b**	**3c**	**4**
a) Consistency with the announcements of the MFF communication:	0	+	+++	++	+	+++
b) Contribution to the EU 2020 strategy	+	++	+++	++	+	++++
c) Improvement of the design and monitoring of the Programme as recommended in the evaluations:	+	+	+++	+++	++	+++
d) Achievement of objectives, thus of the programme:	0	+	+++	++	+	+++
e) Implementation of Commission's legal obligations and Synergies between the actions undertaken for the implementation of legislation and actions undertaken in order to achieve the different specific objectives:	++	+	+++	+++	++	+++
f) Impact of simplification measures:	+	+	+++	+++	++	+++
g) Compatibility with the available resources	+++	+++	+++	+++	+++	0

+++	Satisfactory
++	Limited
+	No

7. MONITORING AND EVALUATION

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

7.1. Multi-annual programming

The proposal is to set up an indicative internal multi-annual work programme before the start of the Programme. It would be based on the priorities and deadlines, whether already existing or yet to be defined, which the Commission would set itself.

It would serve as a guideline for the annual work plans. It would, of course, be flexible enough to allow readjustment of health topics under each specific objective. For instance, between now and the beginning of 2014, new topics may appear and will have to be taken into account in the Programme. Similarly, the structure proposed for the Programme also allows some flexibility at

creating EU added value identified in Section 4.3. would have to be followed.

This will make it possible to limit the annual priority areas and increase the amounts of funding available for those priorities and specific actions for a given year. This will rationalise the preparation of the annual work plans and with fewer projects - the monitoring. It will also allow for more time to follow up results for policy work, dissemination, etc. It will, last but not least, finally facilitate coordination of the Programme with other programmes and Commission departments, including the work plans of the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA), the Executive Agency for Health and Consumers (EAHC) and other agencies.

7.2. The financial mechanisms

A wide range of financial mechanisms will be used in the Programme: calls for proposals, grants for actions with Member States, grants for international organisations, operating grants and public procurement contracts. As said in the evaluations, the experience gained from their introduction in the current Health Programme was positive and considered as an improvement over the system for the previous Public Health Programme. In addition, each financing mechanism seems to contribute positively to achieving the aims of the Health Programme. For example:

- **Projects** involve regional governments and NGOs;
- **Grants for actions** with Member States involve them more closely, suggesting that the results might be used better at national level given the direct involvement of Member States;
- **Operating grants** guarantee the funding of an organisation for a short period (one to two years). However, once this funding comes to an end, the sustainability of the organisation is challenged;
- **Grants for international organisations**, where appropriate without previous call for proposals;
- **Tenders** can be used for specific aims, but their specifications need to be well defined in order to achieve the desired results.

Clear guidelines will continue to be provided to potential participants so that they can decide which financing mechanism would be most appropriate for their proposal. Such guidelines were first provided for call for proposals 2007. According to the mid-term evaluation, this has led to a more straightforward process for those applying for funding.

7.3. Simplification

The design of the new Programme implies the simplification of the implementation and management of the Programme:

1. The level of Union's co-financing for grants for actions, actions co-financed by the competent authorities of the Member States or the third countries, or by non-governmental bodies mandated by these authorities and for operating grants will be harmonized at 60% of eligible costs and up to 80% in cases of exceptional utility.

2. The new possibility to amend the upper limit of co-financing through Delegated Acts procedure will bring more flexibility than under the current Programme**.**

3. The long-term programming of strategic actions of 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 enable 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 to use lump sums whenever possible will be examined so as to reduce the administrative burden.

5. The management by the Executive Agency for Health and Consumers also contributes to the streamlining of procedures in the management of the Programme: an electronic submission procedure shall be introduced, which would deliver savings for applicants as well as for the Commission. From a legal point of view, electronic submission is less prone to contestation, e.g. about loss of documents. However, given the limited number of submissions per year in response to the call for proposals for the Health Programme (for example, 113 in 2011), any such solution would have to be generally applied to other programmes managed by the Executive Agency to make it more cost-effective.

Regarding the **selection procedure**, the mid-term evaluation of the current Programme concluded that the selection process for that Programme is strong at ensuring that appropriate and competent applicants are selected for funding. The action funded to date seems to address issues reflecting public health concerns in the European Union and internationally.

The evaluation process makes use of **external peer reviews**. The objective of peer reviews is to ensure the independence of the evaluation, guarantee the credibility of the organisation performing the evaluation and offer the beneficiaries advice/recommendations from scientific experts. The involvement of external evaluators also guarantees a fair process and equal access. Thus, the current selection process is an improvement compared with the previous Health Programme and will be continued.

Three sets of criteria are considered, one after the other, during the evaluation procedure in order to select proposals for funding:

- The **exclusion** and **eligibility criteria**, which all proposals must comply with, confirm that the applicant is eligible and the proposal complete;
- The **selection criteria** relate to the financial and operational capacity stipulated in the proposal; and
- The **award criteria** include the quality of the action proposed, taking into account its costs. They include the following three factors: relevance to EU policies (block A), technical quality of the project (block B) and management quality (block C).

Proposals that fail to meet the requirements of any one of these categories are rejected. However, the assessment is normally performed in full against all three blocks of award criteria. Consideration could be given to not proceeding further if some proposals have already been rejected in previous steps (e.g. block A).

7.4. Indicators

It is important to remind here that Health for Growth Programme is an EU spending Programme to support health policy. It is thus not possible for the Programme to have impacts other than the effective dissemination of its results and the acceptance of its outcomes by MS so that the results obtained can be put into practice.

In designing the programme, end-users have been clearly defined as well as the reason for which they are can cooperate in the Programme. These are health policy makers and public health practitioners committed to improve quality and sustainability of health systems and take preventive health measures to improve the health of the population. This means that indicators can only be defined at Member State or stakeholders' level. The Programme has no objective on individual citizens and cannot act directly at their level, which remains in Member States' remit.

This also implies that a significant proportion of the activities of the Programme will, as in the past, take the form of production and dissemination of validated knowledge and evidence in the field of public health for health policy makers and health practitioners. This aspect permeates all the specific objectives of the proposed Programme and is in line both with the context of the Programme, as presented in earlier sections, and with the expectations of the Member States.

Thus, output indicators can only measure the production of these best practices, tools, mechanisms, guidelines, that have been developed. And impact indicators can only be about the

uptake of these best practices, mechanisms, guidelines by the end users. Thus, the success of the Programme can only be defined in terms of the rate of implementation, participation by Member States and take-up of the outcome in the different Member States and stakeholder groups, on top of the actual results achieved compared with predefined levels.

In its letter of 29 June to the Commission, the Standing committee of European Doctors[43] also recommends this approach:

"*Implementation of actions and uptake of Programme results are key for the success of the programme and it could represent a good indicator. Hence, the indicator could be defined in terms of the rate of the implementation and uptake of programme outcomes in the different Member States and stakeholder groups as well as the actual rate of predefined results achieved. In addition the visibility and uptake of outcomes of individual actions beyond the actors directly involved are a valuable measurement tool. In order for this to be achieved, however, the communication and evaluation mechanisms within individual actions must be reviewed, so as to allow for meaningful impact assessments.*"

A complete set of indicators is described below:

- there are indicators to measure the achievement of the objectives: outcome indicators and impact indicators for each of the specific objectives;
- there are indicators addressing issues highlighted in the evaluations: on the level of participation of Member States, on communication and dissemination,
- and there are indicators at the level of projects funded: regarding the adequateness of the actions that are proposed for financing which can give an indication about the level of interest of stakeholders on this action; the outcomes of the projects (also intermediate); the quality of the projects.

7.4.1. At the level of the specific objectives of the Programme

As a consequence of the above, for each of the specific objectives, a double set of indicators will be put in place: one outcome indicator and one impact indicator. The outcome indicator provides a means to measure the result of the action taken and the impact indicator to measure the take-up of the outcome by the Member States or stakeholders.

The table below gives examples of outcome and impact indicators for the specific objectives of the Programme. These are not yet finalised, in terms of either numbers or years, and could change, as more work still needs to be done to identify the best indicators. They will also be reviewed in the course of the Programme to see if they need to be revised.

Outcome indicators	Impact indicators
Specific objective 1: develop common tools and mechanisms at EU level to address shortages of resources, both human and financial, and facilitate up-take of innovation in healthcare in order to contribute to innovate and sustainable health system	
Number of tools and mechanisms developed by 20XX, 20YY and 20ZZ	Number of Member States/stakeholders using them by 20XX, 20YY and 20ZZ
Specific objective 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	
Number of functioning ERNs by 20XX,	Number of healthcare specialists using this

[43] CTME Comité permanent des médecins Europeéns, letter to Commission 29/6.

20YY and 20ZZ	expertise by 20XX, 20YY and 20ZZ
Number of guidelines developed by 20XX, 20YY and 20ZZ	Number of Member States/stakeholders using them by 20XX, 20YY and 20ZZ
Specific objective 3: identify, disseminate and promote the up-take of validated best practices for cost-effective prevention measures, in particular 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	
Number of validated best practices developed by 20XX, 20YY and 20ZZ	Number of Member States/stakeholders using them by 20XX, 20YY and 20ZZ
Specific objective 5: develop common approaches and demonstrate their value for better preparedness and coordination in health emergencies in order to protect citizens from cross-border health treats	
Number of common approaches developed by 20XX, 20YY and 20ZZ	Number of Member States/stakeholders using them by 20XX, 20YY and 20ZZ

Measurement of Impact indicators

In short, the impact indicators for the specific objectives can be summarised as the rate of use, by Member States and/or stakeholders, of the tools developed.

To identify and measure the impact of the Programme, it is absolutely necessary to know if, and for which reasons, the outcome of the Programme is used in Member States and if not why not, because this is also a sign that the specific objectives/action are failing to meet Member States' needs.

It is therefore suggested that the National Focal Points (NFP) Network, an informal network already providing support to the current Programme, should be established formally with a clear mandate under the legal base adopted for the Programme.

Impact indicators will have to be defined and evaluation mechanisms put in place in close collaboration with the NFPs (systematic feedback from questionnaires to stakeholders, revision of evaluation methods within the action funded, allowing meaningful impact assessment, etc.).

The success of the Programme could be defined in terms of the rate of implementation, participation by Member States and take-up of the outcomes in the different Member States and by stakeholder groups, on top of the actual results achieved compared with predefined levels.

7.4.2. Other indicators

a) Rate of implementation

In accordance with the objectives of the Programme, as described above, and with the imperatives of the Europe 2020 Strategy, the proposed indicator is that:

- at least 40% of the total budget for the Health Programme (on average for the period 2014–2020) be allocated to action supporting the safety, quality and efficient use of medical technologies (pharmaceuticals, vaccines, medical devices, HTA, genomics, etc.). This indicator would be reviewed and, if necessary, revised after three years following an evaluation of achievements and assessment of needs.

b) Participation by Member States

As regards satisfactory participation by Member States, the proposed indicator could be:

- 50% increase in participation by Member States with a very low participation rate or which were declared inactive in the previous Programmes.

This indicator is very important because it reflects the relevance of the objectives of the Programme to Member States' needs and its inclusive dimension. Inactive Member States will only be motivated to participate in the Programme if its objectives reflect their concerns.

This certainly implies that administrative, financial and language barriers have to be removed. Especially, for Member States with low GNI, the EU contribution should cover at least 80% of the total expenditure on the action taken or some other cost model for EU co-financing should be activated.

c) Communication and dissemination indicators

To make it easier for Member States and stakeholders to take up outcomes and, thus, to make an impact, good communication and systematic dissemination of results are crucial. They make the outcomes visible. In this area, there is room for improvement, as highlighted in audits and evaluations of the two previous Programmes, for 2003-2007 and 2008-2013. Dissemination and good communication should therefore also be monitored, based on the following indicators (to be finalised):

- number of articles published in peer-reviewed scientific and/or specialist journals on the results of action financed under the Programme;
- amount of information related to the output of the Programme available on the web;
- thematic conferences organised to present work in progress (at least one every two years);
- documented systematic promotion of key outcomes of the Programme to policymakers and other stakeholders.

d) Adequateness indicator

Immediately before any action starts, its adequateness can be measured. In particular, if, in response to a call for proposals, no proposals are made for some areas, this has to be analysed to identify the reason for this failure, for example:

- the action was not described clearly and potential beneficiaries did not know what was expected;
- the action is too ambitious in comparison with the indicative amount allocated;
- the action is not interesting for potential beneficiaries.

e) Outcome indicators

At the end of each action, systematic monitoring of outcomes under each of the specific objectives is required. The actual rate of achievement of the predefined results for each action linked to a specific objective could serve to justify continuation of the objective and of the Programme.

For instance, under specific objective 1 'Develop common tools and mechanisms at EU level to address shortages of resources, both human and financial', the following outcome indicators could be used for the action addressing health workforce shortages:

- By 2015, creation of an EU platform enabling Member States to work together on forecasting health workforce needs, workforce planning methods and mobility trends (with at least 18 Member States participating). By 2020, an operational platform covering all EU Member States.
- By 2014, EU guidelines on how to implement the WHO Code of Practice on the international recruitment of health personnel.
- By 2015, bilateral agreements on training for health professionals in place.
- By 2015, routine forecasting of needs for health professionals at EU level.

f) Quality indicators

In addition, quality indicators should be applied systematically to all projects financed under the Programme:

- 100% of projects should comply with the EU added value criteria;
- 100% of projects should be evaluated by internal bodies;
- All long-term projects must be evaluated at appropriate interval in order to determine if continuation of the funding is justified.

7.5. Evaluations

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 mid-term evaluation will include a review of the indicators in order to assess their relevance and revise them if need be or if priorities have changed since the beginning of the Programme. Impact indicators will still be difficult to review as, at mid-term, there will not yet be many outcomes (not many projects will have been finished by then) and thus not much chance of taking up the outcome. The mid-term evaluation will serve the impact assessment exercise for eventual follow-up programme in the area of health post-2020.

Ad-hoc evaluations will also be conducted, to a lesser extent, for specific projects or action as a whole, whenever necessary.

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 and for the design of the future programme.

ANNEX 1: DGs IN THE STEERING GROUP

BUDG

CLIMA

COMM

COMP

DEVCO

EAHC

ECFIN

EEAS

EMPL

ENER

ENTR

ENV

ESTAT

HR

INFSO

JRC-ISPRA

JUST

MARKT

REGIO

RTD

SG

ANNEX 2 - TIMETABLE

Month	Ex post finale evaluation of the PHP 2003-2007	Mid-term evaluation of the Health Programme 2008-2013 and health Strategy	Health Programme Post 2013 -	Consultation Avec les stakeholders
JAN	Reception of the final report	Inception report	Concept paper and the draft Road Map IA	21/01 - National Focal Points meeting (tour de table
FEB			24/02 - Roadmap submitted to SPG meeting and approved.	17/02 - Programme Committee meeting 17/02
MARCH	Approval of final report	Interim report	Drafting of composite Impact Assessment for sec Gen 15/03 - Roadmap sent to Sec Gen 31/03 – Composite IA sent to Sec Gen	18/03 - Meeting of the Senior Working level Group on Health
APRIL			Start the Impact Assessment 15/04 - 1st meeting with the IA Steering Group (ISG on Health)	4-5/04 - Informal EPSCO (Health) Council in Gödöllö
MAY		10/5 - amended interim report	Drafting	19/05 - Health Policy forum 19/05
JUNE		30/6 - Draft final report	10/06 - 2nd meeting of IA Steering group	30/06 – contribution from special working group from the Health Forum
JULY		25/07 - Final report	18/07 – 3rd steering group Finalisation of impact assessment.	
AUGUST			24/08 – at the latest, submission to IAB	
SEPT			21/09 – Impact Assessment Board Drafting of the new programme.	
OCT		Drafting of a Commission staff working paper on this evaluation (unless we can add it to the Impact Assessment)	Finalisation of draft of the new Health Programme and launch of the ISC	
NOV			Transmission of the draft proposal to the College Adoption by the College in a package with other financial frameworks (as per Sec Gen's proposal for calendar)	
DEC				

ANNEX 3: EX-POST EVALUATION OF THE PUBLIC HEALTH PROGRAMME 2003-2007(CONDUCTED BY COWI S/A)

KEY POINTS
Achievement of programme objectives

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

- The e-survey reveals that even though many stakeholders find that the objectives are unclear, there is a general belief that PHP objectives have been achieved to some extent. Beneficiaries are more optimistic compared with other stakeholders.

- The case studies document that the projects funded by the PHP have delivered a number of concrete results in the form of reports, articles, websites and training etc.

- Most of the projects selected for the case studies have a strong potential to contribute to the preparation, development and implementation of EU public health initiatives. However, only limited evidence was found of such contributions at both national and EU level.

- There are projects where dissemination of knowledge generated has been considerable. However, for other projects, the dissemination effort has not been targeted to all relevant stakeholders.

- According to the case studies, sustainability was mainly achieved by making projects results available on websites after the project period and through follow-up projects funded by DG SANCO. There seems to be a need for a clearer focus on dissemination of project results to policy-makers in order to promote sustainability through implementation of policy initiatives.

