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

Mid-term evaluation of the 3rd Health programme 2014-2020 under Regulation (EU) No 282/2014 on the establishment of a third programme of Union action in the field of health (2014-2020)

{SWD(2017) 331 final}
{SWD(2017) 333 final}

1. INTRODUCTION

This report briefly presents the main conclusions from the mid-term evaluation of the Third Health Programme in accordance with Article 13(3)(c) of Regulation (EU) No 282/2014[1]. The report also presents ideas for improving the implementation of the Programme for the remaining programming period (2018 – 2020). The report is accompanied by a detailed staff working document.

2. WHAT IS THE 3RD HEALTH PROGRAMME

The 3rd Health Programme is a sectorial financial instrument under the Multiannual Financial Framework (MFF) 2014-2020, established by Regulation (EU) No 282/2014. It underpins EU health policy coordination in order to complement, support and add value to the national policies of Member States. At the same time, it fully respects their autonomy to define their own health policies and to organise and deliver health services and medical care within their borders. It also supports implementation of EU health legislation.

With a total budget of EUR 449.4 million over seven years, the Programme serves the needs of the Member States under overarching priorities:

- the link between the health status of the population and its contribution to growth and jobs through labour market participation and labour productivity;
- investment in health as a source of economic prosperity and social cohesion;
- societal challenges (such as demographic ageing; inequalities, burden of chronic diseases, effectiveness and resilience of health systems).

2.1. Objectives and priorities

The Programme is designed to complement, support and add value to Member State policies. The main goal is to improve the health of Europeans and reduce inequalities by promoting health, encouraging innovation, boosting the sustainability of health systems and protecting Europeans from serious cross-border health threats. This can be expressed as four specific objectives:

[1] http://eur-lex.europa.eu/legal-content/EN/TXT/;jsessionid=5Qj3TvyCyBqbhfLZzzBttjDGh3gyXkQWYrjhrt36mChMJJlp02XX!2060916514?uri=urisserv:OJ.L_.2014.086.01.0001.01.ENG

(a) promote health, prevent diseases and foster supportive environments for healthy lifestyles,

(b) protect Union citizens from serious cross-border health threats,

(c) contribute to innovative, efficient and sustainable health systems, and

(d) facilitate access to better and safer healthcare for Union citizens.

The Programme focuses on issues where there is potential to generate EU-added value and to make a real contribution to the Commission's main priorities.

HEALTH PROGRAMME CONTRIBUTIONS TO COMMISSION PRIORITIES

- 'growth, jobs and a resilient society': **health of population and health care services as a productive factor for growth and jobs**,
- 'digital single market': **eHealth**,
- 'internal market': actions supporting EU legislation **on tobacco**, **pharmaceuticals, medical devices, cross-border health care directive, and Health Technology Assessment**,
- 'justice and fundamental rights': fighting against **health inequalities** ,
- 'migration' policy: **actions on migrants and refugees;** and
- 'Security in Europe': **preparedness and management of serious cross-border health threats**.

