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THE EUROPEAN PARLIAMENT

THE COUNCIL

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REGULATION
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
ON THE ESTABLISHMENT OF A THIRD PROGRAMME
FOR THE UNION'S ACTION IN THE FIELD OF HEALTH (2014-2020)
AND REPEALING DECISION No 1350/2007/EC

REGULATION (EU) No .../2014
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 March 2014

**on the establishment of a third Programme for the Union's action
in the field of health (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 Committee¹,

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure³,

¹ OJ C 143, 22.5.2012, p. 102.

² OJ C 225, 27.7.2012, p. 223.

³ Position of the European Parliament of 26 February 2014 (not yet published in the Official Journal) and decision of the Council of 11 March 2014.

Whereas:

- (1) In accordance with Article 168 of the Treaty on the Functioning of the European Union (TFEU), a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities. The Union is to complement and support national health policies, encourage cooperation between Member States and promote the coordination between their programmes, in full respect of the responsibilities of the Member States for the definition of their health policies and the organisation and delivery of health services and medical care.
- (2) Continued effort is required in order to meet the requirements set out in Article 168 TFEU. The promotion of good health at Union level is also an integral part of 'Europe 2020: A strategy for smart, sustainable and inclusive growth' ("the Europe 2020 Strategy"). Keeping people healthy and active longer and empowering them to take an active role in managing their health, will have positive overall effects on health, including a reduction of health inequalities, and a positive impact on quality of life, on productivity and competitiveness, while reducing pressures on national budgets. Support for, and recognition of, innovation, which has an impact on health, helps to take up the challenge of sustainability in the health sector in the context of demographic change; and action to reduce inequalities in health is important for the purposes of achieving 'inclusive growth'. It is appropriate in that context to establish the third Programme for the Union's action in the field of health (2014-2020) ('the Programme').

- (3) According to the definition of the World Health Organisation (WHO), "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.". In order to improve the health of the population in the Union and reduce health inequalities, it is essential not to focus only on physical health. According to the WHO, mental health problems account for almost 40 % of years lived with disability. Mental health problems are also wide-ranging, long-lasting and a source of discrimination, and contribute significantly to inequality in health. Moreover, the economic crisis affects factors determining mental health, as protective factors are weakened and risk factors increased.
- (4) 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 No 1786/2002/EC¹ and 1350/2007/EC of the European Parliament and of the Council² ("the previous health programmes"), have been positively assessed as resulting in a number of important developments and improvements. The Programme should build on the achievements of the previous health programmes. It should also take into account the recommendations of the external audits and evaluations carried out, in particular recommendations of the Court of Auditors in its Special Report No 2/2009, 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 that 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.

¹ Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008) (OJ L 271, 9.10.2002, p. 1).

² Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-13) (OJ L 301, 20.11.2007, p. 3).

- (5) 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.
- (6) The Programme should be a means of promoting actions in areas where there is a Union added value that can be demonstrated on the basis of the following: exchanging good practices between Member States; supporting networks for knowledge sharing or mutual learning; addressing cross-border threats to reduce their 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 Union level; improving efficiency by avoiding a waste of resources due to duplication and optimising the use of financial resources.
- (7) The implementation of the Programme should be such that the responsibilities of the Member States, for the definition of their health policy and for the organisation and delivery of health services and medical care, are respected.
- (8) The WHO European Health Report 2009 identifies scope for increasing investment in public health and health systems. In that 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 national health policies.

- (9) 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 in the organisation and provision of health services and medical care, including health promotion and disease prevention interventions, has the potential to improve public health outcomes, enhance the quality of care to patients and respond to unmet needs, and also to foster the competitiveness of stakeholders and to improve the cost-efficiency and sustainability of health services and medical 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 2 June 2006¹.
- (10) The Programme should, in particular in the context of the economic crisis, contribute to addressing health inequalities and the promotion of equity and solidarity through actions under the different objectives and by encouraging and facilitating the exchange of good practices.
- (11) Pursuant to Articles 8 and 10 TFEU, the Union is to promote equality between men and women and aim to combat discrimination. Accordingly, the Programme should support the mainstreaming of gender equality and anti-discrimination objectives in all its actions.