- According to the case studies, a three-year funding period is not always long enough to cover the whole project cycle. Furthermore, the present funding model where projects compete to obtain funding may promote good start-ups but entail less focus on dissemination and implementation of the results.

Implementation of the programme

- All projects selected for in-depth case studies are perceived to be relevant to the PHP and have provided clear European added value - in this way, the projects selected may be regarded as success stories. The Commission staff stated in the interview that the focus on European added value should have higher priority

- The portfolio analysis conducted by COWI shows a good coverage of PHP objectives and work plan priorities.

- However, many stakeholders involved in the implementation of the PHP hold the view that there are too many priority areas in the annual work plans.

- According to the e-survey, most beneficiaries are familiar with the EU public health policy in general. They are also familiar with the general programme objectives and annual priorities of the PHP but to a somewhat lesser extent.

- Other stakeholders employed by international organisations are in general very familiar with the EU public health policy and the way the programme supports this policy.

- It may be somewhat surprising that other stakeholders employed in the public administration of the Member States are not more familiar with the EU public health policy, general programme objectives and annual priorities of the PHP than the e-survey results indicated.

- Small organisations might not have the resources necessary to participate in the programme, especially organisations/research institutions from Eastern Europe.

- According to the e-survey, most beneficiaries have met barriers to receiving funding (language, procedures, cultural differences, new/old EU membership). From the viewpoint of most other stakeholders, there are indeed barriers to receiving funding.

The five highest ranked recommendations

1 DG SANCO should reduce the number of priority areas in the annual work plans by allowing a maximum of five priority areas in each of the three strands to increase the impact within the priority areas, bringing them to not more than 15 per yearly call.

1 DG SANCO should in collaboration with EAHC define clear performance indicators (success criteria) at programme level in order to facilitate follow-up and evaluation of the achievements. These success criteria should be based on a thorough elaboration of the intervention logic underpinning the different areas and priorities of the programme.

2 EAHC should compile brief descriptions of project results, compatible with the existing database, including considerations about use potential and policy recommendations if relevant, and disseminate these to Commission staff and national stakeholders at the political level, under the caveat that such procedures do not increase the administrative burden for the end user and grant holders unnecessarily.

3 DG SANCO should ensure that the priority areas in the annual work plans are focused and based on a thorough analysis of needs and European added value. This analysis should be carried out by public health experts versed in these issues.

4 EAHC and DG SANCO should pursue inclusion of Member States which appear inactive in the programme. These are typically countries with a relatively low GDP/capita. Inclusion could be pursued by providing technical assistance to write proposals (EAHC) or by increasing the EC financial contribution (DG SANCO), possibly on the basis of an alternative cost model.

1.1 Introduction

The overall purpose of this evaluation is to assess the effectiveness, efficiency and utility of the Public Health Programme (PHP). Thus, it is assessed whether the achievements of the programme:

- correspond with its objectives
- are achieved at reasonable resource use/costs
- correspond with needs, problems and issues (of relevance to stakeholders).

Furthermore, the impact of the programmes, projects, and activities on the improvement of public health policies in the Member States and at EU level is assessed. This is done by evaluating the extent to which the programme has achieved the intended outcomes/impacts, delivered inputs to policy, ensured consistent and complementary implementation with respect to the Member States' expected achievements in the field of public health, and been implemented in accordance with the international public health aims. All this will be undertaken with a view to examining European added value.

1.2 Methods

The results of the evaluation are found by combining four types of information sources, namely desk study, e-survey, interviews and case studies - acknowledging the strengths and the weaknesses of the different methods. The different sources contribute in different ways. While e.g. the e-survey has a widespread coverage of beneficiaries and other stakeholders compared with the interviews and case studies, the issues are, in turn, covered in less detail.

In addition to these weaknesses, there are a number of caveats to be aware when analysing the results of applying the evaluation methodology.

The evaluation of the effectiveness of the PHP in contributing to European public health suffers from a lack of an explicit intervention logic that could facilitate the setting of clear and logically linked objectives and corresponding performance indicators. A consequence of intended results and impacts not being clearly set out is that it is difficult to assess whether they have been achieved. Hence, in practice - as done in the present evaluation - the evaluator attempts to establish the invention logic for the programme, and while doing this, seeks to describe how to measure objective achievement. The caveat is thus that the use of the assessment of objective achievement is associated with the additional uncertainty of target specification.

Even without well-specified targets, an evaluation will analyse results and impacts envisaged to have been caused by the PHP interventions. This is, however, also not straightforward - for at least two reasons.

Firstly, changes to, for example, health policies and ultimately improvements to the health of groups of European citizens are typically the result of complex interactions. Since it is difficult to attribute the change in a given health outcome to a specific PHP intervention, the evaluation merely assesses whether the intervention has contributed to a change in the health outcome.

Secondly, the counterfactual situation of what would have happened to the relevant health output, result, or impact indicators anyway - i.e. without the PHP intervention - is unobservable, and furthermore it is in the given context considered difficult to estimate.

Furthermore, the fact that health improvements take time means that many of the results and impacts of the PHP interventions will not have materialised at the time of the evaluation - but may do so in the medium to longer term. Hence, a caveat is that the evaluation to some extent is limited to assessing the actual project deliverables. Another caveat is here that such speculations, in particular by project participants, are likely to be too optimistic - a caveat that in practice is relevant to all evaluation methodologies where assessments are based on subjective opinions.

1.3 Main results and conclusions

1.3.1 European public health needs - relevance and European added value

The extent to which the PHP has addressed the perceived and real needs concerns three issues. Firstly, the extent to which the needs have been addressed in the annual work plans (AWPs) and listed as a priority area is central. This is a precondition to funding of activities in the field. Secondly, it is important whether activities have actually been funded in the priority area. Finally, it concerns whether the needs have been addressed during the implementation of the activities funded, if any, to the extent that some room for manoeuvre remains within the scope of the project defined in the application and contract documents.

In our view, the activities financed under the PHP have in general been relevant to the overall aim of the PHP, the general objectives and the priority areas listed in the annual work plans.

This is in part a consequence of the far-reaching aim, objectives and priorities of the PHP - making it difficult to identify public health issues that may be considered as not relevant. The aim, objectives and priorities of the PHP are very broad and thus may encompass a wide range of issues in the field of public health.

Furthermore, the activities funded show a good coverage of the work plan priorities. Only few possible gaps have been identified.

However, during the PHP period projects have been funded under many different priority areas as defined in the annual work plans (AWPs). Taking into account the limited available financial resources of the PHP, this may have diluted the potential effects of the individual projects compared with a more targeted effort in selected areas. The point of view that there may have been too many priority areas was also put forward by the Court of Auditors in 2008 and Commission staff during this evaluation. However, since the PHP was the first programme in the field of public health at EU level, it can be argued that it was wise and necessary to fund a broad spectrum of activities; but today a more targeted effort in selected areas seems to be of crucial importance.

In general, the projects selected for the in-depth case studies are found to have provided clear European added value. In this way, the projects selected may be regarded as success stories.

There is no clear cut definition of European added value. According to the EAHC homepage, "European added value refers to the European dimension of the problem and of the project. Projects funded within the EU Health Programme are expected to contribute to solving problems at the European level, and the expected impact of co-ordinating the work at European level should be greater than the sum of the impacts of national activities". Thus, our judgment is based on whether the projects are likely to have gained value by being addressed/implemented at the European level rather than at regional/national levels.

It is the view of the evaluator that there could be even more focus on ensuring European added value of the funded activities - both through the compilation of annual work plans, including choice of priority areas, and through decisions on which applications to accept. This point of view was also put forward by Commission staff interviewed during the evaluation.

1.3.2 Effectiveness

The Court of Auditors (CoA) concluded in an audit of the PHP in 2008 that the programme lacks an explicit intervention logic that could facilitate the setting of clear and logically linked objectives and corresponding performance indicators.

While such lack of intervention logic can hinder the effectiveness of programme implementation, it also has implications for an evaluation - if intended results and impacts are not clearly formulated, it is difficult to assess whether they have been achieved. However, a programme without well-specified targets in the programme documents is not the same as saying that the programme does not have objectives and a plan for reaching these objectives. The case studies illustrate that there is a clear logic between the objectives of the PHP and the projects funded, on the one hand, and the potential contribution of the projects to the achievement of the objectives of the PHP, on the other hand.

The evaluation has found that the projects funded by the PHP have delivered a number of concrete results in the form of reports, articles, websites, training etc. The case studies also demonstrated that the programme has supported the establishment and maintenance of networks and sharing of experiences across Europe. The case studies indicate that the projects in general have strong potentials to contributing to the preparation, development and implementation of public health policy initiatives. The evidence of such contributions was, however, limited. This was confirmed by interviews with Commission staff. It seems that the dissemination of project results is not always targeted to policy makers. In addition, the results of the projects are not always reported in a systematic and transparent way in the final reports, and not all final reports are available on-line.

Based on the case studies, we believe that most of the projects funded by the PHP have produced evidence, data or methodologies with significant value. This view was confirmed by the beneficiaries taking part in the e-survey. However, only few good examples were provided by Commission staff during interviews. The case studies indicate that it may be more difficult in general to justify recurrent projects in terms of new results. However, continued funding may be justified on other grounds, e.g. to ensure sustainability.

The projects funded by the PHP have also helped transmit experience/best practices to and from health stakeholders. This conclusion is based mainly on the case studies, but confirmed by interviews with Commission staff. Networks and conferences may be accentuated as good examples in this regard. However, the extent to which such transmission has actually taken place is not well documented.

The dissemination of project output and results is central to reach users and to achieve the PHP objectives. Both the Commission and the beneficiaries have a responsibility in this regard. The Commission makes available information on the output and results of projects to the public on the EAHC website, including in the project database, and by organising conferences. According to Commission staff interviewed as part of the evaluation, the Commission could do more in this field but is restrained by lack of resources. The case studies revealed that in some cases beneficiaries have done a considerable effort to disseminate project results, e.g. through publication of articles, website, training seminars and conferences. In other cases, the dissemination efforts have not been targeted to all relevant stakeholders.

Most of the budget is allocated to calls for proposals. In recent years, the use of calls for tenders has become more common to achieve more focused outcomes. Furthermore, direct grant agreements are considered important to ensure cooperation with international organisations at the strategic level and the pooling of resources. Challenges posed the existing financial instruments include ensuring sustainability. Networks may need continued funding to maintain activities. Furthermore, a three-year funding period may not always be sufficient to cover the whole project cycle.

The Commission has already responded to some of the limitations of the financial instruments by introducing new instruments in the second Health Programme 2008-2013, most notably operating grants and joint actions. Time will show whether introduction of these new instruments are sufficient to overcome the challenges encountered during the implementation of the PHP 2003-2008.

Another problem encountered in this evaluation is that small organisations do not always have the resources necessary to participate in the programme. This is especially true for organisations from Eastern Europe. Both the interviews with Commission staff and the case studies pointed to this problem.

The case studies also revealed that the present funding model by which projects compete to obtain funding may promote good project start but may also entail less focus on dissemination and implementation of the results.

Another important lesson from the case studies is that some traditional public health researchers applying for PHP funds seem to place less emphasis on aspects such as the link to EU public health policies, implications in terms of national policies and the dissemination of project results beyond the narrow circle of experts directly dealing with each topic. In such cases, it must be considered whether the PHP is ultimately meant to support evidence-based developments at the EU level or to subsidise ongoing research activities of the public health community.

1.3.3 Consistency/complementarity

According to the PHP programme decision, consistency and complementary should be ensured between activities implemented under the PHP and those envisaged or implemented under other policies and activities, in particular in the light of the requirement to ensure a high level of human health protection in the definition and implementation of all Community policies and activities.

The Commission, the Member States and the beneficiaries all have a responsibility in this regard. At both Commission and project levels, coordination takes place to some degree, and this evaluation observed a high degree of complementarity with other Commission policies and actions as well as activities in international organisations. However this was not done in a systematic way.

The case studies selected for in-depth study generally show activity either regarding policy at national or EU level or other national/international activities ensuring consistency/complementarity in the field. Some projects have several activities at national and international policy level whereas others have national or international activities at programme and/or project level.

1.3.4 Support/involvement

The e-survey revealed that most of the stakeholders are familiar with the EU public health policy in general. This also holds for the general programme objectives and annual priorities of the PHP but to a somewhat lesser extent. In general, beneficiaries feel more familiar in this area than other stakeholders. However, other stakeholders employed by international organisations are also very familiar with the EU public health policy and the way the programme supports this policy. Stakeholders employed in the public administration of the Member States feel less familiar with this area. This is an important observation as familiarity is considered closely associated with involvement.

Most beneficiaries have met barriers to receiving funding. Possible barriers include language problems, procedures and cultural differences. As an example, requirements to management might be difficult to fulfil by some PHP applicants as pointed out by Commission staff interviewed as part of the evaluation. Furthermore, some stakeholders might have problems finding the supplementary funding necessary to participate in the programme.

The needs of the different Member States may be translated in terms of priorities in the annual work plans (AWPs), activities selected for funding and in terms of involvement in the implementation of the funded activities. The Commission, the Member States and the beneficiaries all have important roles to play in this regard.

The implementation of the programme should promote national involvement at all levels, including actual involvement of Member States in the choice of priority areas for the annual work plans (AWPs). This is important to increase the potential use of project output and results at national level. Furthermore, it is important that the Commission raises awareness among national stakeholders that complementary funding is highly supportive. The introduction of joint actions as a new financial instrument with the second Health Programme 2008-2013 is a step in this direction.

Through participation in the Programme Committee, the Member States have the opportunity to influence the implementation of the programme. According to Commission staff interviewed during the evaluation, the actual participation/involvement of Programme Committee members differs across countries depending on importance attached to the programme by national systems and individual factors. In general, Programme Committee members do not seem to consult operating stakeholders at national level to a sufficient degree. Furthermore, the frequent turnover of Programme Committee members tends to reduce participation/involvement by the country in question.

The case studies point to good examples of projects that ensure participation at national level, e.g. by appointing national coordinators with special knowledge of the needs and terrain of decision-making in their own countries. However, no evidence has been found as to whether and to what extent the project output is actually used at national level. Neither is evidence found as to what extent national interests are taken into account in the implementation of the projects.

1.3.5 Monitoring

Monitoring is a continuous and systematic process carried out during an intervention, which generates quantitative data on the implementation of the intervention but usually not its effect. The intention is to correct any deviation from the operational objectives and thus improve the performance of the programme as well as facilitate the subsequent evaluation.

Progress has been made since the launch of the PHP to ensure that the monitoring system delivers the information needed to support sound implementation of the programme. In our view, there is still room for improvement. During interviews conducted as part of the evaluation, Commission staff expressed that more resources should be allocated to the monitoring of the programme. A vast amount of information is collected through the online applications for funds under the second Health Programme. Furthermore, the beneficiaries are required to compile a final technical implementation report describing the process and deliverables produced. Relevant information on the activities funded should be registered in a database in order to ease the monitoring of the implementation of the programme, including the coverage and results of activities funded. Based on this register, regular reports on the implementation may be produced and distributed to relevant stakeholders.

1.3.6 Sustainability

By sustainability we understand the continuation of activities after the funding period has ended. Sustainability concerns both cooperation between project participants and the dissemination and use of project results. As regards the dissemination and use of project results, the most wide-ranging sustainability is achieved when activities are continued by other players and/or integrated into existing structures, e.g. through policy initiatives.

This evaluation indicates that project results were sustained by still being available on websites after the end of the project period and through follow-up projects funded by DG SANCO. However, little evidence has been found of the sustainability of project results though policy initiatives, neither at EU nor at national level.

No evidence was found of compilation of systematic legacy plans to ensure sustainability of the projects.

In addition to pursuing sustainability of outputs and results actually achieved, the sustainability of the established collaborations - that might deliver outputs and results also after the EC funding has ended - has been assessed. We believe that the EC funding has helped create critical mass of expertise from a more fragmented expert structure through the establishment of networks and conference events, info days etc.

1.4 Recommendations

The table below provides an overview of our recommendations in order of priority in each evaluation dimension. The five highest ranked recommendations are marked in bold.

