



Council of the
European Union

Brussels, 12 May 2016
(OR. en)

8778/16

SAN 177

COVER NOTE

From: Secretary-General of the European Commission,
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 10 May 2016

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of
the European Union

No. Cion doc.: COM(2016) 243 final

Subject: REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT,
THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL
COMMITTEE AND THE COMMITTEE OF THE REGIONS Ex-post
evaluation of the 2nd Health programme 2008-2013 under Decision No
1350/2007/EC establishing a second programme of Community action in
the field of health (2008-2013)

Delegations will find attached document COM(2016) 243 final.

Encl.: COM(2016) 243 final



Brussels, 10.5.2016
COM(2016) 243 final

**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE
COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE
COMMITTEE OF THE REGIONS**

**Ex-post evaluation of the 2nd Health programme 2008-2013
under Decision No 1350/2007/EC establishing a second programme
of Community action in the field of health (2008-2013)**

{SWD(2016) 148 final}
{SWD(2016) 149 final}

1. Introduction

The Commission is required under Article 13(3)(c) of Decision No 1350/2007/EC¹ to transmit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions an external and independent *ex post* evaluation² covering the implementation and results of the 2nd Health Programme.

This report briefly presents the Programme and summarises the main conclusions from the mid-term and ex-post evaluations. It also outlines three areas, where implementation of the current 3rd Health Programme can be improved.

2. The 2nd Health Programme (2008-2013)

The 2nd Health Programme was the main instrument to support health policy coordination to implement the EU's 2008-2013 health strategy *Together for health*³ in line with the priorities of the Europe 2020 strategy.⁴

2.1. The objectives of the Programme

The overall aim of the Programme was to complement, support and add value to Member States' policies and contribute to increased solidarity and prosperity in the European Union by protecting and promoting human health and safety and improving public health.

The Programme financed action geared to achieving three main objectives:

- i. ***improving citizens' health security*** and protecting them from health threats and emergencies, such as pandemics or natural disasters;
- ii. ***promoting health and reducing health inequalities*** across Europe, whether relating to lifestyle, such as access to opportunities for physical activity, or to health care, such as access to the necessary medical intervention; and
- iii. ***generating health information and health knowledge and disseminating them*** to relevant parties, from the general public to policymakers and health professionals.

2.2. Implementation of the Programme through priority actions and financial mechanisms

Under Article 168 TFEU, the Union shall encourage cooperation between the Member States, and support their action, including through the establishment of guidelines and indicators, the organisation of exchange of best practice and support for monitoring and evaluation. Member States' responsibilities for the definition of their health policy and for the organisation and delivery of health services and medical care should be respected.

Action under the Programme was in line with the EU's role in health policy as set out in Article 168 of the Treaty and within its limits. Actions were designed to follow a strategic approach with a focus on those specific initiatives that maximise EU added value. As a result, implementation concentrated on priorities key to economic development and growth. These

¹ 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. 3–13).

² The external evaluation report is annexed, with executive summaries in English and French.

³ COM(2007) 630 final, 23.10.2007.

⁴ COM(2010) 2020 final, 3.3.2010.

priority actions contribute to a healthier population, well-functioning healthcare systems, , and technological and scientific development.

The overall design of the Programme was similar to that of the 1st Public Health Programme, but the scope was extended beyond 'classical' public health issues, such as the promotion of health and protection from communicable diseases, extending it also to new approaches such as e-health and health technology assessment, and to medicinal products. Within the broad range of issues to be covered, programme priorities were streamlined from 2010 to focus more on the Europe 2020 strategy, taking as a starting point the notion that health is a prerequisite for economic recovery and 'inclusive growth', and the fact that the health sector attracts interest for innovation and 'smart' investment.

On the basis of Decision No 1350/2007/EC, the Commission established priorities in the annual work programmes, in close consultation with Member States health authorities serving on the Programme Committee. Implementation of the Programme was entrusted to the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA), which organised the calls and supervised the evaluation procedures leading to the award of co-funding to the best actions. CHAFEA continues to manage the still on-going grants and contracts and disseminates the outputs of Programme actions and results.

