

2009 - 2014

# Plenary sitting

A7-0224/2012

3.7.2012

# \*\*\*I REPORT

on the proposal for a regulation of the European Parliament and of the Council establishing a Health for Growth Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020 (COM(2011)0709 – C7-0399/2011 – 2011/0339(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Françoise Grossetête

RR\908053EN.doc PE486.116v03-00

# Symbols for procedures

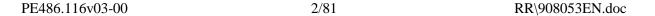
- \* Consultation procedure
- \*\*\* Consent procedure
- \*\*\*I Ordinary legislative procedure (first reading)
- \*\*\*II Ordinary legislative procedure (second reading)
- \*\*\*III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

### Amendments to a draft act

In amendments by Parliament, amendments to draft acts are highlighted in *bold italics*. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the draft act which may require correction when the final text is prepared – for instance, obvious errors or omissions in a language version. Suggested corrections of this kind are subject to the agreement of the departments concerned.

The heading for any amendment to an existing act that the draft act seeks to amend includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend. Passages in an existing act that Parliament wishes to amend, but that the draft act has left unchanged, are highlighted in **bold.** Any deletions that Parliament wishes to make in such passages are indicated thus: [...].



# **CONTENTS**

	Page
DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION	4
EXPLANATORY STATEMENT	54
OPINION OF THE COMMITTEE ON BUDGETS	57
OPINION OF THE COMMITTEE ON INDUSTRY, RESEARCH AND ENERGY	67
PROCEDURE	81

#### DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a regulation of the European Parliament and of the Council establishing a Health for Growth Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020 (COM(2011)0709-C7-0399/2011-2011/0339(COD))

# (Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2011)0709),
- having regard to Article 294(2) and Article 168(5) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0399/2011),
- having regard to the Charter of Fundamental Rights of the European Union, and in particular Article 35 thereof,
- having regard to Article 294(2) and Article 168(5) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0399/2011),
- having regard to its resolution of 9 October 2008 on "Together for Health: A Strategic approach for the EU 2008-2013"<sup>1</sup>,
- having regard to the White paper Together for Health: A strategic Approach for the EU 2008-2013 (COM (2007)0630),
- having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
- having regard to the opinion of the European Economic and Social Committee of 23 February 20122,
- having regard to the opinion of the Committee of the Regions of 4 May 20123,
- having regard to the European Parliament resolution of 8 March 2011 on reducing health inequalities in the EU<sup>4</sup>,
- having regard to Rule 55 of its Rules of Procedure,
- having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Budgets and the Committee on Industry,

-

<sup>2</sup> OJ C 143, 12.5.2012, p. 102.

<sup>3</sup> Not yet published in the Official Journal.

Research and Energy (A7-0224/2012),

- 1. Adopts its position at first reading hereinafter set out;
- 2. Points out that the financial envelope specified in the legislative proposal constitutes only an indication to the legislative authority and cannot be fixed until agreement is reached on the proposal for a regulation laying down the multiannual financial framework for the years 2014-2020;
- 3. Stresses that the amounts of funding referred to in this legislative procedure may have to be adapted to suit the financial envelope of the Health for Growth Programme in the ongoing negotiations on the multi-annual financial framework;
- 4. Recalls its resolution of 8 June 2011 on Investing in the future: a new Multiannual Financial Framework (MFF) for a competitive, sustainable and inclusive Europe<sup>1</sup>; reiterates that sufficient additional resources are needed in the next MFF in order to enable the Union to fulfil its existing policy priorities and the new tasks provided for in the Treaty of Lisbon, as well as to respond to unforeseen events; points out that even with an increase in the level of resources for the next MFF of at least 5% compared to the 2013 level only a limited contribution can be made to the achievement of the Union's agreed objectives and commitments and the principle of Union solidarity; challenges the Council, if it does not share this approach, to clearly identify which of its political priorities or projects could be dropped altogether, despite their proven European added value;
- 5. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
- 6. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

\_

<sup>&</sup>lt;sup>1</sup> Texts adopted, P7\_TA(2011)0266.

#### Amendment 1

# Proposal for a regulation Title

Text proposed by the Commission

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing a Health *for* Growth Programme, the third multiannual programme of EU action in the field of health for the period 2014-2020

#### Amendment

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing a Health *and* Growth *for Citizens* Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020

(This amendment applies throughout the text.)

#### Amendment 2

# Proposal for a regulation Recital 1

Text proposed by the Commission

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

#### **Amendment**

(1) A high level of health protection should be ensured in the definition and implementation of all Union policies and activities, in accordance with Article 168 of the Treaty and Article 35 of the Charter of Fundamental Rights of the European Union. The Union shall complement and support national health policies, encourage the cooperation between Member States and promote the coordination between their programmes, in full respect of the responsibilities of the national authorities for shaping their health policies and organising and delivering health services and medical care.

PE486.116v03-00 6/81 RR\908053EN.doc

#### Amendment 3

# Proposal for a regulation Recital 2

Text proposed by the Commission

(2) Continued effort is required in order to meet the requirements set out in Article 168 of the Treaty. Promoting good health at EU level is an integral part of the 'Europe 2020: A European Strategy for smart, sustainable and inclusive growth'. Keeping people healthy and active for longer will have positive overall *health* effects, and a positive impact on productivity and competitiveness, while reducing pressures on national budgets. Innovation in health helps take up the challenge of sustainability in the sector in the context of demographic change, and action to reduce inequalities in health is important to achieve 'inclusive growth'. It is appropriate in this context to establish a 'Health for Growth' Programme, the third programme of EU action on health (2014-2020) (hereinafter referred to as 'the Programme').

#### Amendment

(2) Continued effort is required in order to meet the requirements set out in Article 168 of the Treaty. Promoting good *mental* and physical health at EU level is an integral part of the 'Europe 2020: A European Strategy for smart, sustainable and inclusive growth'. Keeping people healthy and active for longer and empowering them to take an active role in managing their health, inter alia by improving people's health literacy, will have positive overall effects on health, including reduction of health inequalities, and a positive impact on their quality of life, on productivity and competitiveness, while reducing pressures on national budgets. Support for and recognition of innovation in all factors and measures having an impact on health help take up the challenge of sustainability in the sector in the context of demographic change, and action to reduce inequalities in mental and physical health is important to achieve 'inclusive growth' and contribute to the Union's objective of 'well-being of its peoples' set out in Article 3 of the Treaty on European Union. It is appropriate in this context to establish a 'Health for Growth' Programme, the third programme of EU action on health (2014-2020) (the 'Programme').

# **Justification**

The appropriate measures must be taken to encourage innovation.

#### Amendment 4

Proposal for a regulation Recital 3 a (new)

## Text proposed by the Commission

#### Amendment

(3a) The new Programme should also build on the activities and achievements carried out under the European Pact for Mental Health and Well-being of 13 June 2008 and explicitly recognise the irrefutable link between physical and mental health.

#### Amendment 5

# Proposal for a regulation Recital 4

Text proposed by the Commission

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

#### Amendment

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

# Amendment 6

# Proposal for a regulation Recital 5

Text proposed by the Commission

(5) The programme shall put forward actions in areas where there is evidence of EU added-value on the basis of the following criteria: best practice exchange between Member States; supporting

#### Amendment

(5) The programme shall put forward actions in areas where there is evidence of EU added-value on the basis of the following criteria: best practice exchange between Member States; supporting

PE486.116v03-00 8/81 RR\908053EN.doc

networks for knowledge sharing or mutual learning; addressing cross-border threats to reduce risks and mitigate their consequences; addressing certain issues relating to the Internal Market where the EU has substantial legitimacy to ensure high-quality solutions across Member States; unlocking the potential of innovation in health; actions that could lead to a system for benchmarking to allow informed decision-making at European level; improving economies of scale by avoiding waste due to duplication and optimising the use of financial resources.

networks for knowledge sharing or mutual learning; achieving key social objectives such as promotion of equity and solidarity and reduction of health inequalities; addressing cross-border threats to reduce risks and mitigate their consequences; addressing certain issues relating to the Internal Market where the EU has substantial legitimacy to ensure highquality solutions across Member States; unlocking the potential of innovation in health; actions that could lead to a system for benchmarking to allow informed decision-making at European level; improving economies of scale by avoiding waste due to duplication and optimising the use of financial resources.

#### Amendment 7

Proposal for a regulation Recital 5 a (new)

Text proposed by the Commission

#### Amendment

(5a) The Programme should respect the competences of Member States in the field of health and their freedom to decide what kind of health services they consider it appropriate to provide, in strict compliance with the principle of subsidiarity, including respect for the different management systems and for the specific approaches chosen by the Member States in integrating public and private provision of healthcare services.

#### Amendment 8

Proposal for a regulation Recital 5 b (new)

Text proposed by the Commission

Amendment

(5b) Where ethical issues arise, it should remain within the competence of the

RR\908053EN.doc 9/81 PE486.116v03-00

Member States to determine whether or not a given service constitutes a health service.

#### Amendment 9

# Proposal for a regulation Recital 6

Text proposed by the Commission

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

### Amendment

(6) The World Health Organisation (WHO) European Health Report 2009 identifies scope for increasing investment in public health and health systems. In this regard, Member States are encouraged to identify *mental and physical* health improvement as a priority in their national programmes and to benefit from better awareness of the possibilities of EU funding for health. *To ensure that* the Programme *can usefully* facilitate the uptake of its results into the national health policies, *European resources should be granted only to national programmes that meet given requirements*.

## **Amendment 10**

Proposal for a regulation Recital 6 a (new)

Text proposed by the Commission

#### Amendment

(6a) The austerity measures in all Member States affect health care by decreasing public expenditure and consequently increasing unequal access to health care for people with low income.

# **Amendment 11**

Proposal for a regulation Recital 7

PE486.116v03-00 10/81 RR\908053EN.doc

## Text proposed by the Commission

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

#### Amendment

(7) Innovation in health should be understood as a public health strategy which is not limited to technological advances in terms of products and services. Fostering innovation in the field of public health interventions, prevention strategies, health system management and organisation and provision of care, has the potential to improve public health outcomes, enhance the quality of care to patients and respond to unmet needs while also improving the cost-efficiency and sustainability of care. Therefore, the Programme should facilitate the uptake of innovation in public health and healthcare.

#### Amendment 12

# Proposal for a regulation Recital 7 a (new)

Text proposed by the Commission

## Amendment

(7a) Taking into consideration the increasingly ageing population and the mounting pressure on the public finances and private productivity, due to the increase of expenses for this ageing population which is a structural problem for the Member States, the Programme should also support the firm promotion of the principle of prevention (in terms of medical practices as well as in terms of encouraging healthier lifestyles) and the introduction of e-health services. Health indicators will contribute to significant improvement of the economic indicators.

### **Amendment 13**

Proposal for a regulation Recital 9

### Text proposed by the Commission

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

#### Amendment

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

## Justification

The European Health Literacy Survey (2011), supported by the European Commission, showed the correlation between health literacy and prevention/people's health management. Improving health literacy of citizens and patients leads to better informed choices and is a key element to achieve better health outcomes and a more efficient resource use.