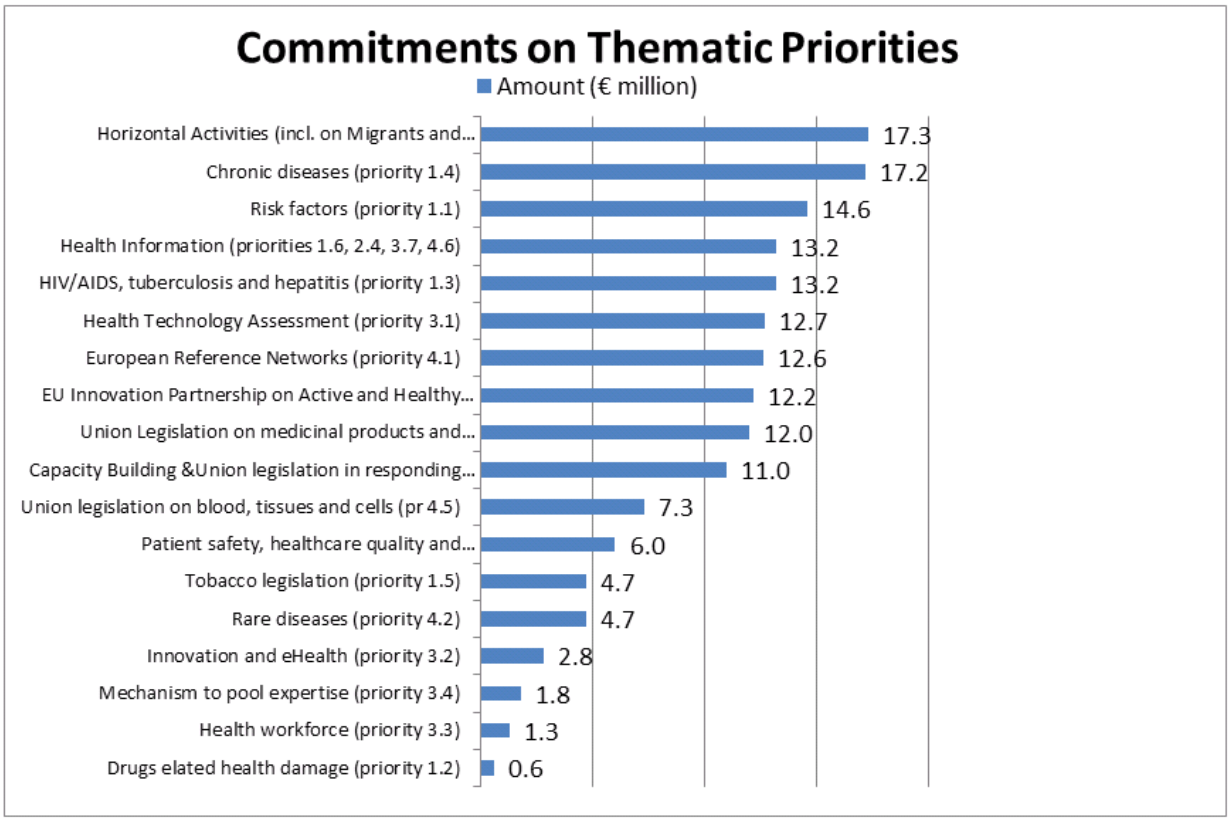
The programme also helps Member States to reach their sustainable development goals (SDG), in particular SDG 3 "Ensure healthy lives and promote well-being for all at all ages"[2].

2.2. Implementation of the Programme in 2014-2016

The Programme is managed by the Commission and implemented through annual work programmes, which are adopted following approval by a programme committee made up of Member State representatives. A multi-annual planning ensures that all thematic priorities are covered and available resources are aligned with priorities and actions. The implementation is entrusted to the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA).
The budget has been attributed between the 23 thematic priorities (Figure 1).

[2] COM (2016) 739 final

Figure 1: Budget attribution by thematic priorities in 2014-2016



Action on migrants and refugees cuts across several areas of action like health inequalities, chronic diseases, mental health, communicable diseases and health information. If looked at as a single entity, action on migrants and refugees represents a public health investment of EUR 14.4 million (EUR 9.5 million funded under horizontal activities, another EUR 3.5 million under capacity building (priority 2.2) and EUR 1.4 million under priority of health information (priority 3.7).

With the remaining EUR 7.8 million under horizontal activities, the Programme supports activities for maintenance and licence of information technologies (*e.g.* the European Commission Public Health website, the Health Policy Platform), communication on EU health policies and dissemination of Programme results through instruments such as the Health-EU newsletter, and the annual EU Health Award for non-governmental organisations whose missions make a real contribution to public health. The award went to NGOs whose work made an impact during the Ebola crisis in 2015[3], contributed to the fight against antimicrobial resistance in 2016[4], and promoted vaccination in 2017[5].

[3] The 1st prize was attributed to The Alliance for International Medical Action (ALIMA), the 2nd prize to Concern Worldwide and the 3rd prize to the Spanish Red Cross.

[4] The 1st prize was attributed to BEUC/The European Consumer Organisation, the 2nd prize to Alliance to Save our Antibiotics – Compassion in world Farming – Soil Association, and the 3rd prize: World Alliance Against Antibiotic Resistance WAAAR

The EU-28 Member States participate in the Programme, as well as the two EFTA countries Norway and Iceland. Serbia and Moldova have also participated since 2016 and Bosnia and Herzegovina joined in April 2017[6]. The increasing interest in the Programme shown by candidate and potential candidates and neighbouring countries could be seen as a sign of the increasing interest the Programme has for those countries that have decided to align their health policies with those of the EU.

