COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 24.5.2006
COM(2006) 234 final

2004/0042 A (COD)

Amended proposal for a

DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

establishing a second Programme of Community action in the field of Health and consumer protection (2007-2013)

Adaptation following the agreement of 17 May 2006 on the Financial Framework 2007-2013

(presented by the Commission pursuant to Article 250(2) of the EC Treaty)

EXPLANATORY MEMORANDUM

I. Introduction

On 6 April 2005, the Commission proposed a wide-ranging and ambitious health and consumer protection programme 2007-2013[1] based on the assumption of a € 1,203 million budget (out of which € 969 million was for health). This proposal foresaw a significant increase in existing Community health action from three to six action strands in order to address cross-border health challenges and to meet stakeholders' expectations.

In its first reading Opinion of 16 March 2006 on the health part of the programme, the European Parliament endorsed the objectives and main actions proposed by the Commission, underlined its preference for a separate health programme, enlarged further the scope of proposed health action and requested a budget of €1,500 million.

However, following the inter-institutional agreement on the Community Financial Framework 2007-2013, the final budget for health action was settled at € 365.6 million, i.e. approximately one third of the budget initially foreseen in the Commission proposal of April 2005.

Given these resource constraints, it is necessary to take a more focused approach to Community health action. The Commission therefore proposes to refocus the scope of the programme along three broad objectives: to improve citizens' health security; to promote health to improve prosperity and solidarity; and to generate and disseminate health knowledge. Priority measures will be identified on an annual basis in order to allow the programme to focus its resources on a few carefully selected areas adapted to the political context and emerging needs.

This is the purpose of the current modified proposal which replaces the original Commission proposal of April 2005 as far as health action is concerned. In presenting a separate proposal for health action only, the Commission is responding positively to the approach favoured by the Parliament and the Economic and Social Committee as regards splitting its proposal into two. A separate proposal tackles consumer protection.

This modified proposal aligns future health action more explicitly with the overall Community objectives of prosperity, solidarity and security and seeks to further exploit synergies with other policies, as highlighted by the European Parliament. The current modified proposal has incorporated to the extent possible the Parliament's concerns on key strategic issues such as the need to promote healthy ageing, to address health inequalities across the EU, to take gender health issues into account and to focus on cross-border issues.

However, in the light of the budgetary constraints, this modified proposal does not include a specific action strand to tackle individual diseases (as in the Commission original proposal which was further strengthened by the European Parliament). Instead, in view of the limited resources, the Commission aims to help reduce the burden of diseases by tackling the most important health determinants. Nevertheless, in cases where there is important added value in

[1] COM(2005) 115, 6.4.2005.

Community level action on a specific disease (e.g. on rare diseases or mental health), provisions are made under the relevant objectives of the modified proposal.

In addition, action on co-operation between health systems (a separate strand in the Commission original proposal) has been considerably streamlined and incorporated into all the three objectives for Community health action described further below.

II. A healthy society as a foundation stone for prosperity, solidarity and security

Improving health is important in its own right. But it is also an important part of the solution to address a number of key challenges facing Europe such as population ageing, security threats or labour shortages. Improving health is necessary to meet the overall Community goals which were set to respond to such problems. As such, health has a role to play in achieving Europe's full potential for prosperity, solidarity and security.

In relation to prosperity, population health is a key factor of productivity and growth. The European Parliament underlined that the promotion of health is a key element for long-term economic growth and social welfare[2]. Better health policies will lead to EU citizens living longer and in better health, which is important to reduce worker absenteeism and premature retirement. The Commission has emphasised, in its annual reports to the Spring European Council, that increasing Healthy Life Years is crucial in attracting people into employment[3]; and that Europe cannot afford to have people drop out of the labour market when they are in their fifties[4]. Poor health is a leading cause of early retirement and productivity loss. Increasing the number of years citizens live in good health is therefore important to fulfilling the Lisbon agenda. In this context and in the light of the Parliament's first reading Opinion, the current modified proposal provides a stronger focus on healthy ageing and also on health's potential to promote growth.

As regards solidarity, achieving the Community goal of a more cohesive Europe, requires reducing the major inequalities across the EU in terms of life expectancy, health status, and access to high-quality health services. This translates into major differences across the EU not only in quality of life, but also in productivity, labour participation and age of leaving the labour force on invalidity grounds. Inequalities in health go hand in hand with inequalities in prosperity. A Europe of solidarity cannot neglect these inequalities. In response to the Parliament's first reading Opinion, the modified proposal focuses more on addressing health inequalities, and also provides for action to improve solidarity between health systems, albeit streamlined in the light of budgetary constraints.

Finally, as regards security, recent developments with avian flu and growing concerns about a possible influenza pandemic, remind us of the urgent need to step up efforts to protect our citizens against cross-border health threats. Improving security requires developing European and national capacity to respond to health emergencies in a co-ordinated and efficient manner, while also respecting human rights protection and the shared values of the European Charter of fundamental rights. Citizens and stakeholders expect the EU to ensure a rapid and efficient assistance to Member States in responding to a possible pandemic and

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[2] **EP Opinion of 15.3.2006 on the 2006 Commission Communication to the Spring European Council, 25.1.2006.**

[3] **2005 Commission Communication to the Spring European Council COM(2005) 24, 2.2.2005.**

[4] **2006 Commission Communication to the Spring European Council, COM(2006) 30, 25.1.2006.**

other serious health threats. The EU cannot fail to act when the safety of its citizens is at stake. The modified proposal therefore continues to put a stress on this issue and in general keeps the range of action foreseen in the original proposal. Action under this programme will be complementary to the work of the European Centre for Disease Prevention and Control (see below).

III. Objectives of the Programme

The programme will pursue three broad objectives in line with the Community overall goals:

1. Improve citizens' health security

2. Promote health for prosperity and solidarity

3. Generate and disseminate health knowledge

Meeting these objectives requires close co-operation and strong synergies with other policies. Mainstreaming health concerns into other policies and exploiting potential for common action is reinforced in this modified proposal in the light of the Parliament's first reading Opinion.

1. Improve citizens' health security

1.1. Protect citizens against health threats

The Community Strategic objectives for 2005-2009[5] stress the importance of countering threats to citizens' health and safety at EU level (including bioterrorism). Lessons from global health threats and recent developments in avian influenza show the need for increased EU capacity to address cross-border threats. The European Centre for Disease Prevention and Control (ECDC)[6] , created in 2004 to analyse, assess and provide advice on risks from communicable diseases, was a key step towards this end.

Action under the programme will cover identification of threats beyond the ECDC remit such as those posed by physical and chemical agents; and support actions underpinning the further implementation of the Decision creating a Community surveillance network[7]. The programme will also support the development of vaccination policies and the establishment of European reference laboratories for rare or high-risk pathogens.

Surveillance simply provides the information necessary for the Community to decide what needs to be done. To protect citizens, the EU needs technical and operational capability to prepare for and respond to health threats (inside or outside the EU). The programme will therefore support the development of EU capacity to co-ordinate a response at European level. It will contribute to enhancing the effectiveness of national structures with action to improve risk management and health emergency planning; facilitate co-ordination of actions in health emergencies; improve preparedness for health emergencies; and facilitate networking and exchange of best practice. The programme will further help Member States

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[5] Strategic objectives 2005-2009, « Europe 2010 », 2005.

[6] Regulation (EC) No 851/2004.

[7] Decision No 2119/98/EC.

to develop their own infrastructure, capacity and co-ordination arrangements needed to respond to a threat.

1.2. Improve citizens' safety

Citizens are confronted with many and varied threats to their safety in addition to possible pandemics. The frequency of avoidable incidents and infections in hospitals raises concerns about patient safety across the EU. The burden of avoidable illness related to injuries and accidents also needs to be addressed. The EU can complement national measures in this area, by increasing awareness, fostering knowledge exchange and contributing to the preparation of guidance material.

In addition, the EU has a key role to play in identifying risks to health (for example related to exposure to chemicals contained in a product) and evaluating their possible impact. Finally, the EU has an important Treaty obligation to set high standards of quality and safety of organs and substances of human origin for medical use. The programme will therefore support the implementation of Community legislation on blood, tissues and cells and help implement the International Health Regulations.

This modified proposal takes account of the Parliament's requests for the Community to treat serious cross-border health threats as a matter of priority, to co-ordinate closely work under the programme with work by the ECDC, and for action to be taken on injury prevention and on organs.

2. Promote health for prosperity and solidarity

2.1. Foster healthy, active ageing and help bridge inequalities

Europe's population is growing older and the proportion of working people is falling. Against this background a key challenge is to ensure that the population ages in good health. "The longer people enjoy good health, the longer they can remain active and work"[8]. The EU needs to encourage policy measures for healthy, active ageing as foreseen in the Community Lisbon Programme[9]. As highlighted to the European Council, Member States need to reduce the high numbers of people who are inactive because of their ill-health[10]. Some Member States foresee health measures in their Lisbon plans, not only to strengthen their labour force[11], but also to improve public finances. It is clear that an ageing population in bad health can make healthcare budgets swell, but evidence shows that improved population health can greatly reduce projected increases in spending. Finally, tackling an ageing society also implies a life-cycle approach to health that ensures a sufficient focus on young people.

This modified proposal takes account of the Parliament's requests for action to increase healthy life years (a structural indicator) to meet the Lisbon goals by preventing diseases and promoting ageing in good health, and also its request to address children's health.

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[8] EP Opinion of 15.3.2006 on the 2006 Commission Communication to the Spring European Council, 25.1.2006.

[9] COM(2005) 330, 20.7.2005, Community Lisbon Programme states that the « Commission will assist the Member States in developing active ageing strategies, including measures to increase healthy life years ».

[10] Annex to COM(2006) 30, 25.1.2006.

[11] COM(2006) 30, 25.1.2006, Commission Communication to the Spring European Council.

Population health and access to high quality health services varies widely among Member States and regions. In addition, poor population health translates into lower productivity and labour participation. Thus a population in bad health impacts negatively on economic growth and the health gap feeds into the economic gap. Member States and regions whose citizens are in relatively bad health (compared to the EU average) therefore expect the EU to show solidarity and to help them to improve their health capacity. The EU Regional policy can support investment in health infrastructure in convergence regions, as well as human resources throughout the European Union. This programme will also encourage Member States to invest in health in co-operation with other policies.

As a response to the Parliament's first reading Opinion, this programme will take forward action to identify the causes of health inequalities within and between Member States with a particular emphasis on the situation in the new Member States; and will encourage exchange of best practice to address such inequalities. This modified proposal therefore takes full account of the Parliament's requests for action on health inequalities to be a priority of the programme and will seek to contribute to bridging the health gap across the EU.

In addition, the modified proposal takes account of the Parliament's request for the programme to focus on cross-border issues. Synergies and complementarities would be sought with the health related cross border projects under the regional policy territorial cooperation objective. The programme will foster co-operation between health systems on a number of growing cross-border issues such as the mobility of patients and health professionals.

2.2. Promote healthier ways of life by tackling health determinants

Key influences on population health are health determinants such as nutrition, alcohol, tobacco and drug consumption as well as the quality of social and physical environments. Action in these areas is essential in order to improve health and wellbeing and prevent premature death and disability. In particular the growing burden of avoidable diseases related to life-style and addiction in all EU Member States calls for Community level action to facilitate co-operation, exchange good practice and complement national measures.

Promoting good health therefore requires tackling the life-style factors (e.g. nutrition, physical activity and sexual health), and addictions (e.g. tobacco, alcohol, drugs) that undermine health, as well as broader socio-economic and environmental health determinants.

This proposal takes into account the Parliament's support for Community action on health promotion and prevention. It foresees focused action in particular on lifestyle determinants and addiction-related determinants.