# **Amendment 14**

# Proposal for a regulation Recital 10

# Text proposed by the Commission

(10) In the context of an ageing society, well-directed investments to promote health and prevent diseases can increase the number of 'healthy life years' and thus enable the elderly to continue working as they grow older. Chronic diseases are responsible for over 80% of premature

#### Amendment

(10) In the context of an ageing society, well-directed investments to promote *physical and mental* health and prevent diseases can increase the number of 'healthy life years' and thus enable the elderly, *if they wish*, to continue working as they grow older, *while encouraging* 

PE486.116v03-00 12/81 RR\908053EN.doc

mortality in the EU. By identifying, disseminating and promoting the up-take of validated best practices for cost-effective prevention measures focused on the key risk factors, namely smoking, *abuse of alcohol* and obesity, *as well as on HIV/AIDS*, the Programme will contribute to *prevent* diseases and promote good health, also bearing in mind underlying factors of a social *and environmental* nature.

active and healthy ageing. Chronic diseases are responsible for over 80% of premature mortality in the EU. By identifying, disseminating and promoting the up-take of validated best practices for cost-effective prevention measures focused on the key risk factors, namely smoking, harmful use of alcohol, an unhealthy diet, a sedentary lifestyle and obesity, drug use, and environmental factors, as well as communicable diseases, the Programme will contribute to prevent diseases and promote good health, operating within a gender-sensitive framework, also bearing in mind underlying factors of a social nature, as well as the impact on health of certain disabilities.

## Justification

All the above risk factors should be taken into account so as to provide suitably effective protection against chronic diseases.

#### **Amendment 15**

Proposal for a regulation Recital 10 a (new)

Text proposed by the Commission

Amendment

(10a) In addition to differences relating to reproductive functions, biological differences between women and men also include, for example, the better infant survival rates of females, sex-specific diseases, distinctions in symptoms of diseases, or women's longer life expectancy, which in combination with existing social factors embodied by gender inequalities such as lesser access to resources, heavier workload, genderbased violence against women and gender-based discrimination, significantly affect the health status of women and therefore call for gender to be adequately integrated into public health policies as a determinant of health.

#### **Amendment 16**

# Proposal for a regulation Recital 10 b (new)

Text proposed by the Commission

**Amendment** 

(10b) Prevention means primary prevention, including health promotion policies, as well as secondary prevention, including vaccination programmes, early diagnosis and appropriate treatment in order to prevent the development of a disease, as well as tertiary prevention, including methods to mitigate and reduce the complications of a disease.

# Justification

Prevention needs to be looked at in its entirety, including primary, secondary and tertiary prevention, in order to stop a disease getting to its final stage.

#### **Amendment 17**

Proposal for a regulation Recital 10 c (new)

Text proposed by the Commission

Amendment

(10c) The links between the environment and health are now well documented. According to the World Health Organisation's (WHO) 2009 report on health in Europe, in the WHO European region more than 1.7 million deaths (18 % of the total) each year can be ascribed to environmental factors. The risk factors have a clear cross-border dimension. By way of example, atmospheric pollution increases the prevalence of respiratory problems and cardiovascular disease. By the same token, the presence of toxic products in the water, the air, the soil, housing and foodstuffs can have a serious impact on health, in particular for the

PE486.116v03-00 14/81 RR\908053EN.doc

most vulnerable groups, such as children or the elderly. The Union should therefore provide the Member States with support in preventing and reducing environmental health risks.

### **Amendment 18**

# Proposal for a regulation Recital 10 d (new)

Text proposed by the Commission

#### Amendment

(10d) Major gaps still exist in expertise and general knowledge about the differences between disease processes in women and men, and further gendersensitive studies, analyses, investigations and sex-disaggregated data would contribute to identifying, disseminating and promoting validated best practices for cost-effective prevention measures addressing gender-specific health conditions and diseases.

#### **Amendment 19**

## Proposal for a regulation Recital 11

Text proposed by the Commission

(11) To minimise the public health consequences of cross-border health threats which could range from mass contamination caused by chemical incidents to pandemics, like those unleashed recently by E coli, influenza strain H1N1 or SARS (severe acute respiratory syndrome), the Programme should contribute to the creation and maintenance of robust mechanisms and tools to detect, assess and manage major cross-border health threats. Due to the nature of these threats, the Programme should support coordinated public health

### **Amendment**

(11) To minimise the public health consequences of cross-border health threats which could range from mass contamination caused by chemical incidents to pandemics, like those unleashed recently by E coli, influenza strain H1N1 or SARS (severe acute respiratory syndrome) or diseases from developing countries which through global population movements are an increasing reality in some European countries, the Programme should contribute to the creation and maintenance of robust mechanisms and tools to detect,

RR\908053EN.doc 15/81 PE486.116v03-00

measures at EU level to address different aspects, building on preparedness and response planning, robust and reliable risk assessment and a strong risk and crisis management framework. In this context, it is important that the programme should benefit from complementarity with the work programme of the European Centre for Disease Prevention and Control in the fight against communicable diseases and the activities supported under the Unions programmes for research and innovation. Special efforts should be undertaken to ensure coherence and synergies between the Programme and global health work carried out under other Community programmes and instruments that address in particular the areas of influenza, HIV/AIDS, tuberculosis and other crossborder health threats in third countries. Action under the programme *may* also cover cross-border threats to health caused by biological and chemical incidents, environment and climate change. As stated in the Commission's Communication 'A Budget for Europe 2020', the Commission has committed to mainstreaming climate change into overall Union spending programmes and to direct at least 20% of the Union budget to climate-related objectives. Spending in the *Health for* **Growth** Programme under objective 4 will contribute in a general manner to this objective by addressing health threats associated to climate change. The Commission will provide information on climate change expenditure within the Health for Growth Programme.

assess and manage major cross-border health threats. Due to the nature of these threats, the Programme should support coordinated public health measures at EU level to address different aspects, building on preparedness and response planning, robust and reliable risk assessment and a strong risk and crisis management framework. In this context, it is important that the programme should benefit from complementarity with the work programme of the European Centre for Disease Prevention and Control in the fight against communicable diseases and the activities supported under the Unions programmes for research and innovation. Special efforts should be undertaken to ensure coherence and synergies between the Programme and global health work carried out under other Community programmes and instruments that address in particular the areas of influenza, HIV/AIDS, tuberculosis and other cross-border health threats in third countries. Action under the programme should also cover cross-border threats to health caused by biological and chemical incidents, environment and climate change. As stated in the Commission's Communication 'A Budget for Europe 2020', the Commission has committed to mainstreaming climate change into overall Union spending programmes and to direct at least 20% of the Union budget to climate-related objectives. Spending in the Programme under objective 4 will contribute in a general manner to this objective by addressing health threats associated to climate change. The Commission will provide information on climate change expenditure within the Programme.

## Justification

Action with regard to cross-border threats to health caused by biological and chemical incidents, environment and climate change should not just be a vague possibility. It should be clarified that the programme will also contribute to those issues.

#### Amendment 20

# Proposal for a regulation Recital 12

Text proposed by the Commission

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

#### Amendment

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

#### **Amendment 21**

# Proposal for a regulation Recital 13 a (new)

Text proposed by the Commission

#### Amendment

(13a) Studies show that the Union is lagging far behind many countries in the world as regards health education and patient awareness of safety and quality issues; it is essential, therefore, to focus more closely on improving EU citizens' health education and raising awareness among patients and healthcare professionals of safety and quality issues.

#### Amendment 22

Proposal for a regulation Recital 15

## Text proposed by the Commission

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

#### Amendment

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

## Justification

Independence is one of the criteria for eligibility for grants. This should be reflected in the recital.

#### **Amendment 23**

# Proposal for a regulation Recital 16

Text proposed by the Commission

(16) The programme should promote synergies while avoiding duplication with related Union programmes and actions. Appropriate use should be made of other Union funds and programmes, in particular the current and future Union framework programmes for research and innovation and their outcomes, the Structural Funds, the Programme for social change and innovation, the European Solidarity Fund, the European strategy for health at work, the Competitiveness and Innovation

#### **Amendment**

(16) The programme should promote synergies while avoiding duplication with related Union programmes and actions. Appropriate use should be made of other Union funds and programmes, in particular the current and future Union framework programmes for research and innovation and their outcomes, the Structural Funds, the Programme for social change and innovation, the European Solidarity Fund, the European strategy for health at work, the Competitiveness and Innovation

PE486.116v03-00 18/81 RR\908053EN.doc

Programme, the Framework Programme for Environment and Climate action (LIFE), the programme of Union action in the field of consumer policy (2014-2020), the Justice programme (2014-2020), the Ambient Assisted Living Joint Programme, (the Education Europe Programme) and the Union Statistical Programme within their respective activities.

Programme, the Framework Programme for Environment and Climate action (LIFE), the programme of Union action in the field of consumer policy (2014-2020), the Justice programme (2014-2020), the Ambient Assisted Living Joint Programme, (the Education Europe Programme) and the Union Statistical Programme within their respective activities and the European Innovation partnership on Active and Healthy Ageing.

#### Amendment 24

Proposal for a regulation Recital 16 a (new)

Text proposed by the Commission

Amendment

(16a) Greater attention should be paid to disease prevention, as this would serve to reduce subsequent spending on treatment.

### **Amendment 25**

Proposal for a regulation Recital 16 b (new)

Text proposed by the Commission

#### Amendment

(16b) The Programme should also contribute to creating synergies with the European research field by introducing and applying innovative breakthroughs in the health sector and making sure that limited national European resources are used efficiently. In order to translate research into actual innovation within health systems, particular attention should be given to actors with specific vulnerabilities, such as women and children, who make, nevertheless, a crucial contribution to social and economic growth and welfare.

#### Amendment 26

# Proposal for a regulation Recital 21 a (new)

Text proposed by the Commission

#### Amendment

(21a) In order to implement the Programme, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of drawing up annual work programmes. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

#### Amendment 27

# Proposal for a regulation Recital 23

Text proposed by the Commission

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

#### Amendment

(23) The Programme should be implemented in full respect of the principle of transparency. Budgetary resources should be shared out between objectives in a manner proportionate to their probable advantages for EU citizens' health. There should not, therefore, be a set order of priority for objectives. Appropriate actions covered by the programme's specific objectives and with a clear EU added value should be selected and funded by the Programme. The annual work programmes should set out, in particular, the essential selection criteria

PE486.116v03-00 20/81 RR\908053EN.doc

activities financed under the Programme, and, where appropriate, the evidence required to demonstrate their independence.

applicable to the potential beneficiaries, in accordance with the Financial Regulation, in order to ensure they have the financial and operational capacity to undertake activities financed under the Programme, and, where appropriate, the evidence required to demonstrate their independence.

## Justification

Ranking objectives by granting each of them a pre-defined financial envelope could limit the scope of certain projects.

# **Amendment 28**

# Proposal for a regulation Recital 24

Text proposed by the Commission

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

#### **Amendment 29**

Proposal for a regulation Recital 28 a (new)

Text proposed by the Commission

#### Amendment

(24) The Commission should monitor the implementation of the Programme using key indicators for assessing results and impacts. The indicators should provide the basis for assessing the extent to which the objectives of the programme have been achieved.

#### Amendment

(28a) According to the WHO, mental health problems account for almost 40% of years lived with disability. One in four Europeans will have a mental health issue at some time in their lives. Mental health problems are also wide-ranging, long-lasting and a source of discrimination, contributing significantly to inequality in health in the Union and therefore challenging the European values at their

core. Moreover the economic crisis affects the factors determining mental health as protective factors are weakened and risk factors increased. The economic consequences of mental health problems, mainly due to a loss of productivity, are estimated to be 3-4% of the gross national product in the Union. Because mental problems often already start in adolescence or young adulthood, the loss of productivity can therefore be longlasting; it is of importance to tackle these problems at an early age. However prevention and service provision are often inadequate and persons do not receive the treatment or support that they need. Social support, a healthy community and environment, having adequate employment and access to mental health services can prevent a person from developing mental health problems and increase productivity as a whole for society.

