157673/EU XXV.GP
Eingelangt am 11/10/17

Brussels, 11.10.2017
SWD(2017) 331 final

**COMMISSION STAFF WORKING DOCUMENT**
*Accompanying the document*

**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 third Health Programme**

**Regulation No 282/2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020)**

{COM(2017) 586 final}
{SWD(2017) 333 final}

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# INTRODUCTION

### 1.1 Purpose of the evaluation

This staff working document accompanies the Commission report and external evaluation study[1] that the Commission is transmitting to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. It presents the conclusions of the mid-term evaluation of the Health Programme 2014-2020 as required under Article 13(3) of Regulation (EU) No 282/2014 establishing the third Programme for the Union's action in the field of health.

The external and independent study supporting the mid-term evaluation of the third Health Programme was carried out in 2016-2017. Its purpose was mainly to assess the implementation of the Programme at mid-term focusing on the 23 thematic priorities and their relevance in relation to the Programme's objectives and their contribution to the Commission's priorities. The evaluation also looked into whether the 23 thematic priorities were still valid and needed to be changed. Moreover, the evaluation also provides input for drawing up the next programming period.

### 1.2 Scope of the evaluation

The mid-term evaluation of the third Health Programme covers the first three years of Health Programme implementation (2014 - 2016). It examines the relevance of the choices made in the Annual Work Plans 2014, 2015 and 2016 and the decisions on proposals submitted and awarded for EU funding under the subsequent calls. Moreover, the evaluation covers the efficiency of the use of resources, the EU-added value of the Programme, the internal and external coherence, and potential for simplification. The evaluation focussed especially on either new or previously under-examined aspects, such as the Annual Work Programmes, the multi-annual planning and the exceptional utility criteria.

## 1. BACKGROUND TO THE HEALTH PROGRAMME 2014-2020

### 2.1 Description and objectives

The Health Programme 2014-2020 is the third programme of EU action in the field of health, established by Regulation (EU) 282/2014. With a budget of EUR 449.4 million over seven years, it is the Commission's main instrument to underpin and support EU health policy development. Designed to help Member States in investing in health, the Programme contributes to the Europe 2020 objective of smart, sustainable and inclusive growth.

The Programme aims to **complement, support and add value to the policies of Member States, in terms of improving the health of EU citizens and reducing health inequalities.** It has four specific objectives which are the following:

(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.

These objectives are served by actions on the following 23 thematic priorities, set out in the Annex I to Regulation 282/2014. See also in Annex I of this document.

[1] Mid-term Evaluation of the third Health Programme (2014 – 2020) - Final report, written by Coffey International Development, SQW and Economisti Associati; ISBN 978-92-79-68447-0; doi: 10.2875/359384 and its two Annexes: Annex A - ISBN 978-92-79-68450-0 ; doi: 10.2875/292289 and Annex B - ISBN 978-92-79-68449-4; doi: 10.2875/16031

The thematic priorities aim to focus the Health Programme on types of issues and action where the potential to generate EU-added value is greatest and therefore contribute to the Commission main priorities for:

(i) 'growth, jobs and a resilient society' (health of the population and healthcare services as a productive factor for growth and jobs);

(ii) 'digital single market' (including eHealth);

(iii) 'internal market' (for pharmaceuticals, medical devices, cross-border healthcare directive, and Health Technology Assessment);

(iv) 'justice and fundamental rights' (fighting against health inequalities);

(v) 'migration' policy, and

(vi) security in Europe (preparedness and management of serious cross-border health threats).

The Programme is managed by the Commission and implemented through annual work programmes that are adopted following a positive opinion of a programme committee composed of Member States' representatives. The work programmes are based on a multiannual perspective in order to ensure that all thematic priorities are covered aligned to the available resources, clustering priorities and actions. The implementation is entrusted with the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA).

In the Programme participate in addition to the 28 EU Member States, the two EFTA countries Norway and Iceland, Serbia and Moldova since 2016, and recently Bosnia and Herzegovina has joined in April 2017. The increasing interest of candidate countries 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.

**2.2 Expected outputs, results and impacts**

**2.2.1. Under specific objective 1 for promoting health and preventing diseases**, the Programme works for the identification, dissemination, and promotion of an effective uptake of evidence based best practices, including measures to be taken for addressing the health inequalities (migrants, ethnic minorities, refugees and other vulnerable groups).

The previous Health Programmes have supported the identification of a considerable number of best practices related to a big number of health issues such as the promotion of healthy lifestyles, the prevention and management of non-communicable diseases and chronic conditions, the patient safety, etc. The third Health Programme does not limit itself to identifying new best practices but rather makes the step further to organise the existing ones, validates and promotes best practices for direct implementation by Member States that wish to make use of them in their national policies.

Article 3 (1) of Regulation 282/2014 provides that objective 1 must 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.

***Risk factors***

Baseline: 12 Member States have had a national initiative on the reduction of saturated fat in 2013

Target: By 2020, all EU-28 should have had a national initiative on the reduction of saturated fat.

***Chronic diseases including cancer***

Baseline: 0 Member States where the European accreditation scheme for breast cancer services is implemented – establishment of the scheme.

Target: by 2020 all EU-28 should have implemented the accreditation scheme for breast cancer services.

**2.2.2 Under specific objective 2 for protecting citizens from cross-order health threats, the Programme** requires the identification and development of coherent approaches and supports and promotes their implementation for better preparedness and coordination in health emergencies.

The Programme brings together and supports competent authorities in addressing a challenge that affects all Member States which in most of the cases can have consequences to the global health and which is best dealt with through cooperation. Supported actions under this objective have served to identify gaps in Member States' capacities, prioritise actions and implement capacity building activities to fill in those gaps. For example through toolkits and guidelines, simulation and post command exercises.

Part of the role of the Health Programme is also to bring together relevant stakeholders to give them an opportunity to revise or agree on emergency procedures, as well as enhancing the evidence base for decision-making which in turn builds capacities. Through the Programme, technical expertise to tackle a specific set of high risk groups (risk group 3 bacteria and risk groups 3 and 4 viruses) has been developed meaning that citizens would be better protected.

Article 3(2) of Regulation 282/2014 provides that objective 2 on crisis preparedness and management must be measured, in particular, through the increase in the number of Member States integrating coherent approaches in the design of their preparedness plans.

Baseline: in 2014, there was no Member State with integrated coherent approaches in the design of their preparedness plans.

Target: by 2020, all EU-28 should have integrated coherent approaches in the design of their preparedness plans.

At the time of drafting this document, 16 Member States have reached this goal. Updated indicators are expected to be available after the next reporting exercise by Member States on preparedness and response planning under Article 4 of Decision 1082/2013/EU (to be completed by November 2017).

**2.2.3 Under specific objective 3 for contributing to innovative, efficient and sustainable health systems,** the Programme identifies and develops tools and mechanisms at EU level to address shortages of human and financial resources and facilitate the voluntary uptake of innovation in public health intervention and prevention strategies. The main ones are the Health Technology Assessment, eHealth, the European Innovation Partnership in Active and Healthy Ageing, the Expert Panel on health and the Commission Scientific Committees.

Article 3 (3) of Regulation 282/2014 provides that this objective must 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.

**Health Technology Assessment (HTA)**

**Baseline: 2 HTA per year**

**Target in 2020: 50 HTA annually involving all EU-28**

**In 2014 and 2015, respectively 6 and 9 HTA have been developed. For further information on HTA please refer to Annex I part B.**

**2.2.4 Under specific objective 4 for facilitating access to better and safer healthcare,** the expectations are for increased access to medical expertise and information for specific conditions also beyond national borders and the facilitation of the application of the research results and the development of tools for improved healthcare quality and patient safety through actions contributing to improved health literacy.

Article 3 (3) of Regulation 282/2014 provides that this objective must be measured, in particular, through the increase in the number of European reference networks established under Directive 2011/24/EU of the European Parliament and of the Council[2], 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.

Baseline: 0 ERN

Target in 2020 : 20 ERNs . This target has been achieved already in 2017 with the establishment of 24 European Reference Networks (ERNs).

Reviewed new target in 2020: 33 ERNs

ERNs are expected to deliver a number of benefits over the medium and long-term: provide the 27-36 million people affected by rare diseases, representing 6-8% of the overall EU population, with greater access to high quality health care and information, accurate diagnosis and appropriate treatment. In this first phase (2016-2018), ERNs include 24 networks and almost 1000 clinics across the EU, set up for complex and rare diseases. In the coming years the concept of ERNs could also cover other complex diseases such as more common cancers or specialised paediatric interventions if resources are made available. This will result in better chances for patients to receive an accurate diagnosis and advice on the best treatment for their specific condition.

ERNs are not directly accessible to individual patients. However, with the patients' consent and in accordance with the rules of their national health system, patient case can be referred to the relevant ERN member in their country by their healthcare provider. By pooling expertise and knowledge, ERNs are able to maximise the speed and scale with which innovations in medical science and health technologies are developed and put into use. Economies of scale can be achieved by connecting existing reference networks found in individual Member States, and greater efficiency and coordination can be achieved by sharing resources and expertise across the EU. Reference networks are also ideal environments for research and innovation (clinical trials, patient registries, training of professionals).

**2.2.5 Cross-cutting actions: actions for migrants and refugees:**

The extraordinary influx of migrants and refugees in 2015 and 2016 was an unprecedented situation and led to unexpected and considerable challenges for Member States health systems providing services to an increased population, sometimes with special health needs.

The Health Programme was able to make a meaningful -while proportionate to the Health Programme budget- contribution to the EU policy on migration, particularly on integration, and to the immediate EU response, assisting Member States in their response.

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[2] 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).

Therefore the Health Programme responded to this crisis, through 11 actions financed with over EUR 14 million. The aim was to support countries in their immediate response to health needs, develop and implement roadmaps and models for improving healthcare access of vulnerable migrants and refugees in Europe, increase awareness and commitment towards improving health and healthcare for refugees and migrant, with focus on pregnant women, deliver recommendations, technical guidance, and training to health professionals, law enforcement officers and health mediators working at local level with migrants/refugees.

Training at EU level is in preparation, including health professionals, law enforcement officers, social workers, and health mediators and will be provided in 2017-2018. It includes knowledge, attitudes and awareness on migrants needs. A first piloting will take place in 10 EU countries and a second phase will address professionals in the 32 countries of the Health Programme.

More specific trainings took place at local level and for the professionals locally involved in some of the funded projects. For example, 494 health professionals and 443 sessions for migrant groups, in one of the projects, 5 trainings on health mediations, 8 training of the health assessment platform and 12 demonstrations, with 71 health mediators and 2 815 migrants reached with awareness raising messages. Online training course packages were also produced, especially for health managers.

Guides for the assessment of health needs of migrants/refugees were produced as well as country profiles and guidelines for the development of action plans. Country missions to Member States were developed.

Health assessments have been carried out: In 2015, 4 275 health assessments have been carried out by the International Office for Migration−which benefited from a Health Programme direct grant−and 8 938 assessments were carried out in 2016. After positive assessment, migrants considered able to travel departed to 21 EU countries and 3 EFTA countries. 1586 personal health records, aiming to reconstruct the medical history of the migrants and refugees, were completed, with 685 persons referred for additional medical diagnostics.

In another project, 2 459 urgent individual health assessments were done with newly arrived migrants and 49 707 physical health assessments, 1 775 mental health ones and 4 811 social consultations, 12 mobile teams were deployed in 9 countries.

In a third project, 11 057 medical examinations were performed in Italy. Protocols for age assessment into hotspots were developed, as well as a syndromic surveillance system.

## 2. METHODOLOGY

### 3.1 Preliminary steps

An Interservice Steering Group for the mid-term evaluation established in October 2015[3], discussed and validated the Roadmap for the mid-term evaluation which was open for public consultation for four weeks (14/12/2015-14/01/2016) [4].

On the basis of this Roadmap and feedback from Member States and non-governmental organisations[5], the Steering Group drafted the evaluation questions and agreed on the terms of

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3 The Commission's Interservice Steering Group was composed by the SEC GEN, DG AGRI, DG CONNECT, DG DEVCO, DG EMPL, DG RTD, DG SANTE and CHAFEA.

4 http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_sante_680_evaluation_mid-term_health_programme_en.pdf

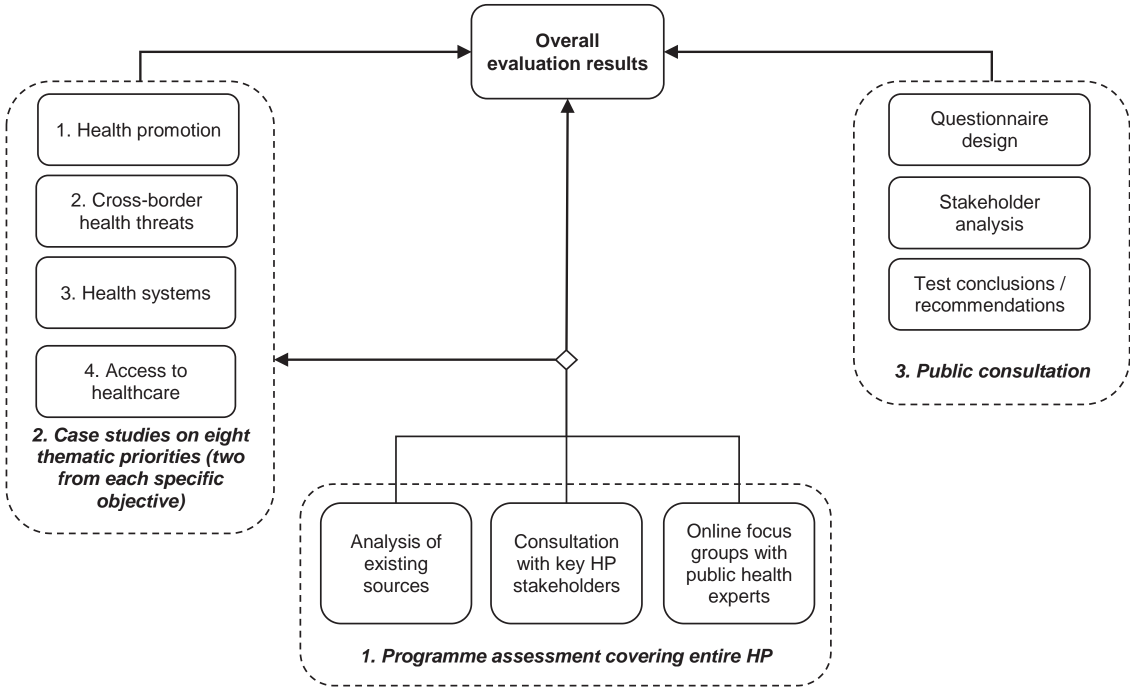
5 Four contributions were received (two from one Member State) and two from two different non-governmental organisations.

reference for the specific contract. Feedback was taken into account, for example, by including one case study on the thematic priority on alcohol policy in the EU or by examining the exceptional utility criterion to see if it really works. This took the form of a specific request for services with a reopening of competition within the Directorate-General for Health and Food safety (DG SANTE) Framework Contract for Evaluations, Impact Assessment and other studies, Lot 1 " Public Health". The independent study started in May 2016 and the final report was delivered a year later. The group met six times to also discuss the inception, interim and draft final reports and provided comments on the methods and organisation of the evaluation. It provided feedback on the quality assessment of the work done and has also been involved in the drafting of the present Staff Working Document which follows the Commission's Better Regulation rules.

**3.2 Process and methods used**

The evaluation involved a variety of quantitative and qualitative data collection and review methods and analytical tools to respond to specific information needs and requirements respecting the principle of triangulation and the Commission standards for evaluation.

**Figure 1: Evaluation approach**




Annex I contains a matrix showing the various tools used to make assessments on the basis of agreed judgment criteria and answer each of the evaluation questions. The evaluation questions are grouped under six categories: 1) relevance, 2) effectiveness, 3) efficiency, 4) EU-added value, 5) coherence and 6) utility. Every category was extensively assessed by the mid-term evaluation through an entire programme assessment, the case studies and the open public consultation.

The contractors used desk research to analyse existing sources (e.g. Annual Work Programmes, legislative texts, internal notes, etc.), reviewed conclusions and recommendations from past Programme evaluations and made direct observations.

They interviewed key Programme stakeholders including Commission staff and the WHO, CHAFEA project officers and project leaders of funded actions. They also discussed with independent[6] public

[6] In the sense that these experts were not involved in actions funded by the Health Programme.

health experts in the four main relevant areas[7] of the Programme and have conducted e-surveys with the Health Programme National Focal Points and the Members in the Programme Committee.

To explore and showcase how actions in the thematic areas are implemented and delivered their specific results, and the main factors and processes that enabled or hindered their success, particularly for aspects such as EU-added value, the contractors have conducted eight case studies on 8 out of the 23 thematic priorities.

The eight thematic priorities for the case studies were selected on the basis of the following criteria:

- actions that already started in 2016 and were at the stage of delivering at least an interim report; and

- a sample of actions representing the spectrum of all the different financial mechanisms (e.g. operating grants have not been examined in previous evaluations).

The detailed list with the selected priorities and actions can be found in Annex II, table 2.

Then an open public consultation carried out by the Commission has served to test preliminary conclusions and recommendations. The on line public consultation which took the form of a questionnaire was available from 23 November 2016 to 23 February 2017. The public consultation was available in English, however replies could be sent in any of the official languages of the EU. A total of 133 contributions were received mainly from individuals/private persons (32%), non-governmental organisations (29%), relevant to health public authorities (19%), academic organisations (9%), international organisations (9%) and professional associations (8%).

The results of the open public consultation are published with a synthesis report at http://ec.europa.eu/health/programme/consultations/midterm_evaluation_en

A synopsis report on stakeholders' consultation activities can be found in Annex V of the present document.

**3.3 Limitations – robustness of findings**

The mid-term external evaluation study was launched in late April 2016 in order to deliver by 30 June 2017. Therefore the evaluation came at a quite early stage in the implementation phase of the Programme: external contractors have had access to the 2014 Programme data; however the second year of Programme implementation (2015) was still in progress while for the third year (2016) the calls were published but the awarding decision was not yet taken. Therefore only partial financial data were available for 2016. This limits the focus of the evaluation to actions from the Annual Work Programme 2014 and in part for 2015. The actions assessed are mainly those having a short duration of only one year (meaning small actions, such as grants to NGOs for support to migrants and refugees or operating grants to NGOs and service contracts for studies). Actions with longer time schedule and bigger potential to contribute to the Programme objectives such as the Health Technology Assessment Joint Action (EUR 12 million) in 2016-2020 had only just started and therefore it was too early to assess them. For this reason, the independent study was from the outset called to focus mainly on effectiveness of the Programme management rather than the effectiveness of the Programme actions.

Furthermore, improvements addressing problems of monitoring and dissemination raised in the ex-post evaluation of the second Health Programme that was published in May 2015 and agreed in an Action Plan between DG SANTE and CHAFEA in December 2015, had not yet been fully implemented. Therefore some recommendations in the mid-term evaluation address the same challenges that were already highlighted in the ex-post evaluation of the previous Programme.

[7] Health promotion and diseases prevention, Cross-border Health Threats, Innovative and sustainable health systems and Access to better and safer health.

Other limitations are related to the sheer number and heterogeneity of thematic priorities and individual actions. Progress indicators exist but these exist at the level of actions not at the level of priorities making it difficult to summarise in a quantifiable way how the whole set of actions fits together and contribute to the Programme objectives.

