



**COUNCIL OF
THE EUROPEAN UNION**

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NOTE

from:	General Secretariat of the Council
to:	Permanent Representatives Committee (Part 1)/Council
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing a Health for Growth Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020 <i>- Partial general approach</i>

I. INTRODUCTION

1. The Commission submitted the above proposal on 9 November 2011. The general objectives of the programme are, together with Member States, to encourage innovation in healthcare and increase the sustainability of health systems, to improve the health of EU citizens and protect them from cross-border health threats.

These general objectives will be pursued through actions grouped under four specific objectives: (1) innovative and sustainable health systems, (2) increased access to better and safer healthcare, (3) prevention of diseases and promotion of good health and (4) protection from cross-border health threats.

2. On 12 December 2011, the Council decided to consult the Economic and Social Committee, which adopted its opinion¹ on the proposal on 23 February 2012 (the rapporteur was Ms Béatrice Ouin, FR).
3. On 12 December 2011, the Council decided to consult the Committee of the Regions, which adopted its opinion² on the proposal on 3 May 2012 (the rapporteur was Mr Tilman Tögel DE/PSE).
4. The ENVI committee of the European Parliament considered its draft report³ on 8 May 2012. The vote on the draft report by ENVI committee is scheduled for 20 June 2012.
5. This proposal was discussed several times by the Working Party on Public Health, following which the Permanent Representatives Committee on 6 June agreed on the text with the exception of Article 7.3(c). Subsequently the Presidency had informal discussion with delegations and a possible agreement is now reflected in recital 14, Article 7.3(c) and Article 11.1(c).
6. The Commission reserves its position on the entire compromise proposal. At the COREPER of 6 June the Commission particularly highlighted its fundamental disagreement on the change of the Title (Article 1), the reordering of the objectives (Article 3), the procedure on how to adopt the work programme (Article 11), the introduction of a no-opinion clause (Article 16.3) and the footnote regarding drug prevention (Annex I, paragraph 1.2).

The UK maintains a parliamentary scrutiny reservation on the entire compromise proposal.

¹ SOC/437
² NAT-V-018
³ PE486.116v02-00

II. PRESIDENCY'S APPROACH

The Presidency aims at reaching a partial general approach on this proposal at the Council (EPSCO) meeting on 22 June 2012. The amount of the financial envelope for the implementation of the Programme (EUR 446 millions in current prices) was specified in the Commission proposal (Article 5) and is not discussed at the present stage as the decision will be taken in the context of the Multiannual Financial Framework (MFF).

III. CONCLUSION

The Permanent Representatives Committee is invited to confirm the agreement and submit the draft partial general approach to the Council (EPSCO) at its meeting on 22 June 2012.

The Council is invited to agree the partial general approach on the basis of the text as outlined in the ANNEX to this note.

* * *

The text in the attachment is marked as follows:

<i>bold italics</i>	Additions to the text of the Commission's proposal
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Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on
the establishment of a Health and Growth Programme, the third multi-annual programme of European Union action in the field of health for the period 2014-2020 and repealing Decision No 1350/2007/EC
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168 (5) thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee⁴,

Having regard to the opinion of the Committee of the Regions⁵,

Acting in accordance with the ordinary legislative procedure,

Whereas:

⁴ OJ C , , p. .

⁵ OJ C , , p. .

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

(2) Continued effort is required in order to meet the requirements set out in Article 168 of the Treaty. *The promotion of good health at **Union** level is **also** an integral part of the ‘Europe 2020: A European Strategy for smart, sustainable and inclusive growth’⁶. 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 **and** Growth’ Programme (***the Programme***), the third programme of **Union** action *in the field of* health (2014-2020).*

(3) The previous programmes of Community action in the field of public health (2003-2008) and in the field of health (2008-2013), adopted respectively by Decisions Nos 1786/2002/EC⁷ and 1350/2007/EC of the European Parliament and of the Council⁸, have been positively assessed as delivering a number of important developments and improvements. The new programme should build on the achievements of the previous ones. It should also take into account the recommendations of the external audits and evaluations carried out, in particular recommendations of the Court of Auditors⁹, according to which "for the period after 2013, the European Parliament, the Council and the Commission should reconsider the scope for **Union** public health activities and the approach of **Union** funding in this area. This should be done bearing in mind the budgetary means available and the existence of other cooperation mechanisms (...) as a means of facilitating collaboration and the exchange of information among stakeholders throughout Europe".