Figure 0-1 Overview of recommendations in order for each evaluation dimension in order of priority

1.Relevance and European added value	1	DG SANCO should reduce the number of priority areas in the annual work plans by allowing a maximum of five priority areas in each of the three strands to increase the impact within the priority areas, bringing them to not more than 15 per yearly call. **(1st priority)**
	2	DG SANCO should ensure that the priority areas in the annual work plans are focused and based on a thorough analysis of needs and European added value. This analysis should be carried out by public health experts versed in these issues. **(4th priority)**
	3	EAHC should reveal gaps in the coverage of a priority area by the supported projects to ensure better coverage in future project funding decisions.
	4	DG SANCO should earmark a part of the budget of each annual work plan to funding of activities in areas with the aim to tackle unexpected public health problems that may arise after the drawing up of the annual work plan.
2. Effectiveness	5	DG SANCO should in collaboration with EAHC define clear performance indicators (success criteria) at programme level in order to facilitate follow-up and evaluation of the achievements. These success criteria should be based on a thorough elaboration of the intervention logic underpinning the different areas and priorities of the programme. **(2nd priority)**
	6	DG SANCO should earmark a part of the budget in the annual work plans as easy accessible funds towards additional dissemination efforts. These should be distributed based on a separate 'fast track' and simple application procedure. However, this might require a change in the financial regulation.
	7	EAHC should develop a final report template on outputs/results/impacts to be used by all beneficiaries as a supplement to the technical implementation report.
3. Consistency/complementarity	8	Member States (e.g. Programme Committee members) should at a regular basis collect information about relevant activities at national level, e.g. through public consultations every two or three years, and pass on this information to the Commission.
	9	EAHC should in cooperation with DG SANCO and other DGs carry out regular mapping of activities under the framework programmes for research and development and thereby increase the motivation of other DGs to engage more actively in inter-service consultations.
4. Support/ involvement	10	EAHC and DG SANCO should pursue inclusion of Member States which appear inactive in the programme. These are typically countries with a relatively low GDP/capita. Inclusion could be pursued by providing technical assistance to write proposals (EAHC) or by increasing the EC financial contribution (DG SANCO), possibly on the basis of an alternative cost model. **(5th priority)**

	11	EAHC should distribute an information package with relevant targeted information about the programme to each Programme Committee and National Focal Point members.
	12	EAHC should encourage that annual information days are still held at both EU and national levels to increase familiarity with the programme and annual priorities.
	13	Each Member State should establish a help desk to provide support to potential applicants to overcome barriers relating to funding procedures and reporting.
5. Monitoring	14	EAHC should compile monitoring reports on a yearly basis based on common management performance indicators.
	15	EAHC should predefine keywords for the categories of interventions, health issues and the target groups. The project applicants must choose the keywords which best describe their projects. This improved information about coverage of health objectives will enhance both funding decisions and evaluation exercises.
6. Sustainability	16	EAHC should compile brief descriptions of project results, compatible with the existing database, including considerations about use potential and policy recommendations if relevant, and disseminate these to Commission staff and national stakeholders at the political level, under the caveat that such procedures do not increase the administrative burden for the end user and grant holders unnecessarily. **(3rd priority)**
	17	Project applicants should e requested by EAHC to include considerations about involvement of potential users during project implementation and sustainability in their project applications.

ANNEX 4 – KEY MESSAGES AND EXECUTIVE SUMMARY OF THE MID-TERM EVALUATION OF THE HEALTH PROGRAMME 2008 - 2013

1. KEY MESSAGES

1.1 Key messages of the evaluation

1.1.1 Conception

HP objectives are broad and therefore cover main Public Health concerns

- The overall objective of the Health Programme is to support actions that are designed to be complementary to health policy actions and systems at the national level. Specifically, the Health Programme targets or aims at the following three main objectives as per programming documentation: (1) Improve citizens' health security (HS); (2) Promote health and reduce health inequalities (HP); (3) Generate and disseminate health information and knowledge (HI).
- The interviews with stakeholders (e.g. EAHC officials; Programme Committee members and national focal points; Policy Committee members; officials of other EU financial programmes and representatives of International Organisations) have indicated that overall, interviewees thought that the objectives of the Health Programme cover much of the main needs of the area of Public Health in Europe. However, especially Programme Committee members thought that the objectives are very broad to the extent that most health-related issues could fit under them under any circumstances.
- The results of the online survey with action leaders show that the vast majority of respondents felt that the Health Programme is focusing on relevant priority areas addressing the main public health issues in Europe, but that more individual thematic areas close to their interest or area of work should be included or considered in the overall design of the Programme.

HP actions contribute to EU wide effects

- While the Health Programme needs to focus more on setting clear and tangible health objectives, these can only be reached if the actions funded respect well defined, proven EU added value criteria. The EAHC has developed seven ways on which to assess European added value, developed on the basis of the subsidiary principle and the Lisbon Treaty. The case studies have illustrated that actions funded under the Health Programme contribute to EU wide effects as defined by the EAHC, most prominently in the areas of the promotion of best practice ("(...) to grant to all citizens the benefit from state of the art best practice, and to ensure the capacity building where necessary") and professional networking ("(...) the priority expected results have the objective to support or create networking activities"). According to the case studies, EU added value is least seen in the area of "Free movement of people" ("(...) to ensure high quality Public Health across EU Member States").
- Programme Committee members were confident that the Health Programme can and already does contribute to EU-wide effects, e.g. by pooling resources across the EU and working on joint solutions. Without the Health Programme there would be fewer networks related to public health and less projects between Member States.
- The online survey with action leaders also suggests that most actions close to their area of interest would not have taken place or would have been undertaken with a less ambitious scope in the absence of Health Programme funding.

1.1.2 Design

Scope for efficiency gains by improving the design of HP

- Desk research has shown that the funding of actions is not spread equally over the three main objectives of the Health Programme, and is not targeting the priority areas to an equal extent.
- According to the stakeholder interviews carried out, important efficiency gains could be achieved by reducing the number of priority actions of the Health Programme, and by targeting them at health issues that are of most concern to Member States.

Good utilisation but mixed satisfaction on the new financing mechanisms

- Desk research has shown that since the introduction of the current Health Programme, actions are more widely dispersed among the different financing mechanisms. It also suggests that the range of different financing mechanisms are better suited to accommodate the actions funded, and might increase the effectiveness of their outputs.
- Stakeholders, among them members of the Programme Committee, had mixed perceptions of the new financing mechanisms in general and the use of specific mechanisms to increase effectiveness in the delivery of the outputs.
- EAHC officials viewed the introduction of new financing mechanisms as a very positive development in general and highlighted the point that different financing mechanisms fulfil different purposes.
- The case study exercise conducted over a number of thematic areas has revealed that, regardless of the financing mechanisms actions are funded under, some of the actions assessed face similar challenges and limitations in that they lack clear intervention logics, definition of objectives, target groups and dissemination strategies, which might have a negative effect on the delivery of their outputs.

1.1.3 Management

Outsourcing of HP management to EAHC has significantly improved delivery

- The online survey and the case studies have revealed that overall, action leaders found the Health Programme's selection and management procedures appropriate and well executed, though they would benefit from more support and guidance from the side of the EAHC in the design of the proposal, the running of actions and the dissemination of results.

Dissemination of results is one of the main challenges of the HP

- According to the stakeholder interviews undertaken, the dissemination of results is one of the main issues of the current Health Programme. Certain stakeholder groups, e.g. Programme Committee members, feel not sufficiently informed about the results of actions funded. Given the overall role and function of PC members at national level, this seriously limits the impact of the Health Programme.
- The case study assessment has shown that there is scope for improvement for actions to better outline their dissemination plans to make their results publicly available to a wide-spread audience. In addition, target groups of individual actions are defined to varying extents in the documentation, and often kept very generic and / or not easily quantifiable. Most actions do not seem to have a clear dissemination plan for their outputs, further limiting the impact of the Health Programme.
- Respondents to the online survey suggested that, in order to improve the dissemination of results, the European Commission could increase the dissemination by making them available through their own publications, ideally in a broad range of languages and specifically targeting relevant stakeholders.

1.2. The five highest ranking recommendations

- The evaluation recommends that DG SANCO looks 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, and for indicators to be determined so that progress can be measured in terms of the extent to which these objectives are achieved.
- To ensure an effective implementation of the Health Programme, it is recommended that DG SANCO develops 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. DG SANCO needs to explain and document this process clearly and provide a rationale / justification behind varying levels of funding for each objective.
- It is also recommended that DG SANCO and the Executive Agency provide clearer guidelines at proposal stage and encourage / follow-up their usage, for example:
    - intervention logics and theories of change to participants (definitions and very clear examples of Inputs, Outputs, Results, Outcomes and Impacts of an action);
    - setting indicators that could provide an insight into the extent to which the outcomes are being / have been achieved. Without these it is difficult to determine how effective an action has been and the extent of its impact at the point of assessment;
    - how to set SMART objectives in order to effectively measure progress;
    - definitions of what is required in certain sections of the application form, i.e. "evidence base", given that applicants might have different understandings of certain terms used (without interfering in the peer review process and without encroaching on the capacity of the applicants to formulate the evidence base);
    - assessing potential "EU added value" along clear and quantifiable criteria (as stated above, this aspect is crucial and therefore guidance on it should be made very clear);
    - defining target groups / dissemination plans / evaluation plans.
- The EU added value of actions should feature to a greater extent in the application process. As a condition sine qua non, applicants should describe the type of EU added value their action will bring, potentially making use of the seven EU added value criteria developed by the EAHC and used as part of this evaluation. The template used for assessing EU added value, developed as part of this evaluation, might be considered a starting point for the future assessment of EU added value in proposals. Applicants could provide a self-assessment of EU added value which would be assessed and validated during the evaluation process.
- In order to ensure the dissemination of results by actions themselves, the evaluation recommends that actions allocate parts of the EC funding to dissemination, and to clearly outline this in the financial statements of proposals. Once actions come to an end, it is recommended that DG SANCO makes better use of its dissemination channels, i.e. the Public Health website, DG SANCO publications, newsletter etc. In order to reach national policy makers, DG SANCO and the EAHC should start disseminating a list of HP project results on an annual basis, i.e. to inform Policy Committee members. DG SANCO could also disseminate information to the European Parliament and the Committee of the Regions to promote the application of results at the regional / local level.

2. EXECUTIVE SUMMARY

2.1 Background, objectives and approach

The **Health Programme 2008-2013**, together with the Health Strategy, was adopted on 27th October 2007, and put in place following Decision No 1350/2007/EC[44]. The Programme covers the period from 1 January 2008 to 31 December 2013 and was introduced as the main financial tool through which the principles and objectives of the Strategy would be achieved. It was endowed with a total budget of **321.5 million Euros** to be allocated to projects that could complement, support and add value to national health policies. In this context, projects were expected to include and involve actors from different participating Member States and their results should be applicable to other countries and regions across Europe and in its neighbourhood.

The purpose of the mid-term evaluation was to assess the Health Programme 2008-2013 at its half-way point in order to steer the preparation and design of the post-2013 programming period and take stock of the actions implemented to date. More specifically, the Tender Specifications requested that the evaluation:

1. Provide an overview of the implementation of the Health Programme in the first three years, including a quantitative and qualitative description of the priorities set, the financial mechanisms used (e.g. operating grants, joint actions, tenders etc), the beneficiaries reached, the actions funded, and the intended results.

2. Assess the relevance, effectiveness and efficiency of the funded actions, taking into consideration the fact that the majority of the actions funded will not have provided all the deliverables and final reports when the evaluation takes place, so the assessment of impact will have to be forward-looking.

3. Assess the consistency and complementarity with other relevant EU financial programmes funded from the EU budget, instruments and funds, and the utility of the Health Programme.

4. Measure the progress made in the light of the recommendations in previous evaluations and audits and their follow-up, the efficiency in the use of resources and the European added value.

To fulfil the above objectives, the evaluators developed a methodology primarily based on:

- an in-depth analysis of a sample of actions funded under the Health Programme, to assess their relevance, effectiveness, efficiency, utility, and their contribution to fulfilling the Programme's objectives by 2013;
- a stakeholder interview programme (incl. EAHC officials; Programme Committee members and national focal points; Policy Committee members; Officials of other EU financial programmes; Representatives of International Organisations);
- an e-survey with leaders of all actions funded under the Health Programme between 2008 and 2010;
- interviews with external public health experts who were involved in the evaluation of HP proposals; and,
- an extensive desk-based research exercise, particularly examining the Programme's Intervention Logic and it's consistency and complementarity with other EU Programmes.

[44] Official Journal L 301 of 20.11.2007, pp. 3-13.

The conclusions and recommendations presented in the following section are grouped around three components considered as being important for a programme evaluation, namely conception (the idea/notion behind the programme), design (the plan that establishes a relationship between programme objectives and resources) and management (the practical organisation and coordination of the programme).

2.2 Key conclusions

Conception

HP objectives are broad and therefore cover main Public Health concerns

The objectives of the Health Programme (2008-2013) are far reaching and encompass most areas of Public Health in Europe. The Programme currently lacks a clear intervention logic. The intervention logic could be improved by better determining and describing: 1. the overall goals of the Programme, 2. how those goals might be reached, and 3. how progress can be accurately and effectively measured against the goals.

Process in place for determining priorities in AWPs

There is a process in place for determining priorities in the Annual Work Programme (AWPs) and for ensuring their alignment with the overall objectives of the Health Programme. However, this process is not considered as particularly clear or consistent. Public health officials from different parts of DG SANCO do not all employ the same process for determining priorities. There is no overarching systematic approach defined for this. In addition, setting priorities in the AWPs has not fully taken into account the needs of Member States in the area of Public Health. It would be beneficial to create a mechanism through which Member States could determine common goals and all contribute to the priority-setting process.

HP actions correspond to HP objectives

The HP actions selected for funding correspond to the objectives of the Health Programme to a large extent. This is ensured through the selection process for actions, in which applicants have to outline the extent to which their proposed action will comply with the priority areas in the AWPs as well as the overall objectives of the Health Programme.

Too early for assessment of extent to which actions' results achieve HP objectives

At this stage, it is too early for an assessment of the extent to which the results of actions funded achieve the objectives of the Health Programme, given that most actions are still ongoing and key outputs have yet to be delivered. In the majority of cases there appears to be little deviation to what is detailed in proposals in terms of action outputs and outcomes.

HP actions contribute to EU wide effects

The majority of actions funded under the Health Programme have contributed to EU wide effects to a great extent when taking into account the seven ways of which to assess European added value developed by the EAHC. The case study assessment shows that EU added value generated by the HP actions appears to feature most prominently in the areas of "promotion of best practice" and "networking", and is seen least in the area of "Free movement of people". "Economies of scale" are foreseen in the majority of actions, though there is little evidence of any actions being able to quantify this effectively and accurately. In addition, it is envisaged that the results of many actions will be carefully examined and potentially used

when considering future legislation, formulating policy and / or basing decisions on public health spending.

Many HP actions would not have gone ahead in absence of HP

Most actions would not have taken place or would have been undertaken with a less ambitious scope in the absence of Health Programme funding. The Health Programme appears to be the main funding mechanism in place to support such a diverse range of health-related activities.

Design

Scope for efficiency gains by improving the design of HP

Efficiency gains could be achieved by reducing the number of priorities and targeting them at health issues that are of most concern to Member States and where there is real value identified at intervening at EU level. Determining the potential "EU added value" of interventions is crucial.

New financing mechanisms have been well taken up

The introduction of specific and new financial instruments has generally been received positively and all instruments have been utilised. However, it is still too early to say if some financial instruments have led to more effective outputs than others. Several actions funded under the different financing mechanisms face similar challenges. With all of them there is scope for proposals and interim reports to better define the action's objectives, to outline the intervention logic, target audiences, the dissemination strategy of deliverables and the "EU added value" of the action.

Selection process seems to ensure selection of appropriate/competent applicants

The selection process of actions funded under the Health Programme is strengthened in ensuring that appropriate and competent applicants are selected for funding. However, while in theory the current process offers equal access for all organisations to the Programme, consortia made up of "tried and tested" organisations seem to be more likely to be awarded funding than those that are small / new to the process. The EAHC is aware of this problem and has taken steps to support smaller organisations in their application process, i.e. by developing a series of seminars introducing the Health Programme and explaining the application process.

Smaller organisations are challenged by application process

Smaller organisations find the current application process challenging given its length and complexity. Such organisations might not have the necessary financial or human resources for putting together a proposal, and the process might incur high costs for them if proposals are submitted but not won.

Level of consistency / complementarity between HP actions and other EU policies

There is a level of consistency and complementarity between the actions funded under the Health Programme and other EU policies and activities, as well as activities at the national and international level, though this varies in its extent according to topic areas.
Several of the actions funded under the current Health Programme are follow-on actions from previous interventions funded through the EU. Actions also often use or build on the results of interventions funded under the Research Framework Programmes or the previous Health Programme. It is therefore necessary to share data more effectively between actions funded under the Health Programme and similar activities at national, European and international level, as well as between DG SANCO and other DGs, in order to create synergies and to better identify overlaps.

Management

Outsourcing of HP management to EAHC has significantly improved delivery

The outsourcing of the management of the Health Programme to the EAHC has resulted in a significant improvement in its delivery. While action leaders are generally satisfied with the selection and management procedures currently in place, they would nevertheless benefit from more support and guidance from the side of the EAHC in the design of proposals, the running of actions and the dissemination of results. However, the work load of individual EAHC project officers is high, and providing more support at the current staffing levels would be a challenge.

Scope for improvement of monitoring / management of HP

The EAHC also takes responsibility for monitoring and assessing the quality of dissemination plans and checking the deliverables produced. However, evidence suggests that monitoring data and results are not actively communicated to external stakeholders. In addition, the evaluation has not found any evidence of what procedures are in place at Commission or Member State level to incite stakeholders to make use of actions' results.

Dissemination of results is one of the main challenges of the HP

The dissemination of action results is one of the main challenges of the current Health Programme and should be improved. There is scope for more detailed dissemination strategies in proposals and interim reports, and for target audiences to be better defined. In addition, there is scope for DG SANCO / the EAHC to play a more active role in disseminating results, particularly when an action has come to an end. The dissemination of results at national level seems to be one of the biggest challenges for the Health Programme. In particular, there would be value in targeting national policy makers directly, as it is unlikely that they proactively look for results of actions themselves.