3. THE MID-TERM EVALUATION

The mid-term evaluation conducted in 2016-2017 mainly focused on the relevance of the thematic priorities, the achievement of the objectives and the effectiveness of the Programme's management. However, it also touched upon other issues such as the efficient use of resources, the Programme's EU-added value and its internal and external coherence. The evaluation was based on an external study and included an open public consultation whose replies of the 133 participants fed into the final evaluation conclusions.

To comply with the legal obligation[7], the mid-term evaluation was carried out quite early in the Programme implementation period, and it was not yet possible to quantitatively assess whether Programme objectives had been met. The actions[8] under the first year of the Programme, which began in early 2015, were only expected to deliver their interim results by the end of 2016 at the earliest. Nonetheless, a series of case studies on 29 actions, (corresponding to eight thematic priorities, two per Programme objective) could be used as a basis for evaluation. These case studies produced ample evidence on the benefits and potential benefits of the funded actions.

3. 1. Results and key achievements

After three years of Programme implementation, the evaluation concludes that most of the funded actions are well on their way to delivering promising results, while some others have only just started. A few examples of priorities under each of the Programme objectives are:

3. 1. 1. Health promotion and disease prevention

The Programme has supported cooperation among Member States through the generation, use, sharing and exchange of knowledge and best practices. This is in line with Article 168 of

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5 Deadline for submission of applications: 30 June 2017.

6 This participation is out of the scope of the mid-term evaluation.

7 Article 13(3)(c) of Regulation (EU) No 282/2014 for a mid-term evaluation by 30 June 2017.

8 Most of the actions have a life span of three years with the exception of operating grants, procurement contracts and some projects for migrants at the end of 2015, which had duration of one year.

the Treaty on the Functioning of the European Union (TFEU) and contributes to the achievement of SDG 3 to "ensure healthy lives and promote well-being for all at all ages"[2].

The Commission, jointly with the OECD and the European Observatory on Health Systems and Policies, is bringing together expertise in the *State of Health in the EU* cycle to strengthen country-specific and EU-wide knowledge in health, supporting Member States in their evidence-based policy making. This recurring two-year cycle of knowledge brokering comprises the *Health at a Glance: Europe* report[9], 28 country profiles, a Companion Report and voluntary exchanges that Member States can request.

Ultimately improving the health information underlying the *State of Health in the EU* cycle, the BRIDGE project[10] brings together expertise in the area of population and health system monitoring, aiming to set up a sustainable and integrated EU health information system.

Exchange of best practice has also been at the heart of several co-funded actions, in areas as diverse as HIV/AIDS and TB prevention[11] or alcohol harm reduction[12]. Other actions are related to:

(a) the development and maintenance of an online reference guide hosted by the Commission Joint Research Centre as a one-stop clearing house for independent, reliable and up-to date information on a wealth of topics related to nutrition, physical activity and prevention of chronic conditions;

(b) the EU-Compass for Action on Mental Health and Wellbeing[13] which is a web-based mechanism used to collect exchange of best practices and analyse information on policy and stakeholder activities in mental health;

(c) the European Quality Assurance scheme for breast cancer services[14],and the publication of European Breast Cancer Guidelines[15],

(d) the European Network of Cancer Registries[16] providing a 'data-brokering' service to ensure integrity of a single European dataset for different purposes; and

(e) the recently published second report on the implementation of the Council Recommendation on cancer screening in the European Union[17].

9 http://ec.europa.eu/health/state/glance_en
10 http://www.bridge-health.eu/
11 https://e-detecttb.eu/
12 http://www.rarha.eu/Pages/default.aspx
13 http://ec.europa.eu/health/sites/health/files/mental_health/docs/ev_20161006_co05_en.pdf
14 https://ec.europa.eu/jrc/en/event/workshop/european-quality-assurance-scheme-breast-cancer-services
15 http://ecibc.jrc.ec.europa.eu/european-guidelines
16 http://www.encr.eu/
17 https://ec.europa.eu/health/sites/health/files/major_chronic_diseases/docs/2017_cancerscreening_2ndreportimplementation_en.pdf

3. 1. 2. Crisis preparedness and management

Activities to support capacity building against health threats have helped to avoid duplication and improve capabilities, delivering added value for the EU and the wider international community. They have served to identify gaps in Member States' capacities, prioritise actions and implement capacity building activities to fill in those gaps, and have also delivered toolkits and guidelines, provided training and testing of EU preparedness and response mechanisms and coordinated external quality assurance exercises. These activities also made it possible to share lessons learned during recent outbreaks.