An informal network of national focal points was established to help CHAFEA promote the Programme and disseminate results. With their support, national information days were organised, dissemination conferences held and informative printed material translated.

In addition to grants for projects and tenders, new funding mechanisms were introduced from the beginning of the Programme in the form of joint actions, operating grants, conferences and direct grants to international organisations.

Projects are used to explore a wide range of subject areas and delivery mechanisms, and to take health policy initiatives forward in an innovative way, almost as 'pilots'. They represent the biggest share of the available Programme budget. However, in the course of the Programme, the proportion of the budget dedicated to projects was reduced in favour of joint actions and tenders. This was also the result of an effort to concentrate the Programme on a few major actions involving as many partners as possible, ideally from all Member States, to generate momentum for wider impact.

Tenders are used to procure specific studies, evaluations and surveys that are needed for the development and implementation of EU health policy and legislation, e.g. rules governing the production, distribution and use of medicinal products. They are also used for Commission-driven actions with very concrete scope and objectives, such as the design and delivery of training courses and exercises with Member States geared to developing capacity to deal with extreme emergency situations.

Joint actions are a type of financial mechanism, introduced for the first time with the 2nd Health Programme, to support Member States' cooperation in areas of high policy relevance. The selected joint actions made a particular contribution to the Europe 2020 objectives of 'smart and inclusive growth'. Joint actions are often the result of long cooperation among authorities and relevant stakeholders and aim to secure Member State authorities' political commitment and endorsement of outcomes and optimise policy coordination. Joint actions typically develop, share and test tools, methods and approaches for specific issues or activities, and involve capacity-building. The gain for the Member States involved in terms of

knowledge and experience exchanged is intended to be substantial and in some cases lead to tangible cost savings. For this reason, the Programme seeks the widest possible participation from all Member States.

Operating grants were used for the first time in the 2nd Health Programme to support the functioning costs of pan-European non-governmental organisations and specific networks.

Conference grants, also introduced with the Programme, were used to support central health conferences under each EU presidency and to co-finance, through an annual competitive call, pan-EU conferences on important health issues.

Finally, **direct grants to international organisations** were used to support international cooperation on major health issues (mainly collection and analysis of health data).

Table 1: 2nd Health Programme spending by funding mechanism

Funding mechanism	Total	%
Projects	€106 293 671.24	36 %
Tenders	€72 053 873.45	25 %
Joint actions	€63 962 704.38	22 %
Operating grants	€20 825 185.85	7 %
Direct grant agreements	€13 805 987.00	5 %
Grants for conferences	€5 268 308.14	2 %
Other ⁵	€11 693 227.81	4 %
Total	€293 902 957.87	100 %

2.3. Programme outcomes

The Programme generated useful knowledge and evidence to serve as a basis for informed policymaking and further research. This took the form of best practice, tools and methodologies that help to secure benefits for both the public-health communities and citizens directly (e.g. with regard to improving diagnostic tests, supporting Member States in developing national actions plans on cancer, improving patient care, etc.). It supported awareness and sustained networking activities (e.g. by co-funding pan-European conferences and networks such as those in the field of public health and health promotion). Also, it supported the collection of comparable data across the Union, covering many Member States and providing information for policymaking purposes, e.g. European core health indicators (ECHIs) and the ORPHANET database on rare diseases, and produced training/educational materials (e.g. to train health professionals on migrant and ethnic minority health) and guidance. Finally, it supported public-health capacity-building at various levels (e.g. by fostering Member States' preparedness in the event of health emergencies) through training and exchange of knowledge between healthcare institutions in the Member States.

⁵ 'Other' includes actions signed and committed to by DG SANTE and CHAFEA, such as special indemnities to experts for their participation in and work for EU scientific committees, an administrative agreement with the Joint Research Centre, publications and various communication initiatives to promote the 2nd Health Programme, sub-delegations to Eurostat, etc.