⁶ Communication from the Commission, COM (2010) 2020 final

⁷ OJ L 271, 9.10.2002, p. 1-12

⁸ OJ L 301, 20.11.2007, p. 3-13

⁹ Court of Auditor's Special Report n°212009 of 5.3.2009, "The European Union's Public Health Programme (2003-2007): an effective way to improve health?"

(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 *Union* added value, and concentrate support on a smaller number of activities in priority areas. The emphasis *should* be placed in accordance with the principle of subsidiarity, on areas where there are clear cross-border or internal market issues at stake, or where there are significant advantages and efficiency gains from collaboration at *Union* level.

(5) The programme *should* put forward actions in areas where there is evidence of *Union* added-value on the basis of the following criteria: best practice exchange between Member States; supporting networks for knowledge sharing or mutual learning; addressing cross-border threats to reduce risks and mitigate their consequences; addressing certain issues relating to the Internal Market where the *Union* has substantial legitimacy to ensure high-quality solutions across Member States; unlocking the potential of innovation in health; actions that could lead to a system for benchmarking to allow informed decision-making at European level; improving economies of scale by avoiding waste due to duplication and optimising the use of financial resources.

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

(7) Innovation in health, in terms of products and services, and in the organisation and provision of care, **including disease prevention and health promotion interventions**, has the potential to enhance the quality of care to patients and respond to unmet needs, while also improving its cost-efficiency and sustainability of care. Therefore, the Programme should facilitate the **voluntary** uptake of innovation in health, **taking into account the common values and principles in European Union Health Systems as set out in the Council conclusions of June 2006¹⁰**.

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

(8a) (new) Taking into account Articles 8 and 10 of the Treaty, the Programme should support the mainstreaming of gender equality and anti-discrimination objectives in all its activities.

(9) 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 **Union** level in order to effectively help patients and in particular those affected by rare diseases to benefit from cross border healthcare.

(10) In the context of an ageing society, well-directed investments to promote health and prevent diseases can increase the number of ‘healthy life years’ and thus enable the elderly to enjoy **a healthy and active life** as they grow older. Chronic diseases are responsible for over 80% of premature mortality in the **Union**. By identifying, disseminating and promoting the up-take of **evidence-based and** good practices for cost-effective **health promotion and disease prevention** measures focused **in particular** on the key **lifestyle related health determinants**, namely **tobacco**

¹⁰ **OJ C 146 of 22 June 2006, p. 1**

use, drug use, harmful use of alcohol and *unhealthy dietary habits*, as well as on HIV/AIDS, *tuberculosis and hepatitis*, the Programme *should* contribute to *the prevention of* diseases, the promotion of health *and the fostering of supportive environments for healthy lifestyles, taking into account* underlying factors of a social and environmental nature.

(11) To minimise the public health consequences of cross-border health threats which could range from mass contamination caused by chemical incidents to pandemics, like those unleashed recently by E coli, influenza strain H1N1 or SARS (severe acute respiratory syndrome), the Programme should contribute to the creation and maintenance of robust mechanisms and tools to detect, assess and manage major cross-border health threats.. Due to the nature of these threats, the Programme should support coordinated public health measures at *Union* 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 Control¹¹ 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.

(11a) 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 Programme under objective 4 *should* 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.

¹¹ The European Centre for Disease Prevention and Control was established by Regulation (EC) 851/2004 of the European Parliament and of the Council.