### 3.4 Quality assessment of the study

The Interservice Steering Group agreed with the contractors' findings, the answers to the evaluation questions and its conclusions within the limitations described above. They approved the final evaluation report and made the following observations:

- The contractors respected the terms of reference and delivered a report on time that was of satisfactory quality. The data they provided are accurate. After several in-depth reviews where the contractor addressed all the issues and further information was exchanged, the report became very clear, legible and precise. On the financial situation of the Programme implementation in 2016, the contractors based themselves on what was actually available as the situation was evolving and made appropriate reference to this kind of limitations.

- The analysis and judgement are based on a clearly explained methodology, the criteria are transparent and the evidence used comes from different sources involving in a balanced way all Programme stakeholders.

- The conclusions are sound and limit themselves to what is feasible at this stage of the Programme implementation. The recommendations flow logically from the conclusions. They are practical, realistic, and addressed to the relevant Programme actors.

## 3. THE FIRST THREE YEARS OF IMPLEMENTATION OF THE PROGRAMME

### 4.1 Budget distribution per objective and thematic priority

So far, objectives 1 (on health promotion) and 3 (on health systems) have received the highest amount of funding, 33 % and 31% respectively. The rest of the funding was allocated 19 % to objective 4 (access to healthcare), 10 % on horizontal or cross-cutting activities and 7% to objective 2 (cross border health threats).

**Table 1: Allocation of budget by objective, 2014 - 2016**

| | Objective | 2014 | 2015 | 2016 | 2014 – 2016 |
|---|---|---|---|---|---|
| 1 | Promote health, prevent disease and foster supportive environments for healthy lifestyles | 31% | 23% | 43% | **33%** |
| 2 | Protect citizens from serious cross-border health threats | 10% | 3% | 8% | **7%** |
| 3 | Contribute to innovative, efficient and sustainable health systems | 33% | 45% | 16% | **31%** |
| 4 | Facilitate access to better and safer healthcare for Union citizens | 20% | 11% | 26% | **19%** |
| Horizontal | | 7% | 18% | 6% | **10%** |

Across the 23 thematic priorities, the funding ranges significantly.

The work on migrants and refugees (a major part is under horizontal actions) cuts across several action areas 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 under priority of health information (priority 3.7).

With the remaining EUR 7.8 million under horizontal activities, the Programme supports also activities for maintenance and licence of information technologies (e.g. the DG SANTE Web page, the Health Policy Platform), communication on EU health policies and dissemination of Programme results, etc.

The priorities of health legislation and health information, are attributed systematically under each of the four objectives covering each time relevant topics such as tobacco legislation under objective 1 for health promotion and prevention of diseases, legislation on health threats under objective 2, legislation on pharmaceuticals and medical devices under objective 3 for health systems, legislation on blood, tissues and cells under objective 4.

The same applies also for the cross-cutting priority of health information, which is split among the four Programme objectives as priority 1.6, 2.4, 3.7 and 4.6; In total support to EU legislation amounts to EUR 27.5 million and support to health information amounts EUR 13.2 million.

**Table 2: Allocation of budget by thematic priority, 2014 - 2016**

| | | 2014 | 2015 | 2016 | Total | Total |
|---|---|---|---|---|---|---|
| Horizontal | | €3.7 M | €10.0 M | €3.6 M | €17.3 M | |
| 1.4 | Chronic diseases | €6.6 M | €0.8 M | €9.9 M | €17.2 M | |
| 1.1 | Risk factors | €5.2 M | €4.8 M | €4.6 M | €14.6 M | |
| 1.3 | HIV / AIDS, TB & hepatitis | €3.3 M | €5.3 M | €4.6 M | €13.2 M | |
| 3.1 | Health Technology Assessment | €0.3 M | €12.0 M | €0.4 M | €12.7 M | |
| 4.1 | European Reference Networks | €5.5 M | €0.4 M | €6.7 M | €12.6 M | |
| 3.5 | EIP on Active & Healthy Ageing | €5.4 M | €6.8 M | €0.0 M | €12.2 M | |
| 3.6 | Union legislation on medicinal products and medical devices | €4.0 M | €3.8 M | €4.2 M | €12.0 M | |
| 3.7 | Health information | €5.0 M | €1.3 M | €2.9 M | €9.2 M | |
| 2.2 | Capacity building | €1.8 M | €1.4 M | €4.3 M | €7.5 M | |
| 4.5 | Union legislation on blood, tisues and cells | €3.3 M | €1.9 M | €2.1 M | €7.3 M | |
| 4.3 | Patient safety & healthcare quality | €0.9 M | €1.0 M | €4.2 M | €6.0 M | |
| 4.2 | Rare Diseases | €0.8 M | €2.3 M | €1.6 M | €4.7 M | |
| 1.5 | Tobacco legislation | €0.2 M | €1.4 M | €3.1 M | €4.7 M | |
| 1.6 | Health information | €1.5 M | €0.4 M | €1.8 M | €3.8 M | |
| 2.3 | Union legislation on cross-border health threats | €3.5 M | €0.0 M | €0.0 M | €3.5 M | |
| 3.2 | Innovation and e-health | €2.4 M | €0.1 M | €0.3 M | €2.8 M | |
| 3.4 | Mechanism to pool expertise | €0.3 M | €1.0 M | €0.5 M | €1.8 M | |
| 3.3 | Health workforce | €0.2 M | €0.2 M | €1.0 M | €1.3 M | |
| 1.2 | Drugs-related health damage* | €0.0 M | €0.0 M | €0.6 M | €0.6 M | |
| 4.4 | Antimicrobial resistance** | €0.0 M | €0.4 M | €0.0 M | €0.5 M | |
| 4.6 | Health information | €0.0 M | €0.2 M | €0.0 M | €0.2 M | |
| 2.1 | Risk assessment | €0.0 M | €0.0 M | €0.1 M | €0.1 M | |
| 2.4 | Health information*** | €0.0 M | €0.0 M | €0.0 M | €0.0 M | |

Source: DG SANTE and CHAFEA

Note: figures are rounded; 2016 allocated budget is based on available data.

*While the funding to thematic priority 2.1 drugs-related health damage appears low, five actions which address among other secondary prevention for drugs users have been funded under the 3HP and are accounted under thematic priority 1.3 HIV/AIDS, Tuberculosis and hepatitis as the main subject was on these communicable diseases.

**While very little funding appears to be allocated to thematic priority 4.4 on antimicrobial resistance, this topic is in fact addressed through some of the action funded through thematic priority 4.3 on patient safety and healthcare quality.

***The scope of health information under objective 2 for health threats relies mainly with the European Centre for Diseases Control (ECDC) mission and this is the reason that no budget has been spent on this priority in the period 2014-2016.

Every year, the Commission adopts Annual Work Programme in close cooperation with Member States.. In every Annual Work Programme, priorities for actions with high public health relevance and EU added value are set out. The Annual Work Programmes are supported by a multiannual planning. This mechanism was introduced for the first time in this third Health Programme and contains a more comprehensive, long-term approach into the programming process.

The following subsections provide a general overview of the funding mechanisms in the Health Programme and the beneficiaries that can be involved.

### 4.2 Budget distribution per financial mechanism

The Annual Work Programmes are implemented through various financial mechanisms, which all assist different kinds of actions and objectives. For this implementation, DG SANTE of the Commission is supported by CHAFEA, which manages calls for grants and tenders. The Commission

is responsible for the implementation of highly policy-relevant service contracts and cross-cutting actions. In the years 2014 to 2016, EUR 165.6 million euros (36.8% of the total funding) has been allocated in total, of which EUR 53.8 million for 2014, EUR 55.4 million for 2015 and EUR 56.4 million for 2016.

The available mechanisms of the third Health Programme are listed below.

**Table 3: Financial mechanisms of the Health Programme8**

| Financial mechanism | Description |
|---|---|
| **Project grants** | They are used to fund a collaborative effort between different organisations in various EU MS, which join forces to perform various tasks on a common set of objectives for a defined period of time[9] |
| **Operating grants** | They provide financial support towards the functioning of a non-governmental body or network, over a period that is equivalent to its accounting year, in order to carry out a set of core activities[10] |
| **Direct grants to international organisations** | They are awarded to international organisations, such as the WHO, with the capacities needed to tackle relevant health priorities. |
| **Joints actions** | They have a clear EU added value and are co-financed either by competent authorities that are responsible for health in the Member States or in the participating third countries, or by public sector bodies and non-governmental bodies mandated by those competent authorities[11] |
| **Procurement contracts** | These contracts cover specific needs related to the support of EU health policies (e.g. studies, development of IT tools, etc.)[12] (Also called service contracts or tenders) |
| **Presidency Conferences** | Thematic conferences on health topics such as personalised medicine to mark Presidency of the EU. |
| **Others** | For example: "Payment of membership fee and reimbursement of expert mission costs", "Reimbursement of auditor mission costs", "Cross sub-delegation to EUROSTAT". |

The total budget for 2014-2016 is split between the seven funding mechanisms. Figure 2 below illustrates how and compares this to the second Health Programme. The largest part of funding is allocated to joint actions (30%), procurement contracts (27%) and projects (24%). Already in the second Health Programme, a progressive shift in funding from projects to joint action was provided, which also applies to this Programme. Smaller proportions of the budget were reserved for operating grants (9%) and direct grant agreements (7%). "Other" mechanisms and conferences took only 2 % and <1 %, respectively, of the total funding in the first three years.

[8] http://ec.europa.eu/chafea/health/index.html

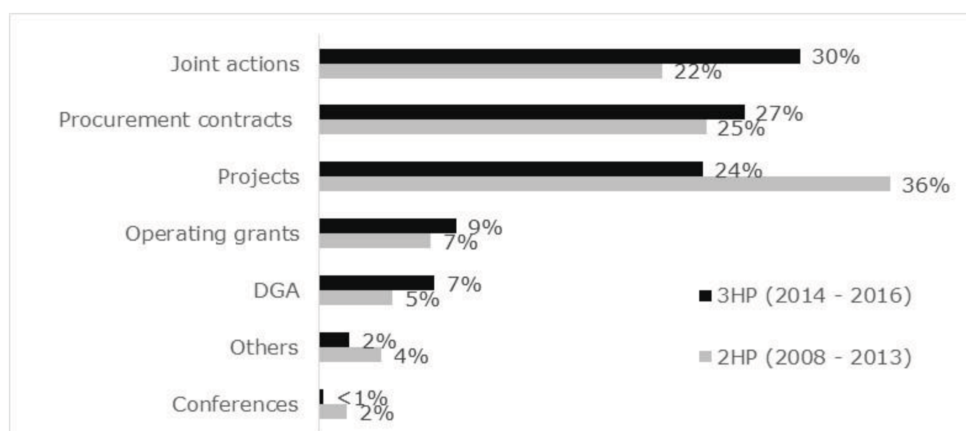
[9] http://ec.europa.eu/chafea/documents/health/hp-factsheets/project-grants/factsheets-hp-pg_en.pdf

[10] http://ec.europa.eu/chafea/documents/health/hp-factsheets/operating-grants/factsheets-hp-og_en.pdf

[11] http://ec.europa.eu/chafea/documents/health/hp-factsheets/joint-actions/factsheets-hp-ja_en.pdf

[12] http://ec.europa.eu/chafea/health/tenders.html

**Figure 2: Proportion of total funding[13] by mechanism for 2HP and 3HP (2014 – 2016)**




Sources: DG SANTE and CHAFEA

The procurement contracts are mainly managed by CHAFEA while a smaller number are sub-delegations, administrative agreements and reimbursement of experts being implemented by DG SANTE.

**Table 4: Budget allocation between DG SANTE and CHAFEA, 2014 – 2016**

| | 2014 | 2015 | 2016[14] | TOTAL |
|---|---|---|---|---|
| CHAFEA | €44.4 M | €48.6 M | €47.2 M | €140.2 M |
| DG SANTE | €9.4 M | €6.8 M | €9.2 M | €25.4 M |
| **TOTAL** | **€53.8 M** | **€55.4 M** | **€56.4 M** | **€165.6 M** |

Source: CHAFEA and DG SANTE

### 4.3 Budget distribution per country

In the third Health Programme participate the 28 EU Member States, two EFTA countries (Norway and Iceland), and since 2016 Serbia and Moldova; in 2017 Bosnia and Herzegovina has also signed a bilateral agreement for participation in the Programme.

65% of the total budget for Joint Actions is distributed between seven of the EU 15 Member States (see graph below) and 52 % of the total budget for projects between four Member States (ES, IT, UK and NL). All organisations receiving below of the average funding are from low GNI countries.

13 Percentages are rounded to the nearest whole percentage point

14 Figures are rounded

**Figure 3: Allocation of funding for joint actions across participating countries**

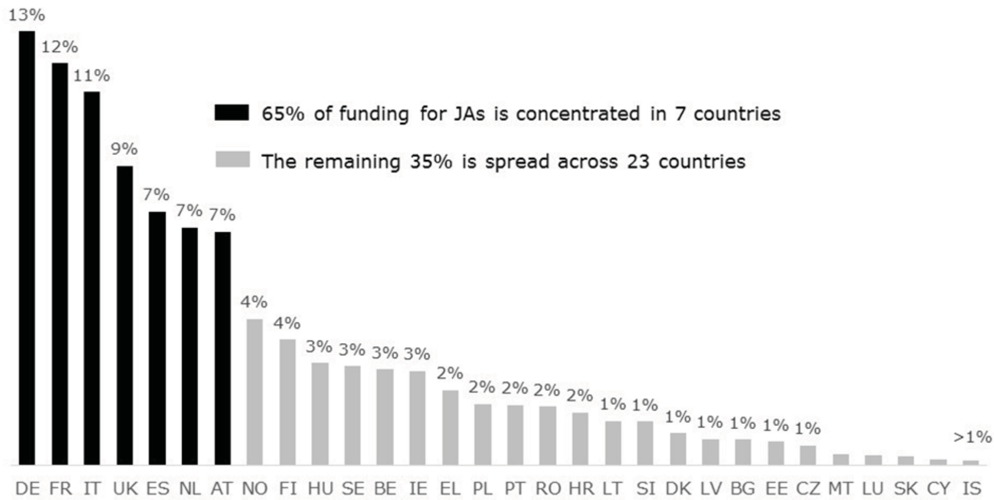



**Figure 4: Average funding received for organisations participating in joint actions by participating country**

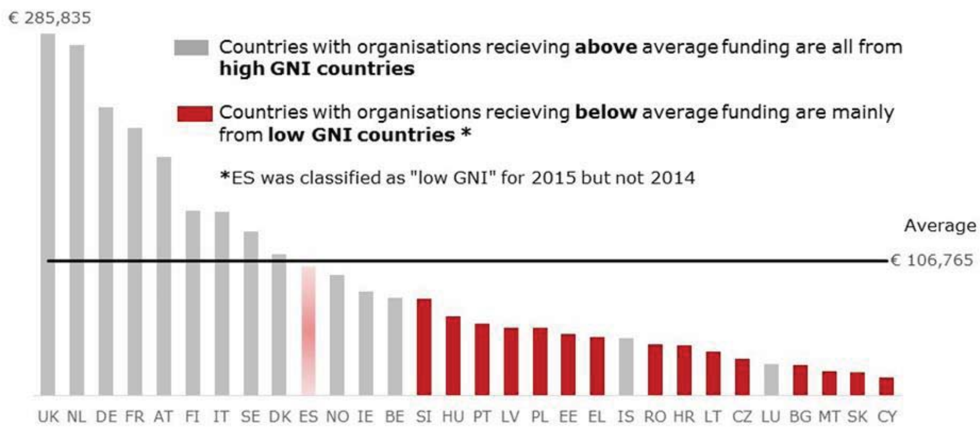
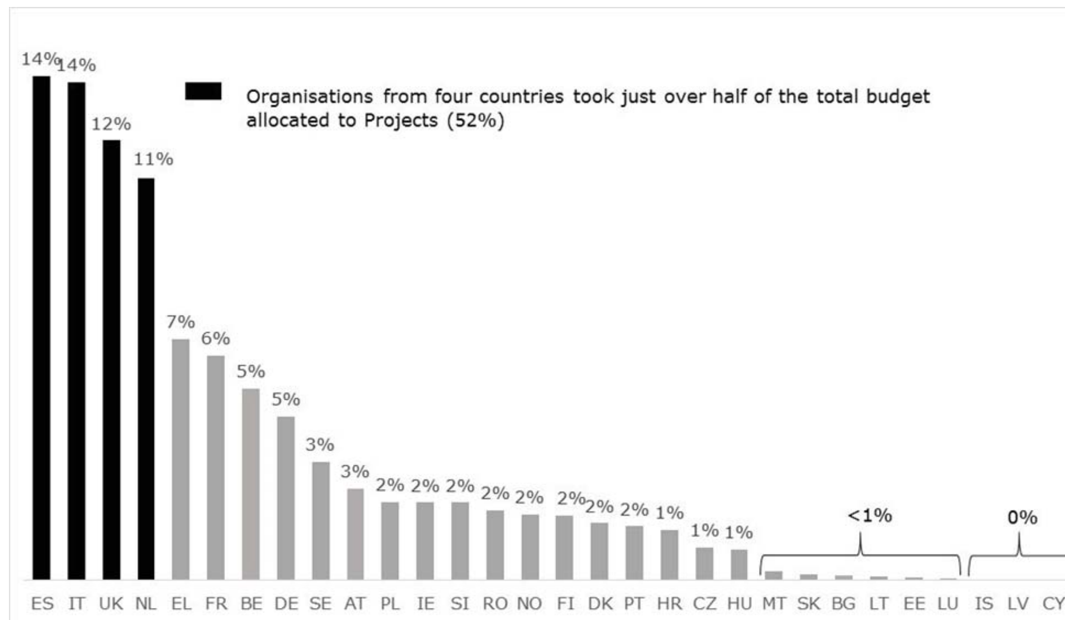



**Figure 5: Allocation of budget to organisations across participating countries, 2014 and 2015**



## 4. ANSWERS TO THE EVALUATION QUESTIONS

The main conclusions to each of the 16 evaluation questions (EQ) presented in the mid-term evaluation are summarised below.