2.3 Key recommendations

Based on the findings and conclusions of the mid-term evaluation, the following recommendations are made to address existing shortcoming and take advantage of room for improvements:

Conception

HP objectives to be more tangible and focussed

The evaluation recommends that DG SANCO looks 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, and for indicators to be determined so that progress can be measured in terms of the extent to which these objectives are achieved.

Better define strategic framework of the HP

It is also necessary to better define a strategic framework for the Health Programme, in which:

- priority areas clearly fit with and complement the objectives of the overall programme;
- clear targets for the Health Programme / the priority areas are introduced;
- a clearer rationale on how DG SANCO has arrived at the priorities in Annual Work Programmes should be provided.

DG SANCO to develop a plan for long-term targets

To ensure an effective implementation of the Health Programme, it is recommended that DG SANCO develops a plan for long-term targets to be achieved by the programme. Appropriate priority actions could then be set, financing mechanisms selected and an appropriate spread among the objectives and priorities ensured. DG SANCO needs to explain and document this process clearly and provide a rationale / justification behind varying levels of funding for each objective.

Consult national health experts when setting priority areas

It would be advisable to introduce a framework / a mechanism through which national health experts could be consulted and engaged earlier in the process of setting priority areas to determine the main health issues of common concern to Member States. It is therefore recommended that DG SANCO works on mechanisms beyond what is already organized via the Programme Committee to make this possible.

Design

Retain current financing mechanisms / Consult action leaders on their experiences with the new FMs

The current system of financing mechanisms should be continued and action leaders should be consulted on their experiences of the new financial mechanisms, the pros and cons of each, and what aspects they would change / improve at the end of each project.

Retain current proposal requirements to show alignment of actions with HP objectives

The evaluation also recommends that the requirement for proposals to outline the extent to which their proposed action complies with the priority areas in the AWPs as well as the overall HP objectives should be retained. DG SANCO officials should continue assessing proposals according to their policy relevance, and external evaluators should continue rating proposals according to their evidence base.

EU added value of actions should feature to a greater extent in the application process

The EU added value of actions should feature to a greater extent in the application process. Applicants should describe the type of EU added value their action will bring, potentially making use of the seven EU added value criteria developed by the EAHC and used as part of this evaluation.

The template used for assessing EU added value, developed as part of this evaluation, might be considered a starting point for the future assessment of EU added value in proposals. Applicants could provide a self-assessment of EU added value which would be assessed and validated during the evaluation process.

Management

EAHC to monitor organisations applying for funding

The EAHC should continue undertaking satisfaction surveys with applicants selected for funding and those rejected to remain aware of problems that organisations might encounter when applying for funding under the Health Programme. The EAHC could also take stock of the type of organisation that are funded / rejected to ensure an equal access for all applicants to receive funding in the future.

The EAHC should also carry out a more in-depth assessment of a sample of actions every year, for example in a case study format similar to the one undertaken for this evaluation. This would enable project officers to develop a more in-depth assessment of actions funded, but also to have data available to publish and further disseminate among stakeholders involved or interested in the Health Programme.

DG SANCO / EAHC to provide clearer guidelines at proposal stage

It is also recommended that DG SANCO and the Executive Agency provide clearer guidelines at proposal stage and encourage / follow-up their usage, for example:

- intervention logics and theories of change to participants (definitions and very clear examples of Inputs, Outputs, Results, Outcomes and Impacts of an action);
- setting indicators that could provide an insight into the extent to which the outcomes are being / have been achieved. Without these it is difficult to determine how effective an action has been and the extent of its impact at the point of assessment;
- how to set SMART objectives in order to effectively measure progress;
- definitions of what is required in certain sections of the application form, i.e. "evidence base", given that applicants might have different understandings of certain terms used (without interfering in the peer review process and without encroaching on the capacity of the applicants to formulate the evidence base);
- assessing potential "EU added value" (as stated above, this aspect is crucial and therefore guidance on it should be made very clear);
- defining target groups / dissemination plans / evaluation plans.

Actions and their results need to be built into a regular reporting system

In order to ensure the dissemination of results by actions themselves, the evaluation recommends that actions allocate parts of the EC funding to dissemination, and to clearly outline this in the financial statements of proposals.

Once actions come to an end, it is recommended that DG SANCO makes better use of its dissemination channels, i.e. the Public Health website, DG SANCO publications, newsletter etc.

In order to reach national policy makers, DG SANCO and the EAHC should start disseminating a list of HP project results on an annual basis, i.e. to inform Policy Committee members. DG SANCO could also disseminate information to the European Parliament and the Committee of the Regions to promote the application of results at the regional / local level.

Data to be shared more effectively

To make full use of the consistencies and complementarities of HP actions with other actions at international, European and national level, it is recommended that data is shared more.

ANNEX 5 – DISCUSSIONS AND CONSULTATIONS WITH HEALTH STAKEHOLDERS AND INSTITUTIONAL INTERLOCUTORS - SUMMARY

National Focal Points and other health stakeholders Summer School of Public Health, Minorca-Spain 20-21/09/2010	National Focal Points meeting 21 January 2011	MS Representatives in Informal Ministerial in Gödölö-Hungary 4-5/04 2011	Health stakeholders and civil society in Health Policy Forum Brussels, 19/05/2011
How to increase the impact of the Health Programme? Participants gave concrete examples of actions financed under the EU Health Programme that has helped in the development of national policies and programmes: • **by providing the model for actions taken at national level** *(INCLA-SNS developed on the basis of ECHI* ***model of key indicators*** *adopted in Spain in 2005* • **by maintaining high on the national political Agenda health issues that the EU Health Programme had dealt with** *(Health inequalities & social determinants of health considered key priority for the Spanish EU Presidency in 2010 - addressing specifically the Roma ethnic minority → adoption of a new public health law in Spain and the support of the Joint Action "Inequalities in Health" funded under the Health programme in 2010.* • **by sharing operational experience and exchanging expertise and knowledge** *(the case of DETERMINE project)*	**Main orientations:** HU (Presidency) underlined the need to **link the Health Programme with:** • **the EU Treaty** (communicable diseases and health threats, tobacco, alcohol) • **EU2020 and digital agenda** (innovation partnership, chronic diseases, healthy ageing; digital agenda – cross-border aspects, active and healthy ageing, supporting health systems), and • **existing legislation** (Cross-Border Health Directive as a clear base for future work). HU underlined **a practical approach:** **– taking into account national challenges** (new health systems/structures – modernisation, sustainability, healthy ageing)**,** and **– EU added value (networks, exchange of expertise to build research, cohesion).**	**Main orientations:** All MS unanimously **supported the need for the future EU Health Programme.** While some underlined **it should be more focused, cost-efficient, based on actions of proven EU added value,** other Ministers underlined it should support existing objectives and wide range of actions. Specifically, BE, LT, IE, NL: **implement adopted and planned Council conclusions** (cross-border, health threats package, joint procurement of vaccines, cancer, chronic diseases, pharma). CY: **supports continuation of the Programme with more active participation of MS**. SE and EL: **no need for major changes**. **Financial procedures** should be **transparent and simplified.** ES: focus on **strategic alliance with pharmaceutical industry**	**Main orientations:** The Forum reasserted that it is **fundamental to have a PHP,** especially **for patients**, and to support health literacy and the fight against health inequalities. The current financial mechanisms for EU public health should at minimum be maintained. A strong emphasis should be put on **health determinants** the Programme should ensure that it is relevant to **immediate health problems**. A **human rights approach** to support EU Public Health was recommended – one that is supported by proper resources and that reflects non discrimination in healthcare provision. Several people expressed their **worry for the future of the PHP**, as they fear that less support will be provided to the work being done towards improved public health and its outcomes.

Future Health Programme: further develop actions to • **enhance dynamic health systems**, • **support evidence based policy making**, • be an instrument to **support the exchange of experiences and practices and the creation of knowledge resources**, and • **support research and actions related to professional and patient mobility**. **The EU Health Programme should be maintained and developed further**, in order to • **support the establishment, extension and operation of EU-wide networks, and** • **emphasise EU-wide activities in key priority areas, including research support in decision making.** • The **financing procedures** should be designed and regulated in a way **to allow the participation of each and all Member States and players, including those with limited financial resources and institutional capacities,** from civil society and academia, **support exchange of experiences and best practice all across the EU.**	<u>Other health topics:</u> **Sustainability & Health systems reform** (PL, MT, PT, CZ, HU) **Healthy ageing & Innovation Partnership, old people, dementia** (FI, MT, CZ, IT, HU) **Health inequalities** (LT, FI, DK, PT) **Inter-sectoral links** (FI) & **especially use of structural funds in health** (MT, SK, HU, CZ) **Cancer** (MT, DK, SK, IT) **Non-communicable & chronic diseases** (MT, DK, IT, HU) **Communicable diseases as they are re-emerging** (HU, MT, CZ) **Alcohol** (FI, DK, HU) **Tobacco** (HU, DK) **Mental Health** (FI, DK) **Promotion and prevention, including promoting healthy lifestyle** (DK, CZ) **Nutrition** (DK) **& Obesity** (FI) **HTA** (MT) **Sexual health policy** (MT) **Networks, exchange of expertise & best practice** (CZ)	<u>Other health topics:</u> **Health systems and organisation of health-care delivery** (BE, FI, IE, LT, NL, PL, PT, UK) **Ageing of population** (IT, LT, NL, PT) **Health inequalities** (LT, PL, SE, UK) **Health in all policies** (ES, PL, PT, SE, UK) **Rare diseases** (FR) **Major and Chronic diseases** (FI, IT, NL, PT, BE) **Communicable diseases and vaccines** (BE, FR, NL, SE, UK) **Prevention/Health Determinants (alcohol, obesity, tobacco etc)** (FI, IE, SE, ES, PT) **Mental Health** (FI) **Health promotion/lifestyles** (IT, PT) **Investment in Health Technology** (FI, IE, IT, LT, NL, PL) **e-health** (IT, NL, PT) **Health indicators** (IT)	<u>Other health topics:</u> **Prioritisation of projects** within the Programme should be **discussed with stakeholders** and that the Programme has longer as well as shorter terms goals. to support **health literacy** and the **fight against health inequalities**. The **difficulty to access** the Programme was raised by some members, even if they understood the need for strict rules for the use of EU funds. In the areas of funding, we **need a balance between Joint Actions and Core funding** added a member. Indicators: **use economical indicators** to measure the impact of the PHPs **as well as other aspects** such as the environment, housing and transport.

ANNEX 6 – LIST OF HEALTH LEGISLATION AND LEGISLATION ON PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

NUMBER	DATE	TITLE
ART. 168 – BLOOD, ORGANS, TISSUES AND CELLS		
BLOOD		
Directive 2002/98/EC of the European Parliament and the Council	27.01.2003 OJ L 33 08.02.2003	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
Commission directive 2005/61/EC	30.09.2005 OJ L 256 01.10.2005	Having regard to Directive 2002/98/EC of the European Parliament and of the Council of 27 January 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
Commission directive 2005/62/EC	30.09.2005 OJ L 256 01.10.2005	implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments
Commission directive 2004/33/EC	22.03.2004 OJ L 91 30.03.2004	implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components
ORGANS		
Directive 2010/45/EU of the European Parliament and the Council	07.07.2010 OJ L 102 06.08.2010	on standards of quality and safety of human organs intended for transplantation.
TISSUES AND CELLS		
Directive 2004/23/EC of the European Parliament and the Council	31.03.2004 OJ L 102 07.04.2004	on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.
Commission directive 2006/86/EC	24.10.2006 OJ L 294 25.10.2006	implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells
Commission directive 2006/17/EC	08.02.2006 OJ L 38 09.02.2006	implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells
Only important basic legislation has been retained here, for the other legislation in relation with blood, organs, tissues and cells please see: http://ec.europa.eu/health/blood_tissues_organs/key_documents/index_en.htm#anchor3		

NUMBER	DATE	TITLE
ART. 168 - COMMUNICABLE DISEASES		
Decision No 2119/98/EC of the European Parliament and the Council	24.09.1998 OJ L 268/1 03.10.1998	setting up a network for the epidemiological surveillance and control of communicable diseases in the Community
Commission Decision 2000/57/EC	22.12.1999 OJ L 21/32; 26.01.2000	on the early warning and response system for the prevention and control of communicable diseases under Decision No 2119/98/EC of the European Parliament and of the Council.
Commission Decision 2000/96/EC	22.12.1999 OJ L 28/50 03.02.2000	on the communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC of the European Parliament and of the Council
Commission Decision 2002/253/EC	19.03.2002 OJ L 86/44; 03.04.2002	laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council
Regulation (EC) No851/2004 of the European Parliament and of the Council	21.04.2004 OJ L 142/1; 30.04.2004	Establishing a European Centre for Disease and Prevention and Control
Health Security initiative	ongoing	The Health Security initiative aims to review and update the existing EU legislation on communicable diseases (Decision 2119/98 and its implementing decisions) and to reinforce the collaboration at EU level on serious cross-border health threats from a global public health perspective ("all- hazards approach" taking account of the existing structures and mechanisms at EU level).
Only important basic legislation has been retained here, for the other legislation in relation with communicable diseases please see:http://ec.europa.eu/health/communicable_diseases/key_documents/index_en.htm#anchor1		

ART. 168 - SCIENTIFIC COMMITTEES		
Commission decision 2010/309/EU	03.06.2010	amending Decision 2008/721/EC as regards indemnities paid to members of scientific committees and experts in the field of consumer safety, public health and the environment.
Commission Decision 2009/566/EC	27.07.2009 OJ L 196, 28.07.2009	amending Decision 2008/721/EC as regards indemnities paid to members of Scientific Committees and experts in the field of consumer safety, public health and the environment
Commission Decision 2009/146/EC	19.02.2009	on the appointment of the members and advisors of the Scientific Committees and the Pool set up by Decision 2008/721/EC
Commission Decision 2008/721/EC	05.08.2008 OJ L 241, 10.09.2008	setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC

NUMBER	DATE	TITLE
ART. 114 - TOBACCO		
Directive 2001/37/EC of the European Parliament and the Council	05.06.2001 OJ L 194 18.07.2001	on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products
Directive 2003/33/EC of the European Parliament and the Council	26.05.2003 OJ L 152 20.06.2003	on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products.
Revision of the Tobacco Products Directive 2001/37/EC concerning the manufacture, presentation and sale	ongoing	Substantial developments in tobacco product regulation have taken place. Therefore, an update of the Directive is necessary in order to address Internal Market issues and respond to recent development (such as new forms of tobacco products and text / picture warnings).
Only important basic legislation has been retained here, for the other legislation in relation with tobacco please see: http://ec.europa.eu/health/tobacco/law/index_en.htm		

ART. 168 AND 114 - PATIENTS' RIGHTS IN CROSS BORDER HEALTH CARE		
Directive 2011/24/EU	09 March 2011	on the application of patients' rights in cross-border healthcare

ART. 114 – PHARMACEUTICAL PRODUCTS		
Regulation EC/726/2004 of the European Parliament and of the Council	31.03.2004	laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
Commission Regulation (EC) No 658/2007	14.06.2007	concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004 of the European Parliament and of the Council
Council Regulation EC/297/95	10.02.1995 OJ L 35, 15.02.1995	on fees payable to the European Agency for the Evaluation of Medicinal Products
Commission Regulation (EC) No 1234/2008	24.11. 2008	concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products
Directive 2001/83/EC of the European Parliament and of the Council	6.11.2001	on the Community code relating to medicinal products for human use
Regulation (EC) No 141/2000 of the European Parliament and of the Council	16.12.1999	on orphan medicinal products
Regulation (EC) No 1901/2006 of the European Parliament and of the Council	12.12.2006	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
Regulation (EC) No 1394/2007 of the European Parliament and of the Council	13.11.2007	on advanced therapy medicinal products and amending Directive 2001/83/EC and regulation (EC) No 726/2004

NUMBER	DATE	TITLE
ART. 114 – PHARMACEUTICAL PRODUCTS		
Directive 2001/20/EC of the European Parliament and of the Council	04.04.2001	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
Directive 2001/82/EC of the European Parliament and of the Council	06.11.2001	on the Community code relating to veterinary medicinal products
Regulation (EC) No 470/2009 of the European Parliament and of the Council	06.05.2009	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
Revision of the Directive on clinical trials to foster clinical research and innovation in the pharmaceutical sector	Ongoing	The objective is to revise the Directive to address the shortcomings identified in previous evaluations conducted by the Commission in order to strengthen knowledge and innovation in clinical research. Issues likely to be addressed are: reduction of administrative delays, overcoming divergent decisions throughout the EU and streamlining of reporting procedures
Proposal for a revision of the Directive on veterinary pharmaceutical legislation	Ongoing	The objective of the review is to increase the availability of medicines on the market, in particular to treat diseases of minor animal species or diseases occurring rarely. In addition, it aims at decreasing the burden on enterprises by streamlining the authorisation processes of veterinary medicines while respecting public health, animal health as well as the environment.
Only important basic legislation has been retained here, for the other legislation in relation with pharmaceutical products, please see: HUMAN: http://ec.europa.eu/health/documents/eudralex/vol-1/index_en.htm VETERINARY: http://ec.europa.eu/health/documents/eudralex/vol-5/index_en.htm		