**Amendment 30** 

Proposal for a regulation Recital 28 b (new)

Text proposed by the Commission

Amendment

(28b) Article 8 TFEU, which states that "in all its activities, the Union shall aim to eliminate inequalities, and to promote equality, between men and women", makes the promotion of equality an objective of the Union. The reduction of inequalities, and in particular health inequalities and the promotion of social cohesion are objectives of the Union, and the Health for Growth programme helps to meet these aims. Reducing health inequalities will be key to achieving 'Europe 2020: A European Strategy for smart, sustainable and inclusive growth' 8 objectives of lifting 20 million people out of poverty. Thus the Programme can

complement the integrated guideline 10 on promoting social inclusion and combating poverty, the Strategy for Equality between Women and Men (2010-2015), the Youth Pact, the Disability Strategy, and the European Pact for Mental Health and Wellbeing. The Programme should help to identify the causes of health inequalities and encourage, among other things, the exchange of best practices to tackle them.

#### Amendment 31

Proposal for a regulation Recital 28 c (new)

Text proposed by the Commission

Amendment

(28c) The Programme should place emphasis on improving the health condition of children and young people and promoting a healthy lifestyle and a culture of prevention among them.

#### **Amendment 32**

Proposal for a regulation Recital 28 d (new)

Text proposed by the Commission

Amendment

(28d) The Programme should address gender-related and ageing-related health issues.

## **Amendment 33**

Proposal for a regulation Article 2

Text proposed by the Commission

Amendment

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

The general objectives of the Programme shall be *to complement*, *support and add* 

RR\908053EN.doc 23/81 PE486.116v03-00

**EN** 

the Member States to encourage innovation in healthcare and increase the sustainability of health systems, to improve the health of the EU citizens and protect them from cross-border health threats.

value to the policies of the Member States in order to improve physical and mental health and access to healthcare for all EU citizens and reduce health inequalities by addressing the health-related, social and economic challenges posed by an ageing population and the increasing number of chronic illnesses, by promoting health and the principle of prevention, encouraging innovation in healthcare, increasing the sustainability and the comparability of health systems, operating within a gender-sensitive framework and protecting EU citizens from serious cross-border health threats.

### Justification

Demographic change gives rise to a certain number of issues and challenges, both for the economy and society at large.

#### Amendment 34

# Proposal for a regulation Article 3 – point 1 – paragraph 1

Text proposed by the Commission

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

#### Amendment

(1) To develop common tools and mechanisms at EU level to address shortages *or surplus* of resources, both human and financial, and to facilitate *voluntary* up-take of innovation in *public health interventions, prevention strategies and* healthcare *management*, in order to contribute to innovative, *efficient* and sustainable health systems.

## **Amendment 35**

Proposal for a regulation Article 3 – point 1 – paragraph 2

Text proposed by the Commission

This objective will be measured in

Amendment

This objective will be measured in

PE486.116v03-00 24/81 RR\908053EN.doc



particular through the increase of number of Member States using the developed tools and mechanisms and pieces of advice.

particular through the *results obtained by* Member *States' health systems*.

### Justification

The programme's objectives must be measured using the relevant indicators, such as average life expectancy in the various Member States.

#### Amendment 36

# Proposal for a regulation Article 3 – point 2 – paragraph 1

Text proposed by the Commission

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

#### Amendment

(2) To increase access to medical expertise and information for specific conditions also beyond national borders, develop shared solutions and guidelines, promote research and comparisons between national health systems to improve health literacy, patient empowerment, healthcare quality and patient safety in order to increase access to better and safer healthcare for EU citizens throughout the Union.

#### Amendment 37

# Proposal for a regulation Article 3 – point 2 – paragraph 2

Text proposed by the Commission

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

#### Amendment

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

RR\908053EN.doc 25/81 PE486.116v03-00

## guidelines.

#### **Amendment 38**

# Proposal for a regulation Article 3 – point 3 – paragraph 1

Text proposed by the Commission

(3) To identify, disseminate and promote the up-take of validated best practices for cost-effective prevention *measure* by addressing the key risk factors, namely smoking, *abuse* of alcohol and obesity, *as well as HIV/AIDS*, with a focus on the cross border dimension, in order to prevent diseases and promote good health.

#### Amendment

(3) To identify, disseminate and promote the up-take of validated best practices for cost-effective prevention *measures* by addressing the key risk factors, namely smoking, *harmful use* of alcohol, *an unhealthy diet, a sedentary lifestyle* and obesity, *drug use and environmental factors, as well as communicable diseases*, with a focus on the cross border dimension, *and operating in a gender-sensitive framework*, in order to prevent diseases and promote good health, *and to empower EU citizens and patients by enhancing health literacy to achieve better and safer health outcomes*.

## Justification

All the above risk factors should be taken into account so as to provide suitably effective protection against chronic diseases.

#### **Amendment 39**

Proposal for a regulation Article 3 – point 3 – paragraph 2

Text proposed by the Commission

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

# Amendment

This objective will be measured in particular through the increase in the number of legislative measures and actions taken by Member States involved in promoting good health and preventing chronic diseases, as well as through the monitoring of health literacy levels across the Union, using appropriate indicators.

## Justification

The programme's objectives must be measured using the relevant indicators in the various Member States.

#### Amendment 40

Proposal for a regulation Article 3 – point 4 a (new)

Text proposed by the Commission

Amendment

(4a) To contribute to evidence-based decision making by fostering health information, collecting and analysing harmonised health data and disseminating key health indicators.

### Justification

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, socioeconomic status and age are important health considerations. Data collection should wherever possible build on existing work, and proposals for new collections should be costed and based on a clear need. The collection of data should be in compliance with the relevant legal provisions on the protection of personal data.

#### Amendment 41

# Proposal for a regulation Article 4

Text proposed by the Commission

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

(1) Contributing to innovative and sustainable health systems:

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

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

- 1.2. Promote the uptake of health innovation and e-Health by increasing the interoperability of e-Health applications;
- 1.3. Support the sustainability of EU health workforce by promoting effective forecasting and planning and efficient recruitment and retention strategies;
- 1.4. Provide expertise to assist Member States undertaking health systems reforms;
- 1.5 Support to the European Innovation Partnership on Active and Healthy Ageing, a pilot project under Europe 2020 flagship initiative Innovation Union;
- 1.6 Actions required by or contributing to the objectives of EU legislation in the fields of medical devices as well as e-Health and Health Technology Assessment provisions in legislation on cross border healthcare;
- 1.7 Foster a health knowledge system, including Scientific Committees, to contribute to evidence-based decision making.
- (2) Increasing access to better and safer healthcare for citizens:
- 2.1. Set up accreditation and support European Reference Networks;
- 2.2. Support action on rare diseases including creation of European Reference Networks (in accordance with 2.1), information and registries based on the common criteria for accreditation;
- 2.3. Strengthen collaboration on patient safety and quality of healthcare, by increasing the availability of information to patients, exchange of best practices and development of guidelines; support action on chronic diseases care and research including development of European guidelines;
- 2.4. Develop guidelines to improve the prudent use of antimicrobials in human

medicine and reduce the practices that increase antimicrobial resistance;

- 2.5. Actions required by or contributing to the objectives of EU legislation in the fields of tissues and cells, blood, organs, patients' rights in cross-border healthcare and medicinal products;
- 2.6. Foster a health knowledge system to contribute to evidence-based decision making.
- (3) Promoting good health and preventing diseases:
- 3.1 Exchange best practices on key health issues such as smoking prevention, abuse of alcohol and obesity;
- 3.2. Supporting the prevention of chronic diseases including cancer, by sharing knowledge and best practice and developing joint activities;
- 3.3. Actions required by or contributing to the objectives of EU legislation in the fields of tobacco products and advertisement;
- 3.4. Foster a health knowledge system, to contribute to evidence-based decision making.
- (4) Protecting citizens from cross border health threats:
- 4.1. Strengthen preparedness and response for serious cross border health threats;
- 4.2. Improve risk assessment capacity by providing additional capacities for scientific expertise and map existing assessments;
- 4.3. Support capacity building against health threats in Member States by inter alia developing preparedness and response planning and coordination, common approaches to vaccination, developing guidelines and mechanisms for joint procurement of medical countermeasures;

- 4.4. Actions required by or contributing to the objectives of EU legislation in the fields of communicable diseases and other health threats;
- 4.5. Foster a health knowledge system to contribute to evidence-based decision making.

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

An indicative list of the relevant legislation is provided in Annex II to this Regulation.

### Justification

All amendments tabled to Article 4 should be deemed to be made to Annex I, which shall be reworded accordingly. (This amendment applies throughout the text of article 4 and Annex 1. Adopting it will necessitate corresponding changes throughout.) There is no need to reproduce in Article 4 the eligible actions that are listed in greater detail in Annex 1. A simple reference to Annex I in Article 4 is sufficient. The Annex has the same legal value as an Article.

#### **Amendment 42**

# Proposal for a regulation Article 7 – paragraph 2 – point a

Text proposed by the Commission

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

#### Amendment

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

## Justification

The evaluation of the Public Health Programme recognised the added value of developing and supporting networks between EU health specialists, national and regional health authorities and other stakeholders who contribute to sharing knowledge and building health capacity in the EU. The experience and expertise of public health and patient organisations is particularly important for policies and programmes on prevention and disease management, to ensure that they are truly patient focused.

PE486.116v03-00 30/81 RR\908053EN.doc

#### Amendment 43

# Proposal for a regulation Article 7 – paragraph 2 – point b

Text proposed by the Commission

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

#### Amendment

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

#### **Amendment 44**

Proposal for a regulation Article 7 – paragraph 2 – point c a (new)

Text proposed by the Commission

Amendment

(ca) projects proposed by nongovernmental bodies that are in pursuit of the implementation of the annual work programme.

#### **Justification**

It is important to allow non governmental bodies, which are not eligible for or seeking funding for their functioning, to receive financial support for specific projects.

# **Amendment 45**

Proposal for a regulation Article 7 – paragraph 3 – point b

Text proposed by the Commission

(b) 60 % of eligible costs for the functioning of a non-governmental body. In cases of exceptional utility such bodies

**Amendment** 

(b) 60 % of eligible costs for the functioning of a non-governmental body *or its projects*. In cases of exceptional utility

RR\908053EN.doc 31/81 PE486.116v03-00

may benefit from a financial contribution up to a maximum of 80% of eligible costs; such bodies may benefit from a financial contribution up to a maximum of 80% of eligible costs;

### Justification

It is important to allow non governmental bodies, which are not eligible for or seeking funding for their functioning, to receive financial support for specific projects.