### 5.1 Relevance

**EQ1: To what extent are the 3rd Health Programme objectives still valid and in accordance with health needs in Europe?**

The Programme objectives are valid and respond to emerging EU needs and evolving challenges. The replies of National Focal Points and Programme Committee members on what is the single most important reason for EU action (as opposed to action at the national, regional or local level) can be summarised as follows:

**Table 5: Why do Member States need an EU action following the Programme objectives?**

| Objective | Most important reason(s) given for EU action by mini-survey respondents |
|---|---|
| 1. Promote health, prevent diseases & foster supportive environments | **Exchange of best practice and expertise**, potential for mutual learning between Member States. At the EU level it is possible to promote activities and engagements that would **not otherwise be a priority for national government**. Also pooling resources was mentioned. |
| 2. Protect citizens from serious cross-border health threats | The fact that **communicable diseases are trans-boundary in nature** and require a trans-boundary response (the EU can support development of early warning systems which prevent the rapid spread of communicable diseases). |
| 3. Innovative, efficient & sustainable health systems | **Exchange of best practices** and innovation. EU action supports MS especially vis-à-vis eHealth and the EIP on active and healthy ageing. |
| 4. Facilitate access to better and safer healthcare | Responses here were wide ranging, somewhat reflecting the objective itself. Reponses ranged from citing **specific areas like antimicrobial resistance (AMR) and European Reference Networks where economies of scale** can be achieved through EU level action to the establishment of **common standards** to prevent disease and ensure equal treatment of all EU citizens thus creating greater cohesion among Member States. |

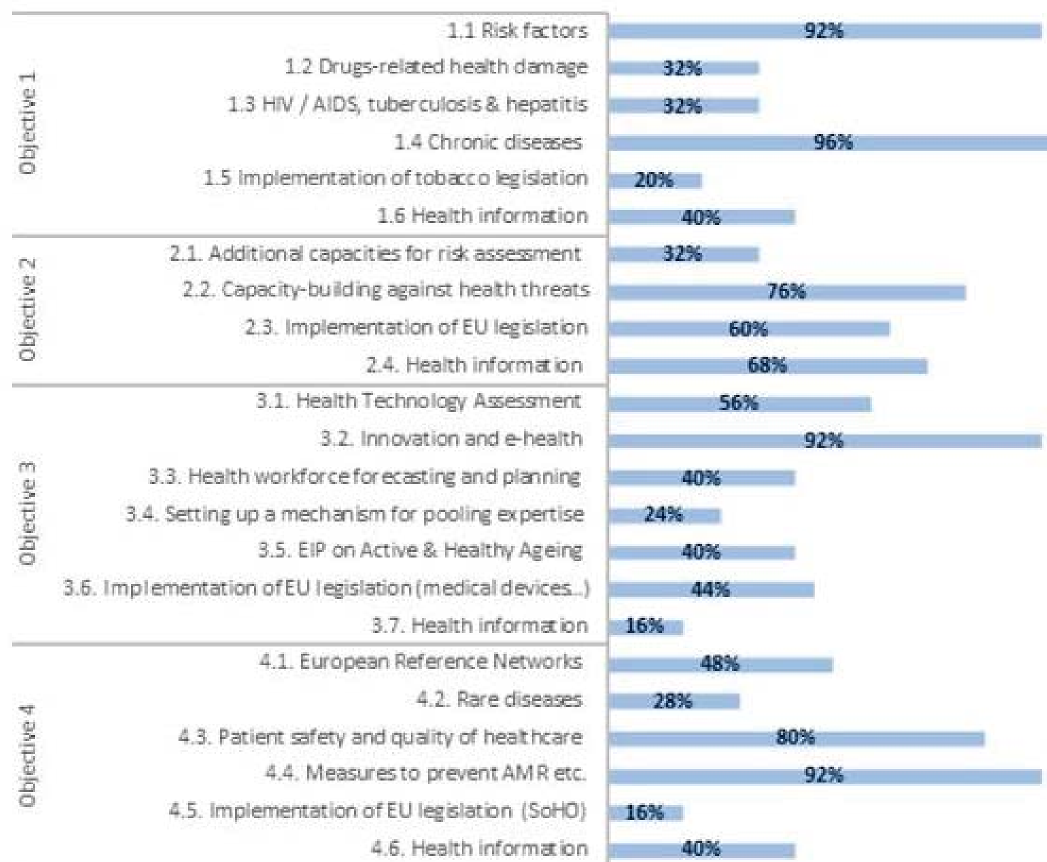
The Programme is addressing to a large extent the relevant health needs. In comparison to the second Health programme it has increased the focus on issues generating the most EU added value, while remaining flexible to respond quickly to emerging health needs. In some cases and despite the fact that the Programme covers mental health under the priority of chronic diseases, public health experts pointed out the need to have this as a distinguished thematic priority for attracting more attention on the importance of mental health issues.

Moreover, the evaluation found that the division in the rationale for action under the objectives is visible. The potential EU-added value is clearest for objective 2 (cross-border health threats) and 4 (access to healthcare), which seems to attract less attention in the Member States but the EU role is clearer in the sense that Member States would struggle to address them on their own. Objective 1 (health promotion) and 3 (health systems) draw larger resources and there the Health Programme can enable the exchange of best-practices and knowledge sharing.

**EQ2: To what extent are the 3rd Health Programme thematic priorities sufficient and sufficiently covered to achieve the 3HP objectives and Commission wider priorities?**

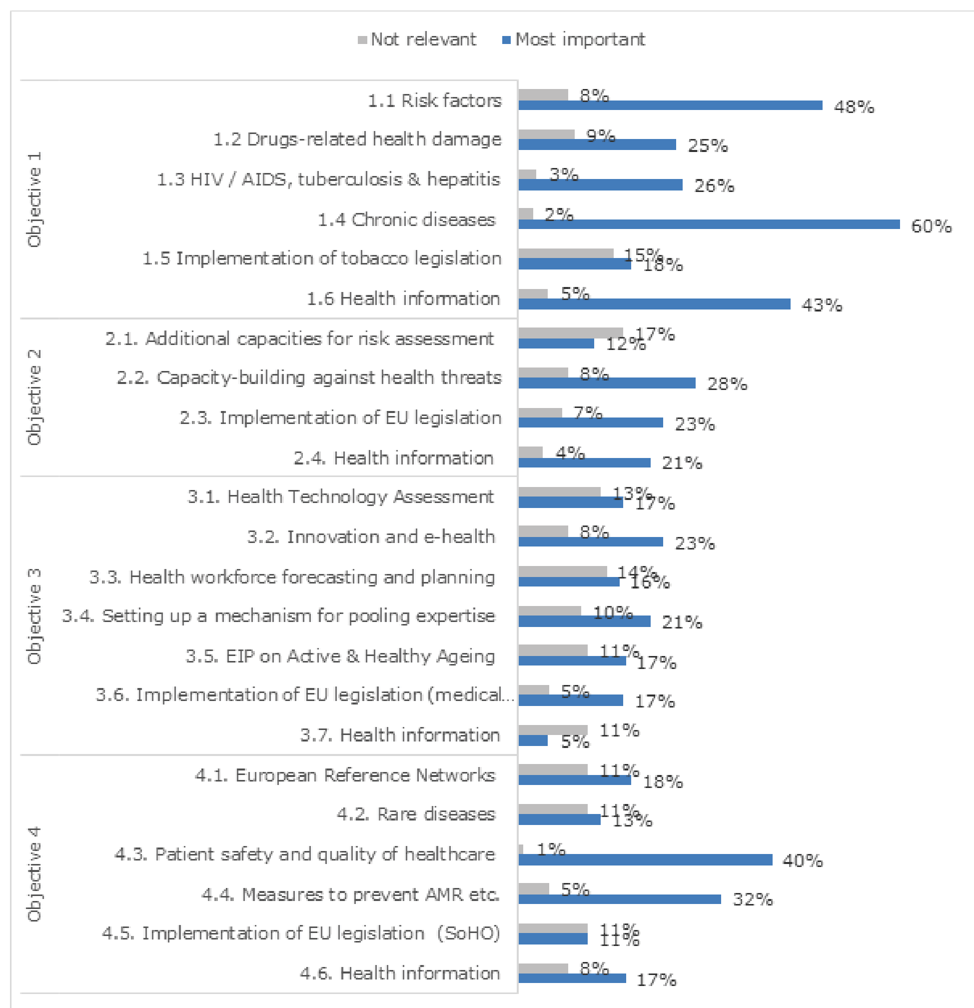
The thematic priorities are successful in defining the purpose of the Programme more precisely than its predecessor programmes thus increasing its coherence and focus. They are relevant and reflect well health needs of Member States. They also serve in the need for actions to be more aligned with high priorities of Member States and with wider policy objectives of the European Commission. Not enough Member States health policy documents were available for the evaluators to rank their priorities, but replies from the National Focal Points and the Programme Committee members on the three thematic priorities that are most important for public health in their country in relation to each objective of the Programme[15] together with replies to the Open Public Consultation provided further insights and showed consistency in priorities among stakeholders and also with the real Programme spending.

**Figure 6: Importance of thematic priorities for public health in Member States according to the Survey with Programme Committee members and National Focal Points**




15 Graphic 1 presents an overview of the responses received (with the percentages of respondents who have chosen each option). The sum up of %ages can be over 100%

**Figure 7: Respective importance of the 23 thematic priorities according to the open public consultation, (number of contributions = 133)**




Objective 1 (health promotion): Risk factors (1.1) and chronic diseases (1.4) are overwhelmingly cited as most important in both surveys.

Objective 2 (cross-border health threats) : the most frequently selected as important thematic priorities are capacity building against health threats (2.2), Health information and knowledge systems to evidence-based decision making (2.4) and the Implementation of EU legislation for cross-border health threats(2.3)

Objective 3 (health systems): respondents seem to agree that innovation and eHealth (3.2) is the most important in this context.

Objective 4 (access to health care): measures to prevent antimicrobial resistance and control healthcare associated infections (4.4) together with patient safety and quality of healthcare (4.3) attract the interest of Member States' representatives and Programme stakeholders.

Stakeholders did not miss any priorities in the list though some wanted more visibility for mental health (currently this is an item under chronic diseases). In the open public consultation other specific areas such as endocrine disruptors in air, soil and water were mentioned that are covered under the environmental programme[16]. On the issue of endocrine disruptors the Scientific Committees financed under the Programme have also issued two opinions[17].

[16] http://ec.europa.eu/environment/chemicals/endocrine/index_en.htm

[17] http://ec.europa.eu/health/sites/health/files/scientific_committees/emerging/docs/scenihr_o_047.pdf
http://ec.europa.eu/health/sites/health/files/scientific_committees/emerging/docs/scenihr_o_040.pdf

**EQ3: To what extent are the actions prioritised in the Annual Work Plans (AWPs) relevant vis-à-vis the 3rd Health Programme's thematic priorities?**

The Health Programme focused and prioritised actions mainly on chronic diseases in Annual Work Programme 2014, Health Technology Assessment in 2015, and the establishment of European Reference Networks in 2016, while actions for increasing the capacity of Member States to respond to cross-border health threats were continuously supported by the Programme throughout the first three years with a particular focus on the refugees' crisis in years 2015 and 2016. All these actions were supported by substantial budgets and correspond to the four Programme objectives (1) for health promotion and disease prevention, (2) for preparedness and crisis management, (3) for innovative and efficient health systems and (4) for better and safer health.

The evaluation examined in the case studies and assessed positively the relevance of these actions[18] and reconstructed the intervention logic of the thematic priorities showing how the actions contribute in the Programme objectives (see in Annex IV).

The current structure of the Programme with explicit objectives and relevant thematic priorities serves to ensure the appropriateness of individual actions. The funded actions have shown to correspond to health needs and are built on clear and relevant objectives, especially when a legal basis exists in the fields of their predilection. In this case the action focuses immediately on achieving concrete outputs (e.g. the establishment of European Reference Networks). Otherwise, for broader priorities in fields without legal commitment (e.g. chronic diseases, expert panel on Health) it is necessary to anticipate collective thinking which is conducive to better planning and agreed objectives already in the design phase of the actions.

The choice of the financial mechanism is also an important aspect and in the case of operating grants it became obvious that this financial mechanism enshrined in the Programme Regulation, supports more a mission rather than specific objectives. This means that the relevance of the mission should be assessed and monitoring and evaluation processes should be available for keeping track of how the organisations benefiting from operating grants perform in relation to the health policy priorities.

**EQ4: To what extent are the actions co-funded through the AWPs relevant to achieving the objectives set out in Article 168 TFEU?**

This evaluation question was addressed together with evaluation question 15 on the coherence and consistency of the Health Programme.

### 5.2 Effectiveness

**EQ5: To what extent is the process for defining and prioritising actions through Annual Work Programmes (AWPs) transparent, equitable and impartial?**

Each year an Annual Work Programme is prepared by DG SANTE in close coordination with the Member States and adopted through Comitology (examination procedure). The Annual Work Programme identifies the actions, describes the desirable outcomes and results, decides on the financial mechanisms to be used for each of the actions and the criteria for the selection and award of funding. This is the master piece in the successful Programme implementation and the contractors approached the question by examining to what extent the Annual Work Programme is open to scrutiny by the relevant stakeholders (transparency), whether its preparation includes the fair participation of and consideration of actors concerned (equity) and is free from political bias (impartiality).

[18] With the exception of Health Technology Assessment.

The evaluation found that the formal process for setting Annual Work Programmes is largely transparent, equitable and impartial.

The formal consultation process includes two rounds of discussions and a final agreement with the Programme Committee which is comprised of Member States representatives. Draft versions of the Annual Work Programme are presented in time, discussed and voted on, while a summary of the procedure, views expressed and decisions taken is recorded with minutes that are also sent to the European Parliament. Given this is made publicly available, it can therefore be considered to be both well-documented and open to scrutiny.

The formal consultation of Member States, CHAFEA and other European Commission departments works well and annually defined priorities synthesize actions in line with current public health needs.

The Programme legal basis provides for an informal consultation[19] with the relevant experts, including National Focal Points. This is done from 2016 onwards only with the Programme Committee Members as an informal consultation before the formal Comitology opinion.

On this informal procedure there is minor criticism on its transparency and fairness implying that some Member States are more influential than others.

The aspects of fairness and transparency in the consultation process are important for the involvement of all countries in the planning process. Some countries feel also that a growing proportion of funding is dedicated to top-down financial mechanisms, such as joint actions and procurement contracts leaving fewer possibilities for Member States to promote their ideas for other actions.

Respondents to the open public consultation asked also for greater transparency implying that there is limited awareness of the consultation processes outside the Programme's core stakeholder groups.

**EQ6: How effective was the Multi-Annual Planning (MAP) for the preparation of the Annual Work Programmes?**

The evaluation shows that the Multi-Annual Planning has improved the preparation of Annual Work Programmes.

Following recommendations from evaluations of previous Programmes, for the third Health Programme the Commission introduced the Multi-Annual Planning as an internal planning exercise in order to incorporate a more holistic, longer-term mind-set into the programming process.

The first Multi-Annual Planning covered the years 2014-2016 (which is the chronological scope of the mid-term evaluation) and explained in an internal note its caveat in planning ahead in the more distant future. A second Multi-Annual Planning exercise was organised in the second half of 2016, covering the remaining years 2017-2020.

The Multi-Annual Planning has contributed to a smoother and faster process for agreeing the Annual Work Programmes. Moreover, it proved to be quite accurate. Taking the number of amendments to the work programme as an indicator we can see a clear reduction of amendments from the second to the third Health Programme; in the second Health Programme, three out of six annual work programmes needed amendment indicating that the planning was not so effective or lacked flexibility. Until now the third Health Programme needed to be amended in 2015 under specific circumstances for helping Member States to cope with the refugees' crisis.

The coherence between the Multi-Annual Planning and the Programme implementation is a measure of its effectiveness as it illustrates that the Multi-Annual Planning not only facilitated the drafting of the Annual Work Programmes but that it was realistic and accurate; its objective was not to set plans in stone but rather a plan which will be flexible to new/unexpected developments (refugees crisis) or to changing timetables (delay in the adoption of legislation for medical devices).

[19] See Regulation (EU) N° 282/2014 whereas n° 33): *"In the application of the Regulation, the Commission should consult the relevant experts, including National Focal Points".*

Moreover, the main focus for years 2014, 2015 and 2016, respectively on prevention of chronic diseases, health technology and innovation and establishing European reference Networks, has been confirmed and acknowledged by the mid-term evaluation.

The independent study found that the introduction of the Multi-annual Planning has improved the ability to purposely focus spending on key areas as reflected in the data provided in detail under efficiency (EQ9).

**EQ7: How effective is the introduction of 'exceptional utility' criteria in the Regulation establishing the 3HP (paragraph 19) in order to incentivise the participation of low GNI Member States?**

The exceptional utility criterion has not been so far effective in incentivising the involvement of low GNI Member States and helping them to be more actively involved and absorb bigger parts of the Programme budget.

The exceptional utility criterion addresses a significant problem for low GNI countries to participate in the Programme. While exceptional utility was also used in the previous Health Programme, the 'exceptionally utility' criterion was enshrined for first time in the Programme Regulation (EU) N° 282/2014 covering only Joint Actions. The rationale behind was to incentivise low GNI countries and keep them participating in the Health Programme especially under the difficult economic circumstances of the financial crisis started after 2009-2010. From the beginning of the Programme implementation in 2014, the criterion has been slightly adapted and has been extended to cover also grants for projects and operating grants.

The new criteria (for their definition see Annex III) were providing for a greater number of countries to be considered for applying higher co-funding rate (up to 80 % for EC contribution).

**Table 6: MS triggering higher co-funding in 2HP and 3HP**

| | BG | CY | CZ | EE | ES | EL | HR | HU | LT | LV | MT | PL | PT | RO | SI | SK | TOTAL |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2HP | ● | | | | | | ● | ● | ● | ● | | ● | | ● | | | **7** |
| 3HP | ● | ● | ● | ● | ●[20] | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | **16** |

However, there is no evidence that participation of low GNI countries is incentivised by the simplified, extended and expanded exceptional utility criteria. On the contrary contractors found examples where both joint actions and projects were fulfilling the criteria but they have not applied for 'exceptional utility' funding of up to 80 %.

In the first three years of Programme implementation the part of funds awarded to high and low GNI countries seem to show a rather retro-gradation (see the below table) implying that either the criteria are not clearly understood by the applicants, or that other unknown factors may intervene.

[20] Taken as low GNI country for 2015 only

**Table 7: Balance of funds to joint action beneficiaries from low and high GNI countries**

| | Low GNI | High GNI |
|---|---|---|
| 2HP | 29% | 71% |
| 3HP[21] | 25% | 75% |

Source: CHAFEA

For projects the situation is also quite similar with no difference between the second and third Heath Programmes.

**Table 8: Balance of funds to projects beneficiaries in low GNI and high GNI countries**

| | Low GNI | High GNI |
|---|---|---|
| 2HP | 28% | 72% |
| 3HP[22] | 26% | 74% |

Source: CHAFEA

The instrument has a low up-take so far and functions less for projects and joint actions in comparison to the operating grants (14 out of 41 of them received exceptional utility). Possible reasons for this low take-up are limited awareness or understanding of the criteria or that the criteria are insufficiently addressing the needs of the GNI countries and so less attractive to overcome other challenges. Indeed, securing co-funding is very important for low GNI countries (11 respondent to the e-survey with National Focal Point and Programme Committee members corresponding to 44% of the total selected and from those eleven, seven are from low GNI countries) but is not the only barrier of participation.

Administrative burden is also mentioned as quite prohibitive by respondents from high GNI countries while irrespectively of the relative income of a given Member State, lacking skills and institutional resourcing challenges were also cited.

**EQ8: In practice, to what extent are the actions in the AWP contributing to the 3HP objectives and thematic priorities and to the Commission policy priorities?**

The Health Programme is being implemented focusing on major Commission priorities, such as: (a) jobs, growth and investment (health of population and health care services as a productive factor for growth and jobs), (b) internal market (for tobacco, pharmaceuticals, medical devices, cross-border health care directive, and Health Technology Assessment), (c) digital single market (including eHealth), (d) justice and fundamental rights (fighting against health inequalities), (e) migration policy, and (f) security (preparedness and management of serious cross-border health threats).