In the light of budgetary constraints, the separate "disease" strand included in the Commission's original proposal is no longer viable. However, tackling the most important health determinants will have the effect of contributing to reducing the disease burden. For example, action to support healthy diets can contribute to reducing heart disease, and action on sexual health can contribute to fighting HIV/AIDS.

3. Generate and disseminate health knowledge

3.1. Exchange knowledge and best practice

There is much scope for exchange of knowledge and best practice on a range of health issues. The Parliament has put a particular emphasis on the need for Community action to provide

added value and focus on cross-border issues. In this context, exchange of best practice will target issues where the Community can provide genuine added-value in bringing together expertise from different countries, as is the case with rare diseases, or cross-border issues related with co-operation between health systems. It will also include horizontal issues stressed in the Parliament's first reading Opinion, such as gender-related aspects of health or children's health. Finally, other key issues of common interest to all Member States such as mental health will also be covered. Exchange of knowledge and best practice will complement national measures and enable Member States to benefit from solutions developed elsewhere in the EU. Such exchange of knowledge may need to be preceded by collection of information.

This modified proposal therefore takes into account the Parliament's request for action in particular on gender aspects of health, and also on children's health (not specifically foreseen in annex 2 of the Commission original proposal). It also addresses the Parliament's request for the Community to focus on added value cross-border health issues such as patient mobility.

3.2. Collect, analyse and disseminate health information

Developing a sound health knowledge base is essential to develop an evidence-base health policy. In addition, stakeholders and policy-makers rely on the EU to provide them with comparable, reliable and up to date health information. To generate and disseminate health knowledge means expanding existing work to develop an EU health monitoring system that feeds into all health activities, using the Community Statistical Programme as necessary.

As supported in the Parliament's first reading Opinion, the programme will continue efforts to develop indicators and other tools, and to collect data and information as a basis for policy-making. In addition, as envisaged in the original Commission proposal, the programme will increasingly focus on providing analysis and disseminating information to citizens in a user-friendly manner, such as the Health portal. A stronger focus on communication with citizens will also underpin efforts to bring Europe – and European health policy – closer to its citizens.

IV. Implementation of the Programme

This modified proposal keeps the instruments and main implementing provisions of the initial Commission proposal of April 2005 and takes on board a number of European Parliament amendments which add detail and transparency to the initial proposal.

In line with better regulation principles, particular efforts will be made to ensure policy coherence between this instrument and other Community programmes. As requested by the Parliament in its first reading Opinion, the programme will strengthen synergies with other Community policies and programmes such as regional development and the Structural Funds, the Community statistical programme, the Community strategy for health and safety at work, the Sustainable development strategy, the Framework research programmes and the Lisbon agenda; and will seek to pursue, where appropriate, joint actions with other policies.

Civil society participation in health policy-making will be promoted. Major initiatives under this programme will take full account of consultation with stakeholders. Health policies will be shaped in partnership with citizens and stakeholders e.g. by providing support to develop organisations representing patients' interests or which take forward the health agenda.

As requested by the European Parliament, a stronger focus is put on reporting regularly the key results of the programme to the other Institutions, and also on the careful evaluation of the impact of future initiatives. In addition, the Commission has taken on board the Parliament's request for the draft Decision to provide clear criteria for NGOs eligible for core grants. This contributes to providing more transparency in the text, in accordance with better regulation principles. However, in the light of budgetary constraints, this modified proposal brings down the maximum core funding in exceptional cases from 95% (as in the original Commission proposal and endorsed by the Parliament) to 80%.

The existing executive agency, set up for the Public Health Programme, should assist in the implementation of the proposed new health programme. To increase cost-efficiency and exploit economies of scale, the same agency should also assist in the implementation of the consumer programme as well as in the implementation of food safety training measures. The Commission therefore envisages to modify accordingly its Decision of 15 December 2004 setting up the executive agency.

The existing Public Health Programme puts a strong focus on co-financing cross-border action through project grants. The Commission proposes that the future programme will reduce the proportion of co-financing of projects and focus more on calls for tender in order to maximise the efficiency, effectiveness and added-value of actions financed under the programme, and as a means to ensure that resources are clearly channelled to needs related to the programme objectives.

Finally, this programme is being developed as part of a broad-ranging health strategy, which will be presented by the Commission in 2007. The programme covers essentially those actions that require financial resources. The future strategy will bring together under a comprehensive framework the broad range of Community heath action and define goals and priorities. Key issues, such as the mainstreaming of health concerns in other policies, addressing health inequalities, and responding to international issues will be developed further in the strategy.

2004/0042 A (COD)

Amended proposal for a

DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

establishing a second[12] Programme of Community action in the field of Health ~~and consumer protection~~ (2007-2013)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article~~s~~ 152 ~~and 153~~ thereof[13],

Having regard to the proposal from the Commission[14],

Having regard to the opinion of the European Economic and Social Committee[15],

Having regard to the opinion of the Committee of the Regions[16],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[17],

Whereas:

(1) The Community can contribute to protecting the health **and** safety ~~and economic interests~~ of citizens through actions in the field~~s~~ of public health ~~and consumer protection~~[18]. **A high level of health protection should be ensured in the definition and implementation of all Community policies and activities. Under Article 152 of the Treaty, the Community is required to play an active role by taking measures which cannot be taken by individual Member States, in accordance with the principle of subsidiary. The Community fully respects the prerogatives of Member States in the organisation and delivery of health services and medical care** [19]**.**

(2) **The health sector is characterised on the one hand by its considerable potential for growth, innovation and dynamism and on the other by the challenges it faces in terms**

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12 **EP am. 1, COM had rejected it initially on grounds of split.**
13 **EP am. 2, COM had rejected it initially on grounds of split.**
14 OJ C **172**~~[…], …~~**of 12.7.2005, p. 25**~~[…]~~.
15 **EESC/2006/230 of 14.2.2006 - OJ** C , , p. .
16 **Opinion COR/2005/147 of 16.2.2006 -** OJ C , , p. .
17 OJ C , , p. .
18 **Part of EP am. 3 which COM had rejected initially on grounds of split.**
19 **EP am. 4.**

of financial and social sustainability and efficiency of the health care systems due, among other things, to the ageing population and to medical advances[20].

(3) **The programme of Community action in the field of public health (2003-2008) was the first integrated European Community programme in this field, and has already delivered a number of important developments and improvements[21].**

(4) **A number of serious cross-border health threats with a possible world-wide dimension exist and new ones are emerging which require further Community action. The Community should treat serious cross-border health threats as a matter of priority. Monitoring, early warning and action to combat serious threats to health require a capacity of the Community to respond in an effective and coordinated fashion[22].**

(5) According to the WHO European Health report 2005, in terms of Disability Adjusted Life-Years (DALYs) the most important causes of the burden of disease in the WHO European Region are non-communicable diseases (NCDs – 77% of the total), external causes of injury and poisoning (14%) and communicable diseases (9%). Seven leading conditions – ischaemic heart disease, unipolar depressive disorders, cerebrovascular disease, alcohol use disorders, chronic pulmonary disease, lung cancer and road traffic injuries – account for 34% of the DALYs in the Region. Seven leading risk factors-tobacco, alcohol, high blood pressure, high cholesterol, overweight, low fruit and vegetable intake and physical inactivity – account for 60% of DALYs. In addition, communicable diseases, such as HIV/AIDS, influenza, tuberculosis and malaria are also becoming a threat to the health of all people in Europe. An important task of the programme, in cooperation when necessary with the Community Statistical Programme, would be to identify better the main health burdens in the Community[23].

(6) Eight leading causes of mortality and morbidity from NCDs in the WHO European Region are cardiovascular disease, neuropsychiatric disorders, cancer, digestive diseases, respiratory diseases, sense organ disorders, musculoskeletal diseases and diabetes mellitus[24].

(7) Microbial resistance to antibiotics and nosocomial infections are becoming a threat to health in Europe. Lack of new effective antibiotics as well as how to ensure the proper use of existing antibiotics are major concerns. Therefore it is important to collect and analyse relevant data[25].

(8) Strengthening the role of the European Centre for Disease Prevention and Control is important in the fight against communicable diseases[26].

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[20] **EP am. 6, accepted by COM. Additional editorial change ("Rise in life expectancy" replaced by "ageing population").**

[21] **EP am. 7.**

[22] **EP am. 8.**

[23] **EP am. 9.**

[24] **From EP am. 10, accepted by COM with modifications. This leaves out detailed wording on diabetes and replaces "deaths" by "mortality and morbidity". This modified proposal also leaves out ams 11 and 12 on diabetes and cancer, initially accepted by COM. In the light of budgetary constraints the modified proposal abandons the disease strand of the original proposal and these ams are no longer appropriate.**

[25] **EP am. 13.**

[26] **EP am. 14 accepted by COM with modifications (as in GRI fiche).**

(9) The Programme builds on the achievements of the previous programme for Community action in the field of public health (2003-2008). It will contribute towards the attainment of a high level of physical and mental health and greater equality in health matters throughout the Community, by directing actions towards improving public health, preventing human diseases and disorders, and obviating sources of danger to health with a view to combating morbidity and premature mortality[27].

(10) The programme should place emphasis on improving the health condition and promoting a healthy lifestyle and a culture of prevention among children and young people[28].

~~Whilst maintaining the core elements and specificities of actions on health and consumer protection, a single integrated programme should help to maximise synergies in objectives and efficiency in administration of actions in these areas. Combining health and consumer protection activities in a single programme should help to meet joint objectives on protecting citizens from risks and threats, increasing the ability for citizens to have the~~ knowledge ~~and opportunity to make decisions in their interests and supporting mainstreaming of health and consumer objectives in all Community policies and activities. Combining administrative structures and systems should enable more efficient implementation of the programme and help to make best use of available Community resources for health and consumer protection.~~

(11) The Programme should support the mainstreaming of health objectives in all Community policies and activities, without duplicating work carried out under other Community policies[29]. Coordination with other Community policies and programmes is a key part of the objective of mainstreaming health in other policies. In order to promote synergies and avoid duplication, joint actions may be undertaken with related Community programmes and actions and appropriate use will be made of other Community funds and programmes including the current and future Community framework programmes for research and their outcomes, the Structural Funds, the European Solidarity Fund, the European strategy for health at work and the Community Statistical Programme[30].

(12) Special efforts will be undertaken to ensure coherence and synergies between this Community health programme and the Community's external actions, particularly in the areas of avian influenza, HIV/AIDS, tuberculosis and other trans-national health threats. In addition, there should be international cooperation in order to promote general health reform and general health institutional issues in countries outside the European Union.

(13) Increasing Healthy Life Years (HLY), also called disability-free life expectancy indicator, by preventing disease and promoting ageing with good health is important for the well-being of EU citizens and helps to meet the challenges of the Lisbon process

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[27] From EP am. 16, partially accepted by COM. Leaves out EP wording on ethnic origin (as in GRI fiche).

[28] EP am. 17, "will place emphasis" was replaced by "should place emphasis".

[29] EP (am. 19, which COM had rejected initially on grounds of split.

[30] From EP am. 38 which COM had rejected initially on grounds of split. The modified proposal has some changes: "will be undertaken" was replaced by "may be undertaken" to align this recital with the wording of article 6; some examples of funds and the last sentence of am. 38 were left out.

as regards the knowledge society and the sustainability of public finances which are under pressure from rising health care and social security costs[31].

(14) The enlargement of the European Union has brought additional concerns in terms of health inequalities within the EU and this is likely to be accentuated by further enlargements. This issue should, therefore, be one of the priorities of the Programme[32].

(15) The Programme should help to identify the causes of health inequalities and encourage, among other things, the exchange of best practice to tackle them[33].