#### **Amendment 46**

# Proposal for a regulation Article 11

Text proposed by the Commission

- 1. The Commission shall *implement the Programme by establishing* annual work programmes setting out the elements provided in the Financial Regulation and in particular:
- (a) the priorities and the actions to be undertaken, including the allocation of financial resources:
- (b) detailed eligibility criteria for the beneficiaries in compliance with Article 8;
- (c) the criteria for the percentage of the financial contribution of the Union, including criteria for assessing whether or not exceptional utility applies, and the applicable rate of the co-financing;
- (d) the essential selection and award criteria to be used to select the proposals receiving financial contributions;
- (e) the time schedule of the planned calls

#### Amendment

- 1. The Commission shall be empowered to adopt delegated acts in accordance with Article 16a in the form of annual work programmes, with the input from health stakeholders and their representative organisations, including independent patients' organisations, setting out the elements provided in the Financial Regulation and in particular:
- (a) the *annual* priorities and the actions to be undertaken, including the allocation of financial resources;
- (b) detailed eligibility criteria for the beneficiaries in compliance with Article 8, in particular concerning legal independence, financial independence, transparency of the applicants' activities and funding and effective assessment of independence;;
- (c) the criteria for the percentage of the financial contribution of the Union, including criteria for assessing whether or not exceptional utility applies, and the applicable rate of the co-financing;
- (d) the essential selection and award criteria to be used to select the proposals receiving financial contributions;

PE486.116v03-00 32/81 RR\908053EN.doc

for the tenders and calls for proposals;

- (f) where appropriate, the authorisation to use lump sums, standard scales of unit costs or flat-rate financing in line with the Financial Regulation;
- (g) the actions co-financed by international organisations active in the area of health without previous call for proposal duly justified.
- 2. The working programme referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 16(2).

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

- (g) the actions co-financed by international organisations active in the area of health without previous call for proposal duly justified, *in accordance with the Financial Regulation and its implementing rules*.
- 2. The Commission shall implement the annual work programmes by setting out:
- (a) the time schedule of the planned calls for tenders and calls for proposals;
- (b) where appropriate, the authorisation to use lump sums, standard scales of unit costs or flat-rate financing in line with the Financial Regulation;
- 2a. The measures referred to in paragraph 2 shall be adopted in accordance with the examination procedure referred to in Article 16(2).
- 3. In implementing the Programme, the Commission, together with the Member States, shall ensure compliance with all relevant legal provisions regarding personal data protection and, where appropriate, the introduction of mechanisms to ensure the confidentiality and safety of such data.

#### **Justification**

As the annual work programme contains elements that are significant policy choices intended to supplement or amend the primary policy shaping elements as established in this Regulation, therefore it is suitable to delegate powers to the Commission in accordance with Article 290 TFEU with respect to adoption of the annual work programme.

#### Amendment 47

# Proposal for a regulation Article 12

Text proposed by the Commission

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

#### Amendment

The Commission shall, in cooperation with the Member States, ensure overall consistency and complementarity between the Programme and other policies, instruments and actions of the Union and the activities of agencies whose remit is covered by the Programme.

#### **Amendment 48**

# Proposal for a regulation Article 13 – paragraph 2

Text proposed by the Commission

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

#### Amendment

2. Member States shall report every two years on the measures undertaken and the resources spent on actions under the Programme, including, in particular, networking activities, exchange of best practices and expertise across borders.

# **Amendment 49**

# Proposal for a regulation Article 13 – paragraph 3 – subparagraph 1

Text proposed by the Commission

3. No later *then* mid-2018, an evaluation report shall be established by the Commission on the achievement of the objectives of all the measures (at the level of results and impacts), the efficiency of the use of resources and its European added value, in view of a decision on the renewal, modification or suspension of the measures. The evaluation shall additionally address the scope for simplification, its

#### Amendment

3. No later *than* mid-2018, an evaluation report shall be established by the Commission *and presented to the European Parliament* on the achievement of the objectives of all the measures (at the level of results and impacts), the efficiency of the use of resources and its European added value, in view of a decision on the renewal, modification or suspension of the measures. The evaluation shall additionally

PE486.116v03-00 34/81 RR\908053EN.doc

internal and external coherence, the continued relevance of all objectives, as well as the contribution of the measures to the *Union priorities of smart*, *sustainable and inclusive growth*. It shall take into account evaluation results on the long-term impact of the predecessor programme.

address the scope for simplification, its internal and external coherence, the continued relevance of all objectives, as well as the contribution of the measures to the *achievement of the objectives set out in Article 168 of the Treaty*. It shall take into account evaluation results on the long-term impact of the predecessor programme.

## Justification

The extent to which a high level of protection of human health as laid down in Article 168 TFEU should be one of the references for the evaluation of the Programme, not the priorities of Europe 2020

#### Amendment 50

# Proposal for a regulation Article 13 – paragraph 4

Text proposed by the Commission

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

#### Amendment

4. The Commission shall make the results publicly available and shall ensure they are widely disseminated in order to document the contribution of the Programme to increasing quality in healthcare for EU citizens.

#### Amendment 51

Proposal for a regulation Article 16 a (new)

Text proposed by the Commission

#### Amendment

#### Article 16a

## Exercise of the delegation

- 1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
- 2. The power to adopt delegated acts referred to in Article 11 shall be conferred on the Commission for a period of seven

RR\908053EN.doc 35/81 PE486.116v03-00

years from...\*.

- 3. The delegation of power referred to in Article 11 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
- 4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
- 5. A delegated act adopted pursuant to Article 11 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

# Justification

As the annual work programme contains elements that are significant policy choices intended to supplement or amend the primary policy shaping elements as established in this Regulation, therefore it is suitable to delegate powers to the Commission in accordance with Article 290 TFEU with respect to adoption of the annual work programme.

#### Amendment 52

Proposal for a regulation Annex 1 – point 1 – introductory part

PE486.116v03-00 36/81 RR\908053EN.doc

<sup>\*</sup> OJ: please insert the date of entry into force of this Regulation.

# Text proposed by the Commission

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

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

Amendment

## Amendment 53

# Proposal for a regulation Annex 1 – point 1 – point 1.2

Text proposed by the Commission

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

#### Amendment

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

# **Amendment 54**

Proposal for a regulation Annex 1 – point 1 – point 1.2 a (new)

Text proposed by the Commission

## Amendment

1.2a. Health innovation and e-Health: use of intelligent transport systems (ITS) by emergency medical services.

#### Amendment 55

Proposal for a regulation Annex 1 – point 1 – point 1.2 b (new)

RR\908053EN.doc 37/81 PE486.116v03-00

# Text proposed by the Commission

# Amendment

- 1.2b. Develop e-Health ICT standards and protocols, in order to turn ICT technologies to good use in the field of health in order to guarantee the protection of personal data and protect patients and their privacy.

## **Amendment 56**

Proposal for a regulation Annex 1 – point 1 – point 1.2 c (new)

Text proposed by the Commission

#### Amendment

- 1.2c. Develop e-Health ICT standards and protocols for emergency services, including the use of intelligent transport systems (ITS) in such services.

#### Amendment 57

# Proposal for a regulation Annex I – point 1 – point 1.3

Text proposed by the Commission

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

## Amendment

1.3. Health workforce: develop effective health workforce forecasting and planning in terms of numbers, gender equality, scope of practice and the extent to which training matches the requisite skills, including the ability to make use of new information systems and other advanced technologies, monitor mobility (within the Union) and migration of health professionals, establish efficient recruitment and retention strategies and capacity development, taking due account of issues of dependency and population aging and conducting periodic assessments of these new requirements.

PE486.116v03-00 38/81 RR\908053EN.doc

# Justification

Particular attention should be paid to the training of healthcare workers in devising an effective strategy to strive for excellence and to meet the different needs of professionals in the EU.

### Amendment 58

Proposal for a regulation Annex I – point 1 – point 1.3 a (new)

Text proposed by the Commission

Amendment

- 1.3a. Support the mobility of health workforce and eHealth development within the Union in order to address shortages or surplus of human resources.

## Amendment 59

Proposal for a regulation Annex I – point 1 – point 1.3 b (new)

Text proposed by the Commission

## Amendment

- 1.3b. Promote and support the exchange of best practices and pilot projects aiming at fostering innovation in the field of public health interventions, prevention strategies and health system management.

## Amendment 60

Proposal for a regulation Annex I – point 1 – point 1.3 c (new)

Text proposed by the Commission

# Amendment

- 1.3c. Support the incorporation of information and communications technology in the health systems in order to facilitate information management and communication processes. Member States may voluntarily encourage the participation of the possible excess health

RR\908053EN.doc 39/81 PE486.116v03-00

# work force in related projects.

## **Amendment 61**

# Proposal for a regulation Annex I – point 1 – point 1.4

Text proposed by the Commission

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

# Amendment

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

# Justification

Reforms to healthcare systems must be carried out with a medium- and long-term vision of social and economic stakeholders.

## **Amendment 62**

Proposal for a regulation Annex 1 – point 1 – point 1.4 a (new)

Text proposed by the Commission

Amendment

1.4a. Creating synergies with the European research field so that the main research breakthroughs can be introduced and actually applied into health systems.

# Proposal for a regulation Annex I – point 1 – point 1.5

Text proposed by the Commission

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

## Amendment

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

# Justification

The partnership must also promote, as a matter of urgency, innovative solutions in the treatment of neurodegenerative diseases, and in care for patents suffering from them.

#### Amendment 64

# Proposal for a regulation Annex I – point 1 – point 1.7

Text proposed by the Commission

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

# Amendment

1.7. Fostering a health knowledge system to contribute to evidence-based decision making including collecting and analysing health data and wide-dissemination of the results of the Programme and including standardised methods for data collection, coordination, collection and monitoring of data on chronic diseases and support to the Scientific Committees set up in accordance with Commission Decision 2008/721/EC.

#### Amendment 65

Proposal for a regulation Annex 1 – point 1 – point 1.7 a (new)

RR\908053EN.doc 41/81 PE486.116v03-00

# Text proposed by the Commission

# Amendment

1.7a. Actions required to facilitate the continuous monitoring of health literacy in the Union and to develop effective approaches for advancing health literacy in the work force and for the design of health-literate service provision.

## **Amendment 66**

Proposal for a regulation Annex 1 – point 1 – point 1.7 b (new)

Text proposed by the Commission

#### Amendment

- 1.7b. Encourage the compilation of statistics comparing individual national health systems in Europe.

#### Amendment 67

Proposal for a regulation Annex 1 – point 1 – point 1.7 c (new)

Text proposed by the Commission

## Amendment

1.7c. Common assessment criteria, to be laid down by the Commission in agreement with the authorities of the Member States for the purpose of evaluating results and the improvements achieved.

## **Amendment 68**

Proposal for a regulation Annex 1 – point 2 – introductory part

Text proposed by the Commission

2. Increase access to medical expertise *and* information for specific conditions also beyond national borders and developing

## Amendment

2. Increase access to medical expertise, information *and treatment* for specific conditions also beyond national borders

PE486.116v03-00 42/81 RR\908053EN.doc

shared solutions and guidelines to improve healthcare quality and patient safety in order to increase access to better and safer healthcare for EU citizens and developing shared solutions and guidelines to improve healthcare quality and patient safety in order to increase access to better and safer healthcare for EU citizens in line with the Union's fundamental values of universality, high quality, equity of access and solidarity.

## Amendment 69

Proposal for a regulation Annex 1 – point 2 – point 2.2

Text proposed by the Commission

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

## Amendment

2.2 Rare diseases: support *European* cooperation, networking and information in the field of rare diseases as well as emerging rare diseases, including support to Member States, patient organisations and other relevant stakeholders. Support actions contributing to the objectives of the Commission Communication on Rare Diseases: Europe's challenges<sup>1</sup> and the Council Recommendation on an action in the field of Rare Diseases<sup>2</sup>. This includes creation of centres of expertise, reference networks (in compliance with point 2.1), information and registries for rare diseases based on the common criteria of accreditation.