From the evidence provided by the case studies (29 actions corresponding to 8 thematic priorities), contractors showcase key examples of meaningful achievement:

Diagnostic microbiology provides crucial results for the clinical management of infectious disease patients, but also for the identification of a given pathogen for public health surveillance, outbreak alert and response. The Commission supports Member States' cooperation on laboratories under the

[21] The figure corresponds to 2014 and 2015 committed spending

[22] Years 2014 and 2015 committed amounts only.

EU Health programme to strengthen preparedness and response to serious cross-border threats to health. The funded laboratory networks addressed preparedness activities aiming at continuous quality improvement in the rapid diagnosis, surveillance, epidemic intelligence and public health risk assessment for infectious diseases as well as risk management activities through rapid identification and characterization of infectious agents which may threaten public health.

The establishment of 24 European Reference Networks is also a key achievement for the development of better and safer healthcare, after years of previous work on rare diseases, and facilitating the implementation of Directive 2011/24/EU on patients' rights in cross-border healthcare (see point 2.2.4 above).

Moreover, the Programme's major contribution to innovative, efficient and sustainable health systems are the approaches to the implementation of Health Technology Assessment (a subject on which the Programme works since 2002-2007). Now under the third Health Programme, the biggest Joint Action to date with EUR 12 million aims to anchor these in Member States practices. As already described under point 2.2.3, the cooperation is currently based on a voluntary mechanism supported by Article 15 of Directive 2011/24/EU which provides that the EU cooperation on Health Technology Assessment can receive EU aid. Although successful, there are also identified shortcomings in the current cooperation arrangement. The Commission is currently finalising an Impact Assessment assessing different options how to strengthen cooperation thus building on the achievements of the Joint Actions, address their shortcomings, and ensure sustainability of the cooperation beyond 2020 when the current Joint Action ends.

In parallel, the Health Programme supports wider Commission priorities such as the Digital Single Market by assisting Member states in including eHealth into health policies while better aligning eHealth investments to health needs[23]. Mechanisms such as the Expert Panel on Health and the Expert Group on Health Systems Performance Assessment produced opinions and advice for the benefit of Member States in the context of the health systems' reforms.

The support to legislation on medicinal products and medical devices guarantees the free movement of these products in the internal market, the safety of Europeans and is also related to the good performance of health systems. The actions funded concern the development and maintenance of databases e.g. the European Database for Medical devices (EUDAMED), which gives relevant agencies in Member States access to information on medical devices available on the market[24] and the list of economic operators; management of marketing authorisations for medicinal products and of maximum residue limits of veterinary medicinal products practices (e.g. European Medicinal Products database);, the issuing of guidelines for harmonised practices, inspector training programmes implemented for medical devices, studies for informing the relevant regulatory frameworks for medicinal products and medical devices.

The Health Programme has supported the identification, dissemination and takes up of best practices in risk factors and chronic diseases (for more information please refer to above point 2.2.1).

The Programme supports also the collection of indicators and data for the State of Health in Europe and the European Core Health Indicators.

The nature of contribution is different from one action to another and among the different objectives they serve. For instance while objectives 2 (health threats) and 4(better and safer health) have appeared likelier to generate concrete benefits in the near future, related to the existence of EU legislation and consequently much better focused actions with undisputable EU-added value, objectives 1(promotion of health) and 3(innovation in health systems) address bigger health needs in

[23] http://jasehn.eu/

[24] Instructions for use, clinical data, post-market surveillance data including vigilance information and information about the economic operators (manufacturers, importers, …) and the notified bodies certifying the medical devices.

Member States and their EU-added value depends on identifying gaps in the sharing/uptake of best practices.

Actions, especially under objectives 1 and 3, are in need of improved intervention logic and credible plans for follow-up. There are also some common challenges for generating sustainable impacts, for instance by ensuring that activities are anchored in the Member States and local contexts, that there is ownership of and input in the results. Also accessibility of the programme to all Member States and other participating countries (see question on exceptional utility) and new players is another important aspect for the success of the Programme objectives.

#### 5.3 Efficiency

**EQ9: To what extent does the design of the 3HP lead to an efficient allocation of resources among objectives / thematic priorities?**

The Programme Regulation (EU) 282/2014 does not include an obligation for spending precise amounts of the EU budget on the four specific objectives and the 23 thematic priorities. On the contrary the legislation provides for enough flexibility and paragraph (5) states that:

> *'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'.*

This said, the Programme has to cover the maximum of the 23 thematic priorities still valid (as concluded by the independent evaluation study) while prioritising and focusing more on some of them.

The table below shows that more than 73% of the overall Programme budget in 2014-2016 was used to focus on a series of major priorities throughout the four specific Programme objectives. Another 23 % has been attributed to actions that are of high EU-added value but on which important synergies exist: it needs to be noted that other funding programmes/actions cover similar objectives. For example health threats are addressed by the European Centre for Disease Control, which has an annual budget of nearly EUR 60 million dedicated to fighting communicable diseases, and by DG RTD with research funding on rare diseases and antimicrobial resistance.

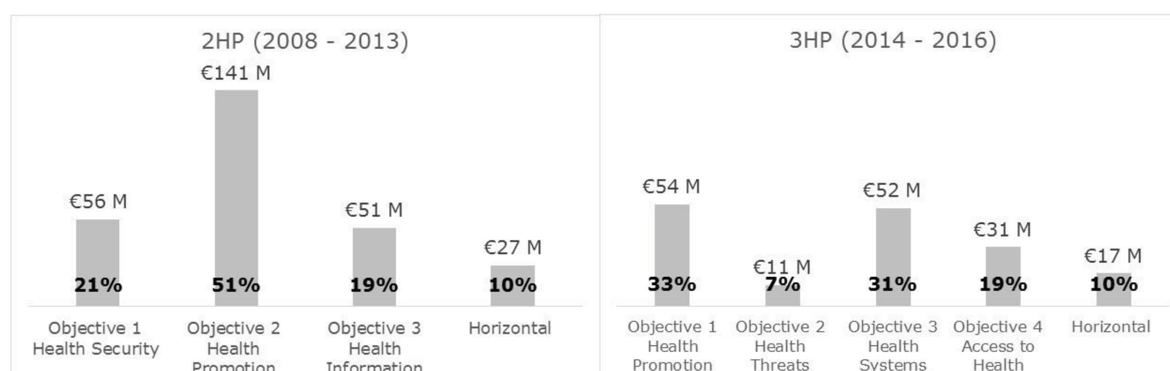
A very small part of the Programme (approximately 4 %) has been used for supporting action in areas such as the health workforce, the prevention and information on drugs related health damage and the expert panel on health. eHealth is an exception under this category and funds for this priority will be increased in the second half of the Health Programme (see below under EQ 16) as the interest in this area increases with the Digital Single Market Strategy. The Health Programme will work more intensively in the coming years to help policy-makers to better understand the digital revolution that is taking place across societies and bring this broader perspective to the specific work on digitalisation in health making sure that Europeans can benefit from the new era of digitalisation in managing their own health.

### Table 9: Budget allocation throughout the thematic priorities

| Priorities receiving more than 12 million | | receiving between approximately 5 to 8 million | | Priorites receiving less than 3 million | |
|---|---|---|---|---|---|
| **Chronic diseases (incl.cancer, mental health and dementia)** | 17.2 | Horizontal activities (incl. communication and dissemination activities) | 7.8 | **Innovation in eHealth** | 2.8 |
| **Risk factors** | 14.6 | **Capacity buiding and legislation on health secutity** | 7.5 | **Mechanisms to pool expertise** | 1.8 |
| **Actions on Migrants and Refugees** | 14.4 | **Union legislation on Blood, tissues and cells** | 7.3 | **Health Workforce** | 1.3 |
| **HYIV/AIDS- Tuberculosis & hepatitis** | 13.2 | **Patient Safety and Antimicrobial Resistance** | 6 | **Drugs related health damage** | 0.6 |
| **Health Technology Assessement** | 12.7 | **Rare diseases** | 4.7 | | |
| **European Reference Networks** | 12.6 | **Tobacco legislation** | 4.7 | | |
| **Health information** | 11.8 | | | | |
| **European Innovation on Active and Healthy Ageing** | 12.2 | | | | |
| **EU legislation on medicinal products and medical devices** | 12 | | | | |
| | | | | | |
| *Total amount* | 120.7 | *Total amount* | 38.0 | *Total amount* | 6.5 |
| *% of budget 2014-2016* | **72.89%** | *% of budget 2014-2016* | **22.95%** | *% of budget 2014-2016* | **3.93%** |

As a consequence, the budget allocation in the first three years of the Programme implementation is in comparison to the past Programme, more strategic and balanced among the different specific objectives as the table below shows:

**Figure 8: Budget allocation by objective 2HP and 3HP (2014 – 2016)**




Although the design of the third Health Programme is different from the second, the above observation is quite clear as depicted in the following figures. Objective 1(health promotion) has seen its budget decreased, the new objective 3 (innovation in health systems) receives a similar proportion of budget as objective 1, and objectives 2(health threats) and 4(better and safer health) which with the exception of ERNs and rare diseases cover what in the previous Programme was called 'health security' have received together with the priority 'HIV/AIDS, tuberculosis and hepatitis' (currently under objective 1)[25] slightly more credits[26] than before.

[25] This priority under the previous second Health Programme was under objective 'Health Security'.

**EQ10: To what extent does the allocation of resources allow for an efficient implementation of the 3HP in terms of: funding mechanisms, simplification measures and operational costs?**

The implementation of the first three years of the Programme confirms trends appeared already at the end of the second Health Programme. The part of the budget dedicated to Joint Actions and procurement contracts continue to be increased in comparison to grants for projects. Moreover, the average budget per action increases also and this is a good indication that the Programme becomes more focused as the consequence is to limit the number of actions. Ultimately the aim is to gain in efficiency.

**Table 10: Average budget of financial mechanisms, 2HP and 3HP**

| for the submission and evaluation of proposals the management of grants and e-reporting and monitoring **Financial mechanism** | **Average budget per action** | |
|---|---|---|
| | **2HP** | **3HP** |
| Joint action | €2.1 m | €3 m |
| Project | €0.7 m | €1.3 m |
| Operating grant | €0.2 m | €0.3 m |
| Direct grant agreement | €0.4 m | €0.3 m |
| Service contracts – CHAFEA | €0.2 m | €0.4 m |
| Service contracts – DG SANTE | €0.2 m | €0.07 m |
| Conferences | €0.07 m | €0.07 m |

Also the costs needed to administer the third Health Programme, provided for an overall of EUR 10.5 million as administrative support credits and another EUR 29.2 million for the functioning of the Executive Agency, for 2014-2020, suggests that the percentage of the total budget proportion dedicated to operational costs is 9 %. Benchmarking with other programmes of similar size (consumer programme) and with much higher budget (Horizon 2020) demonstrated its efficient execution.

**Table 11: Budgetary data for 3HP, Consumer Programme and Horizon 2020 (2014 – 2020)**

| **Programme** | **Administrative support budget** | **Executive Agency budget** | **Total budget** | **Proportion of total budget to administrative support and executive agency** |
|---|---|---|---|---|
| Health Programme | €10.5 m | €29.2m | €449.4 m | **9 %** |
| Consumer Programme | €7.5 m | €10.9 m | €188.8 m | **10 %** |
| Horizon 2020 | €3 594.6 m | €946.2 m | €74 320.4 m | **6 %** |

Moreover, some simplifications already in the design of the Programme such as harmonisation of co-funding rates to 60% (or in case of exceptional utility to 80%), the use of framework contracts on a three years period for the operating grants, simplifications to requirements for amendment procedures, most importantly the ability for beneficiaries to transfer resources between different cost categories without the need for an amendment, the introduction of the Multi-annually planning all these converge into a smoother and less complex Programme implementation.

[26] All together represent EUR 37.5 million which corresponds to 22.6 %; see detail in the list with budget per thematic priority.

Despite the fact that electronic tools have been introduced with the third Health Programme in 2014 for the submission and evaluation of proposals, the management of grants and e-reporting and monitoring, and Programme beneficiaries are satisfied with the online migration of action-level monitoring (it has reduced the administrative burden for both CHAFEA and beneficiaries while making it easier to monitor progress in real time), the administrative burden mentioned by stakeholders as one of the key barriers for participation in the Health Programme (especially from Member States representatives from high GNI countries) and confirmed again through the open public consultation, implies that there is still room for improvement in the efficiency.

However, the contractors recognize that actions require significant investment from all stakeholders for being well prepared and that more importantly and irrespectively of the size of an action, the biggest driver for efficiency is how effective the action is in achieving its goals and therefore the value added.

**EQ11: How may the efficiency of the 3HP be improved regarding number of priorities; funding mechanisms; application and implementation procedures and available resources?**

Increasing the effectiveness and impact of a Programme also increases its efficiency. That is why it is important to keep the Programme focused on a limited number of outcome-oriented actions relevant to Member States needs and aligned to the major Commission priorities.

Although no specific recommendation was made, the independent evaluation study did suggest revising the mission of operating grants to non-governmental organisations and making the link with the specific Programme objectives more explicit.

Additionally, choosing the most appropriate financial mechanisms (see table 7 above) and publishing clear descriptions of the expected outputs in the Annual Work Programme, after having made a good estimation of the necessary budget for the actions, gives stakeholders and other economic actors everything they need to prepare good proposals and/or offers and facilitates effective administrative management for the selection and award of actions to be funded (e.g. avoiding the re-launch of calls for proposals and calls for tenders and making the best use of CHAFEA resources).

Moreover, simplification measures that have been already taken by CHAFEA (e.g. introduction of electronic tools for the e-submission of proposals, e-managing grants and tenders and e-reporting) are expected to yield positive results and in the next years make for more efficient use of CHAFEA resources to improve the monitoring, reporting and dissemination of Programme results, which will also have a positive impact on the Programme's efficiency.

**EQ12: To what extent are the monitoring processes and resources (at the Commission and MS level) sufficient and adequate to plan and promote the results of the Health Programme?**

Following up from the findings on the second Health Programme, substantial efforts have been made to improve the monitoring of the third Health Programme. Indicators at the level of objectives have been introduced[27].

*For Objective 1 (promotion of health and diseases prevention) :* Number of Member States involved in health promotion and diseases prevention, using evidence-based and good practices through measures and actions taken at appropriate level in the Member Sates

- Number of Member States with national initiative for the reduction of saturated fat;
- Number of Member States in which the European accreditation scheme for breast cancer services is implemented –establishment of the scheme.

[27] Please refer to the point 2.2. *'Expected outputs, results and impacts'*

*For Objective 2 (health threats):* Number of Member States integrating coherent approaches in the design of their preparedness plans;

*For Objective 3 (health systems):* Advice produced (in particular the number of HTA produced per year) and the number of Member States using the tools and mechanisms identified in order to contribute to effective results in their health systems (patient summaries data/ePrescriptions in line with EU guidelines)

*For Objective 4 (better and safer health):* Number of ERNs established in line with Directive 2011/24/EU; number of health care providers and centres of expertise joining ERN; number of Member States using the tools developed.

These indicators are still far from being comprehensive. In some cases they are much narrower and more focused than the priorities outlined in the Annex I of the Programme Regulation. For objective 4, the indicator is related only to ERNs which are certainly a big part (EUR 12.6 million) of the overall budget devoted to this objective (EUR 30.6 million).

The diversity of actions funded makes it difficult to design and implement standardised indicators (at objective and/or at priority level) beyond the delivery of concrete actions. For this reason and in addition to the above indicators at Programme level, a set of more specific indicators have been defined and, through the use of e-management tools allowing for electronic monitoring at action level, have been introduced as e-questionnaires for all grants (operating grants, grants to projects, joint actions and direct grants). The idea is to gather information on type of beneficiary, deliverables and the concerned and targeted population as well as dissemination strategy deployed and dissemination activities implemented as part of the action. These indicators common to all actions (with the exception of operating grants) could facilitate aggregation and later assessment of EU-added value.

For operating grants the indicators also include a particular set of indicators on support given on the development of health policies to the Commission, support to patients' empowerment and increase of health literacy.

Unfortunately, due to time constraints the study found little evidence of how the specific indicators for projects, joint actions and direct grants have been used, and therefore was not possible to analyse the information and assess its accuracy for reporting purposes. The e-questionnaires were sent to beneficiaries in late 2016, while the ones for operating grants should have been available for the evaluation since it has been in place for a while.

The problems with the monitoring of the Health Programme are well known also from evaluations of previous Programmes. In those cases, the main reason was the complete absence of monitoring indicators. The mid-term evaluation revealed that despite the substantial efforts for the definition of indicators, significant shortcomings continue to be unaddressed. Information is not stored or organised in an efficient manner so that data are ready to be analysed. The fact that a part of the Programme is managed by CHAFEA and another smaller part by DG SANTE makes it difficult, in the absence of a well-design monitoring tool, to have rapidly the complete and correct picture of how the budget is spent and for which kind of outputs. Linking up data manually with thematic priorities and collate and cross-check the information, as we have done for the outsourced evaluation, is a very resource intensive exercise and prone to error.

It seems that the monitoring is used only for financial accountability purposes, but this is only a part of what has to be the monitoring of a Programme. With a good monitoring tool, the information gathered on actions and their state of implementation including information on progress indicators could be used to better publicise the activity of the Health Programme. By making results of actions and other information publicly available and trying to ensure that the results reach the right kinds of stakeholders, this can facilitate their take-up beyond those who are directly involved in the actions.

The creation of a new project database has been repeatedly postponed by CHAFEA and the existing one has not been updated with the new Programme actions neither improved at the moment this

document was being drafted. The project database[28] currently only contains all actions for year 2014, but no information for Joint Actions 2015, and no information about awarded actions in 2016. Moreover, none of the procurement contracts and direct grants are covered by this database, for all previous Programmes and for the current one.

Positive developments are noted on publication and dissemination actions. Info sheets[29] on 12 health topics and in all 23 EU languages have been published on the CHAFEA Website. CHAFEA together with the National Focal Points have run a variety of well-attended events: 16 events[30] have been organised in 2015-2016, and another 11 that are planned or already implemented in 2017. The report CHAFEA made on these dissemination activities has noted the high-level of satisfaction and success of these events organised mainly in Member States and financed under the third Health Programme.

CHAFEA has developed in cooperation with DG SANTE the dissemination strategy, this also recommended in the ex-post evaluation of the second Health Programme. The study notes the increasing prioritisation and professionalism awarded to dissemination' and mention also the Health Policy Platform[31] launched in 2016 by DG SANTE and the use made of it to disseminate information among relevant stakeholders for instance training packages for health professionals and frontline staff working with refugees and other migrants.

### 5.4 EU-added value

**EQ13: To what extent are the seven EU added value criteria addressed in proposals?**

The EU-added value is defined in the third Health Programme and enshrined in the Programme Regulation (EU) 282/2014 in paragraph (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.'*

The above with the exception of issues related to the internal market and the potential of innovation in health, come from the criteria the Executive Agency has defined and which were used in the second Health Programme.

With the third Health Programme these criteria became a clear while not distinctive part of the evaluation criterion 'contribution to public health in Europe' for Joint Actions and 'policy and contextual relevance' for projects and operating grants. The procurement contracts are not assessed for their EU-added value as this is part of the decision process for launching the procurement procedure and defined in the terms of reference.