(16) It is essential to systematically collect, process and analyse comparable data for an effective monitoring of the state of health in the European Union. This would enable the Commission and the Member States to improve information to the public and formulate appropriate strategies, policies and actions to achieve a high level of human health protection. Compatibility and interoperability of the systems and networks for exchanging information and data for the development of public health should be pursued in the actions and support measures. Gender, and age are important health considerations. Therefore, relevant data should take this into account[34]. The collection of data must be in compliance with the relevant legal provisions on the protection of personal data[35].

(17) Best practice is important because health promotion and prevention should be measured on the basis of efficiency and effectiveness and not purely in economic terms[36]. It is important to promote best practice and latest treatment methods for diseases and injuries in order to prevent further deterioration of health, and to develop centres of reference for specific conditions. It is also important to promote a range of options that can be selected from[37].

(18) Action should be taken in order to prevent injuries by collecting data, analysing injury determinants and disseminating relevant information[38].

(19) The Programme should contribute to the collection of data and the promotion of relevant policies on patient mobility as well as on the mobility of health professionals. It should facilitate the further development of the European e-Health Area, through joint European initiatives with other EU policy areas, including regional policy, while contributing towards work on quality criteria for health-related websites and towards a European health insurance card[39].

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[31] EP am. 20.
[32] EP am. 21.
[33] EP am. 22.
[34] EP am. 23 accepted by COM with modifications (as in GRI fiche). EP wording on ethnic origin left out.
[35] EP am. 24.
[36] (EP am. 25 accepted by COM with additional editorial changes (shortening).
[37] EP am. 26 accepted by COM with modifications (as in GRI fiche).
[38] EP am. 27 accepted by COM with modifications (as in GRI fiche).
[39] EP am. 28 accepted by COM with modifications (as in GRI fiche) mainly to clarify this programme is not responsible for websites criteria.

(20) The promotion of telemedicine applications may contribute to patient mobility and to medical care at home, thereby helping to reduce the burden caused by disease and injury[40].

(21) Environmental pollution is a serious risk to heath and a major source of concern for European citizens. Special action should focus on children and other groups which are particularly vulnerable to hazardous environmental conditions. The Programme should complement the actions taken within the Environmental and Health Action Plan 2004-2010[41].

(22) The Programme should address gender-related and ageing-related health issues[42].

(23) The precautionary principle and risk assessment are key factors for the protection of human health and should therefore be part of further integration into other Community policies and activities[43].

(24) In order to ensure a high level of coordination between actions and initiatives taken by the Community and Member States in the implementation of the Programme, it is necessary to promote cooperation between Member States and to enhance the effectiveness of existing and future networks in the field of public health[44].

~~(25)~~ **The participation of national, regional and local authorities at the appropriate level in accordance with the national systems should be taken into account in regard to the implementation of the Programme[45].**

~~Health and consumer protection policies share common objectives relating to protection against risks, improving decision-making of citizens and integrating health and consumer protection interests in all Community policies, as well as common instruments such as communication, capacity-building for civil society regarding health~~ and ~~consumer protection issues, and promoting international cooperation on these issues. Issues such as diet and obesity, tobacco and other consumption-related choices related to health are examples of cross-cutting issues affecting both health and consumer protection. Taking a joint approach to these common objectives and instruments will enable activities common to both health and consumer protection to be undertaken more efficiently and effectively. There are also separate objectives relating to each of the two areas of health and consumer protection which should be addressed through actions and instruments specific to each of the two areas.~~

(26) It is necessary to increase EU investment in health and health-related projects. In this regard, Member States are encouraged to identify health improvements as a priority in their national programmes. Better awareness about the possibilities of EU funding for

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40 EP am. 29 accepted by COM with modifications (as in GRI fiche).
41 EP am. 30.
42 This seeks to represent the spirit of EP detailed ams 31 and 32, which COM accepted partially.
43 EP am. 34.
44 EP am. 35.
45 EP am. 36.

health is needed. Exchange of experience between the Member States on funding health through the Structural Funds should be encouraged[46]**.**

(27) Non-governmental organisations and specialised networks also play an important role in promoting public health and representing citizens' interests in health policy in the Community. They ~~It is of general European interest that the health, safety and economic interests of citizens, as well as consumer interests in the development of standards for products and services, be represented at Community level. Key objectives of the programme may also depend on the existence of specialised networks that also~~ require Community contributions to enable them to develop and function. **Eligibility criteria and provisions regarding financial transparency for non-governmental organisations and specialised networks qualifying for Community support should be established under this Decision.** Given the particular nature of the organisations concerned and in cases of exceptional utility, the renewal of Community support to the functioning of such organisations **may be exempted from** ~~should not be subject to~~ the principle of gradual decrease of the extent of Community support[47].

(28) ~~Implementation of the Pprogramme should include build upon and extend existing actions and structural arrangements in the fields of public health and consumer protection, including the Executive Agency for the Public Health Programme set up by Commission Decision 2004/858/EC~~ Implementation **of the Programme** should be carried out in close cooperation with relevant organisations and agencies, in particular with the European Centre for Disease Prevention and Control[48] established by Regulation (EC) No 851/2004 of the European Parliament and of the Council[49].

(29) The measures necessary for the implementation of this Decision should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[50], respecting the need for transparency as well as a reasonable balance between the different objectives of the **P**~~p~~rogramme.

(30) The Agreement on the European Economic Area (hereinafter referred to as the EEA Agreement) provides for cooperation in the field~~s~~ of health ~~and consumer protection~~ between the European Community and its Member States, on the one hand, and the countries of the European Free Trade Association participating in the European Economic Area (hereinafter referred to as the EFTA/EEA countries), on the other. Provision should also be made to open the **P**~~p~~rogramme to participation by other countries, in particular the neighbouring countries of the Community, countries that are applying for, candidates for or

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46 **EP am. 39, accepted by COM with modifications. Member States "are encouraged to identify" rather than Member States "should identify".**

47 **EP am. 40 initially rejected by COM on grounds of the split (exclusion of consumer NGOs). In addition, COM changed the text in the last sentence from "should not be subject to the principle of gradual decrease" to "may be exempted from the principle of gradual decrease" to align this recital with the wording used in article 4.3.**

48 OJ L 142, 30.4.2004, p. 1.

49 **Part of EP am. 41 initially rejected by COM on grounds of split. The text of the modified proposal leaves out the last sentence of am. 41.**

50 OJ L 184, 17.7.1999, p. 23.

acceding to membership of the Community, taking particular account of the potential for threats to health arising in other countries to have an impact within the Community[51].

(31) Appropriate relations with third countries not participating in the **P**~~p~~rogramme should be facilitated in order to help achieve the objectives of the **P**~~p~~rogramme, taking account of any relevant agreements between those countries and the Community. This may involve third countries taking forward complementary activities to those financed through the**is** **P**~~p~~rogramme on areas of mutual interest, but will not involve a financial contribution under the **is** **P**~~p~~rogramme.

(32) It is appropriate to develop cooperation with relevant international organisations such as the United Nations and its specialised agencies including the World Health Organisation, as well as with the Council of Europe and the Organisation for Economic Cooperation and Development with a view to implementing the ~~p~~**P**rogramme through maximising the effectiveness and efficiency of actions relating to health ~~and consumer protection~~ at Community and international level, taking account of the particular capacities and roles of the different organisations.

(33) **Progress towards meeting the health objectives under this Programme needs to be measured and evaluated** ~~I~~**i**n order to increase the value and impact of the ~~programme~~ **Programme.** ~~t~~**T**here should be regular monitoring and evaluation, including independent external evaluations, of the measures taken[52].

(34) Since the objectives of the action to be taken on health ~~and consumer protection~~ cannot be sufficiently achieved by the Member States due to the trans-national nature of the issues involved, and can therefore by reason of the potential for Community action to be more efficient and effective than national action alone in protecting the health **and**~~,~~ safety ~~and economic interests~~ of citizens, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this ~~dD~~ecision does not go beyond what is necessary in order to achieve those objectives.

(35) **In accordance with Article 2 of the Treaty, which provides that equality between men and women is a principle of the European Community, and in accordance with Article 3(2) thereof, which provides that the Community shall aim to eliminate inequalities, and to promote equality**~~,~~ **between men and women in all Community activities including the attainment of a high level of health protection, all objectives and actions covered by the Programme of Community action in the field of health contribute to promoting a better understanding and recognition of men's and women's respective needs and approaches to health[53].**

(36) ~~The Commission should ensure an~~ **It is** appropriate **to ensure a** transition between the**is** **P**~~p~~rogramme and the **previous**~~two~~ programme~~s~~ it replaces, in particular regarding the continuation of multi-annual **arrangements** ~~measures~~ **for its management, such as the financing of technical and administrative assistance[54]. As of 1 January 2014, the**

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[51] **EP am. 42 initially rejected by COM on grounds of split.**
[52] **EP am. 44.**
[53] **EP am. 46, accepted with modifications by COM (as in GRI fiche).**
[54] **Part of EP am. 47 initially rejected by COM on grounds of split.**

technical and administrative assistance will ensure, if necessary, the management of actions not yet finalised by the end of 2013~~and administrative support structures such as the Executive Agency for the Public Health Programme~~.

(37) Continued effort is required in order to meet the objectives already established by the Community in the field of public health. It is therefore appropriate to establish a second Programme of Community action on health (2007-2013), hereinafter "the Programme", as set out in this Decision, replacing Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a Programme of Community action in the field of public health (2003-2008)[55]. This Decision should therefore be repealed[56].

HAVE **DECIDED AS FOLLOWS**~~ADOPTED THIS DECISION~~:

Article 1

Establishment of the Programme

The second ~~A~~ programme of **"**Community action in the field of health **(2007-2013)"**~~and consumer protection~~ covering the period from **the day of entry into force of this Decision** ~~1 January 2007~~ to 31 December 2013, hereinafter referred to as 'the **P**~~p~~rogramme' is hereby established[57].

Article 2

Aim and objectives

1. The programme shall complement**,**~~ and~~ support **and add value to** the policies of the Member States and shall contribute to **protecting and** pro**moting human** ~~tecting the~~ health **and**~~,~~ safety **and improving public health**~~and economic interests of citizens~~[58].

2. **The objectives to be pursued through the actions set out in the Annex to this Decision shall be[59]:**

   ~~- The aim referred to in paragraph 1 shall be pursued through common objectives together with specific objectives in the fields of health and consumer protection.~~

   - Improve citizens' health security

   - Promote health to improve prosperity and solidarity

   - Generate and disseminate health knowledge[60]

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55 OJ L 271, 9.10.2002, p. 1. Decision as amended by Decision No 786/2004/EC (OJ L 138, 30.4.2004, p. 7).

56 From EP am. 15, which COM had rejected initially on grounds of split.

57 EP(From am. 48 initially rejected by COM initially on grounds of split).

58 Part of am. 49 initially rejected by COM on grounds of split (From am. 49).

59 Part of EP am. 49.

60 These objectives respond to the need to streamline the programme in the light of the reduced budget. COM has also incorporated the spirit of EP am. 50 in the sub-objectives detailed in the explanatory

~~(a) The common objectives for health and consumer protection to be pursued through the actions and instruments set out in Annex 1 to this Decision shall be:~~

~~– to protect citizens from risks and threats that are beyond the control of individuals;~~

~~– to increase the ability of citizens to take better decisions about their health and consumer interests;~~

~~– and to mainstream health and consumer policy objectives.~~

~~– (b) The specific health objectives to be pursued through the actions and instruments set out in Annex 2 to this Decision shall be:~~

~~– to protect citizens against health threats;~~

~~– to promote policies that lead to a healthier way of life;~~

~~– to contribute to reducing the incidence of major diseases;~~

~~– and to improve efficiency and effectiveness in health systems.~~

~~(c) The specific consumer protection objectives to be pursued through the actions and instruments set out in Annex 3 to this Decision shall be:~~

~~– a better understanding of consumers and markets;~~

~~– better consumer protection regulation;~~

~~– better enforcement, monitoring and redress;~~

~~– and better informed and educated and responsible consumers.~~

Article 3

Methods of implementation

Actions in pursuit of the aim~~s~~ and objectives set out in Article 2 shall make full use of appropriate available methods of implementation, including in particular:

(a) direct or indirect implementation by the Commission on a centralised basis;

(b) and joint management with international organisations**, where appropriate**.