During the Ebola and Zika virus outbreaks, the programme was used to support EU-funded activities to limit the spread of these threats by strengthening Member State preparedness and response in particular through the actions of the Health Security Committee (entry screening, medical evacuations, prevention of transmission in transport and hospital settings).

Examples of further action include implementing the joint procurement of vaccines[18] and medical counter-measures[19]; and improving the capacity of laboratories[20] to rapidly detect new or emerging risks and ensure uniform standards of testing.

The Programme demonstrated its capacities and flexibility when put to the test during the unprecedented high influx of refugees in 2015-2016. It provided a foundation for neighbouring countries and the International Office for Migration to work together to raise awareness and to strengthen their commitment to improve maternal health and healthcare for refugees and migrant women. The Programme was also instrumental in helping to develop and implement roadmaps and models for improving the access to healthcare for vulnerable immigrants and refugees in Europe and to deliver recommendations, technical guidance and training[21] to health professionals and to the law enforcement officers working at local level with migrants/refugees.

3. 1. 3. Innovation in health systems

The Programme works in synergy with other EU Programmes and different policies strands to increase the efficiency of the EU expenditure and maximise its impact:

The Joint Action supporting the eHealth Network[22] on interoperability and standardisation for cross-border health data exchange enables compatibility with Connecting Europe Facility[23]

18 http://ec.europa.eu/health/sites/health/files/preparedness_response/docs/jpa_agreement_medicalcountermeasures_en.pdf

19 https://ec.europa.eu/health/preparedness_response/key_documents_en#anchor0

20 http://www.emerge.rki.eu/Emerge/EN/Home/Homepage_node.html

21 The material for trainings and other relative information is published on the Health Policy Platform at: https://webgate.ec.europa.eu/hpf/

22 http://jasehn.eu/index.php/about-jasehn/background/

23 https://ec.europa.eu/digital-single-market/en/connecting-europe-facility

requirements and therefore promotes digital service infrastructures in public health. Collaboration among EU Health Technology Assessment[24] bodies has delivered common tools and standards, offering potential for significant economies of scale. The sustainability of the network and improved national uptake are at the centre of the current Joint Action, which supports major policy aims such as accessibility, quality and sustainability of health care.

3. 1. 4. Access to better and safer health

24 European Reference Networks[25]for rare diseases have been established to unite the expertise of more than 300 healthcare providers and 900 centres of expertise across Europe and make it available to rare disease patients, who often find it difficult if not impossible to find specialised knowledge and care close to home. To review a patient's diagnosis and treatment, coordinators will convene a 'virtual' advisory board of medical specialists across different disciplines, using a dedicated IT platform and telemedicine tools. Pooling together knowledge, expertise and resources across the EU helps make high quality healthcare accessible to all and helps reduce health inequalities both within and between EU Member States. In years to come, this concept could be expanded beyond rare diseases to other complex conditions.

The Programme also plays a crucial role in addressing Antimicrobial Resistance (AMR) by defining common approaches to fight AMR and to control healthcare-associated infections in line with ongoing EU and international policies, in particular the SDG 3[2].

3. 1. 5. Implementing EU health legislation

To reach its objectives and have its expected impact, EU legislation often requires support to consistently implement it across all Member States. Developing common standards and guidelines is at the heart of various actions funded by the Health Programme, whether for reporting purposes, carrying out audits and inspections, operating authorisation or for vigilance systems.

Several actions have supported implementing legislation on substances of human origin, through initiatives such as developing an IT platform to enable the exchange of organs between Member States; improving an information system and supra-national data sharing on living organ donation; optimising the process for post-mortem organ donation in hospitals by enabling the cooperation between critical care professionals and donor transplant coordinators; and improving inspection guidelines for blood and tissues establishments.

Several actions provided support to prepare delegated and implementing acts of the Tobacco Products Directive, including several studies[26] and an implementation analysis for the future EU system for traceability and security features in the field of tobacco products. The SCOPE Joint Action[27] has developed a curriculum and full set of capacity building and training material

24 http://www.eunethta.eu/
25 http://ec.europa.eu/health/ern/networks_en
26 https://ec.europa.eu/health/tobacco/key_documents_en#anchor0
27 http://www.scopejointaction.eu/

to support national regulators in the implementation of the 2012 pharmacovigilance legislation[28].