(12) In accordance with 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 **Union** legislation in the fields of medicinal products, medical devices, human tissues and cells, blood, human organs, communicable diseases and other health threats, patients' rights in cross-border healthcare and tobacco products and advertisement.

(13) The Programme should contribute to evidence based decision making by fostering a health information and knowledge system, **taking into account relevant activities carried out by international organisations, such as the WHO and the OECD. The system would consist of, inter alia, the use of existing instruments and, as appropriate, further development of standardised health information and tools for monitoring health**, collecting and analysing health data, supporting the scientific Committees¹² and participating in the wide dissemination of the results of the Programme.

(14) **The exchange of best practices is a key instrument of Union policy in the field of health which aims to complement and support national health policies, encourage cooperation between Member States and promote the coordination between their programmes. Such exchange should enable national authorities to benefit from efficient solutions developed in other Member States, reduce duplication of efforts and increase value for money by promoting innovative solutions in**

¹² The Scientific Committees were set up in accordance with Commission Decision 2008/721/EC, OJ L 241, 10.9.2008, p. 21.

health. Therefore, the Programme should focus mainly on cooperation with the competent authorities of the Member States responsible for Health and provide incentives for a wider participation of all Member States as recommended in the evaluations of the former and current health programmes. In particular, Member States whose Gross National Income (GNI) per inhabitant is lower than 90% of the Union average should be actively encouraged to participate in actions co-financed by the competent authorities of the Member States responsible for public health or by bodies mandated by those competent authorities. Such actions should be considered to be of exceptional utility.

(15) Non-governmental bodies and health stakeholders, in particular patients' organisations and health professionals' associations, play an important role in providing the Commission *with* 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 *Union* level, such as for example participation in consultative groups, and in that way contribute to pursuing the Programme's specific objectives.

(16) The programme should promote synergies while avoiding duplication with related Union programmes and actions. Appropriate use should be made of other Union funds and programmes, in particular the current and future Union framework programmes for research and innovation and their outcomes, the Structural Funds, the Programme for social change and innovation, the European Solidarity Fund, the European strategy for health at work, the Competitiveness and Innovation Programme, the Framework Programme for Environment and Climate action (LIFE), the programme of Union action in the field of consumer policy (2014-2020)¹³, the Justice programme (2014-2020), the Ambient Assisted Living Joint Programme, (the Education Europe Programme) and the Union Statistical Programme within their respective activities.

¹³ OJ L, ,p.

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

(18) Appropriate relations with third countries not participating in the programme should be facilitated to help achieve the objectives of the programme, taking *into* account any relevant agreements between those countries and the Union. This may involve *the Union* organising health events or third countries taking forward complementary activities to those financed through the programme on areas of mutual interest, but should not involve a financial contribution under the Programme.

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

(20) The programme should run for a period of seven years to align its duration with that of the Multi-annual Financial Framework as set out in [Article 1] of the Council Regulation laying down the multiannual financial framework for the year 2014-2020. This Regulation lays down *a financial reference amount for the multiannual programme which is to constitute the prime reference, within the meaning of point 37 of the Interinstitutional Agreement of 17 May 2006 between the European Parliament, the Council and the Commission on budgetary discipline and sound financial management, for the budgetary authority during the annual budgetary procedure.*

(21) In accordance with Article 49 of Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities¹⁴, this Regulation provides the legal basis for the action and for the implementation of the Programme.

(22) In order to ensure uniform conditions for the implementation of this Regulation by means of annual work programmes, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers¹⁵.

(23) The Programme should be implemented in full respect of the principle of transparency. ***Budgetary resources should be shared between the different objectives of the Programme in a balanced way throughout the lifespan of the Programme, taking into account the probable advantages for promoting health.*** Appropriate actions covered by the programme's specific objectives and with a clear ***Union*** added value should be selected and funded by the Programme. The annual work programmes should set out, in particular, the essential selection criteria applicable to the potential beneficiaries, in accordance with the Financial Regulation, in order to ensure they have the financial and operational capacity to undertake activities financed under the Programme, and, where appropriate, the evidence required to demonstrate their independence.