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memorandum and in the annex (accepted by COM with modifications) which creates additional objectives on health protection, health inequalities and co-operation between Member States.

Article 4

Financial contributions

1. ~~For the purpose of paragraph 1(a) above,f~~**F**inancial contributions by the Community shall not exceed the following levels:

   (a) 60% **of costs** for an action intended to help achieve an objective forming part of ~~a Community policy within the field of health and consumer protection~~**this Programme**, except in cases of exceptional utility where the Community contribution shall not exceed 80%; and[61],

   (b) 60% **of costs** ~~of expenditure~~ for the functioning of a body **or a specialised network, which is non-governmental, non-profit-making and independent of industry, commercial and business or other conflicting interests, has members in at least half of the Member States and has as its primary objective the promotion of health or the prevention or treatment of diseases in the European Community,** ~~pursuing an aim of general European interest~~ where such support is necessary to ensure representation of health ~~or consumer~~ interests at Community level or to implement key objectives of the **P**~~p~~rogramme. ~~except~~ **I**~~i~~n cases of exceptional utility**,** ~~where~~ the Community contribution shall not exceed **80%.** ~~95%.~~

2. For the purpose of paragraph 1 above, criteria for assessing whether or not exceptional utility applies shall be established in advance in the annual work plan referred to in Article 10(1)(a) and shall be published.

3. The renewal of ~~such~~ financial contributions **set out in paragraph 1(b) to non-governmental organisations and specialised networks** may be exempted from the principle of gradual decrease[62].

4. ~~For the purpose of paragraph 1(a) above, f~~**F**inancial contributions by the Community may, where appropriate given the nature of the objective to be achieved, include joint financing by the Community and one or more Member States or by the Community and the competent authorities of other participating countries. In this case, the Community contribution shall not exceed 50%, except in cases of exceptional utility, where the Community contribution shall not exceed 70%. These Community contributions may be awarded to a public body or a non-profit-making body designated **through a transparent procedure** by the Member State or the competent authority concerned and agreed by the Commission.

5. ~~For the purpose of paragraph 1(a) above, f~~**F**inancial contributions by the Community may also be given in the form of flat-rate **or lump sum** financing where this is suited to the nature of the actions concerned. For such financial contributions the percentage limits

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61 EP (am. 52 initially rejected by COM on the grounds of the split).

62 Part of EP (From am. 53 initially rejected by COM in GRI on grounds of split. This modified proposal incorporates most of the wording of am. 53. It does not incorporate, however, the 75% ceiling requested by the EP in am. 53 nor the wording on obligation of two-year framework partnership conventions. In addition, it changes the exceptional utility contribution from 95 to 80%.).

stipulated in paragraphs **1**, 2, ~~and 3~~ and **4** above shall not apply, **although a co-financing is still required**. ~~The criteria for selecting, monitoring and evaluating such actions shall be adapted as necessary.~~

Article 5~~4~~

Implementation of the Programme

1. The Commission shall ensure the implementation**, in close cooperation with the Member States,** of the **actions and measures set out in the** ~~p~~**P**rogramme in accordance with the provisions of Article**s** **7**~~6~~ **and 10**[63]~~87 and ensuring its harmonious and balanced development~~.

2.~~1a~~ **As part of the implementation of the Programme, the Commission shall ensure the coordination of networks for health monitoring and rapid reaction to health threats**[64]**.**

3.~~1b~~. **The Commission and the Member States shall take appropriate action, within their respective areas of competence, to ensure the efficient running of the Programme and to develop mechanisms at Community and Member State level to achieve the objectives of the Programme. They shall ensure that appropriate information is provided about actions supported by the Programme and that the widest possible participation is obtained**[65]**.**

4.~~1d~~. **For the attainment of the objectives of the Programme, the Commission shall, in close cooperation with the Member States:**

(a) pursue the comparability of data and information, and the compatibility and interoperability of the systems and networks for exchange of data and information on health[66] **and**

(b) ensure the necessary cooperation and communication with the European Centre for Disease Prevention and Control[67]**.**

5.~~1f~~. **In implementing the Programme, the Commission, together with the Member Sates, shall ensure compliance with all relevant legal provisions regarding personal data protection and, where appropriate, the introduction of mechanisms to ensure the confidentiality and safety of such data**[68]**.**

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[63] **EP am. 55, leaving out the sentence on ensuring harmonious and balanced development.**

[64] **EP am. 56, which COM accepted partially, leaving out the EP text "and if necessary the integration of".**

[65] **EP am. 57, which COM accepted partially, leaving out "in actions requiring implementation through local and regional authorities and NGOs".**

[66] **EP am. 59.**

[67] **EP am. 60, in its final consolidated version.**

[68] **EP am. 61.**

Article 6~~4a~~

Joint strategies and actions

1. To ensure a high level of human health protection in the definition and implementation of all Community policies and activities and to promote the mainstreaming of health, the objectives of the Programme may be implemented as joint strategies and joint actions by creating links with relevant Community programmes, actions and funds.

2. The Commission shall ensure that the Programme ties in optimally with other Community programmes, actions and funds, such as with the 7th Framework Programme of Research and the Community Statistical Programme[69].

Article 7~~5~~

Funding

1. The financial framework for the implementation of the ~~p~~**P**rogramme for the period specified in Article 1 is EUR~~1 203 million~~ **365,6 million[70].**~~.~~

2. Annual appropriations shall be authorised by the budgetary authority within the limits of the financial **framework**~~perspective~~.

Article 8

Administrative and technical assistance

1. The financial allocation of this Programme may also cover expenses pertaining to preparatory, monitoring, control, audit and evaluation activities, required directly for the management of the Programme and the realisation of its objectives, in particular studies, meetings, information and publication actions, expenses linked to informatic networks focusing on information exchange, together with all other technical and administrative assistance expense that the Commission may have recourse to for the management of the Programme.

2. It may also cover technical and administrative assistance expenses necessary to ensure the transition between this Programme and the measures adopted under Decision n° 1876/2002/EC. If necessary, appropriations could be entered in the budget beyond 2013 to cover these expenses, to enable the management of actions not yet completed by 31 December 2013.

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69 EP am. 63, which COM accepted with modifications.

70 EUR 324,15 million in 2004 prices.

Article 9~~6~~

Committee

1. The Commission shall be assisted by a Committee (hereinafter 'the Committee').

2. Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at two months.

3. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. The Committee shall adopt its rules of procedure.

Article 10~~7~~

Implementation measures

1. The measures necessary for the implementation of this Decision relating to the following shall be adopted in accordance with the ~~management~~ procedure referred to in Article 9~~6(~~2):

   (a) the annual plan of work for the implementation of the ~~p~~**P**rogramme, setting out:

   – priorities and actions to be undertaken, including the allocation of **financial** resources[71]~~and relevant criteria;~~

   – **criteria for the percentage of Community financial contribution;**

   – **the arrangements for implementing the joint strategies and actions referred to in Article 6**[72]~~4a~~**;**

   (b) selection and award criteria for financial contributions, including those referred to under Article 4.4.

2. ~~The Commission shall adopt~~ **A**~~a~~ny other measures necessary for the implementation of this Decision **shall be adopted in accordance with the procedure referred to in Article 9~~6~~(3)**[73]**.**~~. The Committee shall be informed of them.~~

[71] **EP am. 66.**
[72] **EP am. 146 (with change in numbering).**
[73] **EP am. 69 with small editorial change by COM.**

*Article **11**~~8~~*

Participation of third countries

The **P**~~p~~rogramme shall be open to the participation of:

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

(b) and third countries, in particular countries in the European neighbourhood, countries that are applying for, candidates for or acceding to membership of the Union, and the western Balkan countries included in the stabilisation and association process, in accordance with the conditions laid down in the respective bilateral or multilateral agreements establishing the general principles for their participation in Community programmes.

*Article **12**~~9~~*

International cooperation

In the course of implementing the ~~programme~~**Programme**, relations with third countries that are not participating in the ~~programme~~ **Programme** and relevant international organisations**, in particular the WHO,** shall be encouraged[74].

*Article **13**~~0~~*

Monitoring, evaluation and dissemination of results

1. The Commission, in close cooperation with the Member States, shall monitor the implementation of the actions of the ~~p~~**P**rogramme in the light of its objectives. It shall report to the Committee, and shall keep the Council and Parliament informed.

2. **At the request of the Commission, Member States shall submit information on the implementation and impact of this Programme**[75]**.**

3. ~~At the request of the Commission, Member States shall submit information on the implementation and impact of this programme.~~ **The Commission shall submit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions:**

(a) an external and independent interim evaluation report on the results obtained and the qualitative and quantitative aspects of the implementation of the Programme three years after its adoption; the report shall in particular make it possible to assess the impact of measures on all countries; the report shall contain a summary of the main conclusions and remarks by the Commission;

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[74] EP am. 70.

[75] This corresponds to wording in the original COM proposal in this Article (initially under 10.2).

(b) a Communication on the continuation of the Programme no later than four years after its adoption;

(c) no later than 31 December 2015, an external and independent ex-post evaluation report covering the implementation and results of the Programme[76].

~~(d) at the request of the Commission, Member States shall submit information on the implementation and impact of this Programme.~~

~~3. The Commission shall ensure that the programme is evaluated three years after its start and following the end of the programme. The Commission shall communicate the conclusions thereof, accompanied by its comments, to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.~~

4. The Commission shall make the results of actions undertaken in accordance with this Decision publicly available and shall ensure their dissemination.

Article 14~~1~~

Repeal

Decision~~s~~ No 1786/2002/EC ~~and No 20/2004/EC~~ **is** ~~are~~ repealed **with effect from the entry into force of this Decision[77].**

~~*Article 152*~~

~~Transitional administrative arrangements measures~~

~~The Commission shall adopt any administrative arrangements measures necessary to ensure the transition between the measures adopted under Decisions No 1786/2002/EC and No 20/2004/EC and those to be implemented under theis Pprogramme.78~~

Article 15~~3~~

Final provision

This Decision shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

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[76] **EP am. 71, shortened.**

[77] **EP(From am. 74 initially rejected by COM in GRI on grounds of split (this would leave out consumer legal base).**

~~78 EP (From am. 75 initially rejected by COM in GRI on grounds of split)~~

Done at Brussels,

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

Annex

1. Improve citizens' health security

1.1. Protect citizens against health threats

1.1.1. Develop strategies and mechanisms for preventing, exchanging information on and responding to communicable and non-communicable threats, and threats from physical, chemical or biological sources, including deliberate release acts; action to assure high quality diagnostic co-operation between laboratories, including a Community reference laboratory structure.

1.1.2. Support the development of prevention, vaccination and immunisation policies; improve partnerships, networks, tools and reporting systems for immunisation status and adverse events monitoring.

1.1.3. Develop risk management capacity and procedures; improve preparedness and planning for health emergencies, including preparing for coordinated EU and international responses to health emergencies; develop risk-communication and consultation procedures on counter-measures.

1.1.4. Promote the co-operation and improvement of response capacity and assets, including protective equipment, isolation facilities and mobile laboratories to deploy rapidly in emergencies.

1.1.5. Developing strategies and procedures for drawing up, improving surge capacity, conducting exercises and tests, evaluating and revising general contingency and specific health emergency plans and their inter-operability between Member States.

1.2. Improve citizens' safety

1.2.1. Support and enhance scientific advice and risk assessment by promoting the early identification of risks; analysing their potential impact; exchanging information on hazards and exposure; and fostering integrated and harmonised approaches.

