Regulation (EU) No 282/2014 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)

REGULATION (EU) No 282/2014 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 Committee[(1)],

Having regard to the opinion of the Committee of the Regions[(2)],

Acting in accordance with the ordinary legislative procedure[(3)],

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/EC[(4)] and 1350/2007/EC of the European Parliament and of the Council[(5)] ("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.

(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 2006[(6)].

(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.

(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 Council[(7)], 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 Council[(8)], 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.

(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/EC[9] and the wide dissemination of the results of the Programme.

(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, Members 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.