3. Programme evaluation

External independent evaluations were conducted at mid-term (in 2010-2011) and ex-post (2014-2015). Both gave a positive assessment of the Programme with limitations. They confirmed the relevance of the actions funded, although underlining the weaknesses in the Programme design (large scope and non-explicit specific objectives). They concluded that the Programme demonstrated EU added value mainly regarding identification of best practices, benchmarking for better decision making and networking but to a lesser extent on innovation, EU health legislation and economics of scale, while the actions covering cross-border health threats and free movement of persons were under-represented. They concluded that every relevant need cannot lead to an impactful action; only actions that have an EU added value have the potential to impact on Member States' health policies. The impact depends on the uptake and implementation of the results by the Member States. Therefore the dissemination to the relevant stakeholders, in particular to national health authorities, that set out and implement national health policies, is important. In relation to outreach to relevant stakeholders the actions of the Programme were successful to varying degrees. Another factor that is influencing the uptake by Member States is their buy-in on the actions which was increased through a stronger focus in the second half on Joint Actions.

3.1. Overall assessment

The 2nd Health Programme reflects the development of EU health policy, with more emphasis — in addition to the classical public-health approach (promotion and prevention of diseases, fight against communicable diseases and other cross-border health threats, safety of patients) — on other health issues emerging from the need to innovate and modernise health systems while keeping health expenditure under control, and to optimise actions in areas such as health technology assessment (HTA), e-health and the cross-border directive⁶ for the health and rights of EU citizens. The Programme mobilised relevant stakeholders in all 28 Member States (with more of them being from EU 15 than EU 12 Member States) and three EEA EFTA countries (Norway, Iceland and Lichtenstein). It covered a series of common health concerns (i.e concerning major chronic diseases, the health of an ageing population, the development of capacity to respond to cross-border health threats), provided a wide range of useful tools (i.e the EU information database for rare diseases)⁷ and best practices (i.e. for preventing the spread of HIV/AIDS⁸, addressing obesity⁹ or applying cancer screening) for use at national and regional levels, and promoted cooperation and coordination between Member States' health authorities to keep health issues such as health inequalities¹⁰, mental health¹¹, ageing, etc. high on their agenda.

However, both evaluations pointed out that the lack of explicit objectives and progress indicators in the Programme's design was conducive to the proliferation of priorities and made it difficult to define the overall results in a meaningful way.

⁶ 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. 45-65).

⁷ <http://www.orpha.net/consor/cgi-bin/index.php>

⁸ http://ec.europa.eu/chafea/documents/health/hiv-infopack_en.pdf

⁹ http://ec.europa.eu/chafea/documents/health/nutrition-physical-activity-2014_en.pdf

¹⁰ http://ec.europa.eu/chafea/documents/health/health-inequality-brochure_en.pdf

¹¹ http://ec.europa.eu/chafea/documents/health/mental-health_en.pdf

3.2. Mid-term evaluation¹²

The mid-term evaluation included a number of recommendations to improve the prioritisation of needs, fix more targeted and focused objectives, co-fund fewer actions, monitor on the basis of SMART indicators and better disseminate outcomes.

The pertinent recommendation for streamlining the annual priorities, providing better guidance to applicants and ensuring better dissemination of actions and their results, were implemented immediately in the 2011–2013 annual work programmes. This resulted in more focus (limiting the health topics covered) and better alignment with the Europe 2020 strategy. The CHAFEA improved the guide for applicants and the help-desk services for the calls and concentrated more on the dissemination of results.

The lessons learnt from the evaluation were applied in the impact assessment accompanying the Commission's proposal for the 3rd Health Programme and guided the design of the new Programme. As a result, Regulation (EU) No 282/2014:¹³

- provides for explicit specific objectives and indicators (Article 3);
- establishes a restricted number of clear thematic priorities (Annex I);
- includes specific criteria for gauging EU added value (recital 6) concerning the prioritisation of needs (Annex II) and the awarding of funding;
- formally recognises the role of national focal points (Article 15); and
- underlines the need for better dissemination of the results of actions and overall corporate communication on the Union's political priorities (Articles 13(4) and 9).