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

¹⁴ OJ L 248, 16.9.2002, p. 1.

¹⁵ OJ L 55, 28.2.2011, p 13.

(25) The cooperation of national authorities is essential in sharing information with potential applicants to allow equitable participation in the Programme, and knowledge produced by the programme with the different national health sector stakeholders. Thus, National Focal Points should be designated by the Member States in order to support the above mentioned activities.

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

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

(27a) (new) Since the general objectives of this Regulation, namely to complement, support and add value to the policies of the Member States to improve the health of Union citizens and reduce health inequalities by promoting health, encouraging innovation in health, increasing the sustainability of health systems, and protecting Union citizens from serious cross-border health threats, cannot be sufficiently achieved by Member States and can therefore, by reason of the scale and effects, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

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

HAVE ADOPTED THIS REGULATION:

Chapter I

General provisions

Article 1

Establishment of the Programme

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

Article 2

General objectives

The general objectives of the Programme shall be to ***complement, support and add value to the policies of*** the Member States to ***improve the health of EU citizens and reduce health inequalities by promoting health***, encouraging innovation in health, increasing the sustainability of health systems and protecting ***Union citizens*** from ***serious*** cross-border health threats.

Chapter II

Objectives and actions

Article 3

Specific objectives and indicators

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

- (1) ***In order to promote health, prevent diseases, and foster supportive environments for healthy lifestyles:*** Identify, disseminate and promote the up-take of ***evidence-based and good*** practices for cost-effective ***disease*** prevention ***and health promotion*** measures by addressing ***in particular*** the key ***lifestyle related health determinants*** with a focus on the ***Union added value***.

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

- (2) ***In order to protect citizens from serious cross-border health threats:*** ***Identify and*** develop ***coherent*** approaches and ***promote their implementation*** for better preparedness and coordination in health emergencies.

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

- (3) ***In order to support public health capacity building and contribute to innovative, efficient and sustainable health systems.*** ***Identify and*** develop tools and mechanisms at ***Union*** level to address shortages of resources, both human and financial, and facilitate ***the voluntary*** up-take of innovation in health.

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

- (4) *In order to facilitate access to better and safer healthcare for Union citizens:* Increase access to medical expertise and information for specific conditions also beyond national borders, and develop *tools for the improvement of* healthcare quality and patient safety.

This objective will be measured in particular through the increase *in the* number of European Reference Networks *established in accordance with* Directive 2011/24/EU *of the European Parliament and of the Council of 9 March 2011*¹⁶ on the application of patients' rights in cross-border healthcare (hereinafter referred to as "the European Reference Networks"); the increase *in the* number of *healthcare providers and centres of expertise joining European Reference Networks*; and the increase *in the* number of Member States using the developed *tools*.

Article 4

Eligible actions

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

[Rest of Article 4 deleted]

¹⁶ *OJ L 88, 4.4.2011, p.45*

Chapter III

Financial provisions

Article 5

Funding

1. The financial *reference amount* for the implementation of the Programme for the period from 1 January 2014 to 31 December 2020 is hereby set at [EUR XXX] in current prices.

The annual appropriations shall be authorised by the budgetary authority within the limits of the multiannual financial framework.

Article 6

Participation of third countries

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

- (a) acceding countries, candidate countries and potential candidates benefiting from a pre-accession strategy, in accordance with the general principles and general terms and conditions for their participation in Union programmes established in the respective Framework Agreements, Association Council Decisions or similar Agreements;
- (b) EFTA/EEA countries in accordance with the conditions established in the EEA Agreement;
- (c) neighbouring countries and the countries to which the European Neighbourhood Policy (ENP) applies in accordance with the conditions laid down by a relevant bilateral or multilateral agreement;
- (d) other countries in accordance with the conditions laid down by a relevant bilateral or multilateral agreement.