3. 2. Lessons learned

➢ The Programme is highly relevant to Member States needs and the objectives set are clear, explicit and specific

The 23 thematic priorities help to better focus the Programme's actions and avoid overlaps and potential duplications among the different objectives. At the same, these thematic priorities have the flexibility to allow for synergies that in some cases are clearly required. For example actions for migrants and refugees, an area in which the Programme's design has proven to be flexible and sufficient. However, the Programme could benefit from more coherence and refinement in the future.

The actions financed under the first three years are also relevant to specific Programme objectives and priorities. They benefit from the Programme's design through better alignment of their own objectives and outputs with the requirements of good Programme implementation. However, some actions under broader priorities which are not linked to EU legislation, and/or open-ended funding mechanisms such as operating grants, may lack focus and can risk deviating from their initial objectives. In these cases, particular attention should be paid during the planning stage, and the actions in question should be monitored and evaluated in good time to take any necessary corrective measures.

➢ Programme management has become increasingly effective

The Programme has been restructured following experience from the implementation of the two previous programmes (first programme in 2002-2007 and the second in 2008-2013). Its objectives were set in a very explicit and practical way, announcing the kind of outputs expected and providing indicators for measuring progress.

The Annual Work Programmes are established on the basis of a preliminary multi-annual planning exercise, meeting specific criteria set in the Programme Regulation (Annex II). The process for defining Annual Works Programmes works smoothly and the consultation with Member States takes place in a clear, transparent and equitable way. The multi-annual planning has proven to be a valuable tool for providing a more strategic view of the mid-term planning and allowing for the smoother adoption of annual Work Programmes and limiting the

[28] https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2010_1235/reg_2010_1235_en.pdf

number of amendments. However, stakeholders want to have more opportunities to help determine annual priorities and the actions needed on a multi-annual and annual basis.

The Commission encourages all EU-28 Member States and other third countries to take part in the Programme. The Programme gives them recourse to exceptional utility criteria and provides up to 80% EU co-funding to all actors involved. The co-funding is granted under particularly favourable conditions if a part of the overall budget is transferred for action in low GNI[29] countries. The exceptional utility criteria have not been effective so far. However, despite the difficult economic context and the significant barrier of assuring the remaining co-financing, the Programme is still attracting a similar level of participation from low GNI countries as in the previous Programme.

➢ **The Programme demonstrated its responsiveness and flexibility in the face of emerging needs such as the refugees' crisis in summer 2015,** which made a significant contribution to the Commission's migration policy.

In addition, the Programme also provides support for the first implementation phase of the newly established European Solidarity Corps, which reflects European values of solidarity and humanitarian action. Through the Solidarity Corps, European youth will not only provide assistance where it is needed, but will also broaden their experiences, deepen their cultural understanding, learn the value of service to others, and strengthen their sense of identity as Europeans.

➢ Efficiency is being improved

The Programme focused its limited budget on a strict selection of key objectives and priorities aligned with Commission's main priorities. On this basis, most of the funding was allocated to outcome-oriented actions for modern health policies, stimulating innovation in health and healthcare and providing appropriate tools, methods and training for increased safety and security in the EU.

Objectives (2) for cross-border health threats and (4) for access to better and safer health received comparatively less financing. However they benefit from synergies with the European Centre on Disease Control for risk assessments, collection and analysis of epidemiological data and AMR. Broader thematic areas like health promotion and health systems were identified as priorities by Member States' representatives in e-surveys and by a large number of health stakeholders in the public consultation and received the highest amount of funding. Health promotion includes actions in areas such as risk factors, chronic diseases and health information, health systems including Health Technology assessment.

[29] Gross national income

The Programme has introduced programmatic indicators and action-level monitoring and invests into strategic dissemination activities. These are decisive steps responding to previous recommendations but there is still room for improvement and for speeding up progress.

Moreover, the Programme's administration costs are low, compared to the administrative costs of other comparable Commission programmes. Administration costs represent just 9% of the overall budget.

➢ **Simplification measures have been taken for rules and procedures including the use of electronic tools for the submission and evaluation of proposals, the management of grants, e-monitoring and e-reporting.** While this development is resource intensive in the beginning for the design and testing of tools, the level of satisfaction from applicants and grant beneficiaries justifies these efforts, and financial gains are expected in the next years.