¹ Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

- (12) Patients need to be empowered, *inter alia* by enhancing health literacy, to manage their health and their healthcare more pro-actively, to prevent poor health and make informed choices. The transparency 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 Union level in order to help patients in an effective manner, in particular those affected by rare diseases, to benefit from cross-border healthcare.
- (13) Reducing the burden of resistant infections and healthcare associated infections and securing the availability of effective antimicrobials is essential for the efficiency of health systems and for the safety of patients. The Programme should support sustained efforts to improve methods of analysis to detect and prevent antimicrobial resistance and improve networking among all healthcare actors, including the veterinary sector, in relation to dealing with antimicrobial resistance.

- (14) 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 get older. Chronic diseases are responsible for over 80 % of premature mortality in the Union. The Programme should identify, disseminate and promote the uptake of evidence-based and good practices for cost-effective health promotion and disease prevention measures focused in particular on the key risk factors, such as tobacco use, drug use, harmful use of alcohol and unhealthy dietary habits, obesity and physical inactivity, as well as on HIV/AIDS, tuberculosis and hepatitis. Effective prevention would contribute to increasing the financial sustainability of healthcare systems. Operating within a gender sensitive framework, the Programme should contribute to disease prevention in all its aspects (primary, secondary and tertiary prevention) and throughout the lifetime of the Union's citizens, to health promotion and the fostering of supportive environments for healthy lifestyles, taking into account underlying factors of a social and environmental nature as well as the impact on health of certain disabilities.

- (15) In order to minimise the public health consequences of cross-border threats to health as set out in Decision No 1082/2013/EU of the European Parliament and of the Council¹, 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 health effects resulting from increasing population movements, 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 those threats, the Programme should support coordinated public health measures at Union level to address different aspects of cross-border health threats, building on preparedness and response planning, robust and reliable risk assessment and a strong risk and crisis management framework. In that context, it is important that the Programme benefit from complementarity with the work programme of the European Centre for disease prevention and control, established by Regulation (EC) No 851/2004 of the European Parliament and of the Council², in the fight against communicable diseases and the activities supported under the Union 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 Union programmes and instruments that address, in particular, the areas of influenza, HIV/AIDS, tuberculosis and other cross-border health threats in third countries.

¹ Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

² Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control (OJ L 142, 30.4.2004, p. 1).

- (16) It should be possible for action under the Programme to also cover cross-border health threats 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 the specific objective related to serious cross-border health threats should contribute in a general manner to those objectives by addressing health threats associated with climate change. The Commission should provide information on climate change expenditure within the Programme.
- (17) In accordance with Article 114 TFEU, 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 that objective, the Programme should undertake special efforts to support actions required by, and contributing to, the aims of Union legislation in the fields of communicable diseases and other health threats, human tissues and cells, blood, human organs, medical devices, medicinal products, patients' rights in cross-border healthcare, and tobacco products and tobacco advertising.

- (18) 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 Organisation for Economic Cooperation and Development (OECD). That system should consist of, *inter alia*, 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, support to the Scientific Committees set up in accordance with Commission Decision 2008/721/EC¹ and the wide dissemination of the results of the Programme.

¹ Commission Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC (OJ L 241, 10.9.2008, p. 21).

- (19) Union policy in the field of health is aimed at complementing and supporting national health policies, encouraging cooperation between Member States and promoting the coordination between their programmes. The exchange of good practices is a key instrument of that policy. 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 the field of health. Therefore, the Programme should focus mainly on cooperation with the competent authorities that are responsible for health in the Member States and provide incentives for a wider participation of all Member States as recommended in the evaluations of the previous 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 that are responsible for health in the Member States or by bodies mandated by those competent authorities. Such actions should be considered to be of exceptional utility and, in particular, respond to the objective of facilitating the participation of Member States whose GNI per inhabitant is lower than 90 % of the Union average and making that participation wider. Further and appropriate non-financial support for the participation of those Member States in such actions, for example in terms of the application process, transfer of knowledge and uptake of expertise, should also be considered.