1.2.2. Help to enhance the safety and quality of organs and substances of human origin, blood, and blood derivatives; promote their availability, traceability and accessibility for medical use.

1.2.3. Promote measures to improve patient safety through high quality and safe healthcare, including in relation to nosocomial infections.

1.2.4. Promote actions to help reduce accidents and injuries, notably household accidents.

2. Promote health to improve prosperity and solidarity

2.1. Foster healthy, active ageing and help bridge health inequalities

2.1.1. Promote initiatives to increase healthy life years and promote healthy ageing; support measures to promote and explore health's impact on productivity and labour participation as a contribution to meeting the Lisbon goals.

2.1.2. Support initiatives to address and reduce health inequalities within and between Member States to contribute to prosperity and cohesion; promote investment in health in co-operation with other Community policies and Funds; improve solidarity between national health systems by supporting co-operation on issues such as mobility and cross-border care.

2.2. Promote healthier ways of life by tackling health determinants

2.2.1. Address health determinants to promote and improve health, creating supportive environments for healthy lifestyles and preventing disease; taking action on key factors such as nutrition and physical activity and sexual health, and on addiction-related determinants such as tobacco, alcohol and drugs, focussing on key settings such as education and the workplace and across the life cycle.

2.2.2. Support action on the health effects of wider environmental and socio-economic determinants.

3. Generate and disseminate health knowledge

3.1. Exchange knowledge and best practice

3.1.2. Collection of information and exchange of knowledge and best practice on key health issues within the scope of the Programme, including co-operation between health systems, gender-related aspects of health, children's health, mental health and rare diseases.

3.2. Collect, analyse and disseminate health information

3.2.1. (Collection) Develop further a sustainable health monitoring system with mechanisms for collection of data and information, with appropriate indicators; Collection of data on health status and policies; the statistical element of this system will be developed with the Community Statistical Programme.

3.2.2. (Analysis and dissemination) Develop mechanisms for analysis and dissemination, including Community health reports, the Health portal and conferences; provide information to citizens, stakeholders and policy makers, develop consultation mechanisms and participatory processes; regular report on Health Status in the European Union based on all data and indicators and including a qualitative and quantitative analysis[79].

3.2.3. Analysis and technical assistance in support of the development or implementation of policies or legislation related to the scope of this Programme.

[79] **Wording on the report stems from** EP am. 73 accepted by COM with modifications ("regularly" instead of "every two years").

~~ANNEX 1 – Strengthening synergies through common actions and instruments~~

~~Objectives~~

~~1. To protect citizens from risks and threats that are beyond the control of individuals (e.g. health threats which affect the society as a whole, unsafe products, unfair commercial practices).~~

~~2. To increase the ability of citizens to take better decisions about their health and consumer interests.~~

~~3. To mainstream health and consumer policy objectives.~~

~~Actions and instruments~~

~~1. Improve communication with EU citizens on health and consumer issues~~

~~1.1. Awareness-raising campaigns.~~

~~1.2. Surveys.~~

~~1.3. Conferences, seminars, experts and stakeholders meetings.~~

~~1.4. Publications on issues of interest for health and for consumer policy.~~

~~1.5. Provision of online information.~~

~~1.6. Developing and use of information points.~~

~~2. Increase civil society and stakeholders' participation in policy-making related to health and consumer protection~~

~~2.1. Promote and strengthen Community level consumer and health organisations.~~

~~2.2. Training and capacity-building for consumer and health organisations.~~

~~2.3. Networking of non-governmental consumer and health organisations and other stakeholders.~~

~~2.4. Strengthening of Community-level consultative bodies and mechanisms.~~

~~3. Develop a common approach for integrating health and consumer concerns into other Community policies~~

~~3.1. Development and application of methods to assess the impact of Community policies and activities on health and consumer interests.~~

~~3.2. Exchange best practice with Member States on national policies.~~

~~3.3. Studies on impact of other policies on health and consumer protection.~~

~~4. Promote international co-operation related to health and consumer protection~~

~~4.1. Co-operation measures with international organisations.~~

~~4.2. Co-operation measures with third countries who are not participating in the programme.~~

~~4.3. Encourage health and consumer organisations' dialogue.~~

~~5. Improve the early detection, evaluation and communication of risks by:~~

~~5.1. Supporting scientific advice and risk evaluation, including the tasks of the independent scientific committees established by Commission Decision 2004/210/EC80.~~

~~5.2. The collection and collation of information and establishment of networks of specialists and institutes.~~

~~5.3. Promoting the development and harmonisation of risk assessment methodologies.~~

~~5.4. Actions for collecting and assessing information on the exposure of populations and sub-groups to chemical, biological and physical hazards to health.~~

~~5.5. Establishing mechanisms concerning early detection of emerging risks and action on newly identified risks.~~

~~5.6. Strategies to improve risk communication.~~

~~5.7. Training in risk assessment.~~

~~6. Promote the safety of goods and of substances of human origin~~

~~6.1. Analysis of injury data and development of best practice guidelines in relation to the safety of consumer products and services.~~

~~6.2. Development of methodologies and database maintenance for the purpose of data collection on injuries in relation to the safety of consumer products.~~

~~6.3. Activities to help enhance the safety and quality of organs and substances of human origin, including blood, blood components and blood precursors.~~

~~6.4. Promoting the availability and accessibility across the Community of organs and substances of human origin of high quality and safety for medical treatments.~~

~~6.5. Technical assistance for the analysis of issues related to the development and implementation of policies and legislation.~~

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80 OJ L 66, 4.3.2004, p. 45.

~~ANNEX 2 - HEALTH~~

~~ACTIONS AND SUPPORT MEASURES~~

~~Objective one: protect citizens against health threats~~

~~1. Enhance surveillance and control of health threats by~~

~~1.1.1. Enhancing the capacity to tackle communicable diseases by supporting the further implementation of Decision No 2119/98/EC on the Community network on the epidemiological surveillance and control of communicable diseases, and by ensuring coherence with the action of the ECDC taking into account the activities of the European Centre for Disease Prevention and Control;~~

~~1.1.2. Developing strategies and mechanisms for preventing, exchanging information on and responding to non-communicable disease threats;~~

~~1.1.3. Exchanging information on strategies and developing joint strategies to detect and obtain reliable information on health threats from physical, chemical or biological sources, including those relating to deliberate release acts, and developing and using, when appropriate, Community approaches and mechanisms in coordination with the European Centre for Disease Prevention and Control;~~

~~1.1.4. Improving laboratory co-operation to assure high quality diagnostic capabilities for pathogens across the Community, including a Community reference laboratory structure for pathogens requiring enhanced Community collaboration;~~

~~1.1.5. Developing new and improved prevention, vaccination and immunisation policies, partnerships and tools and monitoring immunisation status;~~

~~1.1.5a Monitoring the resistance of bacteria to antibiotics and of nosocomial infections, and developing strategies to prevent and treat them and developing strategies to address them;~~

~~1.1.6. Developing and implementing vigilance networks and reporting systems for adverse events when using preventive health measures and substances of human origin;~~

~~1.1.7. Technical assistance for the analysis of issues related to the development and implementation of policies and legislation.~~

~~1.2. Deliver response to health threats by~~

~~1.2.1. Elaborating risk management procedures for health emergencies, including procedures for mutual assistance in the event of pandemics, and enhancing capability for coordinated responses to health emergencies;~~

~~1.2.2. Developing and maintaining capacity for appraising and addressing the needs and gaps in preparedness and response and for rapid and reliable communications and consultation on counter-measures;~~

~~1.2.3. Developing risk communication strategies and tools for information and guidance to the public, and health professionals, and improving awareness and interaction among actors;~~

~~1.2.4. Developing strategies and procedures for drawing up, testing, evaluating and revising general contingency and specific health emergency plans and their inter-operability between Member States and conducting exercises and tests;~~

~~1.2.5. Developing strategies and mechanisms for reviewing and improving the availability and adequacy of, and access to facilities (e.g. laboratories) and equipment (detectors etc), as well as readiness, surge capacity and infrastructure of the health sector to react rapidly;~~

~~1.2.6. Developing strategies and mechanisms for assessing the need for and promoting the establishment of public health assets that can be deployed rapidly in emergencies and setting up mechanisms and procedures for health assets transfer to requesting states and international organisations;~~

~~1.2.7. Establishment and maintenance of a trained and permanently available core group of public health experts for global rapid deployment to places of major health crises together with mobile laboratories, protective equipment and isolation facilities.~~

Objective 2: promote policies that lead to a healthier way of life

~~3. Promote health by tackling determinants~~

~~Actions will support the preparation, development and implementation of activities, strategies and measures on health determinants by addressing:~~

~~3.1. Health determinants linked to addictions, notably tobacco, alcohol and drugs and other addictive substances;3 2.1a Practices which lead to a healthier life, in order to improve children's health;~~

~~32.2. Lifestyle related health determinants, notably nutrition and physical activity, sexual health and reproductive health;~~

~~32.2a Injury-related health determinants;~~

~~32.3. Social and economic determinants of health, with a particular focus on inequalities in health,~~ and ~~on the impact of social and economic factors on health, and on discrimination against with a particular focus on vulnerable groups;~~

~~32.4. Environmental determinants of health, with a particular emphasis on the health impact of environmental factors;~~

~~32.5. The quality, efficiency and cost effectiveness of public health interventions;~~

~~32.5e Gender and age aspects of health;~~

~~32.6. Support for public awareness activities, training and capacity building actions related to the priorities set out in the previous paragraphs;~~

~~32.7. Technical assistance for the analysis of issues related to the development and implementation of policies and legislation.~~

~~Objective 3: contribute to reducing the incidence, morbidity and mortality of major diseases and injuries~~

~~43. Prevent diseases and injuries~~

~~In coordination with work on health determinants, the programme Programme shall support:~~

~~43.1. Development and implementation of actions on major diseases of particular significance in view of the overall burden of disease and of the main causes of potential life years lost and incapacities in the Community where Community action can provide significant added value to national efforts;~~

~~43.2. Preparation and implementation of strategies and measures on disease prevention, in particular by identifying best practice and developing guidelines and recommendations, including on secondary prevention, screening and early detection;~~

~~43.2a Preparation of strategies and measures on immunisation and vaccination and recommendations for their implementation;~~

~~43.3. Exchange of best practice and knowledge as well as the coordination of strategies to promote mental health and to prevent mental illness;~~

~~43.3b Promotion of best practise for diseases and injuries in order to prevent further deterioration of health;~~

~~43.4. Preparation and implementation of strategies and measures on prevention of injuries, based on the analysis of injury determinants;~~

~~43.4a Development of best practise and guidelines on injuries based on the analysis of collected data;~~

~~4.5. Support for knowledge exchange, training and capacity building actions related to the diseases addressed and injury prevention.~~

~~Objective 4: improving effectiveness and efficiency in health systems~~

~~54. Achieve synergies between national health systems by~~

~~54.1. Facilitating cross-border healthcare purchasing and provision, including information gathering and exchange to enable sharing of capacity and use of cross-border care;~~

~~54.2. Collecting data and Ssharing information on and managing the consequences of the mobility of health professionals and promoting policies on patient mobility;~~

~~54.3. Establishing a Community system for cooperation on centres of reference and other collaborative structures between health systems of more than one Member State which would promote enable doctors and other healthcare practitioners to apply best practices and best knowledge on prevention and treatment available within the EU;~~

~~54.4. Developing a network for strengthening the capacity to develop and share information and assessments regarding health technologies and techniques (health technology assessment);~~

~~54.5. Providing information for patients, professionals and policy-makers, on health systems and medical care in liaison with overall health information actions, and including mechanisms for~~

