Third programme for the Union's action in the field of health (2014-2020)

2011/0339(COD) - 09/11/2011 - Legislative proposal

PURPOSE: to establish a Health for Growth, the third multi-annual programme of EU action in the field of health for the period 2014-2020.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

BACKGROUND: the healthcare sector is one of the largest in the EU: it accounts for approximately 10% of the EU's gross domestic product and employs one in ten workers, with a higher than average proportion of workers with tertiary-level education. Health therefore plays an important role in the Europe 2020 agenda.

As underlined in its Communication of 29 June 2011 entitled "A budget for Europe 2020", this third programme of EU action in the field of health (2014-2020), 'Health for Growth', strengthens and emphasises the links between economic growth and a healthy population to a greater extent than the previous programmes. The Programme is geared towards actions with **clear EU added value**.

The general objectives of the Health for Growth Programme shall be to work with Member States to:

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

IMPACT ASSESSMENT: the impact assessment looked at different options for the programme and their expected impact:

- ***Option 1*: minimal action:** this option corresponds to the absolute minimum of actions resulting from the legal obligations imposed by the Treaty and the existing EU *acquis* in the field of medicinal products, medical devices, substances of human origin, patients rights in cross border healthcare, Health security (cross border health threats) and tobacco.
- ***Option 2*: baseline scenario:** this option implies continuing the programme in its present form with no changes consequently to the findings of the evaluations, in addition to the direct legal obligations.

    - **Option 3, sub-option A :** this option corresponds to a well structured programme, with SMART objectives, prioritised actions, creating EU added value and with better monitoring of outcomes and impacts. It will be focused on: i) supporting actions required by the current EU health and internal market legislation, ii) supporting the up-take of innovative solutions for improving specific points concerning the quality, efficiency and sustainability of health systems, iii) prevention of diseases at EU level by helping and complementing Member States' efforts to increase their citizens' number of healthy life years (HLY), including the aspect of reduction of health inequalities but mainly by other means than the resources of the Programme and limited to development of working methods and policy evaluation; iv) supporting and complementing Member States efforts in protecting citizens from cross-border health threats.

    - **Sub-option 3, sub-option B:** this option corresponds to a well structured programme but dealing only with one of the general objectives as a trade off. This programme would be

focused on: i) supporting actions required by the current EU health and internal market legislation, ii) supporting the up-take of innovative solutions for improving specific points concerning the quality, efficiency and sustainability of health, iii) supporting and complementing Member States efforts in protecting citizens from cross-border health threats.

- **Sub-option 3, sub-option C:** this option corresponds to a programme limited to supporting actions required by the current EU health related legislation and to supporting solutions for cross border health threats. In addition, there would be some dissemination of the results of the current Health Programme (2008–2013) in order to take into account the conclusions of previous evaluations.

- **Option 4:** this corresponds to a well-structured programme focusing on the same issues as option 3 A but adding a specific objective for addressing wider, social and economic, causes of health inequalities by appropriate financial means. This option would imply a significant increase of the envelope for the Programme.

Following analysis of the results, **Option 3A is the preferred option**.

LEGAL BASIS: Article 168 (5) of the Treaty on the Functioning of the European Union (TFEU).

CONTENT: the general objectives of the Health for Growth Programme shall be to work with Member States to encourage innovation in healthcare and increase the sustainability of health systems, to improve the health of the EU citizens and protect them from cross-border health threats.

It focuses on four specific objectives with a strong potential for economic growth through better health:

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

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

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

4) to develop common approaches and demonstrate their value for better preparedness and coordination in health emergencies in order **to protect citizens from crossborder health threats.**

Eligible actions: the proposal lays down the actions eligible under the programme. Actions that will be eligible will be those that:

Contribute to innovative and sustainable health systems: e.g. developing EU cooperation on Health Technology Assessment; promoting the uptake of health innovation and e-Health by increasing the interoperability of e-Health applications; supporting the European Innovation Partnership on Active and Healthy Ageing, a pilot project under Europe 2020 flagship initiative Innovation Union; fostering a health knowledge system,…

Increase access to better and safer healthcare for citizens: e.g. supporting action on rare diseases including creation of European Reference Networks; strengthening collaboration on patient safety and quality of healthcare, by increasing the availability of information to patients, exchanging of best practices and development of guidelines; developing guidelines to improve the prudent use of antimicrobials in human medicine and reducing the practices that increase antimicrobial resistance,…

Promote good health and preventing diseases: e.g. exchanging best practices on key health issues such as smoking prevention, abuse of alcohol and obesity; supporting the prevention of chronic diseases including cancer, by sharing knowledge and best practice and developing joint activities,…

Protect citizens from cross border health threats: e.g. strengthening preparedness and response for serious cross border health threats; supporting capacity building against health threats in Member States,…

A more detailed description of the content those actions may have is included in Annex I of the proposed Regulation.

Participation of third countries: the Programme shall be open on a cost basis, 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,
- other countries in accordance with the conditions laid down by a relevant bilateral or multilateral agreement.

Types of intervention and participation: financial contributions by the Union may take the form of **either grants or public procurement** or any other interventions necessary for achieving the objectives of the Programme. The proposal describes the forms of intervention by type of action eligible. Overall; the design of the revised programme favours simplification of interventions:

- simplified rules,
- reducing the costs of participation,
- accelerating award procedures, and
- providing a "one-stop shop" to make it easier for beneficiaries to access EU funding.

Budget and rate of co-financing: the programme will have a budget of **EUR 446 million** from 2014-2020. The level of Union co-financing for grants for actions, actions co-financed by the competent authorities of the Member States or third countries, or by non-governmental bodies mandated by these authorities and operating grants will be harmonised at **60% of eligible costs and up to 80% in cases of exceptional utility**.

Provisions are foreseen to define the rules regarding eligibility for grants for actions covered by the Programme. Grants may be awarded to legally established organisations, public authorities, public sector bodies, in particular research and health institutions, universities and higher education establishments and undertakings, in accordance with strictly defined criteria.

Administrative and technical assistance: the financial allocation 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 EU, as well as all other technical and administrative assistance expense incurred by the Commission for the management of the Programme.

Methods of implementation: the Commission shall be responsible for the implementation of the Programme by drawing up **annual work programmes** establishing the priorities and actions to be undertaken, as well as other detailed eligibility criteria for the beneficiaries. In order to ensure uniform conditions for the implementation, 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.

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.

Monitoring, evaluation and dissemination of results: the usual methods of monitoring, evaluation, dissemination of results and combating fraud are foreseen in the proposal. 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 and keep the European Parliament informed thereof.

Reporting: no later then mid-2018, an evaluation report shall be established by the Commission on the achievement of the objectives of all the measures (at the level of results and impacts), the efficiency of the use of resources and its European added value, in view of a decision on the renewal, modification or suspension of the measures. The longer-term impacts and the sustainability of effects of the Health for Growth Programme should be evaluated with a view to feeding into a decision on a possible renewal, modification or suspension of a subsequent programme.

It should be noted that the Member States shall designate National Focal Points which shall assist the Commission in the promotion of the Programme, the dissemination of its results and the information on its impacts in their respective countries.

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

BUDGETARY IMPACT: the financial appropriations for implementing the programme over the period from 1 January 2014 to 31 December 2020 will amount to **EUR 446 million** (in current prices).