- (20) 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 doing so, it is possible that they would require contributions from the Programme to enable them to function. That is why the Programme should be accessible to non-governmental bodies and patient organisations working in the public health area, which play an effective role in civil dialogue processes at Union level, such as participation in consultative groups, and in that way contribute to pursuing the specific objectives of the Programme.
- (21) The Programme should promote synergies, while avoiding duplication with related Union programmes and actions, by promoting, where relevant, the uptake of innovative breakthroughs resulting from research in the health sector. Appropriate use should be made of other Union funds and programmes, in particular the Framework Programme for Research and Innovation 2014-2020 (Horizon 2020), established by Regulation (EU) No 1291/2013 of the European Parliament and of the Council¹, and its outcomes, the Structural Funds, the Programme for Employment and Social Innovation, established by Regulation (EU) No 1296/2013 of the European Parliament and of the Council², the European Union Solidarity Fund, established by Council Regulation (EC) No 2012/2002³,

¹ Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014 - 2020) and repealing Decision No 1982/2006/EC (OJ L 347, 20.12.2013, p. 104).

² Regulation (EU) No 1296/2013 of the European Parliament and of the Council of 11 December 2013 on a European Union Programme for Employment and Social Innovation ("EaSI") and amending Decision No 283/2010/EU establishing a European Progress Microfinance Facility for employment and social inclusion (OJ L 347, 20.12.2013, p. 238).

³ Council Regulation (EC) No 2012/2002 of 11 November 2002 establishing the European Union Solidarity Fund (OJ L 311, 14.11.2002, p. 3).

the Union strategy on health and safety at work (2007-2012), the Programme for the Competitiveness of Enterprises and small and medium sized enterprises (COSME), established by Regulation (EU) No 1287/2013 of the European Parliament and of the Council¹, the Programme for Environment and Climate Action (LIFE), established by Regulation (EU) No 1293/2013 of the European Parliament and of the Council², the Consumer Programme, the Justice Programme, established by Regulation (EU) 1382/2013 of the European Parliament and of the Council³, the Ambient Assisted Living Joint Programme, the programme for education, training, youth and sport (Erasmus+), established by Regulation (EU) No 1288/2013 of the European Parliament and of the Council⁴, the European Statistical Programme, established by Regulation (EU) No 99/2013 of the European Parliament and of the Council⁵ and the European Innovation Partnership on Active and Healthy Ageing, within their respective activities.

¹ Regulation (EU) No 1287/2013 of the European Parliament and of the Council of 11 December 2013 establishing a Programme for the Competitiveness of Enterprises and small and medium-sized enterprises (COSME) (2014 - 2020) and repealing Decision No 1639/2006/EC (OJ L 347, 20.12.2013, p. 33).

² Regulation (EU) No 1293/2013 of the European Parliament and of the Council of 11 December 2013 on the establishment of a Programme for the Environment and Climate Action (LIFE) and repealing Regulation (EC) No 614/2007 (OJ L 347, 20.12.2013, p. 185).

³ Regulation (EU) No 1382/2013 of the European Parliament and of the Council of 17 December 2013 establishing a Justice Programme for the period 2014 to 2020 (OJ L 354, 28.12.2013, p. 73).

⁴ Regulation (EU) No 1288/2013 of the European Parliament and of the Council of 11 December 2013 establishing "Erasmus+": the Union programme for education, training, youth and sport and repealing Decisions No 1719/2006/EC, No 1720/2006/EC and No 1298/2008/EC (OJ L 347, 20.12.2013, p. 50).

⁵ Regulation (EU) No 99/2013 of the European Parliament and of the Council of 15 January 2013 on the European statistical programme 2013-17 (OJ L 39, 9.2.2013, p. 12).

- (22) In accordance with Article 168(3) TFEU, the Union and the Member States are to 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, European Free Trade Association (EFTA)/European Economic Area (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 any relevant bilateral or multilateral agreement.
- (23) Appropriate relations with third countries not participating in the Programme should be facilitated in order to help achieve the objectives of the Programme, taking into account any relevant agreements between those countries and the Union. This could involve the Union organising health events or third countries undertaking activities, which are complementary to those financed under the Programme, in areas of mutual interest, but should not involve a financial contribution under the Programme.
- (24) In order 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 WHO, as well as with the Council of Europe and the OECD.