Article 7

Types of intervention

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

2. Grants may be awarded to fund:

- (a) actions having a clear **Union** added value co-financed by the competent authorities of the Member States responsible for Health or the third countries participating pursuant to Article 6, or by **public sector bodies and** non-governmental bodies mandated by these competent authorities;
- (b) actions having a clear EU added value co-financed by other public, **non-governmental** 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, **explicitly foreseen and** duly justified in the annual work programmes;
- (c) the functioning of non governmental bodies as referred to in article 8(2) where financial support is necessary to the pursuit of one or more of the specific objectives of the Programme.

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

- (a) 60 % of eligible costs for an action aimed at an objective of the Programme. In cases of exceptional utility, the contribution by the Union may be up to 80% of eligible costs;
- (b) 60 % of eligible costs for the functioning of a non-governmental body. In cases of exceptional utility such bodies may benefit from a financial contribution up to a maximum of 80% of eligible costs;
- (c) 60 % of eligible costs for actions referred to in point (a) of paragraph 2. In cases of exceptional utility, the financial contribution for actions referred to in point (a) of paragraph 2 may be up to a maximum of 80% of eligible costs for competent authorities of all Member States or third countries participating in the Programme.

For the purpose of this subparagraph, exceptional utility is achieved, inter alia, if at least 6 Member States whose gross national income per inhabitant is less than 90 % of the Union average participate in actions referred to in point (a) of paragraph 2.

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

Article 8

Beneficiaries eligible for grants

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

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

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

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

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

Article 9

Administrative and technical assistance

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

Chapter IV

Implementation

Article 10

Methods of implementation

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

Article 11

Annual Work programmes

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

- (a) the priorities and the actions to be undertaken, including the allocation of financial resources;
- (b) detailed eligibility criteria for the beneficiaries in compliance with Article 8;
- (c) the criteria for the percentage of the financial contribution of the Union, including criteria for assessing whether or not exceptional utility applies, and the applicable rate of the co-financing *without prejudice to Article 7(3)*;
- (d) the essential selection and award criteria to be used to select the proposals receiving financial contributions *as well as the selection of priorities and actions to be covered by calls for tenders*;
- (e) the time schedule of the planned calls for 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.

Prior to the elaboration of the draft annual working programme , the Commission shall consult Member States in order to exchange views on the elements set out in the first subparagraph, including the priorities and the eligibility criteria.

2. The **annual** work programmes referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 16(2).

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

Article 12

Consistency and complementarity with other policies

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

Article 13

Monitoring, evaluation and dissemination of results

1. The Commission shall, in close cooperation with the Member States, monitor the implementation of the actions under the programme in the light of its objectives and indicators, including **available** information on the amount of climate related expenditure. It shall report thereon to the committee referred to in Article 16, and shall keep the European Parliament and the Council informed.

2. At the request of the Commission, Member States shall submit available information on the implementation and impact of the Programme. ***Such requests for information shall be proportionate and shall avoid imposing any unnecessary increase in the administrative burden on Member States.***

3. No later than mid-2018, *the Commission shall establish* an evaluation report 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 *Union* added value, in view of a decision on the renewal, modification or suspension of the measures. The evaluation shall additionally address the scope for simplification, its internal and external coherence, the continued relevance of all objectives, as well as the contribution of the measures to the Union priorities of smart, sustainable and inclusive growth. It shall take into account evaluation results on the long-term impact of the predecessor programme.

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

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

Article 14

National Focal Points

Member States shall designate National Focal Points which shall assist the Commission in the promotion of the Programme and, *as appropriate*, the dissemination of the results of the Programme.

Article 15

Protection of the financial interests of the Union¹⁷

1. The Commission shall take appropriate measures ensuring that, when actions financed under this Regulation are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the *dissuasive administrative and financial* penalties.

¹⁷ Following horizontal discussions of this Article in the anti-fraud WP and in COREPER II on the 23 May 2012, this Article has been amended as all similar Articles on "protection of the financial interests of the Union" included in all MFF proposals.