➢ A small Programme with big EU-added value

The cooperation at EU level and coordination of preparedness plans and responses to health threats is one of the strongest and best known aspects of the Programme's EU-added value. Activities to support capacity building against health threats have helped to avoid duplication and improve capabilities, delivering added value for the EU and the wider international community. They have served to identify gaps in Member States' capacities, prioritise actions and implement capacity building activities to fill in those gaps. They have also delivered toolkits and guidelines, training and testing of EU preparedness and response mechanisms and external quality assurance exercises and they have enabled the sharing of lessons learned from recent outbreaks and refugees' crisis.

The Programme also helps Member States to increase their capacities in other areas: pooling knowledge, expertise and resources across the EU increases citizens' equitable access to high quality healthcare and contributes to the reduction of health inequalities both within and between EU Member States. For instance, through the 24 European Reference Networks on rare diseases where the possibility exists to expand the pooling of expertise to other complex diseases in the near future. Also through the collaboration between EU Health Technology Assessment bodies to deliver common tools and standards that support major policy aims such as accessibility, quality and sustainability of health care while offering potential for significant economies of scale. Another example is the support given to the eHealth Network for improving the interoperability and standardisation needed for the cross-border exchange of health data and to promote digital service infrastructures in public health.

Cooperating, using and sharing knowledge has high EU-added value: the collection and analysis of comparable data depicting the situation of Health in each of the EU-28 Member States (country-profiles) contributes to political dialogue and informed decision making for health policy. The exchange and implementation of best practice for promoting health and

preventing diseases have also an EU-added value, which can help Member States in their health reforms to overcome threats to their health systems from demographic changes and the burden of non-communicable diseases and other chronic conditions.

➢ Working in coherence and developing synergies

The Programme is in alignment with the Commission's main priorities under Article 168 TFEU and the SDG, and strives to maximise synergies with other EU policies and financial instruments such as Horizon 2020.

The Programme's particularity remains its focus on health policy cooperation. It uses the results of research actions and tests their results in real settings in close cooperation with competent authorities in the Member States. The aim is to help Member States design and implement their own policies so as to build a strong social Europe while taking budgetary constraints and needs for system reforms into consideration.

To up-scale those effective actions and make them integral parts of Member States' national health policies, the Programme should continue to encourage cooperation with the European Structural and Investment Funds[30] and other EU financial instruments. The effective use of such big financial instruments can have a greater impact than using the Programme alone, by building knowledge and capacities for monitoring and implementation and by supporting innovation and effectiveness for health investments.

4. HOW CAN THE IMPLEMENTATION OF PROGRAMME BE IMPROVED

Following the ex-post evaluation of the second Health Programme, the Commission undertook to work on three main aspects of the third Health Programme, as stated in its report to the European Parliament and the Council in May 2016[31:] These commitments were to:

(a) improve monitoring, reporting and dissemination efforts

(b) encourage participation of all Member States and other participating countries, and to work with all Member States, particularly those with greater public health needs; and

(c) develop synergies with the Commission's main priorities and other programmes.

These points are still valid and the Programme will continue to work on these areas. In particular for the dissemination of results which is an area where work must be speeded up as much as possible.

30 https://ec.europa.eu/health/health_structural_funds/used_for_health_en

31 COM(2016) 243 final at http://ec.europa.eu/health/programme/policy/2008-2013/evaluation_en

Moreover, and as suggested in the mid-term evaluation, the Programme should remain focused on issues where EU added value can be achieved. These areas fall mainly under the objectives of protecting against cross-border health threats and the access to better and safer healthcare. For the priorities under the objective of health promotion and prevention of diseases, the Commission is currently working on defining concrete needs in Member States[32] where integrating best practices into national policies could bring the expected results and impact on the population's health and the sustainability of the health systems.

Links to SDG and the wider Commission and EU policy agenda will be improved so as to better prioritise actions and increase impact. This approach could also increase the Programme's visibility and boost its role in the international arena despite its modest budget.

The EU-added value criteria could be further simplified for potential applicants and made easier to understand by using concrete examples.

5. CONCLUSION

The mid-term evaluation was positive and found that implementation of the Programme is on track. All thematic priorities remain valid and most actions deliver useful outcomes with high EU-added value, in particular for crisis management and for the safety and security in Europe.

The open public consultation attracted the attention of a broad selection of interested parties and provided strong support for continued cooperation through the Programme, particularly in areas such as health promotion, disease prevention and eHealth.

[32] http://ec.europa.eu/newsroom/sante/newsletter-specific-archive-issue.cfm?newsletter_service_id=327&newsletter_issue_id=2820&page=1&fullDate=Fri%2017%20Mar%202017&lang=default