- (25) The Programme should run for a period of seven years to align its duration with that of the Multiannual Financial Framework as set out in Council Regulation (EU, Euratom) No 1311/2013¹. This Regulation lays down a financial envelope for the entire duration of the Programme which is to constitute the prime reference amount, within the meaning of Point 17 of the Interinstitutional Agreement of 2 December 2013 between the European Parliament, the Council and the Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management², for the European Parliament and the Council during the annual budgetary procedure.
- (26) In accordance with Article 54 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council³, this Regulation provides the legal basis for the action and for the implementation of the Programme.
- (27) In order to ensure continuity in the financial support provided under the Programme to the functioning of bodies, the Commission should be able, in the annual work programme for 2014, to consider the costs directly linked to the implementation of the supported activities to be eligible for financing, even if they were incurred by the beneficiary before the financing application was submitted.

¹ Council Regulation (EU, Euratom) No 1311/2013 of 2 December 2013 laying down the multiannual financial framework for the years 2014-2020 (OJ L 347, 20.12.2013, p. 884).

² OJ C 373, 20.12.2013, p. 1.

³ Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

- (28) 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 Council¹.
- (29) 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 duration of the Programme, taking into account the probable advantages for promoting health. Appropriate actions covered by the specific objectives of the Programme 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 Regulation (EU, Euratom) No 966/2012, in order to ensure they have the financial and operational capacity to undertake actions financed under the Programme, and, where appropriate, the evidence required to demonstrate their independence.
- (30) 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 could require a longer time period than its duration. Half way through the duration of the Programme, but not later than 30 June 2017, the mid-term evaluation report should be drawn up in order to assess the state-of-play of the implementation of thematic priorities of the Programme.

¹ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

- (31) In order for the Programme to benefit fully from the findings of the mid-term evaluation report on its implementation and to allow for possible adjustments necessary for achieving its objectives, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in order to remove any of the thematic priorities set out in this Regulation or to include new thematic priorities in this Regulation. 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.
- (32) 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 those activities.
- (33) In the application of the Regulation, the Commission should consult the relevant experts, including National Focal Points.
- (34) 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.

- (35) A transition should be ensured between the Programme and the previous programme it replaces, in particular regarding the continuation of multiannual 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.
- (36) 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 the population in the Union 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 the Member States but can rather, by reason of the scale and effects of this Regulation, 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.
- (37) This Regulation replaces Decision No 1350/2007/EC. That Decision should therefore be repealed.

- (38) It is appropriate to ensure a smooth transition without interruption between the previous programme in the field of health (2008-2013) and the Programme, and to align the duration of the Programme with Regulation (EU, Euratom) No 1311/2013. Therefore, the Programme should apply from 1 January 2014,

HAVE ADOPTED THIS REGULATION:

Chapter I

General provisions

Article 1

Establishment of the Programme

This Regulation establishes the third multi-annual programme for Union action in the field of health for the period from 1 January 2014 to 31 December 2020 ("the Programme").

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 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.

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 uptake of evidence-based and good practices for cost-effective health promotion and disease prevention measures by addressing in particular the key lifestyle related risk factors with a focus on the Union added value.

This objective shall be measured, in particular, through the increase in the number of Member States involved in health promotion and disease prevention, using evidence-based and good practices through measures and actions taken at the appropriate level in Member States.

- (2) In order to protect Union 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 shall be measured, in particular, through the increase in the number of Member States integrating 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 to facilitate the voluntary uptake of innovations in public health intervention and prevention strategies.

This objective shall be measured, in particular, through the increase in the advice produced and the number of Member States using the tools and mechanisms identified in order to contribute to effective results in their health systems.

- (4) In order to facilitate access to better and safer healthcare for Union citizens: increase access to medical expertise and information for specific conditions beyond national borders, facilitate the application of the results of research and develop tools for the improvement of healthcare quality and patient safety through, *inter alia*, actions contributing to the improvement of health literacy.