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

3. The European Anti-fraud Office (OLAF) may carry out ***investigations, including*** on-the-spot checks and inspections in accordance with ***the provisions and*** procedures laid down in ***Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF)***¹⁸ and Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities¹⁹ with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the European Union in connection with a grant agreement or grant decision or a contract ***funded under this Regulation***.

4. Without prejudice to paragraphs 1, 2 and 3, cooperation agreements with third countries and ***with*** international organisations, ***contracts***, grant agreements and grant decisions, resulting from the implementation of this Regulation shall ***contain provisions*** expressly empowering the Commission, the Court of Auditors and OLAF to conduct such audits, ***investigations, according to their respective competences***.

Chapter V

Procedural provisions

Article 16

Committee procedure

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

¹⁸ OJ L 136, 31.5.1999, p. 1.

¹⁹ OJ L 292, 15.11.1996, p. 2.

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

3. Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5 (4) of Regulation (EU) No 182/2011 shall apply.

Chapter VI

Transitional and final provisions

Article 17

Transitional provisions

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

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

Article 18

Repeal provisions

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

Article 19

Entry into force

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

Done at Brussels,

For the European Parliament

The President

For the Council

The President

[...]

Types of actions

- 1. *Promoting health, preventing disease and fostering supportive environments for healthy lifestyles taking into account the health in all policies principle***
- 1.1. *Cost-effective promotion and prevention measures, including actions to support the exchange of evidence-based and good practices for addressing key life style related health determinants, such as use of tobacco, harmful use of alcohol, unhealthy dietary habits and physical inactivity with a focus on Union added value.***
- 1.2. *Measures to complement the Member States' action in reducing drugs-related health damage, including information and prevention*²⁰.**

²⁰ *The references to drugs in the Justice Programme have provisionally been deleted. In order to avoid overlaps and gaps between the relevant programmes, the Presidency suggests that activities related to “drug demand reduction” on the basis of Article 168 should be covered by the “Health for Growth” programme. Activities related to “drug supply” should be covered by the instrument for financial support for police cooperation, preventing and combating crime, and crisis management. With regard to both programmes it is of course a precondition for support that the actual activities fall within the objectives of these instruments. This proposal by the Presidency has been put to the relevant working groups on Public Health and the Home Affairs formation of the ad hoc Working Party on JHA Financial Instruments. These working groups will discuss the final drafting of the objectives in this regard. It is understood, that these changes should be reflected in the final allocation of funds to each programme. A considerable majority of delegations supported this approach. There was also general agreement that it may be necessary to address possible gaps between the programmes in the context of the Justice Programme once discussions in the health and police cooperation working groups have been finalised. Therefore it might be necessary to revert to this specific matter, in particular in the context of recitals (6), (7) and (9), and Articles 5(1) and 14.*

- 1.3. Support effective response to communicable diseases such as HIV/AIDS, tuberculosis and hepatitis by identifying, disseminating and promoting the up-take of good practices for cost effective prevention, diagnosis, treatment and care.**
- 1.4. Support European cooperation and networking on preventing and improving the response to chronic diseases including cancer, by sharing knowledge, good practices and developing joint activities on prevention, *early detection and management (including self management)*. Follow up work *on cancer* already undertaken, *including relevant actions suggested by the European Partnership Action against Cancer*.**
- 1.5. 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.**
- 1.6. Fostering a health *information and* knowledge system to contribute to evidence-based decision making, including *the use of existing instruments and, as appropriate, further development of standardised health information and tools for monitoring health*, collection and analysis of health data, and wide dissemination of the results of the Programme.**

2. ***Protecting citizens from serious cross border health threats.***

2.1. ***[deleted]***

2.1. ***Improve risk assessment and*** close gaps in risk assessment capacities by providing additional capacities for scientific expertise and map existing assessments.