**Amendment 70** 

Proposal for a regulation Annex 1 – point 2 – point 2.2 a (new)

Text proposed by the Commission

Amendment

2.2a. Age-related diseases: support actions that promote cooperation,

<sup>&</sup>lt;sup>1</sup> COM(2008)0679

<sup>&</sup>lt;sup>2</sup> (2009/C 151/02)

exchange of information and the development of research programmes on age-related diseases, including neurodegenerative diseases.

#### Amendment 71

# Proposal for a regulation Annex 1 – point 2 – point 2.3

Text proposed by the Commission

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

#### Amendment

2.3. Quality and safety: strengthen collaboration on patient safety and quality of healthcare, through, inter alia, implementing the Council Recommendation on patient safety and the prevention and control of healthcareassociated infections; exchange best practice on quality assurance systems; develop *clinical* and treatment guidelines and tools to promote patient safety and quality; develop health education for EU citizens; increase the availability of information to patients on safety and quality, improve feedback and interaction between health providers and patients; support action to exchange knowledge and best practice on chronic diseases, both lifestyle related chronic disease as well as diseases that have congenital, social or environmental causes, the response of health systems and research including development of European clinical and treatment guidelines.

#### Amendment 72

# Proposal for a regulation Annex I – point 2 – point 2.4

Text proposed by the Commission

2.4. Safety: improve the prudent use of antimicrobial agents in medicinal products and reduce the practices that increase

## Amendment

2.4. Safety: improve the prudent use of antimicrobial agents in medicinal products *in both human medicine and veterinary* 

PE486.116v03-00 44/81 RR\908053EN.doc

antimicrobial resistance; reduce the burden of resistant infections and healthcareassociated infections and secure the availability of effective antimicrobials.

*medicine* and reduce the practices that increase antimicrobial resistance, including in the veterinary sector, particularly in hospitals; reduce the burden of resistant infections and healthcare-associated infections and secure the availability of effective antimicrobials, sustained investment in improving methods of analysis to detect and prevent resistance, particularly by closely scrutinising the dosages in which they are administered, the length of treatment and their use in combination with other medicines, and improve networking among all healthcare actors in relation to dealing with antimicrobial resistance.

# Justification

Closer attention should be paid to hospitals, where the spread of infections could be avoided by taking targeted health measures. This would have the threefold effect of limiting the prevalence of infections, the consumption of antibiotics and resistance to them.

# **Amendment 73**

# Proposal for a regulation Annex I – point 2 – point 2.5

Text proposed by the Commission

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

# Amendment

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

# Proposal for a regulation Annex I – point 2 – point 2.6

Text proposed by the Commission

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

## Amendment

2.6 Fostering a health knowledge system to contribute to evidence-based decision making including collecting and analysing health data and wide dissemination of the results of the Programme, and supporting efforts to periodically update this data and make it more easily comparable from Member State to Member State.

# Justification

The lack of data that can be compared among the Member States is a major stumbling block to socially and economically effective and viable healthcare policies.

## **Amendment 75**

Proposal for a regulation Annex 1 – point 2 – point 2.6 a (new)

Text proposed by the Commission

Amendment

2.6a. Develop comparable Union-wide health indicators in order to help reduce inequalities as regards healthcare in the Union and provide a basis for decision-taking aimed at improving the effectiveness of health policies.

## **Amendment 76**

Proposal for a regulation Annex 1 – point 2 – point 2.6 b (new)

Text proposed by the Commission

Amendment

- 2.6b. Strengthen the patient-centredness and comprehensibility of health systems and enhance citizens' health literacy to make health systems better accessible and

PE486.116v03-00 46/81 RR\908053EN.doc

# understandable for patients.

## Justification

Health literacy depends not only on the capabilities of the individual but also on the understanding of the system. Improving the readability of the health systems, e.g. by improving language, communication skills of healthcare professionals but also the signs in hospitals, is therefore an important aspect that helps the individual navigate the system.

## Amendment 77

# Proposal for a regulation Annex 1 – point 3 – introductory part

Text proposed by the Commission

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

## Amendment

3. Identifying, disseminating and promoting up-take of validated best practices for cost-effective prevention measures by addressing the key risk factors, namely smoking, harmful use of alcohol, an unhealthy diet, a sedentary lifestyle and obesity, drug use, and environmental factors, as well as communicable diseases, with a focus on the cross border dimension, in order to prevent diseases and promote health literacy and good health, and by supporting awareness-raising campaigns promoting healthy lifestyles, with special attention being paid to encouraging the development of healthy lifestyle behaviours in young children.

## **Amendment 78**

# Proposal for a regulation Annex I – point 3 – point 3.1

Text proposed by the Commission

3.1. Cost-effective promotion and prevention measures: this will include actions towards the setting up of pan-European networks and partnerships engaging wide range of actors in

#### Amendment

3.1. Cost-effective promotion and prevention measures *of communicable and non-communicable diseases*: this will include actions towards the setting up of pan-European networks and partnerships

RR\908053EN.doc 47/81 PE486.116v03-00

communication and awareness raising actions on key health issues such as smoking prevention, *abuse of* alcohol, *addressing* obesity with a focus on the cross-border dimension and on Member States with no or little action on these issues.

engaging a wide range of actors in communication, education and awareness raising actions on key health issues such as the elimination of environmental health risks, mental health, smoking prevention, alcohol and drug abuse, unhealthy eating and a sedentary lifestyle within the context of tackling diet-related obesity, and health promotion programmes aimed at the general public, internal and external air pollution with a focus on the cross-border dimension and on Member States with no or little action on these issues, and operating in a gender-sensitive framework.

## Amendment 79

Proposal for a regulation Annex 1 – point 3 – point 3.1 a (new)

Text proposed by the Commission

#### **Amendment**

3.1a. Support effective responses to communicable diseases by identifying, disseminating and promoting the up-take of good practices for cost-effective prevention, diagnosis, treatment and care.

#### Amendment 80

Proposal for a regulation Annex 1 – point 3 – point 3.1 b (new)

Text proposed by the Commission

## Amendment

3.1b. Support the exchange of good practices to reduce drug-related health damage, including information and prevention.

PE486.116v03-00 48/81 RR\908053EN.doc

# Proposal for a regulation Annex I – point 3 – point 3.2

Text proposed by the Commission

3.2. Chronic diseases: support European cooperation and networking on preventing and improving the response to chronic diseases including cancer, by sharing knowledge, good practice and developing joint activities on prevention. *Cancer:* follow-up work already undertaken; set up a European *cancer* information system with comparable data; support *cancer* screening, including voluntary accreditation mechanisms; support the development of European guidelines for prevention where major inequalities exist.

## Amendment

3.2. Chronic diseases: support European cooperation and networking on preventing and improving the response to chronic diseases including cancer and neurodegenerative diseases, operating within a gender-sensitive framework and taking into account the differences between disease processes in women and men, by sharing knowledge, good practice, promoting education, developing guidelines regarding the underlying environmental factors of chronic diseases and developing joint activities on prevention, including with regard to environmental risk factors; follow-up work already undertaken; set up a European *chronic disease* information system with comparable data; support chronic disease screening and early diagnosis of chronic diseases, including voluntary accreditation mechanisms; support the development of European guidelines for prevention and early diagnosis where major inequalities exist.

# Justification

EU cooperation measures should be taken to prevent all chronic diseases, not just cancer.

# **Amendment 82**

Proposal for a regulation Annex I – point 3 – point 3.2 a (new)

Text proposed by the Commission

Amendment

- 3.2a. Supporting the early diagnosis of neurogenerative and other brain diseases, by sharing knowledge and best practice and developing joint activities.

RR\908053EN.doc 49/81 PE486.116v03-00

# Proposal for a regulation Annex I – point 3 – point 3.3

Text proposed by the Commission

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

### **Amendment**

3.3. Actions required by or contributing to the implementation of Union legislation in the fields of *advertising and marketing of* tobacco products, *alcohol* and *foods high in fat, sugar and salt.* Such action may include activities aimed at ensuring the implementation, application, monitoring and review of that legislation.

## Justification

As the EU has legislative powers in the fields of foodstuffs and alcohol, as well as tobacco products, it is logical that these issues should be included in the scope of this Regulation. Marketing is broader than just advertising and the broader aspects such as product content, availability and pricing should be addressed too.

#### **Amendment 84**

Proposal for a regulation Annex I – point 3 – point 3.3 a (new)

Text proposed by the Commission

Amendment

- 3.3a. Advance health literacy in the European population through specific programmes in all areas such as health promotion, prevention and patient-centred care.

#### **Amendment 85**

Proposal for a regulation Annex I – point 3 – point 3.3b (new)

Text proposed by the Commission

Amendment

- 3.3b. Ensure that health systems are

PE486.116v03-00 50/81 RR\908053EN.doc

designed to make citizens able to access, understand, appraise and apply information to make decisions in terms of disease prevention, health promotion and healthcare, and hence make better and more sustainable use of health services.

## **Amendment 86**

Proposal for a regulation Annex I – point 3 – point 3.3 c (new)

Text proposed by the Commission

#### Amendment

-3.3c. Promoting activities aimed at protecting people from second-hand tobacco smoke at workplaces, as referred to in Council Recommendation of 30 November 2009 on smoke-free environments (2009/C 296/02)<sup>1</sup>;

<sup>1</sup> OJ C 296, 5.12.2009, p. 4.

# **Amendment 87**

Proposal for a regulation Annex I – point 3 – point 3.4

Text proposed by the Commission

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

## Amendment

3.4. Fostering a health knowledge system to contribute to evidence-based decision making including collecting and analysing health data and wide dissemination of the results of the Programme, and support efforts to periodically update this data and make it more easily comparable from Member State to Member State.

# Justification

The lack of data that can be compared among the Member States is a major stumbling block to socially and economically effective and viable healthcare policies.

# Proposal for a regulation Annex 1 – point 4 – point 4.1

Text proposed by the Commission

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

#### Amendment

4.1. Preparedness to and response for serious cross border health threats taking into account and coordinating with global initiatives: put in place common components of generic and specific preparedness planning, including for pandemic influenza, and report regularly on implementation of preparedness plans; bring innovation to patients for the prevention, diagnosis and treatment of diseases originating in developing countries which are increasingly becoming a reality in some European countries.

#### **Amendment 89**

# Proposal for a regulation Annex I – point 4 – point 4.3

Text proposed by the Commission

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

# Amendment

4.3. Support capacity building against health threats in Member States: develop preparedness and response planning, public health response coordination, common approaches on vaccination, including the introduction of optimal vaccination cover to effectively combat the resurgence in infectious diseases; develop guidelines on protective measures in an emergency situation, guidelines on information and guides to good practice; set up a new mechanism for joint procurement of medical countermeasures; develop common communication strategies; strengthen cooperation among the Member States in order to address the impact on public health systems from the increasing flows of illegal migration.

PE486.116v03-00 52/81 RR\908053EN.doc

# Justification

The EU should be more proactive in implementing its Europe-wide vaccination strategies by ensuring optimal vaccination cover.

# **EXPLANATORY STATEMENT**

The Health for Growth Programme has been allocated an overall financial envelope of EUR 446 million over the 2014-2020 period, i.e. over EUR 60 million per year. The programme's scope will be essentially limited to areas in which EU action can bring genuine added value in the healthcare sector. It is fully aligned with the Europe 2020 strategy and aims to foster innovation in healthcare, ensure more viable healthcare systems and improve the well-being of EU citizens.