This objective shall 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 Council¹ ("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 tools developed.

¹ Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

Article 4

Eligible actions

The specific objectives of the Programme shall be achieved through actions in line with the thematic priorities listed in Annex I and implemented via the annual work programmes referred to in Article 11.

Chapter III

Financial provisions

Article 5

Funding

The financial envelope for the implementation of the Programme for the period from 1 January 2014 to 31 December 2020 shall be EUR 449 394 000 in current prices.

The annual appropriations shall be authorised by the European Parliament and the Council 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:

- (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, in accordance with the conditions laid down by a relevant bilateral or multilateral agreement, the ENP applies;
- (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 Regulation (EU, Euratom) No 966/2012, financial contributions by the Union shall take the form of grants, public procurement or any other form of intervention 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 that are responsible for health in the Member States or in the third countries participating in the Programme pursuant to Article 6, or by public sector bodies and non-governmental bodies, as referred to in Article 8(1), acting individually or as a network, mandated by those competent authorities;
 - (b) actions having a clear Union added value explicitly provided for and duly justified in the annual work programmes 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, in the latter case, where appropriate, without a previous call for proposals;
 - (c) the functioning of non-governmental bodies as referred to in Article 8(2), where financial support is necessary for the pursuit of one or more of the specific objectives of the Programme.

3. Grants paid by the Union shall not exceed 60 % of eligible costs for an action relating to an objective of the Programme or for the functioning of a non-governmental body. In cases of exceptional utility, the contribution by the Union may be up to 80 % of eligible costs.

For the actions referred to in point (a) of paragraph 2, exceptional utility is achieved, *inter alia*, where:

- (a) at least 30 % of the budget of the proposed action is allocated to Member States whose GNI per inhabitant is less than 90 % of the Union average; and

- (b) bodies from at least 14 participating countries participate in the action, out of which at least four are countries whose GNI per inhabitant is less than 90 % of the Union average.
4. By way of derogation from Article 130(2) of Regulation (EU, Euratom) No 966/2012 and in duly justified cases, the Commission may, in the annual work programme for 2014, consider the costs directly linked to the implementation of supported actions to be eligible for financing from 1 January 2014, even if they were incurred by the beneficiary before the grant application was submitted.

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 bodies which fulfil all the following criteria:
 - (a) they are non-governmental, non-profit-making and independent of industry, commercial and business or other conflicting interests;
 - (b) they work in the public health area, play an effective role in civil dialogue processes at Union level and pursue at least one of the specific objectives of the Programme;

- (c) they are active at 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 envelope 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 Union in so far as they are related to the general objectives of the Programme, expenses pertaining to IT networks focusing on information exchange, as well as all other technical and administrative assistance expenses 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 Regulation (EU, Euratom) No 966/2012.

Article 11
Annual work programmes

1. The Commission shall implement the Programme by establishing annual work programmes in accordance with Regulation (EU, Euratom) No 966/2012 and the criteria set out in Annex II to this Regulation.
2. The Commission shall adopt, by means of implementing acts, annual work programmes which shall set out, in particular, actions to be undertaken, including the indicative allocation of financial resources. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 17(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 17(1), 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. Half way through the duration of the Programme, but not later than 30 June 2017, the Commission shall draw up and present to the European Parliament and to the Council a mid-term evaluation report on the achievement of the objectives of the Programme, the state-of-play regarding the implementation of the thematic priorities set out in Annex I, and the efficiency of the use of resources and the Union added value of the Programme, in view of a decision on the renewal, modification or suspension of its thematic priorities. The mid-term evaluation report shall, additionally, address the scope for simplification, the internal and external coherence of the Programme, the continued relevance of all objectives, as well as the contribution of the actions to the achievement of the objectives set out in Article 168 TFEU. It shall take into account evaluation results on the long-term impact of the previous programme.