ART. 114 – MEDICAL DEVICES		
Directive 90/385/EC of the European Parliament and of the Council	20.06.1990 OJ L 189 20.07.1990	on the approximation of the laws of the Member States relating to active implantable medical devices
Directive 93/42/EC of the European Parliament and of the Council	14.06.1993 OJ L 169 12.07.1993	concerning medical devices
Directive 98/79/EC of the European Parliament and of the Council	27.10.1998 OJ L 331 07.12.1998	on *in vitro* diagnostic medical devices
Directive 2007/47/EC of the European Parliament and of the Council	05.07.2010 OJ L 247 21.09.2007	amending Council Directive 90/385/EEC on the approximation of the laws of the Member States; relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical; devices and Directive 98/8/EC concerning the placing of biocidal products on the market

NUMBER	DATE	TITLE
ART. 114 – MEDICAL DEVICES		
Commission decision 2010/227/EU	19.04.2010 OJ L 102 23.04.2010	on the European Databank on Medical Devices (Eudamed)
Proposal for a Directive concerning medical devices and repealing Directives 90/385/ECC and 93/42/ECC	ongoing	The objective is to simplify and strengthen the rules concerning medical devices in order to ensure a high level of health protection while ensuring the smooth functioning of the internal market and the competitiveness and innovation capacities of the sector. The current regime leads to a number of legal uncertainties regarding products falling outside any specific Union legislation. Moreover, it is necessary to address some weaknesses in the system in particular as regards European coordination of the control of Notified Bodies.
Directive concerning in vitro diagnostic medical devices and repealing Directive 98/79/EC	ongoing	The objective is to simplify and strengthen the rules concerning medical devices in order to ensure a high level of health protection while ensuring the smooth functioning of the internal market and the competitiveness and innovation capacities of the sector. The current regime leads to a number of legal uncertainties regarding products falling outside any specific Union legislation. Moreover, it is necessary to address some weaknesses in the system in particular as regards European coordination of the control of Notified Bodies.
Only important basic legislation has been retained here, for the other legislation in relation with medical devices please see: http://ec.europa.eu/health/medical-devices/documents/index_en.htm		

ANNEX 7: CASE STUDIES

SUMMARY

The following case studies have been developed by the EAHC on the basis of its experience in monitoring actions financed under the 1st and 2nd Health Programmes. They have been chosen as representative of activities to be undertaken or continued in the framework of the Health for Growth Programme proposal (see table below). Each of the case studies' action areas may serve more than one Programme objective, however, it is considered that there is always one focal objective where it can be related to. Their purpose is to illustrate the need to equip the present programme proposal with an outcome-oriented structure and follow a pragmatic approach when defining specific objectives and indicators. Such an approach needs to analyze the relevance of the health problem; to appraise the value of the programme's main and specific objectives and proposed areas of activities, in light of EU and Member States' policies in the area; to ensure that the specific actions funded under the programme are geared to provide EU added value and impact; and thus, to demonstrate the logical framework of the programme action as a whole.

As to the methodology of the case studies, it was centred on an analysis of the EU co-funded actions in the selected areas and covered two sets of broad questions:

1. The relevance of EU funding in a given area was checked through a review of the following issues: (a). The health problem under scrutiny; (b). The objectives and means of EU policies/ actions in that specific area; (c). The member state action in the same area; (d). The EU added value of the co-funded actions. These questions relate to the policy relevance block of the award criteria and provide a good basis for appraisal of the relevance of a proposed action.
2. The impact of EU funding in a given area was checked through a review of the following issues: (a). Review of activities, results and outputs; (b).Identification of target groups; (c). Analysis of project impact, both expected and achieved, with the help of valid "proxy" indicators (such indicators were not included ex ante);

Finally, the case studies provide both a conclusion on the intervention logic of the actions under review, as well as lessons learnt and considerations for future improvement.

Specific objectives	Case studies
1. develop common tools and mechanisms at EU level to address shortages of resources, both human and financial, and facilitate up-take of innovation in healthcare in order to contribute to innovate and sustainable health system	→ HTA
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 citizen	→ Pilot European Reference Networks on Rare Diseases/ possibility of extrapolation to non-rare disease networks → ORPHANET
3. Develop shared guidelines for health care quality, transparency and patient safety	→ Cancer prevention and control, incl. cancer screening
4. identify, disseminate and promote the up-take of validated best practices for cost-effective prevention measures, in particular by addressing the key risk factors, namely smoking, abuse of alcohol and obesity, in order to prevent diseases and promote good health	→ Supporting HIV/AIDS prevention
5. develop common approaches and demonstrate	→ Reference laboratories for highly pathogenic

their value for better preparedness and coordination in health emergencies in order to protect citizens from cross-border health treats	agents → SHIPSAN/ implementation of International Health regulations (IHR)
Core-activities	
I. Health evidence	
II. Health legislation	→ Organ donations and transplantation in Europe

CASE STUDY N°1: Health Technology Assessment (HTA)

Health problem under scrutiny

- Improving cost-effectiveness of health systems is a key intervention area in order to ensure overall sustainability of health expenditure in an environment of reduced resources and capital. In this framework, Health Technology Assessment (HTA) can, by identifying resource-effective, safe and effective interventions, provide health decision-makers with an evidence-based and transparent basis for decisions on the uptake and phase-out of health technologies, optimizing use of health budgets and providing best treatments to patients.
- Evidence base for EU action: HTA is an important tool but related resources, knowledge and expertise are unevenly spread in Europe.

Objectives and means of EU policies/ action in the specific area

Objective: Provide a framework for collaboration in the area of HTA across Europe.

Means of action:

- Legislative action: article 15 of Directive 2011/24/EU, foresees the establishment of a voluntary network of bodies responsible for HTA.
- Establish a regular, well-functioning European network linking HTA bodies in Member States with the following specific objectives:
  - support cooperation between national authorities or bodies;
  - support Member States in the provision of objective, reliable, timely, transparent, comparable and transferable information on the relative efficacy as well as on the short- and long-term effectiveness, when applicable, of health technologies and to enable an effective exchange of this information between the national authorities or bodies;
  - support the analysis of the nature and type of information that can be exchanged;
  - avoid duplication of assessments.

MS action in the same area

A majority of MS have designated bodies using HTA as a tool for the planning and development of their health services. However, the use of HTA differs greatly between countries. The EC action on HTA is clearly complementary to MS action since it aims to improve the interaction between these HTA bodies, establishing a common methodological platform and tools which will allow for more effective collaboration, task-sharing and re-use of HTA information.

Aim of EU co-funded action(s) under evaluation

- Development of a common methodological basis for assessing health technologies (a so-called "core HTA model"), as well as tools for effective interaction and cooperation;
- Exploration of feasible working methods for cooperative assessment work;
- Development of common guidelines to streamline HTA requirements for health-related industries;
- Reduction of the duplication of work in Member States through the re-use of core HTA information, that is of the common set of methods and data that can be easily shared across borders;
- Support to capacity building in Member States with limited resources on the use of HTA in their health decision-making processes;
- Collecting of long term and cross border data on the effectiveness of treatments, in view of supporting the development of personalised healthcare;

- Increasing the capacity of stakeholders to be actively part of the HTA process; particularly health professionals and patients' organisations.
- Standardising requirements for the pharmaceutical industry being asked for additional clinical data from Member States, after market authorisation.

EU added value

Principal type of EU added value:

- Economies of scale, insofar common methodological standards for the assessment of different health technologies lead to simplified sharing and re-use of HTA information generated.
- Economies of scale, insofar it contributes to a defragmentation of the decision-making processes regarding the uptake of new medicinal products and medical devices.

Additional EU added value:

- Promotion of best practice, insofar common methodologies developed within project become state of the art HTA tools to be used in national/regional HTAs used for policy decisions.

Activities (2006-2013)

- Establishment of a European HTA network (EUnetHTA) and development of a generic "core HTA model" and related tools including adaptability to different technologies.
- Testing of adapted versions of the "core HTA model" on selected methodologies (medicine and screening device), and development of tools for supporting and enlarging EU level cooperation.
- Joint Action 2 on HTA (2012-2015); scaling up the number of pilots to gain better insights to feasible cooperation models in a regular, non-project setting, establishing scientific advice guidelines to health-related industries regarding the data needs of HTA agencies, as well as doing training in Member States and for stakeholders on the use of the Core HTA model.

Results/outputs

- Development of a common methodological basis for assessing health technologies (a so-called "core HTA model"), as well as adapted versions for a number of different health technologies.
- Tools for enhancing cooperation across the EU, incl. web-based toolkit, information service and clearinghouse, capacity building activities, as well as development of a general strategy and a business model for sustainable European collaboration on HTA.
- Application and field testing of developed tools and methods.
- Guidelines for scientific advice between HTA bodies and industry.

Target groups

Four are the main target groups of the work on HTA:

- Participating HTA bodies: all HTA agencies/ bodies in the EU participate.
- Healthcare industry and providers: HTA bodies interact with industry and more generally healthcare providers in order to perform their assessment.
- EU and MS level policy makers: HTA is a key decision-making support tool for policy makers at the national, regional and local levels.
- Users of health services: the decisions taken by policy makers and providers alike, on the basis of the HTAs will influence the availability of treatments or interventions, incl. the cost element.

Within these groups it is important to differentiate between the following categories:

° Potential (the wider community of experts, healthcare providers and industry, policy makers and users of health services/ technologies, whether targeted by the action or not)

° Expected (those of the previous group expressly targeted by the activities of the pilot ERNs)

° Reached (those of the previous group effectively reached during the duration of the action).

Impact can be strengthened every time we cross another level.

Expected impact

The nature of the actions so far implemented (development and pilot testing of common methodological tools) argues for the following indicators (in growing order of importance):

° Part of the HTA portfolio of activities covered by the common methodologies and tools:

The "core model" can in principle be adapted to a multitude of technologies and interventions, as per the adaptability toolkit; however, it is necessary to have the data from the pilot testing to verify the validity of the methodologies and tools for this specific indicator.

° Coverage of the target population, in terms of effective dissemination of the tools and methodologies: The participation of all the relevant HTA bodies in the network is an indicator for high coverage, although uptake by the participants needs to be demonstrated.

° Impact from the application of the available methodologies and tools: The availability of a commonly developed methodology and its adaptation to specific areas should lead to achievement of the set objectives, such as reduction of the duplication of work and related economies of scale and/ or positive effect from EU-wide standardised data and information requirements for industry. The same is valid for the positive effect expected in terms of improving transparency and quality of decision making process for access to innovative health technologies across the EU. However, such gains, as well as the impact on HTA work at national level and consequences for health decision-making can only ensue after a sufficient number of pilots.

° Sustainability and impact on the long term

Sustainability on the long term is ensured by the Directive 2011/24/EU, which foresees the establishment of a voluntary network of bodies responsible for HTA. However, the long term impact will depend on the level of uptake and commitment of the MS HTA bodies to make use of the common tools developed under the funded actions.

Is it possible to differentiate the impact of EU funded actions under review from MS action?

° The final decisions on the uptake and phase-out of health technologies remain with the MS; it is therefore not easy to determine the degree to which EU collaboration will guide the national level decision making process. However, the establishment of a formal EU-wide network on HTA to support the implementation of Directive 2011/24/EU will make this easier, as the use of the common tools can be directly linked to the ensuing decisions and their effects.

° The impact of the current collaboration can also be distinguished insofar it supports through capacity building activities, the MS with limited experience in the use of HTA so far.

Conclusion

° The objectives, structure, activities and outputs of EU action in the field of HTA follow a clear and solid intervention logic with, at least, a sufficient degree of expected impact. The real impact achieved can be assessed once a substantial number of joint HTA studies are completed.

Other considerations for the future

- An impact assessment of the EU action (to be done following the HTA JA2) should include a number of elements, such as: the resources necessary to jointly produce HTA studies; to what extent HTA information has been used at national level with no/minimal adaptations; whether streamlining of industry HTA dossier requirements simplifies their work; etc.
- A good example is provided by the early assessments of new pharmaceutical products[45]. Many MS use early single technology assessments, in fact rather "appraisals" than "assessments", since most of the evidence is already produced by the pharmaceutical company. At an average cost of 20 000 €, and with 15 MS making them in parallel, total costs would be 15 million € annually, 70 % of which concern clinical issues which can be shared at EU level. If done in an EU context, the data could in addition be used in all remaining Member States. One can add to those savings the costs for industry of providing adapted clinical data to (often different or diverging) demands. Finally, European cooperation on these assessments could contribute to standardised requirements for industry which would increase transparency and predictability, with additional financial benefit.

[45] Up to 50 such products are given Market Authorisation through the centralised EMA procedure in Europe annually, and Directive 89/105/EEC (the transparency directive) requires MS to take a decision on pricing and reimbursement of these products within 90/180 days.

CASE STUDY 2: Pilot European Reference Networks (ERNs) in the area of Rare Diseases[46]

Health problem under scrutiny

- High overall burden of RD, in terms of significant morbidity, premature mortality, loss of Quality of Life (QoL), with extended impact beyond patients, to the socioeconomic potential of family members (often acting as first line carers) and wider community, due to costly management.
- Low prevalence, as well as low number of patients by disease and per MS leads to large variance in access to diagnosis, to quality care and ultimately, to treatment, for lack of available information on and training about the diseases.
- Evidence base of EU action: the limited number of patients and scarcity of knowledge and expertise at MS level gives high potential added value to EU level action.

Objectives and means of EU policies/ action in the specific area

Objective: Further improve the access and equity to prevention, diagnosis and treatment for patients suffering from a rare disease throughout the EU.

Means of action:

- Legislative action: (a).Communication COM (2008) 679; (b).Council Recommendation (2009/C 151/02); (c).Cross Border Health Care (CBHC) directive 2011/24EU (includes Rare Diseases under arts. 12 and 13).
- Support the policies and initiatives of MS in the following areas: recognition of RD; research; development of national plans and strategies; knowledge production and dissemination; empowerment of patient organizations; setup of pilot European Reference Networks.

MS action in the same area

- National plans or strategies for RD exist in several MS and are in development in others;
- Care pathways and collaboration within national health systems with specialized units/ centres of expertise, incl. budgetary support;
- MS support for RD specific registry work and funding for clinical research.

Aim of EU co-funded action(s) under evaluation

Several pilot reference networks have been funded – although diverse, they share key characteristics, including main and specific objectives:

Main objective:

Share expertise and resources to improve the access and equity to prevention, diagnosis and treatment for patients suffering from the specific rare disease throughout the EU.

Specific objectives:

- Identifying expertise/ networking;
- Sharing expertise for patient management;
- Building up standards of care;

[46] These networks, linking expert centres across Europe, have been setup as pilots focusing on the special needs of the Rare Disease area, before the adoption of the CBHC Directive. Therefore, they should be viewed an effort that can, through its specific experience, contribute to the Directive's future implementation, incl. through the development of generic and not RD specific criteria for ERNs.

- Improving clinical research

EU added value

Principal type of EU added value:

- Generation/translation/validation/dissemination of knowledge and information.

Additional EU added value:

- Networking activities/ Development of partnerships (involvement of national team of clinical and other experts)
- Promotion of best practice (validated state-of-the-art knowledge constitutes best practice)
- Economies of scale (both for knowledge production and dissemination activities, as well as from promotion of quality standards for diagnosis, care and QoLife)

Activities

- Several such networks have been funded spanning both 1st and 2nd Community action Programmes.
- Collection and validation of state-of-the-art information on the specific RD;
- Set up of patients' registries for improving knowledge (natural history of the RD);
- Development of collaborative tools for improving quality of diagnosis, care or QoLife, incl. Quality Assurance scheme for labs, clinical guidelines or central diagnostic capacities
- Dissemination of information to healthcare professionals and patients, mainly through patient organisations when they exist.

Results/outputs

Analysis of networks previously and currently funded show that the most valuable resources developed by these pilot ERNs are:

- Shared databases/ registries;
- Shared tools for expertise in diagnosis and treatment, including tele-expertise;
- Guidelines for clinical care and for biological diagnosis and disease-specific information;
- Training tools and sessions, both for healthcare professionals and patients;

Target groups

Two are the main target groups of the work of the European Information networks on rare diseases:

- Healthcare professionals and other experts in the areas related to the concerned RDs. The pilot ERNs provide validated quality knowledge, enabling them to improve the Qof care they offer.
- The RD patients (and families); The pilot ERNs provide validated quality knowledge, enabling them to improve their life.

Within these two groups it is important to differentiate between the following categories:

- Potential (the wider community of healthcare professionals/ other experts and patients dealing with the specific RD, whether targeted by the action or not)
- Expected (those of the previous group expressly targeted by the activities of the pilot ERNs)
- Reached (those of the previous group effectively reached during the duration of the action).

Impact can be strengthened every time we cross another level.