The funding proved for the programme supplements a number of healthcare promotion measures financed from the structural funds and the Framework Programme for Research and Innovation for 2014-2020. The programme's budget for this period has been increased by 5.7% in relation to the current period (2007-2013).

This funding is potentially available to national authorities, public and private bodies, international organisations and NGOs, who may apply for co-funding for initiatives. Both the programme's modus operandi and procedures for granting such funding must be as straightforward as possible to allow the Member States and healthcare professionals to put it to the best use.

Moreover, healthcare cannot be seen simply as a spur to growth; and the title of the Health for Growth Programme could give rise to confusion. It needs to be stressed that the intention is to show, in this time of economic crisis in Europe, that healthcare more than just synonymous with deficits. The pressures on public finances have made it necessary to reform healthcare systems in order to keep costs under control, while fostering innovation and maximising profitability. Such reforms are essential for healthcare systems to meet rising demand for treatment brought on by population ageing and to continue to provide high-quality treatment for future generations. The title 'Health and Growth' would be a more appropriate one for the programme, so as to avoid any confusion.

The healthcare sector is much more than a way of making progress in the treatment of patients; it must also be a vector for growth, a source of jobs in this time of crisis and a cornerstone of the European economy. In an era characterised by the decline of manufacturing, the healthcare industry is a rare example of a cutting-edge sector that is chiefly based in Europe from the research to distribution stage. It should thus be recognised as a high-technology industry. It should be noted for instance that it takes as many different technologies to produce an anti-cancer drug as to manufacture an Airbus. Progressing from the discovery of an active ingredient all the may to the industrial manufacture of a drug is a challenge in terms of both engineering and technology. Winning the battle of innovation entails greater efforts and resources and cooperation between public and private stakeholders and between researchers in different disciplines.

The programme therefore aims, by more effectively prioritising objectives, to avoid overlaps in its spheres of work and to put its financial resources – which are now scarcer than they were – to better use. It is indispensable that we avoid presenting a catalogue of measures, because that would mean dividing up the available funding. The programme does not aim to

PE486.116v03-00 54/81 RR\908053EN.doc



draw up an exhaustive list of illnesses to combat; what we must do is better concentrate our efforts on a shortlist of priority targets.

Budgetary resources should not be shared out between the four objectives of the programme (fostering innovation, improving healthcare quality, improving protection against disease and protecting the public from cross-border health threats) according to a set method. Ranking objectives by granting each of them a pre-defined financial envelope could limit the scope of certain projects.

Moreover, the sums of funding referred to in this legislative procedure may have to be adapted to suit the financial envelope of the Health for Growth Programme in negotiations on the multi-annual financial framework.

The programme's various objectives should be assessed in the light of results obtained from the relevant performance indicators concerning the Member States' healthcare systems (cost as a percentage of GDP, average life expectancy, number of healthy life years, etc.).

The objective of disease prevention necessitates better identification of risk factors so as to draw up more effective strategies. Due account must be paid of the principal risk factors – including poor diet and a sedentary lifestyle – so as to provide a suitably effective level of protection against chronic illnesses. For example, the fact that large numbers of children are overweight or obese undoubtedly means that they run a greater risk of contracting heart disease later in life.

Without targeting any specific illness, greater attention should still be paid to the effects of population ageing. The increase in life expectancy entails an extremely significant rise in the proportion of elderly people, which is forecast to reach 40% by 2030.

This process gives rise to a certain number of issues and challenges, both for the economy and society at large. By keeping citizens healthy for as long as possible, and thereby enabling them to remain physically and socially active, we can maximise their contribution to our productivity and competitiveness.

Improve the health of Europe's elderly will both shield them from suffering brought on by ageing and lighten the load on society in terms of welfare and medical expenditure.

The programme should thus focus to a greater extent on neurodegenerative diseases such as Alzheimer's and other forms of dementia. These are chronic diseases with specific characteristics: they chiefly afflict the elderly and make the patient completely dependent on others and in need of constant assistance. These diseases afflict a great many people (over 7 million people in Europe suffer from a form of dementia), which has serious consequences for healthcare, the economy and society as a whole.

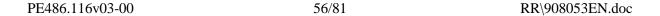
The programme must thus do more to address population ageing and diseases related to old age. This is a cross-cutting issue concurrently affecting objectives No 1 (contributing to innovative and sustainable health systems), No 2 (increasing access to better and safer healthcare for EU citizens) and No 3 (preventing disease and promoting good health).

Efforts must also be made to pre-empt the effects of population ageing, with a view to ensuring that the necessary resources for providing training and life-long learning for workers in this sector are available. The EU must necessarily foster the creation of new jobs either to address new societal challenges such as home support or within structures to help dependent people, whether elderly or not, and must conduct periodical assessments to adapt such structures to the real needs of patents and their carers.

The fourth and final objective of the programme is to protect the public from cross-border health threats; vaccination is a particularly effective way of addressing serious dangers to health.

While vaccination has led to considerable advances in the state of the European public's health, this progress risks being undone by several threats: the high degree of population mobility, the fact that certain groups of people have not yet been vaccinated owing either to insufficient access to healthcare or to an increasing unwillingness to undergo vaccination. Today, the EU must address recent, sustained resurgences in measles, as well as a rise in the number of cases of tuberculosis.

The EU should be more proactive in implementing its Europe-wide vaccination strategies by ensuring optimal vaccination cover. We will succeed in reducing the number of victims caused by these diseases by continued collaboration and innovation, joint planning efforts and by implementing effective prevention measures.



## **OPINION OF THE COMMITTEE ON BUDGETS**

for the Committee on the Environment, Public Health and Food Safety

on the proposal for a regulation of the European Parliament and of the Council establishing a Health for Growth Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020

(COM(2011)0709 - C7-0399/2011 - 2011/0339(COD))

Rapporteur: Angelika Werthmann

## SHORT JUSTIFICATION

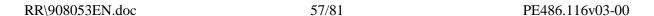
Healthcare is one of largest sectors of the EU economy. It accounts for around 10% of EU GDP and employs one in ten of all workers, including an above-average number of academics. Health in the form of a higher quality of life is not just a value that people treasure in itself, but is also a powerful engine for growth.

The Commission has therefore submitted a proposal for its third 'Health for Growth' EU Action Programme (2014-2020) as part of the forthcoming multiannual financial framework (MFF), in which the focus is on the link between economic growth and public health.

The programme is managed centrally by DG SANCO and the Executive Agency for Health and Consumers (EAHC), and, in part, together with the UN, WHO, COE and OECD.

- 'Health for Growth' focuses on four specific objectives that have a strong potential for economic growth through better health:
- (1) Innovative and sustainable health systems;
- (2) Greater access to better and safer healthcare for EU citizens;
- (3) The prevention of disease and promotion of good health, especially with respect to the key risk factors of smoking, alcohol abuse, obesity and HIV/Aids;
- (4) The protection of citizens from cross-border health threats.

To achieve these objectives, the Commission considers it necessary first and foremost for Member States to take more direct action at national level. It has therefore simplified



implementation and management in the new programme: the level of Union co-financing will be harmonised at 60% of eligible costs and up to 80% in cases of exceptional utility.

By 2020 there will be a shortage of one million health workers in the EU, so 'Health for Growth' should also seek to provide labour market incentives. The programme also aims *inter alia* at setting high standards of safety, quality and efficacy for medical devices, combating the economic impact of the inexorable increase in life expectancy and, especially, preventing chronic diseases, which are the main cause of death and poor quality of life in Europe.

The Programme builds on the results of the first and second Public Health Programmes (2003-2008 and 2008-2013).

The financial appropriations for implementing the programme over the period from 1 January 2014 to 31 December 2020 will amount to 446 million euro (in current prices).

Given the long-term decline in the population of the European Union and the associated steady ageing of that population, the issue of health from an economic perspective is becoming more and more important. For this reason, the 'Health for Growth' programme proposed by the Commission for the period 2014-2020 should be approved with the following amendments.

## **AMENDMENTS**

The Committee on Budgets calls on the Committee on Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

## Amendment 1

Draft legislative resolution Paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Points out that the financial envelope specified in the legislative proposal constitutes only an indication to the legislative authority and that it can not be fixed until agreement is reached on the regulation on the Multiannual Financial Framework;

# Draft legislative resolution Paragraph 1 b (new)

Text proposed by the Commission

#### Amendment

1b. Recalls its resolution of 8 June 2011 on Investing in the future: a new Multiannual Financial Framework (MFF) for a competitive, sustainable and inclusive Europe<sup>1</sup>; reiterates that sufficient additional resources are needed in the next MFF in order to enable the Union to fulfil its existing policy priorities and the new tasks provided for in the Treaty of Lisbon, as well as to respond to unforeseen events; points out that even with an increase in the level of resources for the next MFF of at least 5% compared to the 2013 level only a limited contribution can be made to the achievement of the Union's agreed objectives and commitments and the principle of Union solidarity; challenges the Council, if it does not share this approach, to clearly identify which of its political priorities or projects could be dropped altogether, despite their proven European added value;

## Amendment 3

# Proposal for a regulation Recital 2

Text proposed by the Commission

(2) Continued effort is required in order to meet the requirements set out in Article 168 of the Treaty. Promoting good health at EU level is an integral part of the 'Europe 2020: A European Strategy for smart, sustainable and inclusive growth'.

#### Amendment

(2) Continued effort is required in order to meet the requirements set out in Article 168 of the Treaty. Promoting good health at EU level is an integral part of the 'Europe 2020: A European Strategy for smart, sustainable and inclusive growth'.

RR\908053EN.doc 59/81 PE486.116v03-00

<sup>&</sup>lt;sup>1</sup> Texts adopted, P7\_TA(2011)0266.

Keeping people healthy and active for longer will have positive overall health effects, and a positive impact on productivity and competitiveness, while reducing pressures on national budgets. Innovation in health helps take up the challenge of sustainability in the sector in the context of demographic change, and action to reduce inequalities in health is important to achieve 'inclusive growth'. It is appropriate in this context to establish a 'Health for Growth' Programme, the third programme of EU action on health (2014-2020) (hereinafter referred to as 'the Programme').

Keeping people healthy and active for longer will have positive overall health effects, and a positive impact on their quality of life, productivity and competitiveness, while reducing pressures on national budgets. Innovation in health helps take up the challenge of sustainability in the sector in the context of demographic change, and action to reduce inequalities in health is important to achieve 'inclusive growth'. It is appropriate in this context to establish a 'Health for Growth' Programme, the third programme of EU action on health (2014-2020) (hereinafter referred to as 'the Programme').

# Amendment 4

# Proposal for a regulation Recital 4

Text proposed by the Commission

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

## Amendment

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

## Amendment 5

Proposal for a regulation Recital 6

PE486.116v03-00 60/81 RR\908053EN.doc

# Text proposed by the Commission

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

#### Amendment

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

## Amendment 6

# Proposal for a regulation Recital 10

Text proposed by the Commission

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

#### **Amendment**

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

# Proposal for a regulation Recital 24

Text proposed by the Commission

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

#### Amendment

(24) The Commission should annually monitor the implementation of the programme using key indicators for assessing results and impacts. The indicators, should provide the basis for assessing the extent to which the objectives of the programme have been achieved.

## Amendment 8

# Proposal for a regulation Article 3 – point 3 – introductory part

Text proposed by the Commission

(3) To identify, disseminate and promote the up-take of validated best practices for cost-effective prevention *measure* by addressing the key risk factors, namely smoking, abuse of alcohol *and* obesity, *as well as HIV/AIDS*, with a focus on the *cross border* dimension, in order to prevent diseases and promote good health.