The case studies investigating the application of the EU-added value criterion showed that the process for assessing EU-added value is improving and becoming more systematic. Building the EU-added value criteria into the application process for funding has been a major improvement: most of the

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28 http://ec.europa.eu/chafea/projects/database.html

29 http://ec.europa.eu/chafea/health/hp-infosheets_en.html

30 http://ec.europa.eu/chafea/news/news.html

31 https://webgate.ec.europa.eu/hpf/

potential beneficiaries consider EU-added value when preparing their proposals, and the assessment panels in turn take it into account as part of the decision to award funding.

The short time elapsed since the action plan agreed on recommendations of the ex-post evaluation of the second Health Programme in March 2016, was the main reason for specific recommendations on EU-added value to not being fully implemented by CHAFEA and DG SANTE. This is about the redefinition of three EU-added value criteria related to the exchange of best practice, networking and benchmarking for better decision-making. The recommendation was to make them more detailed, concrete and outcome focused (e.g. plausible plans to see best practices actually implemented than only shared). For best practices the discussion has already started in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases, established in November 2016[32].(see above point 2.2.1).

The study showed that there is still scope for being more systematic in the assessment of the EU-added value criteria and to make it clearer for applicants through concrete examples what the EU-added value is and how it feeds into the award process.

**5.5 Coherence**

**EQ14: To what extent have the thematic priorities of the 3HP led to more synergy, focus and coherence between the funded actions in delivering on the objectives?**

Compared to the previous Health Programme, the structure of the third Health Programme has been revised with improved specific objectives providing more clarity and focus, and further elements for operationalisation have been introduced which was not the case in the previous Programmes. Instead of longer priorities and sub-priorities often repeated under different objectives, now the third Health Programme has consolidated, concrete thematic priorities unique under each of the four specific objectives. In almost all cases actions now fall under one thematic priority, even if synergies with other priorities are possible, the increased purposiveness and topical focus of the thematic priorities enables greater clarity and coherence in the scope of actions. In some cases, it was possible to organise a sizeable action (e.g. 'Best practices in care provision for vulnerable migrants and refugees' in Annual Work Programme 2016) targeting on purpose two thematic priorities simultaneously (priority 1.3 on HIV/AIDS, tuberculosis and hepatitis, and priority 1.4 relating to chronic diseases. There is consensus from all interviewees, public health experts in focus groups, case studies and respondents to the open public consultation that the new structure of the Programme is a success enabling more concretely defined areas of intervention.

Moreover, synergies exist between the actions under the same or different thematic priorities. The structure of the Programme certainly enables such cross-cutting work, but most importantly this is the result of successful exploitation of relations between the different actors/beneficiaries as well as good programme management and communication with stakeholders. For instance the European Cancer League (ECL) which is funded through an operating grant under thematic priority 1.4 for chronic diseases has a memorandum of understanding with the Smoke Free Partnership which receives also an operating grant from the third Health Programme under priority 1.4 on risk factors, creating a framework for joint work and the sharing of perspectives. The ECL is also an associated partner in the CANCON joint Action (funded under the second Health Programme) and provided inputs on survivorship and rehabilitation throughout 2016. ECL uses the CANCON newsletter to promote the European Code Against Cancer one of its key activities funder by the operating grant.

Other examples illustrate how the third Health Programme builds on the success of previous work undertaken in the previous Programme. For instance the Joint Action EMERGE launched in 2014 is

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[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

the result of merging of two networks of highly pathogenic agents, funded in 2010 as the QUANDHIP Joint Action.

In some other cases, the sequencing of different actions (e.g. the Joint Action on rare diseases (RD-Action) which built on the work of the previous joint action in the second Health Programme and supports the adoption of a codification and knowledge management system for rare diseases, which will be necessary for ERNs to diagnose patients and share knowledge and expertise across the EU , together with the Study on the Manual and Toolbox for Assessing ERNs whose objective is to develop an assessment manual that will serve as an evaluation framework for ERNs, all that together prepares and contribute to the creation , implementation and operation of ERNs (see point 2.2.4).

However, there is still risk in areas where the third Health Programme has ambitious goals and the scope is broad (*e.g.* chronic diseases) to see actions fail either because they do not relate closely to other ones (different actions in different areas such as mental health, dementia, cancer) or simply because they cannot make the most of potential links.

**EQ15: To what extent are the objectives and thematic priorities of the 3HP externally consistent/coherent i.e. is there correspondence between: the 3HP and health objectives of Article 168 TFEU, and those of other public interventions (e.g. national health policies, EU policies and Programmes, other international actions)?**

The Health Programme is linked to the high-level priorities of Europe 2020 Strategy[33] and since 2015 is oriented towards the Commission 10 priorities[34] (known as "Juncker priorities") and DG SANTE strategic objectives.

It emphasises the links between economic growth and a healthy population, to a greater extent than previous programmes, concentrates on health systems as a productive factor for growth and jobs, contributes to smooth functioning of the internal market by supporting EU legislation on tobacco, medicinal products and medical devices, cross-border health care directive, and Health Technology Assessment, as well as to the digital single market with actions related to eHealth ; the Programme has demonstrated its ability to undertake rapidly appropriate actions for migrants and refugees[35] as migration is also an important issue, and fights against health inequalities for the respect of justice and fundamental rights. Last but not least, its actions on preparedness and management of serious cross-border health threats for a coordinated response to highly dangerous outbreaks (*e.g.* Ebola and Zika) ensure the protection of EU population's health and security.

In almost all the above mentioned areas the Work Programme works closely with other EU Policies and Programmes such as Horizon 2020 (*e.g.* on Health Technology Assessment, anti-microbial resistance etc.), migration policy, chronic diseases and reduced ability to work, taking into account the principle of ‘health in all policies’.

Other financial mechanisms such as the European Social Fund (ESF) and the European Regional Development Fund (ERDF) from the EU Structural and Investment Funds (ESIF) could also be better used to scale-up actions and results of the Health Programme as objectives and thematic priorities are coherent with these instruments. While the Programme informs about these possibilities and promotes ESIF, evaluators have not found evidence that this happens practically probably due to the early stage of the third Health Programme’s implementation.

[33] Regulation (EU) 282/2014 paragraph (2).

[34] https://ec.europa.eu/commission/priorities_en

[35] € 14.4 million was dedicated for actions on migrants and refugees, making this the second most important budget envelop behind chronic diseases.

At international level, through EuropeAid the EU supports global health initiatives such as the Global Fund to fight HIV/AIDS, Tuberculosis and Malaria, and GAVI, the Global Alliance for Immunizations. The Commission has been a founding member of the Global Fund and has contributed more than EUR 1.6 billion, which corresponds to about 6 % of the USD 30 billion that the Fund has committed to 140 countries so far. As a result, 10 million people are on anti-retroviral therapy for AIDS, 16.6 million people have been tested and treated for tuberculosis, and 713 million insecticide-treated nets have been distributed to protect families against malaria.

Commissioner Mimica pledged in September 2016 a further EUR 475 million to the Global Fund for the period 2017-2019, which is an increase of EUR 105 million (or 28 %) to the current contribution. GAVI has supported the full vaccination of 277 million children in 2010-2015, with the goal of a further 300 million fully vaccinated children in the period 2016-2020. These global initiatives complement thematic priority 1.3 on HIV/AIDS.

Tuberculosis and hepatitis and objective 2 on health threats of the Programme and under this objective close cooperation is developed with WHO and G7 within the Global Health Security Initiative for the creation of an effective and well-organised global strategy for preparedness and responses to potential health threats.

The EU through its development instruments also supports initiatives to provide technical assistance to regional capacities in order to build preparedness and response, such as the West African Regional Centre for Disease Surveillance and Control, and working with the WHO to build robust national animal health and veterinary public health surveillance systems. EU support to the WHO has also made it possible to tackle the growing threat of antimicrobial resistance with a first survey on availability and prices of antibiotics being carried out in the sub-Saharan region. Also through the third Health Programme the EU makes an annual contribution to the WHO's European Observatory on Health Systems and Policies, and the Framework Convention on Tobacco Control (FCTC) in which the EU is part, complements the Programme's priorities 1.1 on risk factors (tobacco use) and 1.5 on tobacco legislation. Furthermore EuropeAid provides support to strengthen the capacity of developing countries that are parties to the WHO FCTC so that they can meet their obligations under the Convention.

However, the Programme remains quite invisible as an international policy instrument and this is expected as it concentrates by definition on capacity building within the EU and the other participating countries. From 2016 onwards, Serbia and Moldova participate in the third Health Programme and Bosnia and Herzegovina from 2017 onwards, while other Western Balkan countries have expressed also interest. This may be interpreted as the increasing importance of the health Programme objectives and priorities for these countries. Moreover, the Programme has a great potential in dealing with issues that come up on the international agenda such anti-microbial resistance and the impacts of the climate change on health and environment.

### 5.6 Utility

**EQ16: To which extent is the 3HP overall useful and, if necessary, how could its overall utility be increased? What are the specific needs of Member States to which the Programme could provide a concrete solution but has not done so yet?**

The Health Programme is our unique financial instrument to support policy coordination with Member States and key health stakeholders (including health professionals), and to make progress on the agreed Programme objectives and strategic targets linked to the Commission priorities.

The Programme is well positioned to serve Member States in areas where EU-added value can be generated:

- under the Commission priority on 'growth, jobs and a resilient society', the Programme is promoting the health of the population and health care services as a productive factor for growth and jobs,

- on the ‘digital single market’, the Programme promotes eHealth and helps Member States to invest in new technologies,
- on the ‘internal market’, the Programme finances actions supporting EU legislation on tobacco, pharmaceuticals, medical devices, the cross-border health care directive, and Health Technology Assessment,
- on‘justice and fundamental rights’, the Programme helps to eradicate health inequalities, and
- makes a significant contribution to the ‘migration’ policy through actions on migrants and refugees;
- on ‘security in Europe’ the Programmes increases the capacity of Member States to prepare for and manage serious cross-border health threats.

Moreover, the Programme covers the development and implementation of EU health legislation (on tobacco, cross-border health threats, medicinal products, medical devices, cross-border healthcare and substances of human origin) and provides support for policy coordination and the development of health information infrastructure.

The programme facilitates networking among the public health community in Europe and with international initiatives, promotes best practices and helps Member States to reach their sustainable development goals, in particular SDG 3 ‘Ensure healthy lives and promote wellbeing for all at all ages’ .

In the coming years the Programme will prioritise the following areas while addressing health inequalities in a cross-cutting manner. :

- country specific and cross country knowledge (addressing all objectives of the programme)
- structural support to health systems and link to digital single market
- cross-border health threats, preparedness and response, including antimicrobial resistance; and
- promotion of health and prevention of non-communicable diseases.

The utility of the Programme increases with the use of the Programme outcomes and the integration of best practices into the national health policies. The Programme works as a tool for policy coordination, for the collection and analysis of harmonised and comparable health data and as an incubator of good practices and pilot projects. The Programme outputs are mainly addressed to policy makers and health professionals who are expected to make use of them on a large scale (e.g. colorectal cancer screening). This will be a real test for the Programme's usefulness.

By undertaking the challenge to create synergies with other bigger EU financial instruments such as the European Structural Funds and the Structural Reform Support Service for the up-scale of its actions, the Programme can take a decisive step that maximises its impact on the health of Europeans and boosts the sustainability of the health systems in the EU.

## 5. CONCLUSION

The third Health Programme is **highly relevant to Member States health needs** and the objectives set are clear, explicit and specific. The 23 thematic priorities are still valid and help the Programme to better focus on outcome oriented actions. In the longer term, contractors recommended to consider further streamlining some thematic priorities to avoid any potential overlap or ambiguities. All of these are indeed relevant to real needs in Member States and are in line with high-level Commission priorities and existing challenges.

**The Programme demonstrates significant progress** in a number of areas building on previous work and **the first signals of its effectiveness** are the establishment of **24 European Reference Networks** for rare diseases, the adoption of common methodologies for **Health Technology Assessment** , the delivery of tools and piloting of joint assessments, the support to Member States for increasing their **capacity building and respond to outbreaks**, the continuing **updating of skills for health professionals and other front line staff working on emergent issues such as the refugees crisis**.

Moreover, the Health Programme supports implementation of EU health legislation in a series of areas such as tobacco, medicinal products, medical devices, cross-border healthcare, etc., closely related to the priority of safe and well-functioning internal market.

The Programme **demonstrated its responsiveness and flexibility** to take into consideration emerging needs such as the influx of refugees in 2015-2016. From 2017 onwards, The Programme supports also the Solidarity Corps.

The **Programme management has become increasingly effective**. The Multi-annual planning has enabled a more strategic approach to medium term planning. The process for the adoption of Annual Work Programmes is clear, well-defined and impartial while it seems to be not so well known by stakeholders and has to be better explained in order to ensure its buy-in and avoid misunderstandings.

The Programme management has been improved in comparison to the past with introduction of indicators, and simplified with the use of electronic tools for submission of proposals and management of grants, but also simplified rules and procedures. There is still need for improvement in better monitoring and reporting on actions, while the dissemination, although improved, needs to be prioritised (new Project database and operationalization of the newly established Dissemination strategy). Otherwise, the Programme suffers from low visibility and risks to lack credible elements demonstrating its progress and utility.

By and large **the allocation of resources is efficient** and the operational costs for its execution remain at acceptable level. By increasing its effectiveness, the Programme can also increase its efficiency.

The Programme attracts participation of all EU Member States and EFTA countries (Norway and Iceland) and three new countries from the Balkan Peninsula (Serbia, Moldova, and Bosnia and Herzegovina) joined it recently. Financial incentives are proposed through exceptional utility criteria for boosting participation from low GNI countries and the increased co-funding rate of 80% applies to all the participants in an action. Evidence from the first three years of Programme implementation shows that these opportunities have not been sufficiently used and low GNI Member States mentioned in the e-survey and in the open public consultation that assuring co-funding is one of the most important barriers for participation in the Health Programme.

**The Programme has increased its ability to target important health needs where it can add value**. By anchoring the seven EU-added value criteria into the Programme Regulation and making them part of the decision-making process for awarding funding, the applicants are informed well in advance and consider the EU added value when they are preparing their proposals. This is conducive to better designed and explained proposals for the consideration of the assessment panels and so, the actions awarded for funding can operate in a way that adds value at EU level. The study showed that there is still scope for being more systematic in the assessment of the EU added value criteria and to make it clearer for applicants through concrete examples what the EU added value is and how it feeds into the award process. Objectives for responding to cross-border health threats and giving access to better and safer health seem to produce outcomes with undisputable high EU-added value.

The Health Programme is coherent with major Commission priorities and policies, and with Sustainable Development Goals. To achieve outcomes and results that addresses the existing challenges in a comprehensive manner, the Health Programme operates in synergies, either among its own priorities and their corresponding actions (internal coherence) but also with other DGs (external coherence) on the basis of the principle of ‘health in all policies’ and with specific EU Programmes such as the Horizon 2020 and/or with its predecessor the 7th Framework Programme. Possibilities to

increase synergies and ensure the up-scale of successful Programme actions and results exist through other financial instruments, such as the EU Structural and Investment Funds and should be used.

## ANNEX I: PROGRAMME DESCRIPTION

### A. Thematic priorities

**1. Promote health, prevent diseases and foster supportive environments for healthy lifestyles**

1.1. Risk factors such as use of tobacco and passive smoking, harmful use of alcohol, unhealthy dietary habits and physical inactivity

1.2. Drugs-related health damage, including information and prevention

1.3. HIV/AIDS, tuberculosis and hepatitis

1.4. Chronic diseases including cancer, age-related diseases and neurodegenerative diseases

1.5. Tobacco legislation

1.6. Health information and knowledge system to contribute to evidence-based decision-making

**2. Protect Union citizens from serious cross-border health threats**

2.1; Additional capacities of scientific expertise for risk assessment

2.2. Capacity-building against health threats in Member States, including, where appropriate, cooperation with neighbouring countries

2. 3. Implementation of Union legislation on communicable diseases and other health threats, including those caused by biological and chemical incidents, environment and climate change

2. 4. Health information and knowledge system to contribute to evidence-based decision-making

**3. Contribute to innovative, efficient and sustainable health systems**

3.1 Health Technology Assessment

3.2. Innovation and e-health

3.3. Health workforce forecasting and planning

3.4. Setting up a mechanism for pooling expertise at Union level

3.5. European Innovation Partnership on Active and Healthy Ageing

3.6. Implementation of Union legislation in the field of medical devices, medicinal products and cross-border healthcare

3.7. Health information and knowledge system including support to the Scientific Committees set up in accordance with Commission Decision 2008/721/EC

**4. Facilitate access to better and safer healthcare for Union citizens**

4.1. European Reference Networks

4.2. Rare diseases

4.3. Patient safety and quality of healthcare

4.4. Measures to prevent antimicrobial resistance and control healthcare-associated infections

4.5. Implementation of Union legislation in the fields of tissues and cells, blood, organs

4.6. Health information and knowledge system to contribute to evidence-based decision-making

**B. Further explanations on what results are being achieved and which are the impacts expected from the Programme?**

**Objective 1: Promote health, prevent diseases and foster supportive environments for healthy lifestyles**

The third Health Programme action is helping to collect evidence and data on e.g. alcohol consumption and alcohol policies in all Member States, as well as national policies related to nutrition, physical inactivity, and overweight and obesity related diseases. To help Member States develop better and more coordinated policies, an online reference guide as 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 is being developed by the Commission's Joint Research Centre financed by the third Health Programme. The guide is written for policy-makers in EU Member States and provides concise information that can be quickly used to answer their questions and translate to their policy work, while it is also open to the other professionals in the relevant fields as well as to the general public.

**Tobacco use, unhealthy diet, physical inactivity and alcohol** consumption are the main risk factors responsible for the biggest part of chronic diseases that affect the capability to work, are costly to treat and ultimately impact economic performance. Chronic diseases account for more than 80 % of the disease burden of the EU and are thus a major cause for high health expenditures. Through the third Health Programme the European Union joins its forces with the 28 Member States to combat chronic diseases and promote active & healthy ageing. To do so, based on previous work undertaken identifying good practices, e.g. in the area of health promotion or defining better care models for multi-morbid patients, the third Health Programme focuses on supporting Member States to make decisive step towards implementing good practices: what has functioned well in other Member States should be piloted elsewhere or up-scaled internally. To strategically enhance the transfer of best practices DG SANTE established a Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases in November 2016[36].

The Health Programme has developed the EU-Compass for Action on **mental health** and wellbeing which is a web-based mechanism used to collect exchange of best practices and analyse information on policy and stakeholder activities in mental health. The Compass is piloting the common criteria on best practices selected at EU level and approved by the Steering group on Promotion and Prevention, and the results will be presented in October 2017.

On **dementia**, and in particular post-diagnostic support, crisis and care coordination, quality of residential care and dementia friendly communities, best practices already selected are being piloting under second Joint Action with Member States competent authorities.

On **cancer**, the European Quality Assurance scheme is being developed in harmonised, evidence-based and flexible way to grant equal and quality-benchmarked treatment to patients. The mid-term evaluation of the breast cancer initiative[37] show that all the activities planned toward the official launch of the European Quality Assurance scheme planned for its final release in 2019 is on-track with the publication of European Breast Guidelines currently ongoing and with the timeline for the launching of the Guideline platform, the digital breast screening training template and the piloting of the European Quality Assurance scheme in 2018. So far 10 recommendations have been published and are currently available for consultation by patients, health care workers and policy makers through the

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[36] The Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases is currently an informal group. For more information: http://ec.europa.eu/dgs/health_food-safety/dyna/enews/enews.cfm?al_id=1736

[37] Interim reports have been regularly provided and a number of annexes and deliverables have been published on the JRC web site.