Expected impact

Taking into account the nature of the action, i.e. collection of information and development of shared tools for exchange of knowledge and expertise, the following indicators can be considered (in growing order of importance):

° Part of the information available on the specific RD currently covered by the network:

This is in reality an output and not an impact indicator. However, the scarcity of knowledge and resources in the RD area makes this a first necessary step.

° Coverage of the target population, in terms of effective dissemination of the available information and access to the shared tools, both for healthcare professionals and other experts, as well as RD patients and their families (see section below). Impact can be measured by simple means, by comparing level of knowledge of target groups before and after the action. Expansion and outreach of the network can significantly increase expected impact, as is the case for some of them (Care-NMD).

° Impact from the use of the available information and shared tools.

The availability of quality knowledge should lead to improved quality of care (QoC) from the healthcare professionals in the field and improved QoL for the patients.

There are several indirect ways to measure this: output indicators of quality could be defined when setting up these networks, based on interventions judged as landmarks of the QofC, or on changes in morbidity of morbidity judged as landmarks in QoL. Impact can also be measured by comparing levels of QoC and QoL before and after the action, for the network participants.

However, the direct link of causality between the action and impact as regards the main objective (i.e. improve the access and equity to prevention, diagnosis and treatment for patients) outside the strict level of project participants is more difficult. Until now, it has been implied that the participation of highly specialized expert centres in the network ensures the uptake and use of the tools developed during the funding period. However, this needs to be demonstrated by appropriate indicators.

° Sustainability and impact on the long term:

Sustainability of the network and continuous updating of the information and tools developed in the initial phases are, together with the necessary outreach to new members, key elements for ensuring impact on the long term.

Is it possible to differentiate the impact of EUfunded actions under review from MS action?

° MS policies and strategies for RD (incl. designation of centres) provide the necessary framework of action and funding for the centres of expertise making up the pilot ERNs. The activities of the networks come on top of the regular, clinical work these centres undertake in the framework of their national health system.

° The pilot ERNs develop the collaborative tools and resources that are conducive to the attainment of the common EU and MS objective, of improving the access and equity to prevention, diagnosis and treatment for RD patients throughout the EU. Therefore, action by MS and action at the EU level (co-funded by the HP) is complementary.

° The contribution of the EU level collaborative work can be measured through the development cost of the collaborative tools/ procedures. Even though it has not been done, the impact can also be measured.

Conclusion

- The objectives, structure, activities and outputs of the pilot ERNs follow clear and solid intervention logic with, at least, a sufficient degree of expected impact. Continued funding in the future should incorporate impact indicators, in order to demonstrate the contribution of the pilot ERNs in terms improving access and equity to prevention, diagnosis and treatment for RD patients.

Other considerations for the future

- The main caveat of funding such networks concerns the question of sustainability: there are currently 5.000 recognized RDs and, until now, approx. 15 pilot ERNs have been funded.
- The initial cost of investment for setting them up (approx. EU co-funding of 750.000€/ / pilot ERN for 3 years) is therefore prohibitive with little chance to achieve meaningful coverage of the RD area under the current and future HP funding. On the other hand, the implementation of the Cross Border Health Care directive 2011/24EU will grant, in the future, legal recognition to such types of networks,. It is therefore important (and urgent) to look at alternative approaches in sharing of costs between MS and ensuring funding both at the setup and maintenance phases.
- Several possibilities exist, as shown by the award of the Operating Grants funding to pilot ERNs since 2010, whereby costs are clearly split between hosting institutions (funded by MS) and the network itself. Additional approaches are: (a). The role of national (and EU) clinical research funding; (b). The role of industry, especially for the registries and databases; (c). Leveraging the role of existing knowledge hubs, such as ORPHANET and EURORDIS, to provide "services for a fee", supporting the setup of new networks, with a much lower cost.

1.1. CASES STUDY N°3; ORPHANET: The EU portal for rare diseases and orphan drugs

Health problem under scrutiny

- High overall burden of RD, in terms of significant morbidity, premature mortality, loss of Quality of Life (QoL), with extended impact beyond patients, to the socioeconomic potential of family members (often acting as first line carers) and wider community, due to costly management.
- Low prevalence, as well as low number of patients by disease and per MS leads to large variance in access to diagnosis, to quality care and ultimately, to treatment, for lack of available information on and training about the diseases.
- Evidence base of EU action: the limited number of patients and scarcity of knowledge and expertise at MS level gives high potential added value to EU level action.

Objectives and means of EU policies/ action in the specific area

Objective: Further improve the access and equity to prevention, diagnosis and treatment for patients suffering from a rare disease throughout the EU.

Means of action:

- Legislative action: (a). Communication COM (2008) 679; (b).Council Recommendation (2009/C 151/02); (c).Cross Border Health Care directive 2011/24EU (includes RD under arts. 12and 13).
- Support the policies and initiatives of MS in the following areas: recognition of RD; research; development of national plans and strategies; knowledge production and dissemination; empowerment of patient organizations; setup of pilot European Reference Networks (ERNs).

MS action in the same area

- There is no national level database on RD such as ORPHANET (nor is there any other international level database);
- National plans or strategies for RD exist in several MS and are in development in some others – they are a prime source for information contained in the dbase;
- National teams of experts validate information for the dbase;
- Information from ORPHANET is translated from EN to five MS languages by national teams/ funds (FR, DE, IT, ES, PT).

Aim of EU co-funded action(s) under evaluation

Main objective:

The overall objective of ORPHANET is to serve as the reference portal and principal source of information dedicated to RD for European citizens and beyond.

Specific objectives (covering more specifically, for the ORPHANET JA, 2010):

- To provide an inventory of rare diseases organised to serve the needs in public health, in diagnosis and care and in research (ontology)
- To produce high quality information on each rare disease and ensure continuous updates;
- To offer a directory of expert services in Europe adapted to the needs of each MS and offer new ways to access and present the information;
- To adapt the governance of ORPHANET and support transition from a project structure based on a specific MS's infrastructure, to a truly EU institutional dimension, ensuring sustainability.

EU added value

Principal EU added value:

- Generation/translation/validation/dissemination of knowledge and information despite scarcity of expertise at MS level.

Additional EU added value:

- Economies of scale (information is gathered, validated and disseminated centrally, at marginal cost for MS)
- Promotion of best practice (validated state-of-the-art knowledge constitutes best practice)
- Networking activities/ Development of partnerships (involvement of national team of experts) + Providing technical support, catalysing change and building sustainable institutional capacity (empowerment and capacity building within MS national teams).

Activities (2011-2013)

- Inventory of diseases: Data collection of RD and of RD classifications, through published articles, books and reports from expert groups, as well as indexation of RD with prevalence data, genes and clinical signs and cross-referencing with ICD10, SnoMed-CT and MedDRA; Preparation of the next edition of ICD to be released in 2014
- RD Encyclopaedia: Updating of summary information for 2,400 new and updated abstracts/ year.
- Translation of the inventory of diseases and summary information into French, German, Italian, Spanish and Portuguese. Other languages are in preparation (Dutch/Flemish; Polish)
- Directory of services: Data collection on expert clinics, medical laboratory activities, networks, registries, research activities, clinical trials, orphan designations, marketed drugs and patient organisations in the participating countries.
- Development of customised websites by country in national language(s).
- Production of review articles (50/ year) in the Orphanet Journal of Rare Diseases.
- Publication of national and international clinical guidelines and patient information packages

Results/outputs

- A reference source of information on RD for European citizens and professionals, contributing to optimal diagnosis and management of these severe, chronic and debilitating diseases.
- Coverage of all of the almost 6,000 rare diseases in at least six languages (and maybe more if additional funding is identified at MS level.
- A directory of expert services as defined by MS, in order to access the appropriate care pathways, coupled with a web tool for policy makers and healthcare managers to disseminate the information on the services and on the clinical guidelines they wish to promote.

Target groups

Three are the main target groups of ORPHANET:

- Healthcare professionals and other experts in the areas related to the concerned RDs. ORPHANET provides validated quality knowledge, enabling them to improve the Qof care (or research, lab testing, etc) they offer.
- The RD patients (and families); ORPHANET provides validated quality knowledge to empower them to improve their Qof life.

- Policy makers at EU and MS level are provided with views on the public health impact of rare diseases and on the healthcare services available in Europe.

Within these three groups it is important to differentiate between the following categories:

- Potential (the wider community of healthcare professionals/ experts active in the area of RD, all the patients and family members, all policy makers). As a comprehensive global reference portal of information, ORPHANET has the ambition to reach out to the entire potential target population)
- Expected (those of the previous group expressly targeted by the activities of ORPHANET)

In this case, we have

- Reached (those of the previous group effectively reached during the duration of the action).

Coverage of the target population

- It is estimated that today in the EU, 5-8000 distinct rare diseases affect 6-8% of the population, i.e between 27 and 36 million people. ORPHANET has 20.000 hits/ daily, or 73 Million/ year.

Expected impact

Taking into account the nature of the action, i.e. production and dissemination of knowledge, the following indicators can be considered (in growing order of importance):

- Part of the information available on RD currently covered by the dbase:

This is in reality an output and not an impact indicator. However, the scarcity of knowledge and resources in the RD area makes this a first necessary step.

ORPHANET ranks highly on this criterion. As it is the reference information portal worldwide, coverage is comprehensive, including all rare diseases.

- Coverage of the target population, in terms of effective dissemination of the available information, both for healthcare professionals/ experts, as well as RD patients and their families (see section below). Impact can be measured by simple means, by comparing level of access to information packages of target groups, the expansion of target groups before and after the action and to their expressed satisfaction through online surveys. Expansion and outreach of the dbase can significantly increase expected impact. Measurement of use of the dbase, incl. steady increase in hits shows very extensive dissemination, as also does the interest of countries outside the EU to join and self-fund their participation.
- Impact from the use of the available information.

The availability of quality knowledge should lead to improved quality of care (QoC) (or other outcomes, research, etc.) for the healthcare professionals/ experts in the field and improved QoL for the patients. There are several indirect ways to measure this: by comparing levels of implications of MS in the production/adaptation/translation of clinical guidelines; of the use of the Orphanet nomenclature in the health information systems of the participating countries; of the use of the Orphanet data for public health and research studies; by considering the trends with time in number of uses of each of the proposed services.

However, the direct link of causality between the action and impact as regards the main objective (i.e. improve the access and equity to prevention, diagnosis and treatment for patients) is more difficult to establish. Until now, it has been implied that the base corresponds to the needs of the target groups and therefore, access to the information contained in ORPHANET (notably by highly specialized experts) will lead to its use and therefore better outcomes. However, this needs to be demonstrated by appropriate indicators.

- Sustainability and impact on the long term

Sustainability of the dbase depends not only on renewed funding, but also in ensuring current levels and quality of coverage in the future, while also adapting to emerging trends in IT in general/ in the specific knowledge area and to EU and MS health policies in the RD field.

Is it possible to differentiate the impact of EU funded actions under review from MS action?

- Until today, efforts for information gathering and data validation are ORPHANET driven and not MS driven.
- The initial and continuing investment by FR (through the support to the main beneficiary INSERM), needs to be highlighted – this initial investment and cost has the advantage to lower the necessary investment that individual MS need to provide for offering to their citizens a high quality information in the national language(s).

Conclusion

- The objectives, structure, activities and outputs of the ORPHANET follow clear and solid intervention logic with, at least, a sufficient degree of expected impact.
- Coverage of the target population is comprehensive, while the database also covers the totality of the knowledge area, being today the worldwide reference in the field. Use of the database is very high and steadily increasing, as also does the interest of countries outside the EU to join and self-fund their participation.
- Funding in the future should incorporate impact indicators, in order to demonstrate the contribution of the use of knowledge produced by ORPHANET in improving access and equity to prevention, diagnosis and treatment for RD patients.

Other considerations for the future

- Sustainability will be ensured by transforming the operational framework and governance of ORPHANET into a truly EU institutional dimension, to also include adequate funding component.

CASE STUDY N°4: Projects in the area of cancer prevention and control, incl. cancer screening

Health problem under scrutiny

° Cancer is the second cause of death in the EU. Scientific insights developed over the past decades on specific factors that can lower mortality, demonstrate the value of well designed and implemented large-scale prevention and cancer control activities.

Objectives and means of EU policies/ action in the specific area

Objective: contribute to the reduction of cancer burden in the EU by supporting the Member States in their efforts to tackle cancer by: (a). Providing a framework for identifying and sharing information, capacity and expertise in cancer prevention and control, and (b). Engaging relevant stakeholders across the European Union in a collective effort.

Means of action:

° Legislative action: (a). Communication COM (2009) 291/4, which encompasses previous texts in an updated policy framework[47].

° Support the policies and initiatives of MS in the following areas: Prevention, as the most cost-effective response; Applying best healthcare approaches in practice - identification and dissemination of good practice; Cooperation and coordination in cancer research; Benchmarking process – providing the comparable information necessary for policy and action

MS action in the same area

Each MS has developed a specific action plan against cancer. The EU action against cancer is clearly complementary to MS action since it is supposed to concentrate knowledge and means where economies of scale are likely; to further disseminate good practices; and to provide a framework for identifying and sharing information, capacity and expertise in cancer prevention and control, to include benchmarking across the EU MS or regions.

Aim of EU co-funded action(s) under evaluation

As mentioned, several actions have been funded in the area of cancer, starting before the adoption of the 1st and 2nd health programmes – although diverse, they share key characteristics:

Main objective:

Working together on a European level to prevent and control cancer more effectively and reduce inequalities in cancer incidence and mortality.

Specific objectives:

The activities developed by the different actions have been very diverse. In light of the objective of the present case study, it is more relevant to review the specific objectives of the 2010 Joint Action, which completes and summarizes past actions:

° The building up of a guideline for National Cancer Plan to support integrated and coordinated cancer measures in the MS.

° Raising awareness about cancer prevention among targeted groups

° To improve cancer screening and early detection in EU

° To identify, assess and exchange best practices in cancer care across the EU

[47] Council Recommendation 2003/ 878EC; Council Conclusions of 10/06/2008; Commission Communication 2009/291

- To develop a concerted and coordinated approach for one third of all funding sources dedicated to cancer research.
- To identify areas of data availability and needs in order to get better cancer burden indicators (incidence, mortality, survival and prevalence) across EU.

EU added value

Principal EU added value:

- Economies of scale through the concentration of knowledge and skills: evidence based guidelines for screening are prepared once for all and can be taken up by all MS; the same is valid for the guidelines for preparing a high level standard NCP.
- Economies of scale related to awareness raising actions all across EU are likely as well. Finally the concentration of funding for research is expected to produce not only economies of scale, but also a clear leveraging effect.

Additional EU added value:

- Promotion of best practices: for screening and early diagnosis, for National Cancer Plans development and for cancer care.
- Availability of good data/ information should lead to benchmarking for decision-making. However as a general rule, the link between data comparison and decision-making still needs to be demonstrated.
- Finally, any action putting together all stakeholders at such a large scale is expected to bring added value through networking, as a clearly beneficial additional side effect.

Activities (2003-2013)

- Several such actions have been funded spanning both 1st and 2nd Community action Programmes.
- Development of screening guidelines: it has been the case for colorectal and breast cancers or/and screening promotion as for example cervical cancer.
- Standardisation of data collection: collaboration, networking and standardisation for patients' registries and data collection, including fight against inequalities in cancer care.
- Support to raising awareness: through conferences and dissemination of general information on cancer, through support of health promotion activities such as the week against cancer.

Results/outputs

- Edition of evidence based screening guidelines for colorectal and breast cancers.
- Support of EU-wide promotion/prevention activities: European week against cancer, EU code against cancer, AURORA project for screening of cervical cancer, EPIDERM project for skin cancers, conferences such as Europa Donna Breast cancer, ECPC cancer summit, etc.
- Support of cancer network and among others towards new MS.
- Standardisation of data in relation with the European Community Health Indicators system.
- Support of the European Network of Cancer Registries

Target groups

Three are three main target groups of actions funded in the area of cancer:

- Policy makers at EU and MS level are provided with evidence-based tools (such as the guidelines), enabling the latter for example, to improve their national prevention programmes.

- Healthcare professionals are also specifically targeted, through the sharing of expertise and data.
- The EU citizens, those already affected by the disease, as well as those that may be in the future.

Within these groups it is important to differentiate between the following categories:

- Potential (the wider community of healthcare professionals/ experts active in the area, all the patients and family members, all policy makers).
- Expected (those of the previous group expressly targeted by the funded activities).
- Reached (those of the previous group effectively reached during the duration of the action).

Expected impact

- The impact of screening related actions can be demonstrated by the uptake of the guidelines by the MS, a clear positive result at the level of the policy makers target group. It is more difficult to evaluate impact on health professionals because use of guidelines greatly depends on MS policy. This causality link is even more difficult to establish at the level of the population target group.
- The impact of standardised data collection is clear with regards to the development of the European cancer registries network; data are essential for health policy in general and quality of care policy in particular. Here also the impact is mainly at the level of policy makers.
- Impact of raising awareness is likely when a European campaign is organised at the EU level and has the whole population as a target group. The assessment of this impact is by far more difficult.

Is it possible to differentiate the impact of EU funded actions under review from MS action?