#### Amendment

(3) To identify, disseminate and promote the up-take of validated best practices for cost-effective prevention *measures* by addressing the key risk factors, namely smoking, abuse of alcohol, *a sedentary lifestyle*, *bad eating habits*, *environmental pollution*, obesity, *and* HIV/AIDS, with a focus on the *cross-border* dimension, in order to prevent diseases and promote good health.

## Amendment 9

# Proposal for a regulation Article 3 – point 3 – subparagraph 1

Text proposed by the Commission

(3) To identify, disseminate and promote the up-take of validated best practices for cost-effective prevention measure by addressing the key risk factors, namely smoking, abuse *of alcohol* and obesity, as

#### **Amendment**

(3) To identify, disseminate and promote the up-take of validated best practices for cost-effective prevention measure by addressing the key risk factors, namely smoking, *alcohol and drug* abuse and *diet*-

PE486.116v03-00 62/81 RR\908053EN.doc

well as HIV/AIDS, with a focus on the cross border dimension, in order to prevent diseases and promote good health.

**related** obesity, as well as HIV/AIDS, with a focus on the cross border dimension, in order to prevent diseases and promote good health.

#### **Amendment 10**

# Proposal for a regulation Article 4 – point 3.1

Text proposed by the Commission

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

#### Amendment

3.1. Exchange best practices on key health issues such as smoking prevention, *alcohol and drug* abuse and *diet-related* obesity;

#### Amendment 11

# Proposal for a regulation Article 6 – paragraph 1 – point d

Text proposed by the Commission

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

#### Amendment

deleted

## **Amendment 12**

# Proposal for a regulation Article 7 – paragraph 2 – point b

Text proposed by the Commission

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

## Amendment

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

# Proposal for a regulation Article 11 – paragraph 1 – point g

Text proposed by the Commission

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

#### Amendment

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

# **Amendment 14**

# Proposal for a regulation Article 13 – paragraph 1

Text proposed by the Commission

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

#### Amendment

1. The Commission shall, in close cooperation with the Member States, monitor the implementation of the actions under the programme in the light of its objectives and indicators, including information on the amount of climate related expenditure. It shall report thereon to the committee referred to in Article 16 (1) and shall also inform the European Parliament and the Council once a year.

## **Amendment 15**

# Proposal for a regulation Article 13 – paragraph 3

Text proposed by the Commission

3. No later then mid-2018, an evaluation report shall be established by the Commission on the achievement of the objectives of all the measures (at the level of results and impacts), the efficiency of the use of resources and its European added value, in view of a decision on the renewal, modification or suspension of the measures. The evaluation shall additionally

## Amendment

3. No later then mid-2018, an evaluation report shall be established by the Commission on the achievement of the objectives of all the measures (at the level of results and impacts), the efficiency of the use of resources and its European added value, in view of a decision on the renewal, modification or suspension of the measures. The evaluation shall additionally

PE486.116v03-00 64/81 RR\908053EN.doc

address the scope for simplification, its internal and external coherence, the continued relevance of all objectives, as well as the contribution of the measures to the Union priorities of smart, sustainable and inclusive growth. It shall take into account evaluation results on the long-term impact of the predecessor programme.

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

address the scope for simplification, its internal and external coherence, the continued relevance of all objectives, as well as the contribution of the measures to the Union priorities of smart, sustainable and inclusive growth. It shall take into account evaluation results on the long-term impact of the predecessor programme.

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

## **Amendment 16**

# Proposal for a regulation Annex I – point 3.1

Text proposed by the Commission

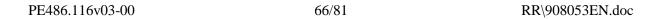
3.1. Cost-effective promotion and prevention measures: this will include actions towards the setting up of pan-European networks and partnerships engaging wide range of actors in communication and awareness raising actions on key health issues such as smoking prevention, abuse *of alcohol*, addressing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

## Amendment

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

# **PROCEDURE**

Title	Health for Growth Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020
References	COM(2011)0709 – C7-0399/2011 – 2011/0339(COD)
Committee responsible Date announced in plenary	ENVI 30.11.2011
Opinion by Date announced in plenary	BUDG 30.11.2011
Rapporteur Date appointed	Angelika Werthmann 6.2.2012
Date adopted	31.5.2012
Result of final vote	+: 28 -: 3 0: 1
Members present for the final vote	Marta Andreasen, Richard Ashworth, Francesca Balzani, Zuzana Brzobohatá, Jean-Luc Dehaene, Göran Färm, José Manuel Fernandes, Eider Gardiazábal Rubial, Salvador Garriga Polledo, Jens Geier, Lucas Hartong, Sidonia Elżbieta Jędrzejewska, Sergej Kozlík, Jan Kozłowski, Alain Lamassoure, Giovanni La Via, Juan Andrés Naranjo Escobar, Nadezhda Neynsky, Dominique Riquet, Alda Sousa, László Surján, Monika Hohlmeier, Jutta Haug, Ivailo Kalfin, George Lyon
Substitute(s) present for the final vote	Alexander Alvaro, Charles Goerens, Edit Herczog, Jürgen Klute, Paul Rübig, Peter Šťastný, Gianluca Susta



# OPINION OF THE COMMITTEE ON INDUSTRY, RESEARCH AND ENERGY

for the Committee on the Environment, Public Health and Food Safety

on the proposal for a regulation of the European Parliament and of the Council establishing a Health for Growth Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020

(COM(2011)0709 - C7-0399/2011 - 2011/0339(COD))

Rapporteur: Maria Badia i Cutchet

## SHORT JUSTIFICATION

The Health for Growth Programme arises at a time of great challenges, linked with globalisation and the fragile economic situation, which is having a particular impact on the European Union. In the context of the 2020 Strategy and new financial perspectives for the 2014-2020 period, the Commission is launching Health for Growth as a means of promoting innovation in healthcare, achieving more sustainable healthcare systems, improving the health of EU citizens and protecting them from cross-border health threats. With this programme, the Commission is complementing existing initiatives to build a dynamic and competitive EU economy. Health is thus perceived, in economic terms, as an essential, priority asset: the health and wellbeing of Europe's citizens is a solid investment in its future.

Nevertheless, the Commission's proposal also presents - from the rapporteur's point of view - numerous opportunities for strengthening the EU's priorities and action in other health-related areas. The scope of the Health for Growth Programme could be broadened to include crosscutting proposals for action. With this in mind, the rapporteur:

- highlights the need to take advantage of the Health for Growth Programme to promote medical research and coordinate it at European level, to ensure that the available resources are efficiently used. Development of the European health research field will encourage its growth and sustainability;
- calls for more attention to be paid to poverty-related and neglected diseases (PNRD), which are responsible for the high mortality rate and deteriorating quality of life of millions of people in the developing countries, and are becoming an increasing reality in some European countries due to globalisation and migration trends. The EU needs to increase its action in this area, while at the same time helping to improve living standards in developing countries and boost their economies;

- points out that Health for Growth essentially complements the flagship initiative 'New Skills for New Jobs', particularly in terms of white jobs (jobs in the health and social services sector). The EU needs to guarantee the necessary resources for providing training and life-long learning for workers in this sector, which employs around 20 million people and presents a sound outlook for growth, mainly due to the aging population;
- considers that, with respect to training opportunities for health sector employees, and
  in order to modernise workplace tools and resources, it is important to exploit the
  possibilities offered by new technologies for fully developing the health services'
  potential and improving their effectiveness and efficiency. Advances in technologies
  based on radio-frequency identification (RFID), such as the Internet of Things, are of
  particular interest.

## **AMENDMENTS**

The Committee on Industry, Research and Energy calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

## Amendment 1

# Proposal for a regulation Recital 1

Text proposed by the Commission

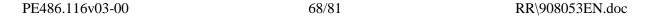
(1) A high level of health protection *should* be ensured in the definition and implementation of all Union policies and activities, in accordance with Article 168 of the Treaty. The Union shall complement and support national health policies, encourage the cooperation between Member States and promote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

## **Amendment**

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

## Amendment 2

Proposal for a regulation Recital 5 a (new)



# Text proposed by the Commission

#### Amendment

(5a) The actions scheduled in the programme should help to strengthen European public health systems as they are a crucial mechanism to keep social welfare and to tackle inequalities that are worryingly increasing due to the current economic uncertainty.

## Amendment 3

# Proposal for a regulation Recital 10 a (new)

Text proposed by the Commission

## Amendment

(10a) About 20 million people across the EU are employed in "white jobs" in the health and social services sector, a figure which is expected to increase in the coming years due to the aging population. Training and life-long learning in this sensitive sector should be a key priority. Therefore, the need for white jobs and for investments in modern skills, such as using information technologies, has to be assessed more precisely.

# **Amendment 4**

# Proposal for a regulation Recital 11

Text proposed by the Commission

(11) To minimise the public health consequences of cross-border health threats which could range from mass contamination caused by chemical incidents to pandemics, like those unleashed recently by E coli, influenza strain H1N1 or SARS (severe acute respiratory syndrome), the Programme should contribute to the creation and

## Amendment

(11) To minimise the public health consequences of cross-border health threats which could range from mass contamination caused by chemical incidents to pandemics, like those unleashed recently by E coli, influenza strain H1N1 or SARS (severe acute respiratory syndrome) or diseases from developing countries which through

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

global population movements are an increasing reality in some European countries, the Programme should contribute to the creation and maintenance of robust mechanisms and tools to detect, assess and manage major cross-border health threats.. Due to the nature of these threats, the Programme should support coordinated public health measures at EU level to address different aspects, building on preparedness and response planning, robust and reliable risk assessment and a strong risk and crisis management framework. In this context, it is important that the programme should benefit from complementarity with the work programme of the European Centre for Disease Prevention and Control<sup>12</sup> in the fight against communicable diseases and the activities supported under the Unions programmes for research and innovation. Special efforts should be undertaken to ensure coherence and synergies between the Programme and global health work carried out under other Community programmes and instruments that address in particular the areas of influenza, HIV/AIDS, tuberculosis and other crossborder health threats in third countries. Action under the programme may also cover cross-border threats to health caused by biological and chemical incidents, environment and climate change. As stated in the Commission's Communication 'A Budget for Europe 2020', the Commission has committed to mainstreaming climate change into overall Union spending programmes and to direct at least 20% of the Union budget to climate-related objectives. Spending in the Health for Growth Programme under objective 4 will contribute in a general manner to this objective by addressing health threats associated to climate change. The Commission will provide information on climate change expenditure within the Health for Growth Programme.

# Proposal for a regulation Recital 16 a (new)

Text proposed by the Commission

### **Amendment**

(16a) This programme should also contribute to creating synergies with the European research field by introducing and applying innovative breakthroughs in the health sector and making sure that limited national European resources are utilized efficiently. In order to translate research into actual innovation within health systems, particular attention should be given to actors with specific vulnerabilities, such as women and children, who make, nevertheless, a crucial contribution to social and economic growth and welfare.

## Amendment 6

# Proposal for a regulation Recital 23

Text proposed by the Commission

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

#### **Amendment**

(23) The Programme should be implemented in full respect of the principle of transparency. The way in which the budget is allocated between objectives should be proportionate to the benefits we may expect regarding the improvement of European citizens' health. Appropriate actions covered by the programme's specific objectives and with a clear EU added value should be selected and funded by the Programme. The annual work programmes should set out, in particular, the essential selection criteria applicable to the potential beneficiaries, in accordance with the Financial Regulation, in order to ensure they have the financial and

required to demonstrate their independence.

operational capacity to undertake activities financed under the Programme, and, where appropriate, the evidence required to demonstrate their independence.