In the mid-term evaluation report, the Commission shall, in particular, indicate the following:

- (a) if it is not possible to implement and achieve one or more of the thematic priorities listed in Annex I in line with the objectives of the Programme and within the remaining duration of the Programme;
- (b) whether the evaluation identified one or more specific, significant thematic priorities which are not listed in Annex I, but which have become necessary to achieve the general and specific objectives of the Programme;
- (c) the reasons for the conclusions referred to in points (a) and (b).

The long-term impact and the sustainability of effects of the Programme shall be evaluated with a view to feeding into a decision on the 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 that they are widely disseminated in order to contribute to improving health in the Union.

Article 14

Follow-up to the mid-term evaluation report

1. Where the mid-term evaluation report identifies that one or more thematic priorities cannot be implemented and achieved in line with the objectives of the Programme and within the duration of the Programme, the Commission shall be empowered to adopt, by 31 August 2017, delegated acts in accordance with Article 18 in order to remove the thematic priority or priorities concerned from Annex I. Only one delegated act removing one or more thematic priorities may enter into force pursuant to Article 18 throughout the duration of the Programme.
2. Where the mid-term evaluation report identifies one or more specific, significant thematic priorities which are not listed in Annex I, but which have become necessary to achieve the general and specific objectives of the Programme, the Commission shall be empowered to adopt, by 31 August 2017, delegated acts in accordance with Article 18 in order to add the thematic priority or priorities concerned to Annex I. A thematic priority shall be achievable within the duration of the Programme. Only one delegated act adding one or more thematic priorities may enter into force pursuant to Article 18 throughout the duration of the Programme.
3. Any such removal or addition of thematic priorities shall be in line with the general objectives and with the relevant specific objectives of the Programme.

Article 15
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 and the available information on the impact of the Programme as referred to in Article 13(2).

Article 16
Protection of the financial interests of the Union

1. The Commission shall take appropriate measures to ensure 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 dissuasive administrative and financial penalties.
2. The Commission, or its representatives, and the Court of Auditors shall have the power of audit, on the basis of documents and on-the-spot, over all grant beneficiaries, contractors and subcontractors who have received Union funds 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 (EU, Euratom) No 883/2013 of the European Parliament and of the Council¹ and Council Regulation (Euratom, EC) No 2185/96² with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the 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 and investigations, in accordance with their respective competences.

Chapter V

Procedural provisions

Article 17

Committee procedure

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

¹ Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).

² 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 irregularities (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.

Article 18

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 14(1) and (2) shall be conferred on the Commission for the duration of the Programme.
3. The delegation of power referred to in Article 14(1) and (2) 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 act 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 14(1) and (2) 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.

Chapter VI

Transitional and final provisions

Article 19

Transitional provisions

1. The financial envelope 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 20

Repeal

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

Article 21

Entry into force

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

It shall apply from 1 January 2014.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg,

For the European Parliament

The President

For the Council

The President

ANNEX I

THEMATIC PRIORITIES

1. Promote health, prevent diseases and foster supportive environments for healthy lifestyles taking into account the 'health in all policies' principle
 - 1.1. Cost-effective promotion and prevention measures in line, in particular, with the Union strategies on alcohol and nutrition, and including actions to support the exchange of evidence-based and good practices for addressing risk factors such as tobacco use and passive smoking, harmful use of alcohol, unhealthy dietary habits and physical inactivity, taking into account the public health aspects of underlying factors, such as those of a social and environmental nature, with a focus on Union added value.
 - 1.2. Measures to complement the Member States' action in reducing drug-related health damage, including information and prevention.
 - 1.3. Support effective responses to communicable diseases such as HIV/AIDS, tuberculosis and hepatitis by identifying, disseminating and promoting the uptake of evidence-based and good practices for cost effective prevention, diagnosis, treatment and care.
 - 1.4. Support cooperation and networking in the Union in relation to preventing and improving the response to chronic diseases including cancer, age-related diseases and neurodegenerative diseases, by sharing knowledge, good practices and developing joint activities on prevention, early detection and management (including health literacy and self management). Follow up work on cancer which has already been 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 field of tobacco products, advertising and marketing. Such action may include activities aimed at ensuring the implementation, application, monitoring and review of that legislation.
- 1.6. Foster a health information and knowledge system to contribute to evidence-based decision-making, including the use of existing instruments and, where appropriate, further development of standardised health information and tools for monitoring health, collection and analysis of health data, and the wide dissemination of the results of the Programme.
2. Protect Union citizens from serious cross-border health threats
 - 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; address the increasing health threats resulting from global population movements; 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, including the introduction of optimal vaccination coverage to effectively combat the resurgence in infectious diseases and 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. Foster a health information and knowledge system to contribute to evidence-based decision-making, including the use of existing instruments and, where appropriate, further development of standardised health information and tools for monitoring health, collection and analysis of health data, and the wide dissemination of the results of the Programme.
3. Contribute to innovative, efficient and sustainable health systems
 - 3.1. Support voluntary cooperation between Member States on health technology assessment under the network on health technology assessment set up by Directive 2011/24/EU. Facilitate the uptake of the results streaming from research projects supported under the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013), adopted by Decision No 1982/2006/EC of the European Parliament and of the Council¹, and, in the long term, the activities which will be undertaken in the Framework Programme for Research and Innovation (Horizon 2020).