2.2. Support capacity building against health threats in Member States, ***including, where appropriate, cooperation with neighbouring countries***: develop preparedness and response planning ***taking into account and coordinating with global initiatives, components of generic and specific preparedness planning***, public health response coordination, ***non-binding*** approaches on vaccination; develop guidelines on protective measures in an emergency situation, guidelines on information and guides to good practice; ***contribute to the framework for*** a ***voluntary*** mechanism for joint procurement of medical countermeasures; develop ***coherent*** communication strategies

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

2.4. Fostering a health ***information and*** knowledge system to contribute to evidence-based decision making, including ***the use of existing instruments and, as appropriate, further development of standardised health information and tools for monitoring health***, collection and analysis of health data, and wide dissemination of the results of the Programme.

3. *Contributing to innovative, efficient and sustainable health systems*

3.1. Support *voluntary* cooperation *between Member States* on Health Technology Assessment (HTA) under the network on Health Technology Assessment set up by the Directive 2011/24/EU of the European Parliament and of the Council²¹. Facilitate the uptake of the results streaming from research projects supported under 7th Framework Programme and the in the longer term the activities which will be undertaken in the forthcoming research and innovation programmes 2014-2020 (Horizon 2020).

3.2. *Promote the voluntary uptake of* health innovation and e-Health *by* increasing the interoperability of patient registries 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.

3.3. *Support the sustainability of the* health workforce *by* developing 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, *foster* efficient recruitment and retention strategies and capacity development.

²¹ OJ L 88, 4.4.2011, p. 45.

- 3.4. ***Provide expertise and share good practise to assist Member States undertaking*** health systems reforms ***by setting*** 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).
- 3.5. Support ***actions which address health issues in an ageing society, including relevant actions suggested by*** 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.
- 3.6. Actions required by or contributing to the implementation of Union legislation in the field of medical devices, ***medicinal products*** and cross border healthcare. Such action may include activities aimed at ***facilitating*** the implementation, application, monitoring and review of that legislation.
- 3.7. Fostering a health ***information and*** knowledge system to contribute to evidence-based decision making, including ***the use of existing instruments and, as appropriate, further development of standardised health information and tools for monitoring health,*** collection and analysis of 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.

4. *Facilitating access to better and safer healthcare for Union citizens*

- 4.1. Support the establishment of a system of European Reference Networks to enable *inter alia* the **exchange** of medical expertise for patients with conditions requiring highly specialised care and a particular concentration of resources or expertise, like in the case of rare diseases, on the basis of criteria to be set under Directive on the application of patients' rights in cross-border healthcare (Directive 2011/24/EU)²².
- 4.2. 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 common criteria.
- 4.3. Strengthen collaboration on patient safety and quality of healthcare, through, *inter alia*, implementing the Council Recommendation on patient safety, **including** the prevention and control of healthcare-associated infections²³; exchange best practice on quality assurance systems; develop guidelines and tools to promote **quality and** patient safety; increase the availability of information to patients on safety and quality, improve feedback and interaction between health providers and patients.
- 4.4. Improve the prudent use of antimicrobial agents and reduce the practices that increase antimicrobial resistance; **promote effective prevention and hygiene measures to prevent and control infections**; reduce the burden of resistant infections and healthcare-associated infections and secure the availability of effective antimicrobials.

²² OJ L 88, 4.4.2011, p. 45.

²³ OJ C 151, 3.7.2009. p. 1

- 4.5. Actions required by or contributing to the implementation of Union legislation in the fields of tissues and cells, blood, organs, **medical devices**, medicinal products, and patients' rights in cross-border healthcare. Such action may include activities aimed at **facilitating** the implementation, application, monitoring and review of that legislation.
- 4.6. Fostering a health **information and** knowledge system to contribute to evidence-based decision making, including **the use of existing instruments and, as appropriate, further development of standardised health information and tools for monitoring health**, collection and analysis of health data, and wide dissemination of the results of the Programme.

[ANNEX II deleted]