~~sharing and disseminating information with the action plan for a European e-health area, while establishing strict helping to promote quality criteria for health-related websites;~~

~~54.6. Developing instruments for assessing the impact of Community policies on health systems, including the consequences of enlargement and the Lisbon strategy;~~

~~54.7. Developing and implementing actions to promote patient safety and high-quality care;~~

~~54.7a Promoting the availability, traceability and accessibility across the Community of organs and substances of human origin of high quality and safety for medical use;~~

~~54.8. Supporting health systems policy development, in particular linked to the open method of coordination on healthcare and long-term care.~~

~~Actions and instruments contributing to all the above objectives:~~

~~5. Data Collection, Health Monitoring And Information~~

~~65.1. To improve health information and knowledge for the development of public health byData collection, health monitoring and dissemination of information:~~

~~65.1.1. Continue further developing a sustainable health monitoring system, paying special attention to health inequalities and covering data on health status, health determinants, health systems and injuries; the statistical element of this system will be further developed, using as necessary the Community Statistical Programme.~~

~~65.1.1b Collecting and analysing data on lifestyle related factors (e.g. nutrition and tobacco and alcohol consumption) and injuries, establishing Europe-wide registries for major diseases (e.g. cancer), and developing methodologies and database maintenance;~~

~~65.1.2. Providing other relevant health related knowledge;~~

~~65.1.3. Defining relevant additional indicators;~~

~~65.1.4. Developing appropriate mechanisms of reporting;~~

~~65.1.5. Arranging for regular collection of such information, together with the Statistical Programme, international organisations, agencies and through projects;~~

~~65.1.6. Supporting analysis of Community health issues through regular Community health reports, the maintenance of diffusion mechanisms such as the Health Portal, support for consensus conferences and targeted information campaigns coordinated between concerned parties;~~

~~65.1.7. Focusing on providing a regular and reliable source of information to citizens, to decision makers, to patients, carers, health professionals and to other interested parties;~~

~~65.1.8. Developing strategies and mechanisms for preventing, exchanging information on and responding to rare diseases.~~

~~5.2. Cooperation and integration~~

~~5.4. Risks, safety and horizontal issues~~

~~5.6. Improve the early detection, evaluation and communication of risks by:~~

~~5.6.1. Supporting scientific advice and risk evaluation, including the tasks of the independent scientific committees established by Commission Decision 2004/210/EC1.~~

~~5.6.2. Collection and collation of information and establishment of networks of specialists and institutes.~~

~~5.6.3. Promoting the development and harmonisation of risk assessment methodologies.~~

~~5.6.4. Actions for collecting and assessing information on the exposure of populations and sub-groups to chemical, biological and physical hazards to health, including the effects of such hazards.~~

~~5.6.5. Establishing mechanisms concerning early detection of emerging risks and action on newly identified risks.~~

~~5.6.6. Strategies to improve risk communication.~~

~~5.8. Horizontal issues~~

~~Technical assistance for the analysis of issues related to the development and implementation of policies and legislation~~

~~ANNEX 3: Consumer Policy – Actions and Support Measures~~

~~Objective I - A better understanding of consumers and markets~~

~~Action 1: Monitoring and assessment of market developments with an impact on the economic and other interests of consumers, including price surveys, inventory and analysis of consumer complaints, analysis of cross-border marketing and business-to-consumer purchases, and surveys of changes in the structure of markets.~~

~~Action 2: The collection and exchange of data and information that provide an evidence base for the development of consumer policy and for the integration of consumer interests in other Community policies, including, surveys of consumer and business attitudes, consumer-related and other market research in the financial services area, collection and analysis of statistical and other relevant data, the statistical element of which will be developed using as necessary the Community Statistical Programme.~~

~~Action 3: The collection, exchange, analysis of data and development of assessment tools that provide a scientific evidence base on consumer exposure to chemicals released from products.~~

~~Objective II - Better consumer protection regulation~~

~~Action 4: Preparation of legislative and other regulatory initiatives and promotion of self-regulatory initiatives, including:~~

~~4.1. Comparative analysis of markets and regulatory systems~~

~~4.2. Legal and technical expertise for policy making on the safety of services~~

~~4.3 Technical expertise in relation to assessment of the need for product safety standards and the drafting of CEN standardisation mandates for products and services~~

~~4.4 Legal and technical expertise for policy development on the economic interests of consumers~~

~~4.5 Workshops with stakeholders and experts.~~

~~Objective III - Better enforcement, monitoring and redress~~

~~Action 5: Coordination of surveillance and enforcement actions linked to the application of consumer protection legislation, including:~~

~~5.1 Development and maintenance of IT tools (e.g. databases, information and communication systems)~~

~~5.2. Training, seminars, conferences on enforcement~~

~~5.3. Planning and development of joint enforcement actions~~

~~5.4. Pilot joint enforcement actions~~

~~5.5. Analysis of enforcement problems and solutions~~

~~Action 6: Financial contributions for specific joint surveillance and enforcement actions to improve administrative and enforcement cooperation on Community consumer protection legislation, including the General Product Safety Directive, and other actions in the context of administrative cooperation.~~

~~Action 7: Monitoring and assessment of the safety of non-food products and services, including:~~

~~7.1. Reinforcement and extension of the scope and operation of the RAPEX alert system, taking developments in market surveillance information exchange into account~~

~~7.2. Technical analysis of alert notifications~~

~~7.3. Collection and assessment of data on the risks posed by specific consumer products and services~~

~~7.4. Further development of the consumer product safety network as provided for in Directive 2001/95/EC of the European Parliament and of the Council81.~~

~~Action 8: Monitoring of the functioning and assessment of the impact of alternative dispute resolution schemes on consumers.~~

~~Action 9: Monitoring of the transposition and implementation of consumer protection legislation by Member States, notably the Unfair Commercial Practices Directive, and of national consumer policies.~~

~~Action 10: Provision of specific technical and legal expertise to consumer organisations to support their contribution to enforcement and surveillance actions.~~

~~Objective IV. Better informed and educated and responsible consumers~~

~~Action 11: Development and maintenance of easily and publicly accessible databases covering the application of and case-law on Community consumer protection legislation.~~

~~Action 12: Information actions about consumer protection measures, particularly in the new Member States, in cooperation with their consumer organisations.~~

~~Action 13: Consumer education, including the actions targeted at young consumers, and the development of interactive consumer education tools.~~

~~Action 14: Representation of the interests of Community consumers in international forums, including international standardisation bodies and international trade organisations.~~

~~Action 15: Training for staff members of regional, national and Community consumer organisations and other capacity building actions.~~

~~Action 16: Financial contributions for joint actions with public or non-profit bodies constituting Community networks that provide information and assistance to consumers to help them exercise~~

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81 OJ L 11, 15.1.2002, p. 4.

~~their rights and obtain access to appropriate dispute resolution (the European Consumer Centres Network).~~

~~Action 17: Financial contributions to the functioning of Community consumer organisations representing consumer interests in the development of standards for products and services at Community level.~~

~~Action 18: Financial contributions to the functioning of Community consumer organisations.~~

~~Action 19: Provision of specific technical and legal expertise to consumer organisations to support their participation in, and input into, consultation processes on Community legislative and non-legislative policy initiatives, in relevant policy areas, such as internal market policies, services of general interest and the 10-year framework programme on sustainable production and consumption.~~

~~Common to all objectives~~

~~Action 20: Financial contributions for specific projects at Community or national level in support of other consumer policy objectives.~~

LEGISLATIVE FINANCIAL STATEMENT

1. NAME OF THE PROPOSAL :

Health programme (2007-2013)

2. ABM / ABB FRAMEWORK

Policy area: Health and Consumer Protection (SANCO, Title 17)

Activities: Public health:

3. BUDGET LINES

3.1. Budget lines (operational lines and related technical and administrative assistance lines (ex- B..A lines)) including headings :

Current budget lines:

ABB 17 03 06 Community action in the field of Health and Consumer protection — Public health

ABB 17 01 04 06 : Public Health – Expenditure for Administrative management

ABB 17 01 04 30 : Public health –Operating subsidy to the Executive Agency for the Public Health Programme.

A new budget structure will be defined after approval of the Interinstitutional Agreement on Financial Framework 2007-2013.

3.2. Duration of the action and of the financial impact:

Total allocation for action : 365,6 € million for commitment

Period of application: day of entry into force of the decision in 2007 – 31 December 2013

3.3. Budgetary characteristics:

Budget lines	Type of expenditure		New	EFTA contribution	Contributions from associated countries	Heading in financial framework
17 03 06	Non-comp	diff	NO	YES	YES	No 3b
17 01 04 06	Non-comp	Non-diff	NO	YES	YES	No 3b
17 01 04 30	Non-comp	Non-diff[82]	NO	YES	YES	No 3b

4. SUMMARY OF RESOURCES

4.1. Financial Resources

4.1.1. Summary of commitment appropriations (CA) and payment appropriations (PA)

EUR million (to 3 decimal places)

Expenditure type	Section no.		2007	2008	2009	2010	2011	2012	2013 and later	Total
Operational expenditure[1]										
Commitment Appropriations (CA)	8.1	a	38,80	45,20	47,00	45,70	47,30	49,70	51,50	325,20
Payment Appropriations (PA)		b	11,64	25,20	39,30	45,25	46,52	47,51	109,78	325,20
Administrative expenditure within reference amount[2]										
Technical & administrative assistance (NDA)	8.2.4	c	5,30	5,50	5,80	5,70	5,90	6,00	6,20	40,40
TOTAL REFERENCE AMOUNT										
Commitment Appropriations		a+c	44,10	50,70	52,80	51,40	53,20	55,70	57,70	365,60
Payment Appropriations		b+c	16,94	30,70	45,10	50,95	52,42	53,51	115,98	365,60
Administrative expenditure not included in reference amount[3]										

[82] Non-differentiated appropriations hereafter referred to as NDA.

Human resources and associated expenditure (NDA)	8.2.5	d	5,18	5,18	5,18	5,18	5,18	5,18	5,18	36,29
Administrative costs, other than human resources and associated costs, not included in reference amount (NDA)	8.2.6	e	3,10	3,11	3,13	3,14	3,16	3,17	3,19	15,66

[1] Expenditure that does not fall under Chapter xx 01 of the Title xx concerned.

[2] Expenditure within article xx 01
04 of Title xx.

[3] Expenditure within chapter xx 01 other than articles xx 01 04 or xx 01 05.

Total indicative financial cost of intervention

										total
TOTAL CA including cost of Human Resources		a+c+d+e	52,38	58,994	61,11	59,726	61,541	64,057	66,073	423,88
TOTAL PA including cost of Human Resources		b+c+d+e	25,22	38,993	53,411	59,276	60,762	61,867	124,353	423,88

Co-financing details

Not applicable

4.1.2. Compatibility with Financial Programming

X Proposal is compatible with Financial Framework 2007-2013.

4.1.3. Financial impact on Revenue

X Proposal has no financial implications on revenue

4.2. Human Resources FTE (including officials, temporary and external staff) – see detail under point 8.2.1.

Annual requirements	2007	2008	2009	2010	2011	2012	2013
Total number of human resources*	48	48	48	48	48	48	48

* of which 2 new posts in 2007, covered within the pre-allocation of the Directorate General in the PDB for 2007

5. CHARACTERISTICS AND OBJECTIVES:

5.1. Need to be met in the short or long term

The need is identified in the explanatory memorandum.

5.2. **Value added** of Community involvement and coherence of the proposal with other financial instruments and possible **synergy**

The EU, national and regional authorities, citizens, businesses and civil society have a role to play in improving the health, wellbeing and welfare of European citizens. There are however several health policy challenges that only action at EU level can tackle. Greater mobility and more communication have benefited citizens. But they have also increased the risk of spreading health threats such as SARS and other communicable diseases (which cannot be addressed by individual Member States alone). The complexity of modern life has brought more choice for citizens. But it has also made it harder for them to make the best choices.