¹ Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) (OJ L 412, 30.12.2006, p. 1).

- 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 cooperation on e-Health in the Union, in particular on registries, and its uptake by health professionals. This will serve the voluntary network on e-Health set up by Directive 2011/24/EU.
- 3.3. Support the sustainability of the health workforce by developing 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, foster efficient recruitment and retention strategies and capacity development, taking due account of issues of dependency and population ageing.
- 3.4. Provide expertise and share good practices to assist Member States undertaking health system reforms by setting up a mechanism for pooling expertise at Union level, to provide sound and evidence-based advice on effective and efficient investment and innovation in public health and health systems. Facilitate the uptake of the results streaming from research projects supported under the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) and, in the long term, the activities which will be undertaken in the Framework Programme for Research and Innovation (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 in 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. Foster a health information and knowledge system to contribute to evidence-based decision-making, including the use of existing instruments, further development, where appropriate, of standardised health information and tools for monitoring health, collection and analysis of health data, the wide dissemination of the results of the Programme, and support to the Scientific Committees set up in accordance with Decision 2008/721/EC.
4. Facilitate access to better and safer healthcare for Union citizens
 - 4.1. Support the establishment of a system of European reference networks for patients with conditions requiring highly specialised care and a particular concentration of resources or expertise, as in the case of rare diseases, on the basis of criteria to be established under Directive 2011/24/EU.

- 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 the creation of reference networks (in compliance with point 4.1), Union wide information databases 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 of 9 June 2009 on patient safety, including the prevention and control of healthcare-associated infections¹; exchange good practices 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. In line with the Action Plan against the rising threats from antimicrobial resistance, improve the prudent use of antimicrobial agents and reduce the practices that increase antimicrobial resistance, particularly in hospitals; 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.

¹ 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 human tissues and cells, blood, human organs, medical devices, medicinal products, and patients' rights in cross-border healthcare, while fully respecting the competences and ethical choices of Member States in those fields. Such action may include activities aimed at facilitating the implementation, application, monitoring and review of that legislation.
- 4.6. Foster 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 the wide dissemination of the results of the Programme.
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ANNEX II

CRITERIA FOR ESTABLISHING ANNUAL WORK PROGRAMMES

The annual work programmes shall be established in accordance with the following criteria for the duration of the Programme:

- the relevance of proposed actions for the objectives set out in Articles 2 and 3 and for the thematic priorities set out in Annex I and for the EU Health Strategy "Together for Health";
 - the Union added value of the proposed actions in line with the thematic priorities in Annex I;
 - the public health relevance of proposed actions, in terms of promoting health and preventing diseases, protecting Union citizens from health threats and in terms of improving the performance of health systems;
 - the relevance of the proposed actions to supporting the implementation of Union health legislation;
 - the pertinence of the geographical coverage of the proposed actions;
 - the balanced distribution of budgetary resources between the different objectives of the Programme, taking into account the probable advantages for promoting health;
 - the adequate coverage of the thematic priorities set out in Annex I.
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