- The impact of the first programmes against cancer (1985 – 2000) has been evaluated via a study in term of mortality reduction (10%) compared to a pre-defined strategic objective (15%). This impact assessment was oriented towards the population at large as target group, but it has several weaknesses, including: the difficulty to demonstrate the exact role of the programme in the mortality decrease observed; the difficulty to differentiate the action at EU level and the action at MS level.

Conclusion

- The objectives, structure, activities and outputs of the projects in the area of cancer follow a clear and solid intervention logic with, at least, a sufficient degree of expected impact. The structure of the current EPAAC JA provides a coherent framework for future action.
- Funding in the future should incorporate impact indicators, in order to demonstrate the contribution of specific actions to the reduction of the burden of cancer in the EU.

Other considerations for the future

The impact of EU action against cancer is not easy to assess: the evidence base of several actions is not so clearly demonstrated and it is difficult to differentiate the impact of EU level actions vis a vis MS action. However the following methods/ indicators can be considered for assessing impact of future actions:

- Screening guidelines: computation of economies of scale by doing one set of Evidence Based guidelines instead of 27.
- Screening guidelines: increased population reached by screening activities in the EU. The impact of the EU action could be identified by, for example, benchmarking countries that have introduced the guidelines in their screening activities, vis a vis those that have not. Additionally, some specific studies could be launched on the impact of the MS activities on the screening population in order to better identify the specific impact and added value of the EU programme.

- Impact of awareness raising activities on the cancer burden has to be demonstrated for example by literature systematic review or specific study and the impact of EU action should then be clearly demonstrated in relation with MS actions.
- For indicators and registries: impact on the decision making process should be demonstrated first (how does an indicator actually influence the political decision making process?).
- Impact of National Cancer Plans: a clear link between a "state of the art" plan and impact on cancer care and/or prevention has to be demonstrated for example by systematic literature review on published impacts or a specific data study.
- For research: economies of scale due to the regrouping of funding (or leveraging effect) can be demonstrated; impact on cancer burden has probably to be measured at various levels (Quality of life, survival, incidence, progression of impact in different population, links between screening and access to care in low capacity health systems).

Breast cancer is a very good example of how to structure the activities of the present programme proposal to maximize impact:

There is a body of evidence demonstrating that screening for women between 49 and 70 years is an effective method for prevention and control of cancer. The way screening has to be organised is put in a guideline after systematic review of the scientific literature. The guideline includes a clear description of the training and quality control activities.
The production of the guidelines in a single, joint effort presents indisputable EU added value. However, this activity does not by itself ensure impact – this requires activities to disseminate the guidelines across the EU; ensure uptake by the MS; monitoring the development and implementation of screening programmes at different levels (national, regional); measuring the effects of the implementation f the screening programmes.
If these activities are carried out, then impact could be assessed by:

- √ Measuring the level of dissemination of the guidelines among MS.
- √ Measuring the uptake of the guidelines by MS including regional and local levels.
- √ Measuring the coverage of the target population involved in screening activities (percentage of women participating in screening activities among all 49-70 years old women in the EU on the basis of a good standardized registration of this indicator).
- √ Measuring the decrease of lead time before diagnosis and decrease of mortality as endpoint of the assessment, taking into account the other factors having an impact on these indicators.
- √ Comparison of MS with good uptake and MS with weak uptake to assess the specific role of EU action, taking into account the differences in the organisation of the screening activities in the MS under comparison.

CASE STUDY N°5: Supporting HIV/AIDS prevention in Europe

Health problem under scrutiny

- HIV/ AIDS infection remains of major public health importance in the EU/EEA; not only is there no cure or preventive vaccine for HIV infections, but new infections are increasing at particularly alarming rates in Eastern Europe, while un-diagnosis and late diagnosis of patients is frequent, with serious consequences.
- Evidence base for EU action: the differences in rates of infections between MS and the threat that this poses due to the free movement of persons, argue for collaborative work on evidence based methods to support prevention and stop the transmission of the infection.

Objectives and means of EU policies/ action in the specific area

Objective: To support actions for the prevention of HIV/AIDS and reduce the burden of the disease.

Means of action:

- Legislative action: (a). Commission Communication 569/2009 "Combating HIV/AIDS in the European Union and neighbouring countries, 2009-2013 serves as framework to support national strategy developments and steers HIV policy coordination between EU countries; (b). Commission Decision No 2119/98/EC setting up the epidemiological surveillance and control of communicable diseases, with sexually transmitted diseases included in the annex I)[48]; (c). Additional existing political commitments to improve HIV/AIDS prevention as e.g. expressed in the Dublin, Vilnius (2004) and Bremen ministerial declarations (2007).
- Support MS activities in HIV/AIDS prevention, as well as in improving quality and access of health services, including testing for HIV and co-infections and treatment and care, especially for vulnerable groups.

MS action in the same area

- Several if not all MS have a strategy or an action plan in the area of HIV/AIDS prevention; moreover, MS have the advantage of controlling all the policy "levers" to ensure effective prevention and access to diagnosis and treatment for vulnerable groups, including social services, access to the competencies and services of local authorities, skills of the informal sectors (NGOs, volunteers, etc). The concrete organisation and implementation of these plans depends on the MS authorities; moreover, the MS have also undertaken specific individual engagements, alongside those of the EC (see above).

Aim of EU co-funded action(s) under evaluation

The EU health Programme has funded more than 60 actions to tackle the HIV/AIDS epidemic in Europe and Neighbourhood countries, mainly focused on prevention activities.

The same strategic aim, i.e. reducing the burden of the disease by improving HIV/AIDS prevention in Europe, will be the subject of a Joint action (planned under the 2012 Work Plan, to be lead by the German Ministry of Health), with a particular focus on the following areas: ,

[48] Additional texts with relevance to HIV/AIDS: Decision No 1150/2007/EC establishing the Programme 'Drug prevention and information' 2007-2013 having as one of the general objectives to prevent and reduce drug use, dependence and drug-related harm; Communication COM/2009/0567 'Solidarity in health: reducing health inequalities in the EU, addressing health inequalities in the Member States as well as the question of disparities in life expectancy, especially for vulnerable groups.

- To promote the integration of quality assurance (QA) and quality improvement (QI) practices into HIV/AIDS prevention programmes (by development of methodologies and tools for QA/QI in HIV prevention);
- To support the implementation of interventions targeting key priority groups, by developing key evidence based projects promoting testing and universal access to treatment.

EU added value

Principal type of EU added value:

° Free movement of persons is relevant to the spread of HIV/AIDS, while in Eastern European MS infections are often accompanied by a high degree of co-infections such as (multi-drug resistant) tuberculosis or hepatitis B and C.

Additional EU added value:

° Several instruments are established for defining benchmarking to support decision making, like the existing European surveillance networks for HIV/AIDS, STI and TB and the 2010 progress report on implementation of the Dublin declaration.

° Networking: actions funded under the Health Programme funding have established expert networks, bringing together Public health authorities, civil society organisation and academic organisations.

° Exchange of best practice: provided by sharing validated prevention methods to reach vulnerable groups.

Activities

As mentioned before, the EU health Programme has funded more than 60actions to tackle the HIV epidemic in Europe and Neighbourhood countries, including actions focusing on improving quality and access of health services, including testing for HIV and co-infections and treatment and care, for vulnerable groups[49]

Results/outputs

° Setup of several specialized networks on HIV/ AIDS prevention, with a special focus on vulnerable groups.

° Capacity building activities for health professionals and civil society organisation, in the promotion of HIV/AIDS voluntary, counselling and testing and universal access to HIV/AIDS treatment, and co-infections (hepatitis and tuberculosis).

° Exchange of good practises in the different areas of promotion, prevention, access to care and treatment.

Target groups

Two are the main target groups of actions funded in the area of HIV/AIDS prevention:

° Persons living with HIV/AIDS and their relatives, with a special focus towards vulnerable groups, belonging to the social excluded population groups, ethnic and sexual minorities.

[49] (a). **ENCAP** project on HIV/AIDS prevention among Intravenous Drug Users in the Baltic countries; (b). **ACTIVATE** (capacity building and Training project in HIV/AIDS Treatment and management across Europe; (c). **SIALON Network** on combined and targeted prevention on MSM population; (d).**EATG** in promoting the availability and accessibility of HIV treatment and care and/or affordable cost of HIV treatment across Europe; (e). **Correlation network** to improve prevention, care and treatment services among vulnerable and high risk populations (e.g. drug users, young people at risk); (f). **The Eurosupport network**, aiming to prevent HIV/AIDS and other sexually transmitted infections by supporting delivery of services on sexual and reproductive health (SRH) .

- Health care and social welfare professionals, as first line carers and support for those affected by the disease, as well as civil society organisations who are active on HIV/AIDS prevention.

Within these two groups it is important to differentiate between the following categories:

- Potential (the wider community of healthcare professionals/ experts active in the area, all the patients and family members).
- Expected (those of the previous group expressly targeted by the funded activities)
- Reached (those of the previous group effectively reached during the duration of the action).

Expected impact

The nature of the actions so far implemented (development, implementation and dissemination of validated prevention methods and other interventions) argues for the following indicators (in growing order of importance):

- To which degree the tools and interventions developed cover well defined thematic fields or geographical areas on HIV/AIDS prevention: although numerous, the individual projects have a very restricted thematic or geographical focus, leading to an overall very fragmented approach (with the exception of SIALON project).
- Coverage of the target population, in terms of effective dissemination of the tools and interventions: such dissemination is extensive within the networks funded, but there is no structured methodology for reaching stakeholders outside the project groups. Moreover, uptake by the participating partners needs to be demonstrated.
- Impact from the implementation of the available tools and interventions: the availability of a validated intervention, whether in prevention or access to care, should lead to the achievement of the set objectives, such as the reduction of the burden of the disease and/ or the improvement of prevention. However, it is difficult to establish the causality link between the implementation of an intervention within a project setting and its impact.
- Sustainability and impact on the long term

The HIV/IDS actions on prevention suffered a major limitation due to the lack of European dimension, mostly conditioned by the availability of resources, limiting the involvement of specific organisations, from some cities/countries and not allowing a generalised intervention. Addiitionally, targeting the most vulnerable groups with effective prevention means ensuring that the action has a sufficient length of time to ensure impact.

Is it possible to differentiate the impact of EU funded actions under review from MS action?

- The European MS are committed to tackling HIV/AIDS in Europe, as they have supported the establishment of extensive European networks and the co-funding of the Health Programme actions, for the implementation of effective prevention policies. However, it is difficult to currently establish the degree to which the tools and interventions developed under the EU funded projects have found their way into the national actions on HIV/AIDS.
- The specific focus on the upcoming Joint Action on quality assurance (QA) and quality improvement (QI) practices into HIV/AIDS prevention programmes may remedy this situation insofar as he participating MS to this JA commit to integrate such quality attributes and measure in their national actions.

Conclusion

- Several projects in the area of HIV/AIDS may be structured so as to ensure impact in their specific context and in line with the main and specific objectives which they have set to achieve. Such, is for example, the case of SIALON, where the project has succeeded in reaching a very significant

part of its target population and where the tools used have been identified as a good practice in the area of prevention.

- However, the same cannot be said of the entire portfolio of projects in the specific area - the problem does not lie with the specific projects, but with the lack of focus on one or two specific areas where a difference can be made and to which adequate resources should then be addressed.

Other considerations for the future

- The potential of tackling HIV/AIDS and its co-infections in Europe is high. Additionally, there is sufficient evidence of effective methods to stop the transmission of the infection and Europe has the expertise developed after more than 30 years of public health programmes and policies.
- However, the present programme proposal should prioritize actions to one or two specific areas where a difference can be made because of the collaboration at the EU level and to which adequate resources should then be addressed. There are especially some potent "quick wins": for example eradication of mother-to-child transmission (MTCT) in Europe can be achieved with relatively low investments on antenatal screening and effective treatment of pregnant women and newborns, independent of their social status or if they belong to an ethnic minority group. The same is valid for HIV/AIDS testing and HAART treatment, which is an effective prevention means to reduce transmission of the infection onwards, limiting the disease burden and producing savings by averting new HIV/AIDS cases.

CASE STUDY N°6: Reference Laboratories for highly pathogenic agents (JA QUANDHIP)[50]

Health problem under scrutiny

° Europe is facing continuous threats related to emergent communication diseases, with natural or intentional release as illustrated by several events caused by highly pathogenic agents in the recent past (H5N1, Marburg, Chikungunya, Lassa fever, C.difficile 027, H1N1, E. coli, etc.) in recent years. Such threats will, by definition not stop at borders and preparedness and response depends on timely and accurate identification of the specific agent.

° Evidence base for EU action: The laboratory preparedness among EU MS is heterogeneous, with some laboratories using well-established methods for identification of highly pathogenic bacteria and virus (Bio-safety group 3 and 4).

Objectives and means of EU policies/ action in the specific area

Objective: Ensure quality diagnostic capacity in order to provide the scientific evidence for response at the level of the European frontline responders: health care professionals, security officers and forensic experts.

Means of action:

° Legislative action:

➢ Commission Decision No 2119/98/EC setting up the epidemiological surveillance and control of communicable diseases.

➢ Commission Communication (2009)0273on Strengthening Chemical, Biological, Radiological and Nuclear Security in the European Union - an EU CBRN Action Plan

➢ International Health Regulations (IHR) 2005 requiring MS to assess and develop core capacities to meet their requirements in relation to surveillance and response

° To support the MS capacity to identify and respond to threats and foster necessary cross-border collaboration with national European, and International organisations.

MS action in the same area

MS have the responsibility for national laboratories; they have also developed national plans for preparedness and response, as well as Quality Assurance schemes for national laboratories. However, the cost of setting up and ensuring required diagnostic quality for such laboratories is very high, while not all MS have the same technical capacity.

Aim of EU co-funded action(s) under evaluation

QUANDHIP will perform European Quality Assurance Exercises (EQAEs) for bacteria and viruses, including antimicrobial susceptibility test for bacteria; extend the repository for bacteria and virus; improve the existing checklists for laboratory infrastructure, containment, and operational bio-safety and bio-security; and develop standards operating procedures to support the coordination of response to cross-border highly infectious pathogens events.

EU added value

Principal type of EU added value:

[50] Establishment of the Quality Assurance Exercises and Networking on the Detection of Highly Infectious Pathogens (QUANDHIP) Joint action, which is an innovative initiative bridging frontline responders and the specialised (ENP4Lab) and (EQADeBa) networks, involving 33 laboratories from 21 EU MS.

- Economies of scale: the development of the European laboratories of reference network with individual laboratories covering more than one MS has increased the return on investment, while the cost of creating such highly specialised laboratories at individual EU MS was prohibitive.

Additional EU added value:

- Promotion of best practice: insofar the check list on bio-safety and bio-security and the quality of laboratory diagnostic methodologies developed under the EU network conforms to "best laboratory practice" standards.
- This is an internationally recognised initiative, strengthening the EU as an effective actor in the Global Health security initiative, particularly on laboratory preparedness (GHSAG -LN).

Activities

QUANDHIP JA builds on previous levels of collaboration, as follows:

- The EQADeBa project (Establishment of Quality assurances for detection of highly pathogenic bacteria of potential bioterrorism risk), developed the validation and improvement of the diagnostic capacities for bacteria based threats (risk group 3).
- The ENP4 Lab project (European Network of P4 Laboratories) enhanced the European preparedness for the detection of emerging virus based threats (risk Group 4).

Results/outputs

QUANDHIP JA, builds on previous levels of collaboration, as follows:

- EQADeBa project delivered: the establishment of a repository of quality-controlled reference samples of high-threat bacteria; the performance of three External quality assurance exercises; and the development of training programme for laboratory assurance of quality, bio-safety and bio-security
- ENP4 Lab project delivered: the inventory of EU P4 Laboratories capabilities, including the agents of expertise; the development of check list for performing Bio-safety and Bio-security audits; the standardisation of Group 4 agents' diagnostics through quality assurance exercises; and the elaboration of a Mobile laboratory feasibility study report

QUANDHIP JA will continue these efforts to:

- Perform external quality assurance exercises (proficiency testing) for highly pathogenic agents group 3 and 4;
- Develop bio-safety and bio-security check list used for the auditing of the laboratories; and
- provide a feasibility study of the Mobile laboratories, applied by Instrument of Stability from DEVCO.

Target groups

Three are the main target groups:

- MS authorities, with responsibility in implementing health protection policies and procedures and more specifically the laboratories themselves as key actors for the organization of the response.
- Laboratory workers dealing with high threat pathogens, frontline health care workers and forensic responders, bio safety experts, transport carriers of biologically dangerous goods, other categories with occupational risk.
- European citizens in case of event of natural outbreaks and non-natural release of highly infectious pathogens.

Within these three groups it is important to differentiate between the following categories:

- Potential (the wider community of healthcare professionals/ other experts, MS authorities and EU citizens that may be affected by an event as described above)
- Expected (those of the previous group expressly targeted by the activities of the actions under review)
- Reached (those of the previous group effectively reached during the duration of the action).

Impact can be strengthened every time we cross another level.