The mid-term evaluation of the 3rd Health Programme, will assess whether and to what extent the above changes contribute effectively to improved implementation and the achievement of Programme objectives.

3.3. Ex post evaluation¹⁴

The *ex post* evaluation reviewed key aspects of Programme implementation, including follow-up of the mid-term review recommendations. It focused on the management of the Programme, the dissemination of its results, the Programme's effectiveness, and synergies with other EU programmes. This meant that it was possible to concentrate on issues that could not yet have been sufficiently explored in the mid-term evaluation and avoid duplicating previous evaluation work. Given the fact that in health it usually takes a long time for results and impacts to manifest, and that in any case the impact of the Programme depends on the uptake of actions' outcomes by Member States, which is out of the Programme's control, evaluators approached the issue with a view to the next programming period and sought to elicit elements for a better understanding of how the Programme could impact on health policies in the Member States. The conclusions identified both success factors and factors that

¹² The findings and conclusions of the mid-term evaluation were transmitted to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions, as required by Decision No 1350/2007/EC, with staff working document SWD(2012) 83 final of 29 March 2012.

¹³ 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 (OJ L 86, 21.3.2014, p. 1–13).

¹⁴ The findings and conclusions of the final evaluation are discussed in detail in the Commission staff working document annexed to this report.

negatively influence the potential impact of actions funded under the 2nd Health Programme. Those lessons learnt will be used for improving the implementation of the 3rd Health Programme and will feed into the three following main areas of action below.

(a) Improved monitoring, reporting and dissemination efforts

The management of the Programme was substantially improved. Programme priorities were streamlined in the second half of the period around the Europe 2020 initiatives and its objectives for smart, sustainable and inclusive growth. Monitoring data were (and continue to be) collected and a more systematic approach for their collection, analysis and regular use will provide an improved evidence basis for setting of annual priorities, for reporting¹⁵ on outputs and results, and for better targeting dissemination to relevant stakeholders.

The success of the Programme depends to a large extent on the willingness of Member States and other participating countries to take up the results and integrate them into national initiatives and policies (i.e. the guide for cancer screening now adopted by all Member States; the preparedness plans of Member States for responding to health threats and emergencies). It is therefore important that the actions and their results are well known to the relevant key stakeholders. This is key for the Programme's visibility, accountability as regards the use of its resources and above all its usefulness.

The Commission has intensified dissemination activities in the past two years. The main dissemination tools have been CHAFEA's project database,¹⁶ brochures¹⁷ presenting the co-funded actions by policy theme (e.g. health inequalities, rare diseases, etc.), the regular organisation of 'cluster meetings'¹⁸ with journalists (e.g. on organ transplantation¹⁹ and HIV/AIDS)²⁰ and a high-level conference on the Programme in 2012.²¹ Since 2014, the Programme has supported Member State authorities in the organisation of conferences and other events²² promoting the dissemination to key audiences of Programme results on specific health topics. This intensified support for the dissemination efforts of individual actions has shown to be useful and to help extend the reach of relevant results. However, in light of the diversity and breadth of action, they cannot make up for the fact that some projects have not promoted their results to the specific audiences they are most relevant for. Therefore, in the 3rd Health Programme an effective dissemination strategy must be defined early on for all actions.

(b) Encouraged participation of all Member States and other participating countries

The Programme is an instrument to support policy development, coordination and implementation in the area of health. While competence in this area lies largely with Member States, the Programme helped them to develop initiatives at EU level for more effective and efficient solutions to common health concerns, e.g. the 'European

¹⁵ The Commission reports annually to the European Parliament and to the Council on the implementation of the Health Programme (see http://ec.europa.eu/health/programme/policy/index_en.htm).

¹⁶ <http://ec.europa.eu/chafea/projects/database.html>.

¹⁷ http://ec.europa.eu/chafea/publications/publications_for_health_programme.html.

¹⁸ Meetings organised in cooperation with competent Member State authorities to provide journalists and other interested audiences with an opportunity to learn about EU health policy and a portfolio of relevant Health Programme actions in a given topic area.