Joint Research Centre (JRC) interactive IT tool[38]. A further publication of 20 recommendations has been forecasted before the end of 2017. On the implementation of breast centres in the Member States the Commission receives the official information that although breast units are required by law in few countries. They are recommended and implemented in 17 Member States.

The activities of the European Network of Cancer Registries coordinated by the JRC delivers important results providing a 'data-brokering' service to ensure integrity of a single European dataset for different purposes. 128 Cancer Registries from 29 European countries are regularly providing data to JRC with more than 25 900 000 records so far in the database.

The CANCON joint action from the previous second Health Programme reached the end in March 2017 delivering the European Guide on Quality Improvement in Comprehensive Cancer Control and five policy papers. The Guide has been adopted by the Expert Group on Cancer Control and it will be the base for the further upgrade of the National Cancer Plans and their implementation during the oncoming years[39].

Finally the Health Programme supports the involvement of civil society in a continuous dialogue with the EU on health issues by granting almost EUR 5 million annually to non-governmental bodies. It is expected that these non-governmental bodies assist the Commission with the information and advice necessary for the development of health policies and the implementation of the Programme objectives and priorities. It is also expected that non-governmental bodies will work on increased health literacy and promotion of healthy life styles, the organisation of science policy conferences and contribute to the optimisation of healthcare activities and practices by providing feedback from and facilitating communication with patients thus empowering them.

A prize for non-governmental organisations is organised annually by the Health Programme for encouraging those organisation that made a significant contribution fighting against the Ebola outbreak in 2015, reducing antimicrobial resistance in 2016, and for the promotion of vaccination in 2017.

**Objective 2: Protect Union citizens from serious cross-border health threats**

In brief, actions funded under this objective are geared towards ensuring on the ground safety, i.e. it included the possibility of switching 'mode' from preparation to response mode in the event of an outbreak.
For instance during the Ebola and Zika outbreaks, part of the funds of the programme were used to support interventions 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). The budget in 2014-2016 for strengthening EU response to health threats amounted to EUR 11 million.

[38] See at: http://ecibc.jrc.ec.europa.eu/

[39] The implementation of measures and the update of the National cancer Plans will be developed as part of the new Joint Action on Cancer Prevention and Control (Annual Work Programme 2017). Specific best practices will be integrated in the National Cancer Plans with the support of the Steering Group on Health Promotion, Disease Prevention and management of Non-Communicable Diseases.

**Objective 3: Contribute to innovative, efficient and sustainable health systems**

**Health Technology Assessment (HTA)**

Based on the lessons, successes and products of the earlier EUnetHTA Joint Actions , the third Health Programme in 2015 provided EUR 12 million for a third Joint Action on HTA in 2016-2020.

The cooperation has grown to include 81 organisations from 29 countries which constitute a network of strong partners across Europe working together for better access to health technologies for Europeans.

This joint action contributes to the use, quality and efficiency of joint HTA work at European level and supports evidence-based, sustainable and equitable choices in healthcare and health technologies and support re-use in regional and national HTA reports and activities.

The previous joint actions produced in total 20 Joint Assessment, 15 on pharmaceuticals and 5 on medical devices. The target of the third joint action is to have by 2020, a total of 80 Joint Health Technology Assessments done including on pharmaceuticals and medical devices.

Although the joint actions have been successful in building the necessary trust between HTA bodies to establish methodologies, tools and piloting of joint assessments, they have also showed some shortcomings. Notably, 1) the non-sustainable financing (i.e. Joint Actions are only supposed to "kick-start" cooperation and are not a tool to sustain scientific and technical cooperation indefinitely) , 2) limited uptake of joint work (i.e. joint assessments or jointly agreed tools and methodologies, are not always used in national/regional HTA activities) and 3) a project based model not providing the necessary continuity of established work (i.e. the time need to set up and close a Joint Action and negotiate a new one, lead to important production gaps, during which no joint assessments or scientific work was performed) .

**Innovation and ehealth**

The overall ambition from EU Member States (MS) is to better include eHealth into health policy and better align eHealth investments to health needs. A central aspect is the transferability of health data across borders of Member States and therefore the organisational, technical, semantic and legal interoperability. In order to ensure progress and to bridge the gaps between the governance, strategy and operational levels, a dedicated mechanism for eHealth at EU level has been established in 2011 and represents the highest decision-making body at EU political level.

The Health Programme has provided regular support to the eHealth Network and in the period 2014-2017 a Joint Action has brought together Member States' competent authorities to ensure further common political leadership and ongoing integration of eHealth into health policy in order to continue developing eHealth services responding to health systems needs and health objectives.

For this political recommendations and instruments for cooperation have been developed in the below four specific priority areas that are specified in the eHealth Network's multi-annual work plan 2015-2018 and were adopted by the eHealth Network in May 2014: (i) Interoperability and standardisation, (ii) monitoring and assessment of implementation, (iii) exchanging knowledge and (iv) cooperating on a global level. These results can feed into the reflection on the contribution of health in the Digital Single Market.

**European Innovation Partnership on Active and Healthy Ageing**

Based on several projects and one joint action which focus on the topics of frailty, one overall European Framework for Frailty Prevention is being developed as well as practical tools e.g. to screen older adults for (pre)frailty and innovative care paths.

**Expert Panel on Health**

Sound and timely scientific advice is an essential requirement for providing information and knowledge so as to pursue modern, responsive and sustainable health systems. To this end, the Commission has set up a multi-sectorial and independent Expert Panel[40] which provides advice on effective ways of investing in health. The concept of this expert panel became particularly compelling during the times of financial crisis and budgetary constraints in part due to the ongoing reflection processon health systems within the European Commission. In the period 2014-2016, the panel delivered 12 Opinions[41] in line with the Mandates raised (i.e. in relation to primary care and access to healthcare), and has provided expert advice and input to Member States and the European Commission. By calling on additional expertise from a database of experts and from the European and international health care expert community, the expert panel has the potential for promoting innovation in health, and generating economies of scale by connecting expertise in areas of identified importance.

**Scientific Committees**

The Health Programme supported the functioning of the Commission Scientific Committee on Health and Environmental Risks (SCHER), the Committee on Health, Emerging and Newly Identified Risks (SCENIHR)[42] and the Scientific Committee on Consumer Safety (SCCS) which provided scientific advice and risk assessment to the Commission in the areas of health, environment, consumer safety and emerging risks. In the period 2014-2016, the SCHER produced 5 Opinions, the SCENIHR 18 Opinions and the SCCS 64 opinions, on topics such as the safety of cosmetic ingredients including nanoform, the safety of medical devices such as surgical meshes or PIP breast implants, the health and environmental effects of mercury from dental amalgam, the potential health effects of exposure to electromagnetic fields, health effect of UV from sunbeds used for cosmetic purposes, the definition of synthetic biology and risk assessment methodology, additives in tobacco products. A report on the activities of the Scientific Committees is publicly available[43] as well as the opinions issued[44].

**Objective 4: Facilitate access to better and safer healthcare for Union citizens**

**European Reference Networks on Rare Diseases**

The programme finances the coordination activities of 23 of the networks applying for multiannual grants. These are virtual networks involving healthcare providers across Europe. They aim to tackle complex or rare medical diseases or conditions that require highly specialised treatment and a concentration of knowledge and resources. To review a patient's diagnosis and treatment, ERN coordinators will convene a "virtual" advisory board of medical specialists across different disciplines, using a dedicated IT platform and telemedicine tools. This way, it is the medical knowledge and

[40] Commission Decision 2012/C 198/06.

[41] http://ec.europa.eu/health/expert_panel/opinions_en?page=1

[42] End of April 2016, SCHER and SCENIHR merged to become the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER)

[43] See at http://ec.europa.eu/health/sites/health/files/scientific_committees/docs/activity_report_sc_20132016_en.pdf

[44] http://ec.europa.eu/health/scientific_committees/policy_en

expertise that travel rather than the patients, who have the comfort of staying in their supportive home environments.

The first ERNs are up and running in 2017. Invitation for new healthcare providers to join the existing Networks, as well as calls for new ERNs will follow. The new target is to establish and finance the coordination of up to 33 European Reference Networks till 2020. Over the next five years, as the ERNs reach full capacity, thousands of EU patients suffering from a rare or complex condition can expect to benefit. This investment will need to be sustained over time. For more information please refer to https://ec.europa.eu/health/sites/health/files/ern/docs/2017_brochure_en.pdf

**Rare diseases**

The Joint Research Centre is developing and maintaining the European Platform on Rare Diseases Registration receiving specific financial support from the Health Programme. The Platform is promoting the interoperability of existing registries and will help in the creation of new ones, including those developed by the European Reference Networks. The migration of the two databases - the European Surveillance of Congenital Anomalies (EUROCAT) and the Surveillance of Cerebral Palsy in Europe (SCPE) – has been successfully implemented.

Joint Action on rare diseases (RD-ACTION) is supporting Member States in the development and implementation of actions in the area of rare diseases. Three main goals of the RD-Action are to:

1) support the further development and sustainability of the Orphanet database;

2) contribute to solutions to ensure an appropriate codification of RD in health information systems; and

3) continue implementation of the priorities identified in Council Recommendation on patient safety including the prevention and control of healthcare associated infections (2009/C151/02) and the Commission Communication on rare diseases (COM(2008)679).

In the area of rare diseases codification general rules for routine coding with Orphacodes have been established and guidelines are provided to achieve internationally standardised data collection.

For the current and previous work in the area of rare diseases (EU collaboration to help patients with rare disease) DG SANTE won the first EU Ombudsman Award for Good Administration[45].

**EU health legislation and health information**

The programme also provides the resources for implementing the EU's political commitments and legal obligations in health (e.g. implementation of the tobacco or health threats legislation, the EU regulatory framework for medicinal products and medical devices, for substance of human origin, and cross-border health care). It also supports the Member States implementation of this legislation through the development of common tools, such as networks, IT platforms, guidance and sharing of best practices. The development and maintenance of these tools (e.g. EUDAMED database, Euripid database) is essential in order to ensure the smooth operation of the Internal Market in these sectors. It is estimated that in the years 2014-2016, 30% of the Programme's overall annual budget was dedicated for the above mentioned purposes.

The programme supports work on health information: EUR 13.2 million spent in 2014-2016 for the collection and analysis of health information, data and indicators in cooperation with the Organisation for Economic Cooperation and Development (OECD), the World Health Organisation (WHO) and the

[45] https://www.ombudsman.europa.eu/en/activities/eventdocument.faces/en/77458/html.bookmark

Observatory on Health Systems and Policies, as well as ESTAT and Joint Research Centre (JRC), contributing to the development of country specific and cross-country knowledge to inform policies at national and EU level, through such actions as the State of Health in the EU cycle[46].

The BRIDGE health project has been coordinating, improving, and advancing some of the most influential EU health indicator development networks since its 2015 inception, creating synergies between the efforts of several earlier projects on health information. These expert networks have been developing and maintaining indicators in the domains of population health and health systems, health examination surveys, and population injury, and developed methods to produce health indicators more cost-effectively in various areas using disease registries and administrative health data collection systems. Various options to improve the sustainability of producing indicators to underpin health policy and research in the EU have been developed, and a blueprint for a more sustainable organisation of these activities is being finalised.

[46] Health at a Glance: Europe 2016 report, and country health profiles

# ANNEX II: METHODOLOGICAL ANNEX

## Table 1: Evaluation questions matrix

| Evaluation criteria | Evaluation questions | Judgement Criteria | Indicators | Sources of evidence |
|---|---|---|---|---|
| Relevance | 1. To what extent are the **3HP objectives** still valid and in accordance with health needs in Europe? | - The extent to which the 3HP objectives address the current needs of health stakeholders across the EU<br>- The extent to which new and emerging health needs at the EU and MS level can be accommodated through the existing HP objectives | The level of agreement among stakeholder groups that the design of the HP and its objectives are:<br>- aligned with identified health needs<br>- aligned with the health needs of policy-makers, stakeholders and / or citizens in their MS<br>- flexible enough to address emerging / new health needs<br><br>Instances where new and / or emerging health needs are identified, and ways in which these were incorporated within the programme. | **Programme assessment**<br>Documentation on public health problems and needs (Annex B – table 1 & table 4)<br>Survey with NFP and PC (Annex C)<br>Interviews with external experts (see Table 8 main report)<br>Focus Group (Annex E)<br>**Case studies**<br>Especially "Policy context"<br>See findings from **question 13** (on EU added value) |
| | 2. To what extent are the 3HP **thematic priorities** sufficient and sufficiently covered to achieve the 3HP objectives and Commission wider priorities? | - The extent to which the thematic spread is narrow / wide enough to cover the 3HP objectives<br>- The extent to which the number of thematic priorities is small / large enough to allow focused actions<br>- The extent to which individual priorities are balanced across, and in line with, the different needs of stakeholder groups<br>- Taken together, the extent to which the thematic priorities support Commission wider priorities | The level of agreement among stakeholders that the thematic priorities:<br>- are sufficient in number to cover the objectives in a focused and practical way<br>- are clearly defined and narrow / broad enough in scope to allow focused action<br>- are aligned with objectives<br>- are important and individually relevant to stakeholders' health needs<br>- fit with the Commission's wider priorities<br><br>The extent to which the priorities are based on a clear and coherent intervention logic | **Programme assessment**<br>Documentation on public health problems and needs (Annex B – table 1)<br>Interviews with DG SANTE (see Table 8 main report)<br>Focus Group (Annex E)<br>**Case studies**<br>Especially "Theory and Practice" ("Strategy and design") |
| | 3. To what extent are **the actions** prioritised in the Annual Work | - To what extent do the individual actions prioritised in the AWP | The level of agreement among stakeholders that the actions | **Programme assessment**<br>Documentation on HP |

| Evaluation criteria | Evaluation questions | Judgement Criteria | Indicators | Sources of evidence |
|---|---|---|---|---|
| | Programmes (AWPs) relevant vis-à-vis the 3HP thematic priorities? | support progress under each thematic priority? | supported:<br>- are sufficient in number to cover the thematic priorities in a focused and practical way<br>- are clearly defined and relevant / targeted to each thematic priority<br><br>The extent to which the actions in the AWP support the priorities' intervention logic | implementation (Annex B – table 2)<br>Interviews with CHAFEA (see Table 8 main report)<br>**Case studies**<br>Especially "Theory and Practice" ("Delivery") |
| | 4. To what extent are the **actions** co-funded through the AWPs relevant to achieving **the objectives** set out in Article 168 TFEU? | Considered to cover the coherence of the HP (treated later under **question 15**) | | |
| Effectiveness | 5. To what extent is the process for **defining and prioritising actions through Annual Work Programmes (AWP)** transparent, impartial and equitable? | To what extent can the process for defining and prioritising actions through the AWP be considered:<br>- Transparent (i.e. open to scrutiny)?<br>- Impartial (i.e. without political bias towards any one Member State)?<br>- Equitable (i.e. fair participation of and consideration for needs of all concerned actors)? | The level of agreement amongst stakeholders on whether the process for defining and prioritising actions through the AWP is:<br>Transparent:<br>- Existence of a full documentation trail for this decision-making process (i.e. meeting minutes available to EP)<br>- There is public access to the AWP and its supporting documentation<br>Impartial:<br>- The process for defining AWP allows for and demonstrates the incorporation of proven EU health needs (e.g. through the consultation of experts / use of existing evidence of health needs)<br>Equitable:<br>- (in)existence of participation mechanisms for all concerned actors (MS, CHAFEA and other DGs)<br>- Stakeholder awareness of these participation mechanisms | **Programme assessment**<br>Documentation HP implementation documentation and past reports, evaluations and audits (Annex B – table 2 and 3)<br>Survey questions for PC (Annex C)<br>Interviews with SANTE and CHAFEA (see Table 8 main report) |

| Evaluation criteria | Evaluation questions | Judgement Criteria | Indicators | Sources of evidence |
|---|---|---|---|---|
| | | | - Evidence that these participation mechanisms are perceived by stakeholders to be fair and inclusive.<br>- Instances where stakeholders have participated in the AWP process and ways in which their suggestions and needs were incorporated into the programme. | |
| | 6. How effective was the **Multi-Annual Planning (MAP)** for the preparation of the AWP? | - To what extent has the MAP process led to an enhanced strategic approach across years, resulting in more clarity in resources available over time and budget allocation (by objective and thematic priority)? | The level of agreement amongst stakeholders that:<br>- the setting of the priorities on a multi-annual basis is more strategic than it previously was (there is more long-term thinking evidenced in the MAP)<br>- there is more clarity regarding the availability of resources and budget allocation over time<br>- the adopted AWP provide evidence that the priorities set in the MAP have been followed (or it can be explained why this is not the case) | **Programme assessment**<br>Documentation HP implementation documentation and past reports, evaluations and audits (Annex B – table 2 and 3)<br>Interviews with SANTE (see Table 8 main report) |
| | 7. How effective is the introduction of the **"exceptional utility" criteria** (para 19, Regulation of 3HP) in order to incentivise the participation of low GNI countries? | To what extent has the introduction of "exceptional utility" criteria incentivised the participation of low GNI countries (i.e. lower than 90% of EU average)? | The level of agreement amongst stakeholders that:<br>- The "exceptional utility" criteria address the needs (i.e. the barriers to participation) of the low GNI countries<br>- There is (increased) participation of low GNI MS in the 3HP | **Programme assessment**<br>Documentation HP implementation documentation and past reports, evaluations and audits (Annex B – table 2 and 3)<br>Survey (Annex C)<br>Interviews with SANTE and CHAFEA (see Table 8 main report) |
| | 8. In practice, to what extent are the actions in the AWP contributing to the:<br>- 3HP objectives and thematic priorities<br>- Commission policy priorities? | The extent to which the actions implemented to date have (or are expected) to contribute to:<br>- 3HP objectives and corresponding thematic priorities<br>- Commission policy priorities | The level of agreement amongst stakeholders confirming that:<br>- The actions operationalised to date are clearly defined, aligned with and directly address the individual 3HP objectives and thematic priorities<br>- The actions implemented to date | See also **question 2 and 3** (evidence of relevance of thematic priorities and actions)<br>**Case studies**<br>Especially "Benefits" (Theory and Practice) |