The proposed strategy and programme aim to implement article 152 of the Treaty as regards Community action on health, by complementing national action with **value-**added measures which cannot be taken at national level.

The Health programme builds on the existing programme and maintains its core elements. In addition, it aligns future health action more explicitly with the overall Community objectives of prosperity, solidarity and security and with the Lisbon agenda in particular, and seeks to further exploit synergies with other policies.

Synergies will be ensured with other major instruments. For example health has been more closely associated to the Structural Funds and the research programme when designing the new legal base. Particular attention has also been given to ensure synergies with the Solidarity Fund.

5.3. Objectives and expected results of the proposal in the context of the ABM framework

The general objective of the ABM "public health" activity is to aim for a high level of human health protection in the development and implementation of all Community policies, through the promotion of an integrated health strategy, notably by implementation of the multi-annual health programme, and to enhance the capability of the EU to address, in a timely and coordinated fashion, threats to public health.

The objectives of the proposal are identified in the explanatory memorandum.

The expected results are:

1. Improved health security, in particular increased capacity at European and national level to respond to cross-border health threats and also to contribute to strengthened health-related safety across the EU (for example to fulfil the Treaty mandate as regards

safety and quality of substances of human origin for medical use, or as regards the assessment of risks to citizens' health).

2. Stronger health promotion at European level. This would include effective measures to encourage healthy ageing, greater awareness of health's impact on productivity and growth, a narrowing of the health gap across the EU, in particular concerning improvement in health status in the new Member States. The programme should also result in healthier ways of life across the EU, a greater awareness about the impact of lifestyles and addictions on health, and a set of solutions developed through exchange of good practice. By acting on the most important health determinants, the programme will have the result of helping to reduce the disease burden.

3. More and better health knowledge, more dissemination. The programme will result in a health knowledge system, with more comparable data and indicators, higher -quality analysis, and effective dissemination to stakeholders. The programme will further result in Member States taking inspiration from best practice identified through the programme to improve their health systems.

5.4. Method of Implementation (indicative)

Show below the method(s)[83] chosen for the implementation of the action.

X ***Centralised Management***

- X Directly by the Commission
- ☐ Indirectly by delegation to:
  - X Executive Agency
  - ☐ Bodies set up by the Communities as referred to in art. 185 of the Financial Regulation
  - ☐ National public-sector bodies/bodies with public-service mission

☐ ***Shared or decentralised management***

- ☐ With Member states
- ☐ With Third countries

X ***Joint management with international organisations***

[83] If more than one method is indicated please provide additional details in the "Relevant comments" section of this point.

6. MONITORING AND EVALUATION

6.1. Monitoring system

The Commission will monitor the most pertinent indicators throughout the implementation of the new programme. The indicators listed are related to the objectives described under part 5.3 .

Objectives	Indicators
1. Improve citizens' health security	
1.1. Protect citizens against health threats	Number of projects in this area Number of beneficiaries ECDC fully operational Increased European co-ordination capacity for responding rapidly to threats Increased Member States' capacity to address health threats
1.2. Improve citizens' safety	Number of scientific opinions given Community initiatives embodying the scientific opinions Number of projects on patient safety/ high quality and safe healthcare Number of projects on accidents and injuries Number of initiatives on organs / substances of human origin.
2. Promote health to improve prosperity and solidarity	
2.1.Foster healthy, active ageing and help bridge health inequalities	Number of projects on healthy ageing Number of initiatives on health's impact on growth and economic development Number of measures to bridge inequalities between Member States; number of projects benefiting the new Member States Number of projects to improve solidarity between national health systems
2.2. Promote healthier ways of life by tackling health determinants.	Number of new measures proposed and carried out Number of projects in this area Number of thematic platforms created Number of information, publications and target audience reached

3. Generate and disseminate health knowledge	
3.1. Exchange knowledge and best practice	Number of projects in this area Number of best practice solutions identified Number of Member States that took inspiration from good practice to introduce improvements in their health systems Number of health themes addressed
3.2. Collect, analyse and disseminate health information.	Number of projects in this area Number of information/awareness raising publications and target audience reached Number of hits of health portal Number of Health reports and other publications Number of conferences & participants

The implementation of the Community programme entrusted to the executive agency is subject to the control of the Commission and this control is exerted according to the methods, the conditions, the criteria and the parameters which it lays down in the act of delegation defined by Council Regulation (EC) N° 58/2003 laying down the statute for executive agencies to be entrusted with certain tasks in the management of Community programmes[84], Article 6 (3).

6.2. Evaluation

6.2.1. Ex-ante evaluation

This programme proposal is built on a series of existing Community programme and measures, some of which have been operational for many years, and which have been the subject of a comprehensive sequence of evaluations, as well as a substantial corpus of experience of administering and implementing the programmes in the Commission (and a former technical assistance office) and within the Member States and other participating countries (particularly the candidate countries).

The hypothesis of taking no action was considered:

- No action means failure to meet the provisions of article~~s~~ 152 of the Treaty.
- No action means that the Commission would not meet the requirement of having a proper legal basis for health actions during the period 2007-2013 as imposed by the new financial framework. (The Health Programme expires at the end of 2008). This would make it very difficult to fulfil various legal obligations.

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

- No action would mean that the Commission would not fulfil its commitment to present a health strategy, following an open consultation in 2004, intended to help prepare the ground for a new strategy. In terms of effects on health, some serious negative impact would arise following the expiry of the current health programme. Health protection in Europe would be undermined as essential health threat alert mechanisms would find it difficult to operate. There would be inadequate information about important health trends and developments as mechanisms to collect and analyse the data would not function effectively. This would make it harder for health authorities to plan and develop policies and for citizens to take decisions. There would also be a great reduction in actions against trans-frontier health threats eg HIV/AIDS and bioterrorism.

- No action would also mean that the Commission stopped work in areas of central concern to its citizens daily lives and thus lost the possibility to increase visibility and to demonstrate the relevance of its action to them.

  Building a new programme will bring citizens' issues to the forefront of the EU agenda by providing a new framework for a policy that impacts on citizens' day-to-day life.

  In addition the existing executive agency for the public health programme would have its current mandate adapted to be able to ensure the management tasks of the new programme, including budgetary tasks, which would constitute the best management instrument at the disposal of the Commission[85]. This will in particular ensure :

  – Multiplier effect (leverage) enabling the Commission to concentrate on its core competencies;

  – Effectiveness and flexibility in the implementation of outsourced tasks;

  – Simplification of the procedures used;

  – Proximity of the outsourced action to the final beneficiaries.

The public health programme 2003-2008, adopted in September 2002[86], represents a major step forward for the implementation of the provisions of Article 152 of the EC Treaty. It provides for the integrated development of a strategy aimed on the one hand at ensuring a high level of health protection in all Community policies and actions and, on the other, at supplementing and coordinating policies and actions carried out by the Member States in the field of health surveillance and information systems, combating transmissible diseases and disease prevention.

In designing the new joint programme proposal, special attention was given to building upon the experience acquired during the first years of operation of the 2003-2008

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85 See also the study "Cost-effectiveness assessment of externalisation of European Community' s public health action programme" by Eureval-C3E, of 21.6.2002.

86 Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008), OJ L 271, 9/10/2002.

programme, as well as to integrating the work carried out in various consultations, fora and groups.

Preparatory work on the health strategy

An open consultation on the future Health Strategy was launched in July 2004. The consultation was carried out on the basis of a public consultation document published on the web-site. All interested parties from the public health area, public bodies, interest groups and individual citizens, were invited to participate in the consultation, by means of a written contribution. Almost 200 contributions from national and regional authorities, NGOs, universities, individual citizens and companies have reached the Commission, Following the analysis of the results, a number of policy priority areas have been identified making it necessary to re-orient existing work in order to refine the policy priorities. The result is available in the Commission website[87].

Approximately 1/4 of all respondents including Ireland, Sweden, the Netherlands, Germany, the UK, Lithuania Malta and Poland urged the EU to pro-actively promote health and prevent illness. Measures proposed include the need to focus on children and teenagers, to implement a nutrition/obesity strategy, to tackle smoking and alcohol, to address a wide range of issues affecting health and to act on important diseases including cancer, respiratory and cardiovascular diseases.

Approximately 1/5 of all respondents including France, Germany, Ireland, the Netherlands, Sweden, Finland and Lithuania asked the EU to mainstream health. Respondents urged the Commission to implement a comprehensive and coherent EU approach to health, encompassing policies as diverse as Education, Trade, Internal Market, Social, Environment, Agriculture, External, Transport and Regional development. Several respondents including France, Ireland, Sweden and Finland raised the need for a Health Impact Assessment system.

The need to position health as a driver of economic growth and to disseminate evidence was raised by Ireland, France, the Netherlands, Malta and the UK. Some NGOs and Germany, Ireland and Sweden asked for health to become part of the Lisbon agenda.

Many stressed the need to address health inequalities by increasing funding for health. Respondents also urged the EU to involve stakeholders more closely in policy-making, to support the civil society, to take a stronger role on international health and to step up efforts in the analysis and dissemination of data.

Finally, many respondents also urged the EU to increase resources allocated to health, for the Public Health Programme to better serve policy priorities, to improve dissemination of project results, to cover neighbouring countries and to increase co-funding.

Respondents raise a large number of additional specific issues including the need to focus more on mental health, the challenges posed by an ageing population, the need to increase quality in healthcare, to secure patients' rights and safety, to set clear rules for patient and professional mobility, for health technology assessment and research.

Health systems

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87 http://europa.eu.int/comm/health/ph_overview/strategy/reflection_process_en.htm.

In 2003, a high level reflection process on patient mobility and healthcare developments in the EU was launched at ministerial level. Working groups composed of Member State health ministers or senior representatives, and stakeholders met throughout the year. In December 2003, a ministerial level meeting including ministers from acceding countries, adopted a report containing 19 recommendations for action at EU level. The Commission responded in presenting three Communications[88] in April 2004. To take forward these recommendations, a High Level Group on health services and medical care was established with working groups on the following areas : cross-border healthcare purchasing and provision, health professionals, centres of reference, health technology assessment, information and e-health, health impact assessment and health systems, patient safety. Reports setting out progress and orientations for future work were endorsed by the Council in December 2004 and in December 2005.

Involvement of stakeholders

Health policy making must respond to the needs and concerns of citizens. It is necessary to build up the organisations representing patients and those developing the public health agenda so that civil society is able to make the constructive contribution needed to public health policy.

Currently, patient groups and non governmental organisations in the health field can find it difficult to develop initiatives at EU level and to stabilise their organisations because they have inadequate resources.

For example active participation in the EU Health policy forum, which brings stakeholders together to discuss policy issues, requires a level of organisational capacity and resources that many NGOs lack. Associations are not funded for their core work as such, because the legal basis of the Public Health Programme 2003-2008 does not allow such direct funding. The Commission is therefore proposing operational grants as well as project grants to provide core funding to certain NGOs, including patient groups, in order to help them develop their organisational capacity and put themselves on a sound basis.

As underlined in the Lisbon process, there is a need to reduce the major differences between Member States in terms of life expectancy, health status and health systems capability. Following enlargement, supporting in particular the new Member States to develop their health systems requires additional resources. In addition to infrastructure investment and human resources to which the Community Structural Funds can contribute, there is a need for the Community to help these countries in terms of training, expertise, capacity building, preparedness, prevention and promotion, as well as a need for analysis on their health investment needs.

Finally, ageing of the EU population and its potential impact on the sustainability of public finances, not least from the relative decline in the working population, requires EU action to help Member States cope with this challenge.