# Amendment 7

# Proposal for a regulation Article 3 – paragraph 1 – point 1 – subparagraph 1

Text proposed by the Commission

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

#### Amendment

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

## **Amendment 8**

# Proposal for a regulation Article 3 – paragraph 1 – point 2 – subparagraph 1

Text proposed by the Commission

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

## Amendment

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

## Amendment 9

# Proposal for a regulation Article 3 – paragraph 1 – point 3 – subparagraph 1

Text proposed by the Commission

Amendment

(3) To identify, disseminate and promote

(3) To identify, disseminate and promote

PE486.116v03-00 72/81 RR\908053EN.doc



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

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

## Amendment 10

Proposal for a regulation Article 3 – paragraph 1 – point 4 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

1a. To develop joint approaches and actions and to demonstrate their value for better preparedness and coordination of research into, prevention and treatment of rare diseases which, owing to their low rate of occurrence, can only effectively be addressed at a pan-European level.

## **Amendment 11**

Proposal for a regulation Article 4 – point 1.2 a (new)

Text proposed by the Commission

Amendment

- 1.2a. Develop e-Health ICT standards and protocols, in order to turn ICT technologies to good use in the field of health in order to guarantee the protection of personal data and protect patients and their privacy;

## Amendment 12

Proposal for a regulation Article 4 – point 1.2 b (new)

# Text proposed by the Commission

# Amendment

- 1.2b. Develop e-Health ICT standards and protocols for emergency services, including the use of intelligent transport systems (ITS) in such services;

## **Amendment 13**

# Proposal for a regulation Article 4 – point 2.2

Text proposed by the Commission

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

## Amendment

- 2.2 Support action on rare diseases including information and registries based on the common criteria for accreditation;

#### Amendment 14

# Proposal for a regulation Article 4 – point 3.1

Text proposed by the Commission

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

# Amendment

Exchange best practices on key health issues such as smoking prevention, *drug use*, abuse of alcohol and obesity;

# **Amendment 15**

# Proposal for a regulation Article 4 – point 3.2

Text proposed by the Commission

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

# Amendment

- 3.2 Supporting the prevention of chronic diseases including *cardiovascular disease*, *hepatitis B and C and* cancer, by sharing knowledge and best practice and developing joint activities;

PE486.116v03-00 74/81 RR\908053EN.doc

# Proposal for a regulation Article 7 – paragraph 2 – point b

Text proposed by the Commission

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

## Amendment

(b) actions having a clear EU added value co-financed by other public or private bodies, as referred to in article 8 (1), including international organisations active in the area of health and for the latter, where appropriate without previous call for proposal, duly justified in the annual work programmes, in accordance with the Financial Regulation<sup>1</sup> and its implementing rules<sup>2</sup>;

## Amendment 17

# Proposal for a regulation Article 8 – paragraph 2 – point a

Text proposed by the Commission

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

#### **Amendment**

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

RR\908053EN.doc 75/81 PE486.116v03-00

<sup>&</sup>lt;sup>1</sup> Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities (OJ L 248, 16.9.2002, p. 1).

<sup>&</sup>lt;sup>2</sup> Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002 laying down detailed rules for the implementation of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities

# Proposal for a regulation Article 11 – paragraph 1 – point g

Text proposed by the Commission

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

#### **Amendment**

(g) the actions co-financed by international organisations active in the area of health without previous call for proposal duly justified, *in accordance with the Financial Regulations and its implementing rules*.

#### Amendment 19

Proposal for a regulation Article 13 – paragraph 2 a (new)

Text proposed by the Commission

#### Amendment

2a. The Commission shall submit an annual report to the European Parliament on the way in which the programme is being implemented and on its impact.

## Amendment 20

# Proposal for a regulation Article 13 – paragraph 3 – subparagraph 1

Text proposed by the Commission

No later then mid-2018, an evaluation report shall be established by the Commission on the achievement of the objectives of all the measures (at the level of results and impacts), the efficiency of the use of resources and its European added value, in view of a decision on the renewal, modification or suspension of the measures. The evaluation shall additionally address the scope for simplification, its internal and external coherence, the continued relevance of all objectives, as

#### Amendment

No later then mid-2018, an evaluation report shall be established by the Commission *and presented to the European Parliament* on the achievement of the objectives of all the measures (at the level of results and impacts), the efficiency of the use of resources and its European added value, in view of a decision on the renewal, modification or suspension of the measures. The evaluation shall additionally address the scope for simplification, its internal and external coherence, the

PE486.116v03-00 76/81 RR\908053EN.doc

well as the contribution of the measures to the Union priorities of smart, sustainable and inclusive growth. It shall take into account evaluation results on the long-term impact of the predecessor programme. continued relevance of all objectives, as well as the contribution of the measures to the Union priorities of smart, sustainable and inclusive growth. It shall take into account evaluation results on the long-term impact of the predecessor programme.

## **Amendment 21**

# Proposal for a regulation Annex I – point 1.2

Text proposed by the Commission

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

#### Amendment

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

#### Amendment 22

Proposal for a regulation Annex 1 – point 1 – point 1.2 a (new)

Text proposed by the Commission

# Amendment

1.2a. Health innovation and e-Health: use of intelligent transport systems (ITS) by emergency medical services.

# **Amendment 23**

# Proposal for a regulation Annex I – point 1.3

Text proposed by the Commission

1.3. Health workforce: develop effective health workforce forecasting and planning

#### Amendment

1.3. Health workforce: develop effective health workforce forecasting and planning

RR\908053EN.doc 77/81 PE486.116v03-00

EN

in terms of numbers, scope of practice and skills, monitor mobility (within the Union) and migration of health professionals, establish efficient recruitment and retention strategies and capacity development. in terms of numbers, scope of practice and skills, including the ability to make use of new information systems and other advanced technologies, monitor mobility (within the Union) and migration of health professionals, establish efficient recruitment and retention strategies and capacity development.

#### Amendment 24

Proposal for a regulation Annex 1 – point 1 – point 1.4 a (new)

Text proposed by the Commission

#### Amendment

1.4a. Creating synergies with the European research field so that the main research breakthroughs can be introduced and actually applied into health systems.

## Amendment 25

# Proposal for a regulation Annex 1 – point 2

Text proposed by the Commission

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

#### Amendment

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

# **Amendment 26**

Proposal for a regulation Annex 1 – point 4.1

PE486.116v03-00 78/81 RR\908053EN.doc

# Text proposed by the Commission

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

## Amendment

4.1. Preparedness to and response for serious cross border health threats taking into account and coordinating with global initiatives: put in place common components of generic and specific preparedness planning, including for pandemic influenza, and report regularly on implementation of preparedness plans; bring innovation to patients for the prevention, diagnosis and treatment of diseases originating in developing countries which are increasingly becoming a reality in some European countries.

# **PROCEDURE**

Title	Health for Growth Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020
References	COM(2011)0709 - C7-0399/2011 - 2011/0339(COD)
Committee responsible Date announced in plenary	ENVI 30.11.2011
Committee(s) asked for opinion(s) Date announced in plenary	ITRE 30.11.2011
Rapporteur(s) Date appointed	Maria Badia i Cutchet 14.12.2011
Discussed in committee	28.2.2012
Date adopted	24.4.2012
Result of final vote	+: 54 -: 1 0: 1
Members present for the final vote	Gabriele Albertini, Amelia Andersdotter, Josefa Andrés Barea, Zigmantas Balčytis, Ivo Belet, Bendt Bendtsen, Jan Březina, Reinhard Bütikofer, Maria Da Graça Carvalho, Jürgen Creutzmann, Pilar del Castillo Vera, Christian Ehler, Vicky Ford, Gaston Franco, Adam Gierek, Norbert Glante, Robert Goebbels, András Gyürk, Fiona Hall, Edit Herczog, Kent Johansson, Romana Jordan, Krišjānis Kariņš, Lena Kolarska-Bobińska, Judith A. Merkies, Angelika Niebler, Jaroslav Paška, Aldo Patriciello, Vittorio Prodi, Miloslav Ransdorf, Herbert Reul, Jens Rohde, Paul Rübig, Francisco Sosa Wagner, Konrad Szymański, Patrizia Toia, Claude Turmes, Niki Tzavela, Marita Ulvskog, Vladimir Urutchev, Adina-Ioana Vălean, Kathleen Van Brempt, Alejo Vidal-Quadras
Substitute(s) present for the final vote	Maria Badia i Cutchet, Yves Cochet, Ioan Enciu, Vicente Miguel Garcés Ramón, Roger Helmer, Jolanta Emilia Hibner, Yannick Jadot, Seán Kelly, Eija-Riitta Korhola, Werner Langen, Zofija Mazej Kukovič, Vladimír Remek, Silvia-Adriana Ţicău

# **PROCEDURE**

Title	Health for Growth Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020
References	COM(2011)0709 – C7-0399/2011 – 2011/0339(COD)
Date submitted to Parliament	9.11.2011
Committee responsible Date announced in plenary	ENVI 30.11.2011
Committee(s) asked for opinion(s) Date announced in plenary	BUDG EMPL ITRE FEMM 30.11.2011 30.11.2011 30.11.2011
Not delivering opinions Date of decision	EMPL FEMM 17.11.2011 27.4.2012
Rapporteur(s) Date appointed	Françoise Grossetête 15.12.2011
Discussed in committee	8.5.2012
Date adopted	20.6.2012
Result of final vote	+: 63 -: 0 0: 0
Members present for the final vote	Elena Oana Antonescu, Sophie Auconie, Pilar Ayuso, Paolo Bartolozzi, Sergio Berlato, Lajos Bokros, Martin Callanan, Nessa Childers, Tadeusz Cymański, Chris Davies, Esther de Lange, Edite Estrela, Jill Evans, Elisabetta Gardini, Matthias Groote, Françoise Grossetête, Cristina Gutiérrez-Cortines, Satu Hassi, Jolanta Emilia Hibner, Dan Jørgensen, Christa Klaß, Eija-Riitta Korhola, Holger Krahmer, Peter Liese, Kartika Tamara Liotard, Zofija Mazej Kukovič, Linda McAvan, Miroslav Ouzký, Vladko Todorov Panayotov, Andres Perello Rodriguez, Mario Pirillo, Pavel Poc, Frédérique Ries, Anna Rosbach, Oreste Rossi, Dagmar Roth-Behrendt, Carl Schlyter, Richard Seeber, Bogusław Sonik, Claudiu Ciprian Tănăsescu, Salvatore Tatarella, Anja Weisgerber, Åsa Westlund, Glenis Willmott, Sabine Wils, Marina Yannakoudakis
Substitute(s) present for the final vote	Margrete Auken, Erik Bánki, Cristian Silviu Buşoi, Nikos Chrysogelos, Minodora Cliveti, Gaston Franco, James Nicholson, Vittorio Prodi, Michèle Rivasi, Crescenzio Rivellini, Birgit Schnieber-Jastram, Rebecca Taylor, Marita Ulvskog, Kathleen Van Brempt, Anna Záborská, Andrea Zanoni
Substitute(s) under Rule 187(2) present for the final vote	Véronique Mathieu
Date tabled	3.7.2012