| Evaluation criteria | Evaluation questions | Judgement Criteria | Indicators | Sources of evidence |
|---|---|---|---|---|
| | | | have concrete links with the Commission policy priorities which can be evidenced<br>Evidence and examples confirming that progress has been made and that the actions constitute action that would not have been achieved without the HP (EU added value)<br><br>Evidence and examples showing that steps have been taken to disseminate results. | |
| Efficiency | 9. To what extent does the design of the 3HP lead to an efficient **allocation of resources** among objectives / thematic priorities? | - To what extent is the distribution of funding across the thematic priorities aligned with the EU health needs which the HP aims to address?<br>- To what extent is funding at the level deemed critical to have an impact? | The level of agreement amongst stakeholders that there is a correlation between:<br>- The identified relevance of thematic priorities and allocation of resources; and<br>- The allocation of resources are proportional to the expected results | See findings from assessment of Relevance (**questions 1-4**)<br>**Programme assessment**<br>Documentation HP implementation documentation and data analysis (Annex B – table 2)<br>Interviews with SANTE and CHAFEA (see Table 8 main report) |
| | 10. To what extent does the allocation of resources allow for an **efficient implementation** of the 3HP in terms of:<br>- funding mechanisms<br>- simplification measures<br>- operational costs? | - To what extent are the implementation costs proportional to the expected results?<br>- The extent to which the simplification measures allow for the most cost-effective implementation of the 3HP<br>- To what extent do the current funding mechanisms lead to an allocation resources that allows for the most cost-effective way of implementing the 3HP? | The level of agreement amongst stakeholders that:<br>- (management costs of) funding mechanisms are reasonable given the objective and expected result<br>- the funding mechanisms allow for an allocation of resources that achieves the most cost-effective implementation of the 3HP<br>- simplification measures have reduced the administrative costs for applicants and for CHAFEA<br>- the operational costs associated with the 3HP (design and implementation) are at the minimum level deemed necessary to achieve expected | **Programme assessment**<br>Documentation HP implementation documentation and data analysis (Annex B – table 2)<br>Interviews with CHAFEA (see Table 8 main report)<br>**Case studies**<br>Cross-cutting analysis of lessons learned from Delivery |

| Evaluation criteria | Evaluation questions | Judgement Criteria | Indicators | Sources of evidence |
|---|---|---|---|---|
| | | | results | |
| | 11. How **may the efficiency of the 3HP be improved** regarding:<br>- number of priorities<br>- funding mechanisms<br>- application / implementation procedures<br>- available resources? | To what extent is there scope to improve the efficiency of the 3HP in terms of:<br>- increasing / decreasing the number of priorities<br>- making the funding mechanisms more cost-effective<br>- streamlining procedures<br>- achieving the highest impact possible with the available resources (financial and human) | The level of agreement amongst stakeholders that efficiency gains can be realised vis-à-vis:<br>- **The number of priorities**: evidence that there should be more / fewer priorities so that resources are not too concentrated / stretched<br>- **Funding mechanisms**: evidence that the current balance of mechanisms can be adjusted to allow for a more optimal and cost-effective allocation of resources<br>- **Established procedures**, including additional simplification measures – evidence that the current procedures need to be further fine-tuned / simplified.<br>- **The availability of resources** (financial and human) – evidence showing a need for more / fewer resources to be able to deliver the expected results efficiently | See **question 9 and 10** (findings and sources). |
| | 12. To what extent are the **monitoring** processes and resources (at the Commission and MS level) sufficient to **plan and promote** the results of the 3HP? | At both the Commission and MS level:<br>- To what extent do the current monitoring processes allow for the efficient management of actions supported?<br>- To what extent does the monitoring framework in place consist of: indicators at the action level, targets at the level of thematic priority and objectives and measurement of results against targets?<br>- To what extent are these indicators and targets relevant, clearly defined and aligned with | - Evidence that the resources, processes and systems allocated to the monitoring of results are considered to be reasonable and sufficient (at both the EU and MS level).<br>- Indicators have been set<br>- Indicators are SMART and there are processes in place to measure them<br>- Evidence of there being a dissemination strategy in place and examples to show that this is being implemented.<br>- The level of agreement amongst stakeholders that the | **Programme assessment**<br>Documentation on HP high level and implementation (Annex B – table 1 and 2)<br>Survey questions for NFP (Annex C)<br>Interviews with SANTE and CHAFEA (see Table 8 main report)<br>**Case studies**<br>Especially "Benefits" (Theory and Practice) |

| Evaluation criteria | Evaluation questions | Judgement Criteria | Indicators | Sources of evidence |
| --- | --- | --- | --- | --- |
| | | individual thematic priorities and 3HP objectives?<br>- To what extent is there an effective dissemination strategy in place for the promotion of 3HP results?<br>- To what extent are there adequate resources allocated to support the monitoring and promotion of 3HP results?<br>- To what extent are these monitoring processes equally effective across each MS? | dissemination strategy is working - *or is expected to work* - in practice (i.e. internal and external stakeholders make - *or are expected to make* - use of results) | |
| EU added value | 13. To what extent are the **eight EU added value criteria** addressed in proposals? | - In principle, to what extent are the 8 EU added value criteria well defined and evidenced in the proposals?<br>- To what extent is each criterion relevant? | The level of agreement amongst stakeholders confirming that the 8 EU added value criteria are:<br>- Sufficient in number and necessary<br>- SMART<br>- Relevant<br>- Equally addressed in proposals | **Programme assessment**<br>Documentation on HP implementation (Annex B – table 2)<br>Interviews with external experts (Table 8)<br>Focus Groups discussion analysis (Annex E)<br>**Case studies**<br>Especially "Strategy and Design" (Theory and Practice) |
| Coherence / consistency | 14. To what extent have the thematic priorities of the 3HP led to **more coherence and synergies between the funded actions** in delivering on the objectives? | **Internal coherence**<br>To what extent are the thematic priorities:<br>- not contradictory<br>- complementary<br>- not unnecessarily overlapping? | The level of agreement amongst stakeholders confirming:<br>- The extent to which there are synergies between the funded actions<br>- the types of synergies at the level of the thematic priority | **Programme assessment**<br>Documentation on public health problems and needs (Annex B – table 1 & table 4)<br>Interviews with SANTE (see Table 8 main report)<br>Analysis of Focus Group discussions (Annex E)<br>**Case studies**<br>Especially "Benefits" (Theory and Practice)<br>And, cross-cutting analysis by objective |
| | 15. To what extent are the objectives and thematic priorities of the 3HP **externally consistent/coherent**, i.e. correspondence between:<br>- the 3HP and health objectives of | **External coherence**<br>To what extent are the objectives and thematic priorities:<br>- not contradictory<br>- complementary | The level of agreement amongst stakeholders confirming the:<br>- extent to which there are synergies<br>- the types of synergies | **Programme assessment**<br>Documentation on high-level HP documentation and public health problems and needs (Annex B – table 1 & table 4) |

| Evaluation criteria | Evaluation questions | Judgement Criteria | Indicators | Sources of evidence |
|---|---|---|---|---|
| | Article 168 TFEU<br>- the 3HP objectives and those of other public interventions (e.g. national health policies, EU policies and Programmes, other international actions)? | … with health objectives in Article 168 TFEU and other public interventions? | between different types of public interventions (EU and non-EU)<br><br>The extent to which each type of public intervention contributes a unique added value that other interventions do not offer | Interviews with SANTE and external experts and other EU funds (see Table 8 main report)<br>Analysis of Focus Group discussions (Annex E) |
| Utility | 16. To what extent is the 3HP overall useful and, if necessary, how could its **overall utility be increased**?<br>What are the **specific needs of Member States** to which the 3HP could provide a concrete solution but has not done so yet? | - To what extent does the 3HP create added value in meeting EU public health needs?<br>- To what extent does the 3HP meet stakeholders' health needs in a way that other public health interventions do not?<br>- To what extent is there a need to expand the 3HP in meeting more / other health needs in MS? | - Instances where the 3HP could meet certain health needs that it has not already met<br>The level of agreement amongst stakeholders that:<br>- The 3HP has met health needs which other public interventions have not been able to do<br>- The 3HP has justified costs and proven its value for money<br>- The 3HP can be made more efficient whilst still meeting intended results<br>- There are no specific needs of stakeholders which the 3HP should in principle address, but does not | Summary of **questions 1 - 15** |
| | 17. Regarding the objective n° 3 for increasing the public health capacity building, how has this been achieved a) in terms of generic public health capacity building and b) in terms of specific capacity building that supports implementation of policy priorities such as HTA, e-health and the Innovation Platform? | This is considered to be covered under effectiveness (see **question 8**) | | |

## Table 2: Case studies

The methodology for the case studies consisted of eight mini theory-based evaluations (including the reconstruction of their own intervention logic), with a review of relevant documentation for a maximum of five individual funded actions per case study under the selected thematic priorities, followed by interviews and consultation with the public health experts.

The contractors described the policy context for each of the eight selected thematic priorities explaining how the thematic priority relates to EU health needs and then makes the case for EU action. Then, they have presented the intervention logic for the thematic priority, and discussed in depth its main parts in terms of both theory and practice. The aim was to get insights that are useful for answering higher-level questions relating in particular to relevance, effectiveness and lessons learned, all these feeding the overall evaluation findings and conclusions.

| Thematic priority | Actions | Year of call | Funding mechanism | Budget (EUR)[1] |
|---|---|---|---|---|
| 1.1. Risk factors such as use of tobacco and passive smoking, harmful use of alcohol, unhealthy dietary habits and physical inactivity | 1. Monitoring of the national policies related to alcohol consumption and harm reduction | 2014 | Direct grant agreement | 500,000 |
| | 2. Joint Action on Nutrition and Physical Activity | | Joint action | 1,200,000 |
| | 3. Obesity Training And Information Services for Europe | | Operating grant | 162,619 |
| | 4. Smoking prevention in action: the Smoke Free Partnership Coalition | | Operating grant | 352,054 |
| | 5. EPHA 2015: Protecting and improving public health and well-being in all policies | | Operating grant | 487,441 |
| 1.4. Chronic diseases including cancer, age-related diseases and neurodegenerative diseases | 1. Joint Action on Dementia 2015-2018 | 2014 | Joint action | 1,498,710 |
| | 2. Mental Health - Trimbos Instituut | | Service contract | 799,777 |
| | 3. Participation to Healthy Workplaces And Inclusive Strategies in the Work Sector (PATHWAYS) | | Project | 969,379 |
| | 4. Alzheimer Europe (2015-2017) | | Operating grant | 422,880 |
| | 5. Cancer Leagues Collaborating in Cancer Prevention and Control at the EU and National Level | | Operating grant | 314,972 |
| 2.2. Capacity-building against health threats in Member States, including, where appropriate, cooperation with neighbouring countries | 1. Preparedness activities relevant to the monitoring, the assessment and the coordination of the response | 2014 | Service contracts | 643,559 |
| | 2. Post exercise on serious cross border threats to health | | | 458,989 |
| | 3. Preparedness and response activities in the context of the Ebola epidemic in West Africa | | | 499,719 |
| | 4. Study on cost-benefit analysis of reference laboratories for human pathogens | | | 199,942 |
| | 5. Study on the Public Health law network supporting the implementation of Decision 1082/2013/EU | 2015 | | 303,490 |
| 2.3. Implementation of Union legislation on communicable diseases and other health threats, including those caused by biological and chemical incidents, environment and climate change | 1. Efficient response to highly dangerous and emerging pathogens at EU level | 2014 | Joint action | 3,499,873 |
| 3.4. Setting up a mechanism for pooling expertise at Union level | 1. Expert panel on effective ways of investing in health[2] | 2014 | 2 Service contracts | 242,550 |
| | | | | 16,170 |
| 3.6. Implementation of Union legislation in the field of medical devices, medicinal products and cross-border healthcare | 1. European Pharmacopoeia | 2014 | Direct grant agreement | 1,100,000 |
| | 2. Statistical data and Guidance Document for medicinal product pricing and for the use of ERP | | Project | 300,000 |
| | 3. Study on the regulation of advanced therapies | | Service contract | 161,500 |
| | 4. Study on off label use of medicinal products in the European Union | | | 226,500 |
| | 5. Market surveillance of medical devices | 2015 | Joint Action | 849,488 |
| 4.1 European Reference Networks | 1. Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases | 2014 | Joint action | 4,379,979 |
| | 2. Development of a manual and toolbox for the assessment of European reference networks | | Service contracts | 499,254 |
| | 3. Study on services to be provided by European reference networks | | | 172,660 |
| 4.5. Implementation of Union legislation in the field of medical devices, medicinal products and cross-border healthcare | 1. Vigilance and Inspection for the Safety of Transfusion, Assisted Reproduction and Transplantation | 2014 | Joint action | 2,328,664 |
| | 2. Good Practices for demonstrating safety and quality through recipient follow-up | 2015 | Project | 1,032,030 |
| | 3. European Cornea and Cell Transplantation Registry | | | 424,567 |
| | 4. Organ donation | | Service contract | 199,030 |

[1] Rounded to the nearest EUR

## ANNEX III: THE EXCEPTIONAL UTILITY CRITERIA FOR BOOSTING LOW GNI COUNTRIES' PARTICIPATION

Through the use of exceptional utility criteria the Health Programme provides financial incentives to involve as much as possible all Member States and participating countries, in particular for participation in Joint Action where it is question for more close cooperation with health competent authorities on a series of health issues for political endorsement and direct implementation of results. The criteria for exceptional utility in Joint actions are enshrined in the Programme Regulation (EU) N° 282/2014 Article 7 point 3. Criteria for exceptional utility in Projects and operating grants have been defined on a similar basis and been introduced in the Annual Work Programmes.

**Table 1: Key features of the "exceptional utility" criterion**

| Mechanism | Criteria for exceptional utility under 3HP (2014 – 2016) |
|---|---|
| **Joint Actions** | 1. At least 30% of the budget of the proposed action is allocated to MS whose gross national income (GNI) per inhabitant is less than 90% of the Union average. This criterion intends to promote the participation from Member States with low GNI.<br><br>2. Bodies from at least 14 participating countries participate in the action, out of which at least four are countries whose gross national income (GNI) is less than 90 % of the Union average. The criterion promotes wide geographical coverage and the participation of Member States authorities from countries with a low GNI. |
| **Projects** | 1. At least 60 % of total budget must be used to fund staff. This criterion intends to promote capacity building for development and implementation of effective health policies .<br><br>2. At least 30 % of the budget of the proposed action is allocated to Member States whose gross national income (GNI) per inhabitant is less than 90 % of the Union average. This criterion intends to promote the participation of health actors from Member States with low GNI.<br><br>3. The proposal must demonstrate excellence in furthering public health in Europe and a very high EU-added value. |
| **Operating grants** | 1. At least 25 % of the members or candidate members of the non-governmental bodies come from Member States whose gross national income (GNI) per inhabitant is less than 90 % of the Union average … to promote the participation of non-governmental bodies from Member States with a low GNI.<br><br>2. The reduction of health inequalities at EU, national or regional level is manifested in the mission as well as the AWP of the applicant… to ensure that co-funded non-governmental bodies directly contribute to one of the main objectives of the third Health Programme, i.e. to reduce health inequalities |