Cost-effectiveness

The adaptation of the existing Public Health Programme executive agency to support the new proposed programme will also lead to savings in terms of input as regards tasks

[88] COM(2004) 301, COM(2004) 304, COM(2004) 356.

related with tendering and organisation of meetings. The outsourcing of such administrative tasks to the executive agency will also enable the Commission to focus on policy making and conception tasks, including developing significant links with other policies.

The programme foresees improving the way projects results are exploited and disseminated, which will increase projects' impact and visibility. The outsourcing of administrative tasks will enable the Commission to focus on ensuring that health crises and emergencies are better handled, that project results are better disseminated, to expand work with stakeholders and to develop policy work on e.g. health inequalities, ageing and children's health.

6.2.2. Measures taken following an intermediate/ex-post evaluation (lessons learned from similar experiences in the past)

Ex post evaluation of the former 8 public health programmes

The role of the European Community in the field of public health, as defined by the Treaty, is to complement Member States' action by promoting research, providing health information and education, encouraging cooperation and fostering policy coordination among Member States through incentive measures. An evaluation of the 8 Community programmes of 1996-2002 was carried out in 2004[89]. The main objective was to assess whether the goals were achieved in the EU through these action programmes and to locate the genuine added value of European intervention in the field of public health.

The evaluation shows that the Programmes had an overall positive added value and calls for further investment by the EU in Public Health. It gives a number of recommendations : some of the issues raised have already been addressed when building the Public health programme 2003-2008. However room for improvement remains for the following areas:

- develop a complete and coherent theory of action for the general public health framework;
- clarify the priorities the programme seeks to meet and the levels targeted;
- be structured and research synergies and complementarities between the policy instruments and the research areas;
- in the area of health determinants, redirect a substantial part of the new programme towards the aspects of these diseases which have not been fully researched and towards tackling the issue of diseases from a preventive point of view;

[89] Deloitte report of 2004 : "Final Evaluation of the eight Community Action Programmes on Public Health (1996-2002) – web link : http://europa.eu.int/comm/health/ph_programme/evaluation_en.htm.

- to allow more room, in cases regarding the share of responsibilities between the EU and the Member States, for a re-orientation of the EU priorities towards emerging issues and innovative approaches;

- to maximise the possibilities to exchange information and knowledge between Member States, notably to allow bridging the gap between countries lagging behind the most advanced states, specially considering the recent enlargement;

- to set up a systematic internal and external communication policy;

- to enhance training activities, as it is the most valuable way of disseminating methods and best practices;

- to reserve financing in the new programme for the effective and large networks, i.e. which are representative in terms of partners involved and coverage of the EU as a whole, so to ensure their sustainability.

These recommendations will be reflected as far as possible in the construction of the new programme.

6.2.3. Terms and frequency of future evaluation

Details and frequency of planned evaluation:

(See Article 13 of the proposed Programme)

An external and independent interim evaluation, i.e., mid-term report will be undertaken three years after adoption of the programme. The object of this report is to provide an initial assessment of the impact and effectiveness of the programme on the basis of the results obtained. The report shall in particular make it possible to assess the impact of measures on all countries. Any changes or adjustments that are deemed necessary will be proposed by the Commission for the second half of the programme.

Communication on the continuation of the Programme no later than four years after its adoption.

Ex post evaluation, i.e. final Report: A detailed external independent evaluation report covering the entire period of operation of the Programme will be carried out by 31 December 2015, to assess the implementation of the Programme.

Furthermore, the Commission plans to audit beneficiaries in order to check that Community funds are being used properly. The results of audits will form the subject of a written report.

Evaluation of the results obtained:

Information providing a measure of the performance, results and impact of the Programme will be taken from the following sources:

- statistical data compiled on the basis of the information from application dossiers and the monitoring of beneficiaries' contracts;

- audit reports on a sample of programme beneficiaries ;
- use of the results of the executive agency's evaluations and audits.

7. Anti-fraud measures

All the contracts, conventions and legal undertakings concluded between the Commission and the beneficiaries under the programme foresee the possibility of an audit at the premises of the beneficiary by the Commission's services or by the Court of Auditors, as well as the possibility of requiring the beneficiaries to provide all relevant documents and data concerning expenses relating to such contracts, conventions or legal undertakings up to 5 years after the contractual period. Beneficiaries are subject to the requirement to provide reports and financial accounts, which are analysed as to the eligibility of the costs and the content, in line with the rules on Community financing and taking account of contractual obligations, economic principles and good financial management.

8. DETAILS OF RESOURCES

8.1. Objectives of the proposal in terms of their financial cost

Commitment appropriations in EUR million (to 3 decimal places)

(Headings of Objectives, actions and outputs should be provided)	Type of output	Av. cost	2007		2008		2009		2010		2011		2012		2013 and later		TOTAL	
			No. outputs	Total cost	No. outputs	Total cost	No. outputs	total costs	N outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost
OPERATIONAL OBJECTIVE No.1 citizen's health security																		
Action 1.1 : protect citizens against health threats	Projects, conferences, studies, meetings, networks	0,600	13	7,760	15	9,040	16	9,409	15	9,137	16	9,467	17	9,933	17	10,301	108	65,048
Action 1.2 : improve citizen's safety	Projects, conferences, studies, meetings, networks	0,600	6	3,880	8	4,520	8	4,705	8	4,569	8	4,734	8	4,966	9	5,151	54	32,524
Sub-total Objective 1	-	-	19	11,640	23	13,561	24	14,114	23	13,706	24	14,201	25	14,899	26	15,452	164	97,572
OPERATIONAL OBJECTIVE No.2 : promote health																		
Action 2.1 : foster healthy, active ageing and help bridge inequalities	projects, networks, conferences, meetings	0,600	8	5,04	10	5,876	10	6,116	10	5,939	10	6,154	11	6,456	11	6,696	70	42,281

Action 2.2 : Promote healthier ways of life by tackling health determinants	**projects, networks, conferences, meetings**	**0,600**	**14**	**8,54**	**17**	**9,944**	**17**	**10,350**	**17**	**10,051**	**17**	**10,414**	**18**	**10,926**	**19**	**11,332**	**119**	**71,553**
Sub-total Objective 2	**-**	**-**	**22**	**13,58**	**27**	**15,821**	**27**	**16,466**	**27**	**15,990**	**27**	**16,568**	**29**	**17,382**	**30**	**18,027**	**189**	**113,834**
OPERATIONAL OBJECTIVE No.3 generate and disseminate health knowledge																		
Action 3.1: Exchange knowledge and best practice	**-**	**0,600**	**10**	**5,82**	**11**	**6,78**	**12**	**7,05**	**11**	**6,86**	**12**	**7,10**	**12**	**7,46**	**13**	**7,73**	**81**	**48,78**
Action 3.2: Collect, analyse and disseminate health information	**-**	**0,600**	**13**	**7,76**	**15**	**9,04**	**16**	**9,40**	**15**	**9,14**	**16**	**9,46**	**17**	**9,94**	**17**	**10,30**	**108**	**65,04**
Sub-total Objective 3	**-**	**-**	**23**	**13,58**	**26**	**15,82**	**28**	**16,45**	**26**	**16,00**	**28**	**16,56**	**29**	**17,40**	**30**	**18,03**	**190**	**113,82**
TOTAL COST	**-**	**-**	**64**	**38,80**	**76**	**45,20**	**79**	**47,00**	**76**	**45,70**	**79**	**47,30**	**83**	**49,70**	**86**	**51,50**	**543**	**325,20**

8.2. Administrative Expenditure

8.2.1. Number and type of human resources

Types of post		Staff to be assigned to management of the action using existing and/or additional resources (number of posts/FTEs)						
		2007	2008	2009	2010	2011	2012	2013
Officials or temporary staff[1] (17 01 01)	A*/AD	22	22	22	22	22	22	22
	B*, C*/AST	11	11	11	11	11	11	11
Staff financed[2] by art. 17 01 02		15	15	15	15	15	15	15
Other staff [3] financed by art. 17 01 04/05								
TOTAL		48	48	48	48	48	48	48

The calculation includes the existing resources devoted to the current programme, and the new requested staff, subject to agreement under the annual procedure of resources allocation (APS/PDB). The increase in the Commission staff is needed to~~.~~ undertake the conceptual and strategic preparatory work during the first year~~s~~ of the programme.This increase should be covered within the pre-allocation of the DG in the PDB for 2007.

It does not include the executive agency's staff.

8.2.2. Description of tasks deriving from the action

This is explained in the explanatory memorandum.

8.2.3. Sources of human resources (statutory)

(When more than one source is stated, please indicate the number of posts originating from each of the sources)

X Posts currently allocated to the management of the programme to be replaced or extended

X Posts pre-allocated within the APS/PDB exercise for year 2007

☐ Posts to be requested in the next APS/PDB procedure

☐ Posts to be redeployed using existing resources within the managing service (internal redeployment)

☐ Posts required for year n although not foreseen in the APS/PDB exercise of the year in question

8.2.4. Other Administrative expenditure included in reference amount (XX 01 04/05 – Expenditure on administrative management)

EUR million (to 3 decimal places)

Budget line (number and heading)	2007	2008	2009	2010	2011	2012	2013 and later	TOTAL
1 Technical and administrative assistance (including related staff costs)								
Executive agencies[1]	4,10	4,10	4,30	4,30	4,40	4,50	4,60	30,30
Other technical and administrative assistance								
- intra muros	1,000	1,190	1,280	1,018	1,257	1,245	1,182	8,172
- extra muros	0,200	0,210	0,221	0,382	0,243	0,255	0,418	1,928
Total Technical and administrative assistance	5,30	5,50	5,80	5,70	5,90	6,00	6,20	40,40

These costs include the programme's contribution to the operating costs of the Public Health Executive agency, and notably the personnel costs to the agency for this programme. These costs correspond to an estimation of 26 people (statutory personnel at the agency and contractual agents)

8.2.5. Financial cost of human resources and associated costs not included in the reference amount

EUR million (to 3 decimal places)

Type of human resources	2007	2008	2009	2010	2011	2012	2013 and later
Officials and temporary staff (17 01 01)	3,5646	3,5646	3,5646	3,5646	3,5646	3,5646	3,5646
Staff financed by Art 17 01 02 (auxiliary, END, contract staff, etc.) (specify budget line)	1,62	1,62	1,62	1,62	1,62	1,62	1,62
Total cost of Human Resources and associated costs (NOT in reference amount)	5,184	5,184	5,184	5,184	5,184	5,184	5,184

Calculation – Officials and Temporary agents

Calculation includes overheads expenses and is based on the average cost in the Commission

Calculation– ***Staff financed under art. XX 01 02***

Calculation includes overheads expenses and is based on the average cost in the Commission

8.2.6 Other administrative expenditure not included in reference amount

EUR million (to 3 decimal places)

	2007	2008	2009	2010	2011	2012	2013	TOTAL
17 01 02 11 01 – Missions	0,525	0,528	0,530	0,533	0,536	0,538	0,541	2,657
17 01 02 11 02 – Meetings & Conferences; Committees	1,400	1,407	1,414	1,421	1,428	1,435	1,443	7,085
17 01 02 11 04 – Studies & consultations	0,420	0,422	0,424	0,426	0,428	0,431	0,433	2,125
17 01 02 11 05 - Information systems	0,525	0,528	0,530	0,533	0,536	0,538	0,541	2,657
2 Total Other Management Expenditure (XX 01 02 11)	2,870	2,884	2,899	2,913	2,928	2,942	2,957	14,524
3 Other expenditure of an administrative nature (specify including reference to budget line) Total Administrative expenditure, other than human resources and associated costs (NOT included in reference amount)	2,870	2,884	2,899	2,913	2,928	2,942	2,957	14,524

Calculation - ***Other administrative expenditure not included in reference amount***

The needs for human and administrative resources shall be covered within the allocation granted to the managing Directorate-General in the framework of the annual allocation procedure.