¹⁹ http://ec.europa.eu/chafea/health/EAHC_conference_2013_-_Transplantation_Blood_Transfusion.html.

²⁰ http://ec.europa.eu/chafea/health/hiv-athens-2014-presentations_en.html.

²¹ http://ec.europa.eu/health/programme/events/ev_20120503_en.htm.

²² http://ec.europa.eu/chafea/health/events_en.html.

Guide for Quality National Cancer Control Programmes', which provides an outline for policy-makers on the basic tenets of cancer control policy; better knowledge of the quality and effectiveness of the systems for organ donation and transplantation in participating countries; diagnostic tools and a laboratory network to boost Member States' preparedness and cooperation in the event of health threats; or the rights of patients living and working in a Member State other than their own.

All Member States, the three EEA EFTA countries (Iceland, Liechtenstein and Norway) and Croatia participated in the Programme to varying degrees. Despite the fact that EU 15 Member States have participated more than the EU 12 Member States in the programme in general, and as coordinators of actions in particular, the Health Programme involved Member States with low GDP/GNI more than the FP7. The participation of as many countries as possible creates the necessary networking environment to identify common health concerns, raise awareness of key emerging health problems and transfer knowledge in order to improve health status and address inequalities. Health can be a smart incentive for investment²³ in the economy and plays a key role in European cohesion and inclusion.

Difficult economic circumstances are stated as among the reasons for some Member States' low participation. To address this the Commission has included the principle of 'exceptional utility' in the current 3rd Health Programme²⁴ as a financial incentive to involve all Member States. Information days to promote the Programme should continue to be organised in all Member States and participating countries, the aim being that at least half of these events will take place in Member States underrepresented in the previous Programme period. More information material should be available in all EU languages.

The Programme is also open on a cost basis to acceding, candidate and potential candidate countries, where it functions as a mechanism that can help countries adapt to the *acquis communautaire* in the health area through their cooperation with Member States in projects and joint actions.

(c) Implementation of the Programme in synergy with other European programmes and Commission priorities

The uptake of Programme outcomes and their integration into national policies remains the determining factor whether or not the Programme is a success. Given the limited budget and the tremendous health needs and challenges, developing synergies with other programmes to spread its outcomes further, promote their use and build on them has already been more extensively pursued with the Union research Programmes (FP7 and Horizon 2020) and to a lesser degree with the European Structural and Investments Funds (ESIFs).

Breaking down 'silos' and working more closely with other Union programmes is part of the Commission's vision for delivering on its 10 major priorities²⁵ in a coordinated

²³ *Investing in health* (staff working document SWD(2013) 43 final, 22.2.2013) http://ec.europa.eu/health/strategy/docs/swd_investing_in_health.pdf.

²⁴ The Commission provides up to 80 % co-funding as a financial incentive for joint actions that involve at least 14 participating countries, of which at least four are Member States with a GNI per inhabitant below 90 % of the Union average, and for which 30 % of the budget is spent on involving such countries (Article 7(3) of Regulation (EU) No 282/2014).

²⁵ See at http://ec.europa.eu/priorities/index_en.htm

way. The 3rd Health Programme offers possibilities for such cooperation in supporting health in areas such as migration, dealing with emerging diseases relating to environmental factors such as climate change, innovation in health, health-sector reform and global health. Finally, the Programme involves assessments of health systems and generates country-specific and cross-country knowledge to inform policies at national and European level.

4. Conclusion

In the coming years, the Commission will make a particular effort to improve monitoring, reporting and dissemination, support the participation of less active Member States in the Programme and develop synergies with other EU programmes. The results and ideas emanating from the Programme could be communicated more actively through existing networks of contacts in health ministries and via coherent and comprehensive coordination with actors in Union programmes that cover, but do not deal exclusively with, health.

After 18 years of EU Health Programmes, at the end of the 3rd Health Programme in 2020, the Commission will assess the extent to which the first three Programmes have produced positive impacts on Member States health policies in an effective, efficient, coherent and relevant way ensuring EU added value. The monitoring arrangements for the 3rd Health Programme will be used to support this broader assessment.