Expected impact

The potential impact on public health is high, as most of the BSL3 and BSL4 are highly pathogenic, causing high morbidity and mortality. Taking into account the nature of the action, i.e. EQAE for P3 and P4 laboratories, the following indicators can be considered (in growing order of importance):

- Part of the area of diagnostic capacity for highly pathogenic agents effectively covered by the actions: building on EQADeBa and ENP4 Lab projects, QUANDHIP covers the entire field.
- Coverage of the target population in terms of effective dissemination of the results: the actions under review bring together (i.e. cover) all the laboratories which would be required at the EU level to identify the pathogenic agents in question and are at the root of the response systems, while also engaging the relevant MS authorities.
- Impact from the use of the available tools: the impact of the EQAE on the performance of the participating labs is very high, as the capacity of detection for highly pathogenic bacteria has improved significantly, from 62.6% to 92%, from 2006-2009.
- In principle, such performance should also positively affect the level of impact to the European frontline responders; to other categories with occupational risk; as well as to the EU citizens at large. However, this can only be substantiated in the case of an outbreak – even though modelling/ forecasting exercises could quantify the positive effect of high quality and rapid diagnosis of a highly pathogenic agent in reducing the impact of an outbreak. Sustainability and impact on the long term:

Sustainability of the network and continuous quality assurance and control measures need to be ensured.

Is it possible to differentiate the impact of EU funded actions under review from MS action?

- It is, simply because the actions under evaluation lead to sharing of diagnostic capacity between MS, which would not have happened without the contribution of EU funded actions.

Conclusion

- The objectives, structure, activities and outputs of EU action in the field of reference laboratories for diagnostic support towards preparedness and response to health threats emanating from highly pathogenic agents follow a clear and solid intervention logic with, at least, a sufficient degree of expected impact.
- The creation of a network of reference laboratories improves detection capability in general across the EU, by the standardisation of methods, by fostering collaboration, through exchange of knowledge, training, and development of scientific evidence.

Other considerations for the future

N/A

CASE STUDY N°7: Support the acquisition of the core capacities for the implementation of the International Health regulation (IHR 2005) by the EU MS

Health problem under scrutiny

- Europe is facing continuous threats related to emergent communication diseases, with natural or intentional release as illustrated by several events caused by infectious pathogens, air borne diseases (influenza, measles, legionella), water and food borne diseases (virus and E. coli, etc) in recent years. Such threats will, by definition not stop at borders and preparedness and response depends on timely and accurate identification of the specific agent.
- Evidence base for EU action: In the past, differences in public health preparedness and response have repeatedly been seen within the EU resulting in delayed public health interventions. Different responses to similar health threats in the different EU countries are likely to negatively affect the acceptance of the general public and the compliance by health professionals.

Objectives and means of EU policies/ action in the specific area

Objective: To support the EU MS to assess and develop core capacities to comply with IHR 2005 requirements[51].

Means of action:

- Legislative action: (a). Commission communications (2003/545 and 2006/5520), followed by Council conclusions (30/11-1/12/2006): the Commission will help the implementation of the IHR at EU level by strengthening collaboration with WHO; (b). Directive 2010/65 on reporting formalities from ships arriving and/or departing from ports; (c). Decision No 2119/98/EC setting up the epidemiological surveillance and control of communicable diseases (annex I incl. diseases covered by the international health regulations and other unclassified serious epidemic disease)[52];
- Strengthening the risk assessment and capacity to respond to health threats due to biological, and chemical agents, and create a sustainable and integrated strategy at EU level for safeguarding the health of citizens and preventing the cross-border spread of diseases.

MS action in the same area

- Member states are in the process of developing national plans to strengthen their core capacities in relation to surveillance and response to all health threats in line with their legal obligations under the IHR.

Aim of EU funded action(s) under evaluation

To support the EU MS to acquire the core capacities for the implementation of the International health regulation (IHR 2005), including the emission and exchange the maritime declaration of health in electronic format, in compliance with Directive 2010/65, no later than 1 June 2015.

EU added value

Principal type of EU added value:

[51] The IHR 2005 set implementation deadlines for parties to assess and develop core capacities to meet its requirements in relation to surveillance and response to all health threats and to have developed and implemented plans to ensure that these core capacities are present and functioning within their territories (within 5 years of entry into force, i.e.2012)

[52] The EC is currently developing an impact assessment for an initiative on "Health Security in the European Union", which examines inter alia options for legal basis of the Health Security Committee to support the Council in achieving a coherent approach to the preparedness for and response to health threats and especially public health emergencies of international concern as defined in IHR 2005;

- Implementation of legislation: supporting the EU MS to acquire the core capacities for the implementation of the International health regulation (IHR 2005)

Additional EU added value:

- Exchange of good/ best practices: the sanitation inspections SHIPSAN TRAINET European Manual, proves the benefit of adopting common inspection standards and complying with the maritime declaration of health.
- Networking: the relevant EU networks are a key tool for supporting the implementation of IHR 2005, involving a multidisciplinary group of experts, strengthening cooperation between different sectors, national and international organisations.

Activities

The EU health Programme has funded several actions to develop a framework to identify and exchange good practice in all preparedness activities, including their transferability and procedures for travel related contact tracing[53].

Results/outputs

The European networks have produced results relevant to support the EU MS acquisition of the core capacities for the implementation of the IHR 2005.

- The SHIPSAN project has developed the European Manual for hygiene standards and Communicable Disease surveillance on passenger ships.
- The REACT project developed training tools and models addressing generic preparedness and response for the international spread of infectious disease at European level.
- The Episouth project developed reports and concept for future collaboration in Cross-border epidemic intelligence, Vaccine preventable diseases and migrants, Cross-border emerging zoonoses and Training in applied epidemiology, and developing the Mediterranean network.
- The EpiSouth+ is working on the establishment of the Mediterranean regional laboratories network, development of generic preparedness plan and risk management procedures.

Target groups

Three are the main target groups:

- MS authorities and decision makers, with responsibility in implementing health protection policies and procedures and more specifically the key actors for the organization of the response.
- Those directly involved in the maritime transport industry, travellers, workers in transport sector, port authorities (for SHIPSAN); experts and public health professionals for the other projects.
- European citizens at large at risk in case of outbreaks.

Within these three groups it is important to differentiate between the following categories:

- Potential (the wider community of healthcare professionals/ other experts, MS authorities and EU citizens that may be affected by an event as described above)
- Expected (those of the previous group expressly targeted by the activities of the actions under review)
- Reached (those of the previous group effectively reached during the duration of the action).

Impact can be strengthened every time we cross another level.

[53] SHIPSAN, SHIPSAN II, REACT, EpiSouth, EpiSouth+

Expected impact

Taking into account the nature of the funded actions, i.e. networking, development and exchange of good/ best practices and support to implementation of legislation, the following indicators can be considered (in growing order of importance):

° Part of the areas relevant to the IHR 2005 effectively covered by the actions: for SHIPSAN, the successive projects address all of the relevant stakeholders and cover a significant part of the thematic area. The other actions have a more limited scope, both thematic (generic preparedness and capacity building), as well as geographic (Southern European MS)

° Coverage of the target population in terms of effective dissemination of the results: again there is a difference between SHIPSAN and the other actions; the sanitation inspections manual refers to an obligation for the reporting formalities for ships and therefore, dissemination and coverage is ensured. For the other projects such dissemination is extensive within the networks funded, but there is no structured methodology for reaching stakeholders outside the project groups. Moreover, uptake by the participating partners needs to be demonstrated.

° Impact from the implementation of the available tools and interventions: again, the expected impact is different for SHIPSAN and the other projects: the hygiene inspections applying common sanitation standards are expected to have a significant contribution to the reduction of food borne and waterborne diseases, as demonstrated by US Vessel Sanitation Programme (VST). Additionally, experience acquired with SHIPSAN will be useful for the development of the cargo ships manual and inspection programme.

For the other actions, the networking and exchange of experience elements could lead to the achievement of the set objectives, such as strengthening of core capacities and the development of a coordinated public health culture of risk assessment and risk management of hazards events. However, it is difficult to establish the causality link between the implementation of an intervention within a project setting and its impact.

° Sustainability and impact on the long term

The need for strengthening core capacities and fostering European collaborations (networking) with the aim of developing risk assessment and risk management skills and tools is permanent. However, each of the networks has a restricted thematic or geographical focus, which may affect its sustainability, unless they are streamlined in a more structured, long term framework.

Is it possible to differentiate the impact of EU funded actions under review from MS action?

° The responsibility to develop core capacities to comply with IHR 2005 requirements with each MS individually as signatory party to the international agreement. However, at least for the area covered by SHIPSAN, the link is clear between the EU level collaboration and strengthening of core capacities at MS level.

Conclusion

° The objectives, structure, activities and outputs of EU action in the field of support to the implementation of the IHR 2005 follow clear and solid intervention logic with, at least, a sufficient degree of expected impact.

° Activities under SHIPSAN cover in a comprehensive manner the entire thematic area and its deliverables are directly linked to reporting formalities for ships, its effects finding fertile ground outside its initial scope (from passenger ships to cargo).

Other projects in the area are also structured so as to ensure impact in their specific context and in line with the main and specific objectives which they have set to achieve; however, it is more difficult

to establish the causality link between the implementation of each of the actions and the desired result in terms of strengthening core capacities.

Other considerations for the future

- The experience acquired with SHIPSAN will be useful for the development of the cargo ships manual and inspection programme covering chemical hazards what will increase the EU added value by the development of the risk assessment tools for chemical threats in the cargo transportation in Europe and the definition of measures for prevention, control and use of adequate decontamination measures, to avoid the risk for seafarers, passengers and port officers.
- Other actions reveal the difficulties to effectively cover gaps in MS capacities: for example the communicable disease surveillance of health care workers (frontline responders) is difficult, costly and in some countries even impossible due to the legal barriers.
- Future efforts should address the fact of the restricted thematic or geographical focus of the networks and the need to streamline them in a more structured, long term framework.

CSE STUDY N°8: Projects in the area of Organ donation and transplantation in Europe

Health problem under scrutiny

- The availability of donor organs is often a question of life and death for patients requiring a transplant (28.000 patients per/ year in the EU for a waiting list of approx. 80.000). The overall insufficient availability of organs in MS is tackled by exchanges of organs across the EU, with the benefits of also ensuring a better match between donor and recipient and thus improving the quality of the transplantation.
- Evidence base for EU action: Available organs should be able to cross borders without unnecessary problems and delays. Inconsistent safety and quality of organs and different levels of efficiency in national transplant systems require EU-wide action.

Objectives and means of EU policies/ action in the specific area

Objective: Ensure availability of organs of human origin for transplantation across the EU, while adhering to the best standards for safety and quality.

Means of action:

- Legislative action: (a). Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation; (b). Commission Action Plan on Organ Donation and Transplantation, strengthened cooperation between Member States (COM (2008 819/3))
- Support projects and joint actions that help Member States to develop common knowledge, share experience and expertise, identify and share good practices, identify and foster cooperation in the overall area of organ donation and transplantation.

MS action in the same area

- The concrete organisation of donation and transplantation is to be taken up at national level by the national competent authorities. National competent authorities are regularly invited to present their activities and national action plans to their peers in the network of competent authorities, for mutual inspiration and learning.

Aim of EU co-funded action(s) under evaluation

Several projects have been funded – although diverse, they share key characteristics, including main and specific objectives:

Main objective:

Support MS in their efforts to achieve a consistent high number of safe and qualitative organ transplants.

Specific objectives:

- Developing common standards and procedures for safety and quality;
- Raising awareness with a view to increase donation rates;
- Identifying, documenting and sharing good practices to increase organs from deceased donors, as well as to obtain organs from living donors;
- Fostering cooperation and supporting exchange of know-how and capacity building activities;

EU added value

Principal type of EU added value:

- Implementing different aspects of EU legislation on safety and quality of organs

Additional EU added value:

- Economies of scale: it would be too complex and demanding for one Member State to develop all aspects of knowledge e.g. development of registries for patient follow-up or utilisation and need for transplant centres can be optimized by establishing multi-country collaborations
- Promotion of best practices: variation in efficiency, organisation and number of donations/transplants, as well as safety indicated strong potential for identification and sharing of good/best practices
- Benchmarking for decision making: several project outputs serve as guidance for next legislative steps at EU level.
- Free movement of persons: while patients could go cross-border to access surgery, access to organs abroad is to be coordinated between Member States
- Networking: different projects bring competent authorities of different Member States regularly together. Twinning brings specific experts of 2 or more Member States together.

Activities

- Development of common standards and procedures of safety and quality:
  - firstly in Directive 2010/53/EU and the (planned) implementing legislation
  - specific procedures/elements are further addressed in different projects like post-transplant follow-up or registries on living donors.
- Development of campaigns to raise public awareness/willingness to donate.
- Identification, documentation and sharing of good practices to increase organs from deceased donors.
- Identification, documentation and sharing of good practices to obtain organs from living donors.
- Expert visits, exchanging of know-how between national experts.
- Establish cooperation between different EU Member States.

Results/outputs

Analysis show that the most valuable resources developed are:

- Shared models for standards, procedures and databases/registries;
- Manuals/toolboxes with guidance for organisational set-up and training programmes;
- Exchange of expertise and knowledge, especially on quality systems and indicators;
- Cross-border collaborations;
- Increased public awareness/willingness for organ donation;

Expected short term outcomes of above actions are:

- The set up of a national competent authority and establishment of national safety and quality standards;
- The set-up and identification of donor coordinators;
- The monitoring of activity of transplant centres.

Target groups

Three are the main target groups of the work:

- Policy makers: specifically national competent authorities and all institutions/ organizations involved in coordinating and overseeing activities within a MS;
- Healthcare professionals and other experts in the related areas: transplant centres, procurement/donor centres, health professionals active in transplantation, etc.
- The general public, i.e. those that may or may not be affected by the specific health problem, either as transplant candidates or organ donators.

Within these three groups it is important to differentiate between the following categories:

- Potential (the wider community of healthcare professionals/ other experts, authorities and citizens, whether targeted by the action(s) or not)
- Expected (those of the previous group expressly targeted by the funded activities)
- Reached (those of the previous group effectively reached during the duration of the action).

Impact can be strengthened every time we cross another level.

Expected impact

The funded actions consist of supporting MS in their efforts to implement EU legislation; this is done by initiating different types of activities addressing specific issues that are critical for the application of the legislation and included in the action plan (i.e. safety and quality issues; awareness issues; increased organ availability; etc.). These efforts are supported by a network of national competent authorities which ensure linkage between actions at the EU and MS level.

In view of the above, the following indicators can be considered (in growing order of importance):

- Part of the issues related to ensuring the objectives of the EU action covered by the actions: The portfolio of funded actions ranks highly on this level, as all relevant areas which are critical for the successful implementation of the EU legislation and the achievement of its goals are covered. The
- Coverage of the target population, in terms of effective dissemination of the results of the funded actions (development of common standards, exchange of best practices, capacity building and cooperation, etc): at this level, impact can be measured by simple means, by comparing levels of access of target groups to the knowledge and tools developed under the programme; by the expansion of the target groups before and after the action, to include other MS: by measuring the degree of uptake of the knowledge, standards, good practices and tools by the different target groups. For example, effective implementation of quality and safety standards by responsible authorities in MS or setup of registries, etc. The horizontal linkage of the different thematic actions through the network of national competent authorities is a factor that can lead to a wider and more active uptake by MS.
- Impact from the use of the tools and knowledge developed under the funded actions:

The use of the tools and knowledge produced in the framework of the funded actions should lead to achieving the objectives of EU action in the area, i.e. a well organized transplantation system ensuring the quality and safety of human organs, increasing organ availability and enhancing the efficiency and accessibility of transplantation systems in the EU.

It is however difficult to pinpoint the concrete impact due to missing long term indicators. For example, transplant donor coordinators undertook training, but it is too early to identify the effects of that training in improving their skills and its effects on organ availability. The development of campaigns for raising awareness poses the same problem, i.e. a long time frame is required to measure the impact of awareness actions and their effect in increasing availability of organs, etc.

- Sustainability and impact on the long term:

  The directive incorporates a monitoring element which, together with the functioning of the networks of national competent authorities will provide a long term framework for action.

Is it possible to differentiate the impact of EUfunded actions under review from MS action?

The development of knowledge, tools, manuals, training courses and organisation of exchange of expertise between Member States can be clearly identified at EU level. Nevertheless, to have full impact, results/inputs of EU activities are to be taken up in national activities, in particular by national competent authorities. A consistent and comparable evaluation of national uptake would further contribute to enable the concrete measurement of impact of EU activities.

Conclusion

- The objectives, structure, activities and outputs of the actions funded in the area of organ donation and transplantation follow a clear and solid intervention logic with, at least, a sufficient degree of expected impact.
- The fact that these activities are undertaken under a specific legal framework and in close relation with the network of the national competent authorities enhances their impact by ensuring transferability: the results of the different funded actions can be expected to be up taken in the MS and contribute to the improvement of the situation as regards quality, safety and availability of organs, as well as quality of the transplantation process.

Other considerations for the future

- The setup of programme level objectives and indicators could facilitate the measurement of concrete impact with respect to the projects funded under this topic area.