# ANNEX IV: INTERVENTION LOGIC

**Figure 1: Intervention logic for thematic priority 1.4 (Chronic diseases)**

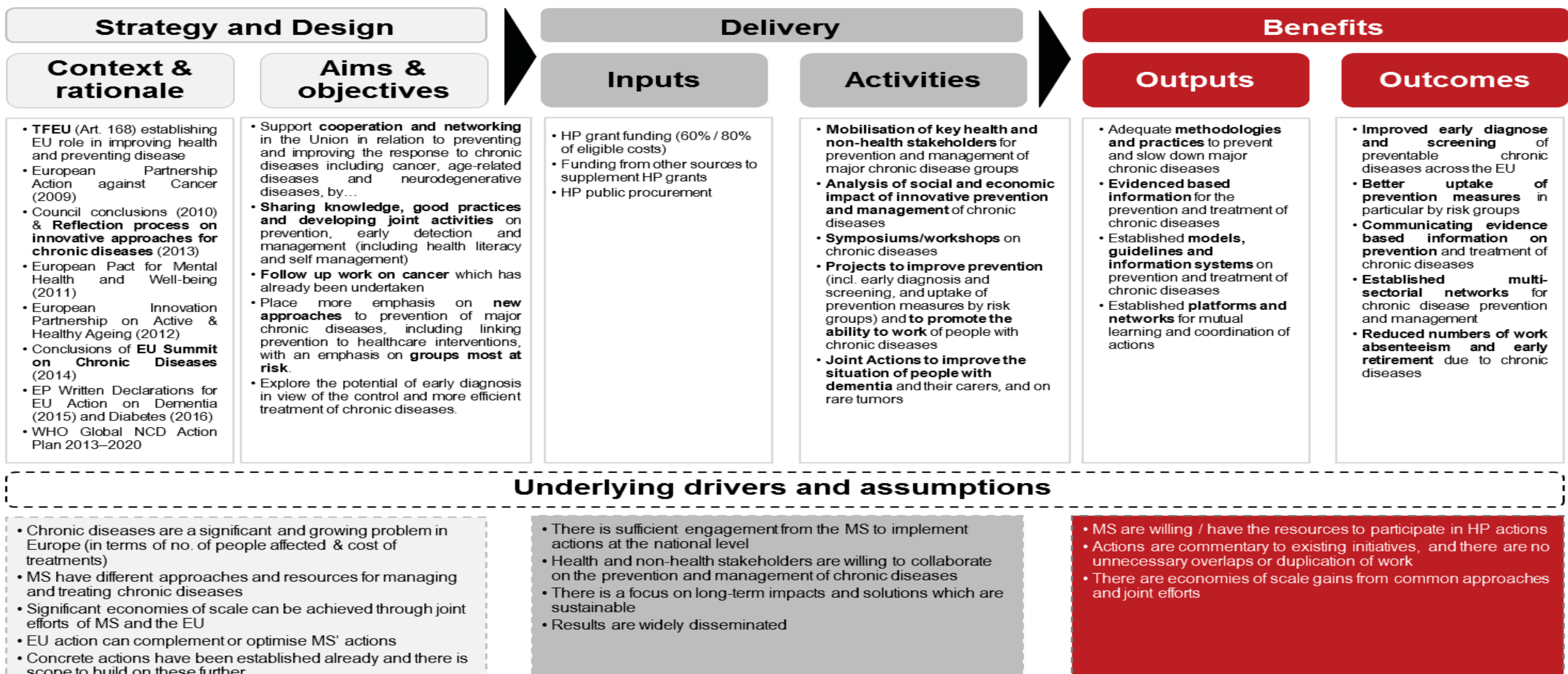


**Figure 2: Intervention logic for thematic priority 2.2 (Capacity building)**

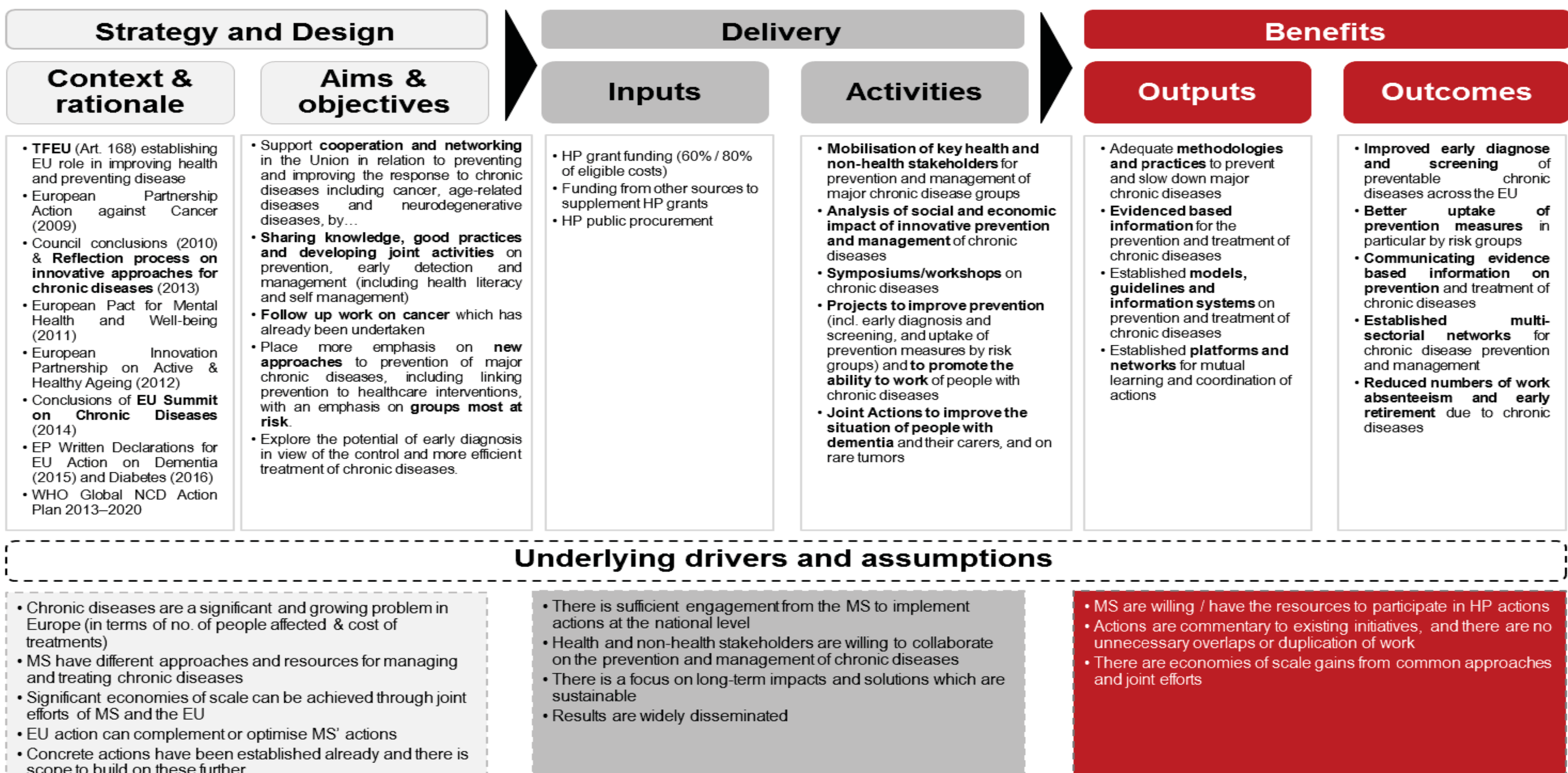
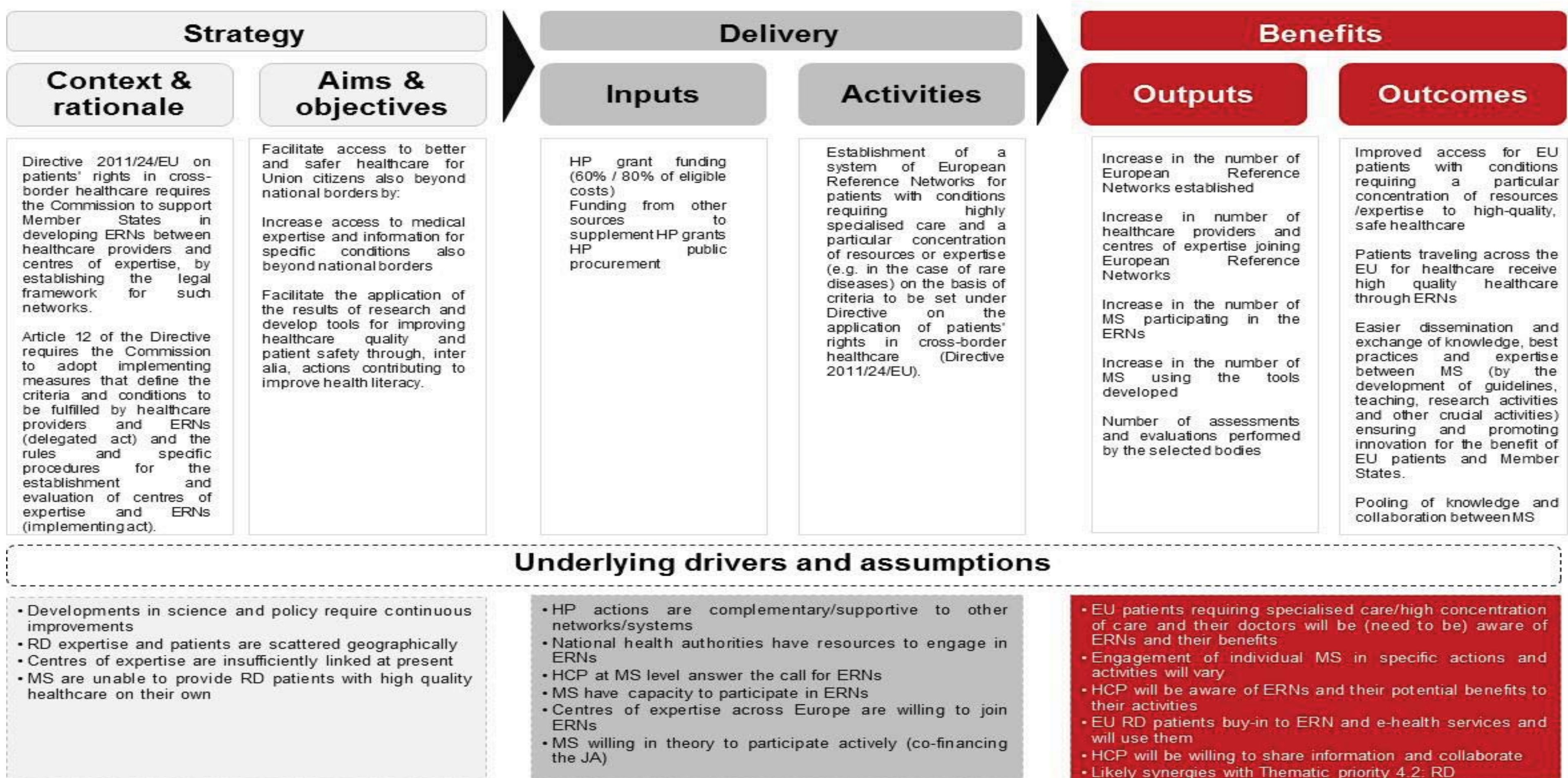


**Figure 3: Intervention logic for thematic priority 4.1 (European Reference Networks)**



# ANNEX V

## SYNOPSIS REPORT ON STAKEHOLDERS' CONSULTATION ACTIVITIES

### INTRODUCTION

The present report presents the outcome of the consultation activities with stakeholders conducted for the mid-term evaluation of Regulation (EU) No 852/2014 on the establishment of the third Programme for the Union's action in the field of health (hereinafter: the Regulation). The consultation covered aspects relating to the evaluation criteria used in this context, namely relevance, added value, efficiency, effectiveness, and coherence. It addressed institutional stakeholders notably the Programme Committee members and National Focal Points as well as the direct beneficiaries of the grants awarded under the Regulation, and stakeholders which are indirectly involved in the funded activities, especially non-governmental organisations, public health authorities, academic and research organisations, international organisations, professional association, private companies and individual persons.

Stakeholders had the opportunity to provide their feedback on a Commission evaluation roadmap[47] before the elaboration of the Terms of Reference for the mid-term evaluation on Regulation (EU) No 852/2014, during a 4-week period starting on 15 December 2015.

During the evaluation and as part of that exercise, targeted on-line consultations with Public Health Experts and e-surveys with National Focal Points and Programme Committee members were conducted, and complemented by targeted interviews of Commission and International Health Organisation officers, and direct beneficiaries mainly project leaders/coordinators of actions funded under the Programme.

In addition, an open public consultation (OPC)[48] of all interested parties has been conducted using the European Commission 'Public consultations' website and the DG SANTE '*Health Programme*' web page. The link to the OPC was disseminated via the CHAFEA and SANTE websites, shared on the Health Policy Platform and distributed via stakeholder mailing lists and National Focal Points. The participants were invited to complete the online questionnaire available only in English. However, the participants were able to submit contributions in any official EU language. No use of this possibility has been made by them.

The open public consultation was carried out between 23 November 2016 and 23 February 2017.

### 1. FEEDBACK ON THE EVALUATION ROADMAP

Two NGOs provided feedback to the Evaluation Roadmap: the first through the Secretariat General platform on 14 January 2016 and the second one 21 October 2016 (with 10 months delay) when the evaluation was entering in its final stage.

Hungary provided also feedback through the National Focal Point and the Programme Committee Member with direct messages to DG SANTE.

All three relevant feedbacks have been taken into consideration in the evaluation :

- One of the case studies includes the thematic priority covering the alcohol policy in the EU and how the Health Programme contributes to reduce the risk factors such as harmful use of alcohol

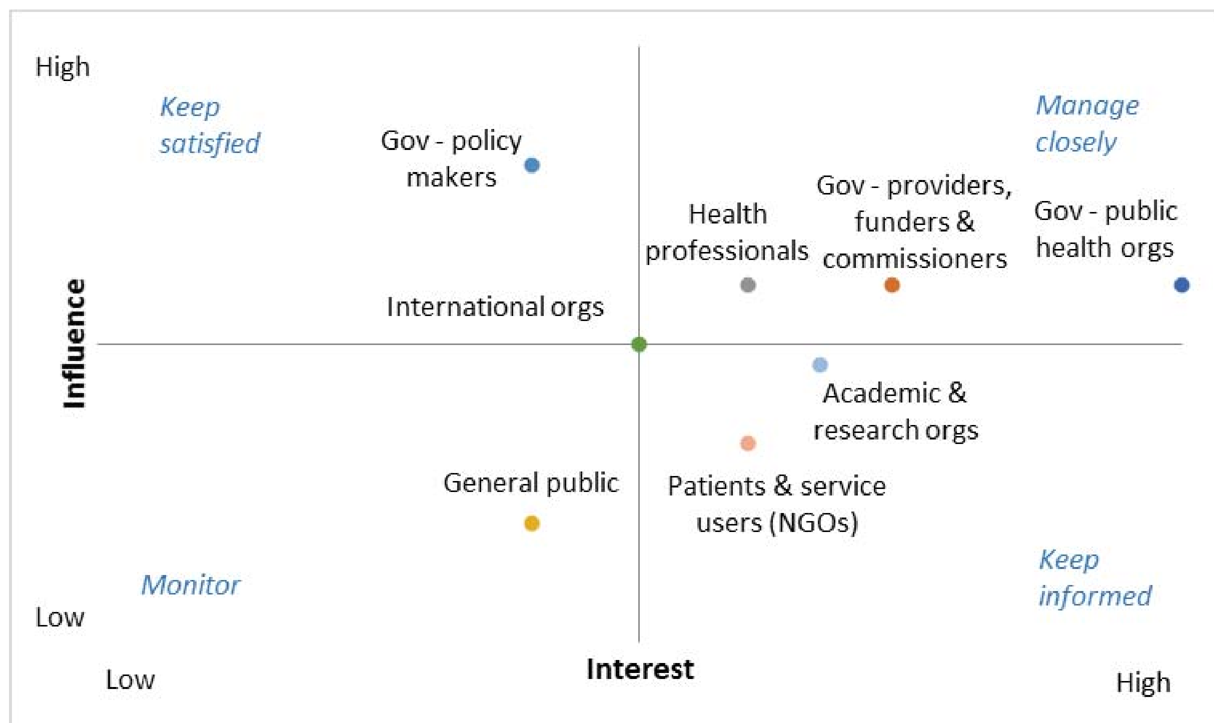
47 http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_sante_680_evaluation_mid-term_health_programme_en.pdf
48 https://ec.europa.eu/health/programme/consultations/midterm_evaluation_en

- The analysis of data provides clear information on how the budget is spend: per thematic priority, per country, per financial mechanism
- The exceptional utility criteria have been examined and conclusions have been drawn on their effectivenes and the need of incentives for low GNI MS to participate in the Health Programme.

## 2. TARGETED CONSULTATIONS

Targeted consultation have been used to acquire specific information from particular stakeholders' groups. The stakeholders were identified by the stakeholder mapping exercise during the ex-post evaluation of the second Health Programme[49] and the strategy of consultation in has been based on the folowing stakeholders'map.

**Figure 1 : Stakeholders' map**




### 2.1 ON-LINE FOCUS GROUPS

Three on-line focus groups with relevant public health experts were organsined on the Health Policy Platform using, one each for specific objectives 1 (Health promotion), 3 (Innovative, efficient and sustainable health systems) and 4 (Access to better and safer healthcare) of the Programme[50].

Overall 15 experts have participated representing mainly academics, politicians and representatives of international organizations with comprehensive knowledge on Health Promotion, the Health Programme and the current developments. The experts were from Austria, Belgium, Estonia, Finland, Germany, Hungary, Italy, Malta, Norway, Poland Portugal, Slovenia, Spain, Sweden, United Kingdom, and as well as experts from EU Office of WHO.

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49 https://ec.europa.eu/health/sites/health/files/programme/docs/ex-post_ev-hp-2008-13_final-report.pdf, p. 45

50 Given the political sensitivity of specific objective 2 (Cross-border health threats), the originally foreseen focus group was replaced with interviews with members of the Health Security Committee, which are still being carried out.

The purpose was to gain insight into such issues as the relevance of the Programme and its specific objectives and thematic priorities in relation to health needs, EU added value and synergies with other actions at EU and other levels.

Each group was moderated by one of the evaluation team's sector experts, based on a discussion paper prepared and circulated in advance. The groups were carried out on 17-18 August 2016 and each lasted from 1.5 to 2 hours.

## CONCLUSIONS

### FROM THE ON-LINE GROUP ON HEALTH PROMOTION OBJECTIVE

The experts rated the objective as "very relevant", but pointed out that the "specification via the thematic priorities could be improved, made more logical, and complemented by a more social determinant-based approach". It was suggested to focus on major determinants and large and growing burdens of diseases. The Health Programme should encourage more integrated approaches and put the emphasis on scaling up and dissemination across MS.

Capacity building efforts should focus on mapping existing capacities and addressing the weaknesses. With regard to policy-making, the experts considered the EU was adding value in the definition of economic, social and health policies and the formulation of country–specific recommendations (e.g. through the European Semester, the EU's annual cycle of economic policy guidance and surveillance). The experts concluded to put more emphasis on evidence of economic benefits of any action as they felt that the lack of resources is the biggest threat to health prevention and care.

A stronger leadership of the Health Programme and more sustainability were identified as necessities for an enhanced EU added value.

### FROM THE ON-LINE GROUP ON INNOVATIVE, EFFICIENT AND SUSTAINABLE HEALTH SYSTEMS' OBJECTIVE

The experts unanimously agreed that "Contributing to innovative, efficient and sustainable health systems" is a laudable goal which relies upon a strong infrastructure through a capable, well trained and flexible workforce and should be absolutely included as the objective in the Programme of the EU. However, they propose that the objective should include, amongst others, healthcare staff governance and dissemination of innovation, health self-management and sharing of best practices.

The EU can contribute by informing policy-makers on good practices that improve efficiency and sustainability and by helping countries to adapt and implement such practices. Money remains a good incentive to convince decision-makers to make the right choices and the EU should make the best of its financial capacity to influence policy-making in the right direction.

The EU has the responsibility of supporting actions that benefit all its Member States in delivering highly complex services or highly specialized training and research on the treatment of autoimmune, infectious and rare diseases, health literacy and mental health including mental health of youth and health workforce.

Cost reduction strategy in health services cannot be implemented without considerations for its health outcomes as it could have a significant negative impact on the care provided. Since effective, satisfied and well trained health workforce is the backbone of the sustainable health system, the action, attention and political will to support its governance, development and planning should be clearly reflected and addressed by the EU Programme.

### FROM THE ON-LINE GROUP ON ACCESS TO BETTER AND SAFER HEALTH OBJECTIVE

"Facilitate access to better and safer healthcare for Union citizens" would be achieved through increasing access to medical expertise and information for specific conditions, also beyond national

borders. It would also entail helping to apply research results and developing tools for the improvement of healthcare quality and patient safety through, inter alia, actions contributing to improve health literacy.

Even if goals (partly political) are clear, they are not credible if sufficient resources are not allocated for implementation. In addition, goals must be more specific: experts suggested to put the emphasis on monitoring efficiency and effectiveness to ensure the sustainability of healthcare systems.

Greater emphasis should be put on lesson learning, the definition of guidelines and constitution of a strong evidence base, and the dissemination of these best practices in all MS – rather than leaving national stakeholders responsible for the implementation without much guidance. To some extent this is already happening, but we need robust descriptions of best practices also on broader healthcare areas.

Too many priorities imply a fragmented budget, which cannot translate into any meaningful impact. In this regard, instead of very specific targets which affect (the health of) a small proportion of EU citizens, those issues need to be addressed which are more prevalent and in the interest of a wider population.

Needs like smoking, sexually-transmissible diseases, infant mortality rates, rare diseases, migrants' health or medical tourism could be domains where funds can be spent more effectively. An enhanced focus of health action should be one of the best practices in health policy (including prioritising and ethics), supported by robust implementation mechanisms.

## 2.2 E-survey with Programme Committee members and National Focal points

The e-survey was distributed by email to all National Focal Points (NFPs) and Programme Committee members (PCs) of the Third Health Programme on 20 July, 2016. The survey remained open for almost a month and sought to collect information on perceptions of these key stakeholders in terms of the following issues:

- Suitability of the four objectives of the Programme and ability to address (emerging) health needs
- Existence of health needs which have not been addressed by the Programme and whether they should be covered by action at the EU level
- Implementation of the Programme: barriers to the participation of interested organisations; sufficiency of support and guidance provided by DG SANTE / CHAFEA (NFPs only); and actions to be supported in the Annual Working Programme (AWP) (PCs only).

Responses were provided by 45 National Focal Points and Programme Committee members, covering all EU-28 Member states with the exception of Estonia, plus Norway and Republic of Serbia.

The results of the eSurvey have been shared with the national Focal Points and Programme Committee Members in the respective regular meetings on 7 and 8 December 2016.

In these meetings it was agreed with them to complement the eSurvey with an additional three questions as to be possible to obtain additional feedback on specific issues:

- such as whether or not action is needed at EU level rather than only national / regional / local levels (the most important reason according to them justifying EU action for each specific objective of the Programme)

- outline the three thematic priorities that are most important for public health in their country in relation to each objective of the Programme.

-the initial survey mentioned several potential barriers that could prevent interested organisations from participating in the Programme in their country. Respondents to the mini survey were invited to select the potential barrier that they consider most important in their country.

The mini survey was completed by eight Programme Committee Members (or alternates), nine National Focal Points (or alternates) and nine respondents who stated that they fulfil both a Programme Committee Member and a National Focal Point roles (or their alternates).

Representatives from 11 low-GNI Member States participate, whereas the National Focal Points and Programme Committee Members from high-GNI Member States to respond were 14.

The esurvey was informative for the understanding of EU added value the Programme's institutional stakeholders make, confirmed the suitability of Programme objectives, the sufficiency of guidance and support for the implementation of the Programme by CHAFEA and DG SANTE, and provided information about the prioritisation of the thematic priorities and the barriers the Member States and other third countries are encountering in participating to the Programme.

**Figure 2: Importance of thematic priorities for public health in Member States**

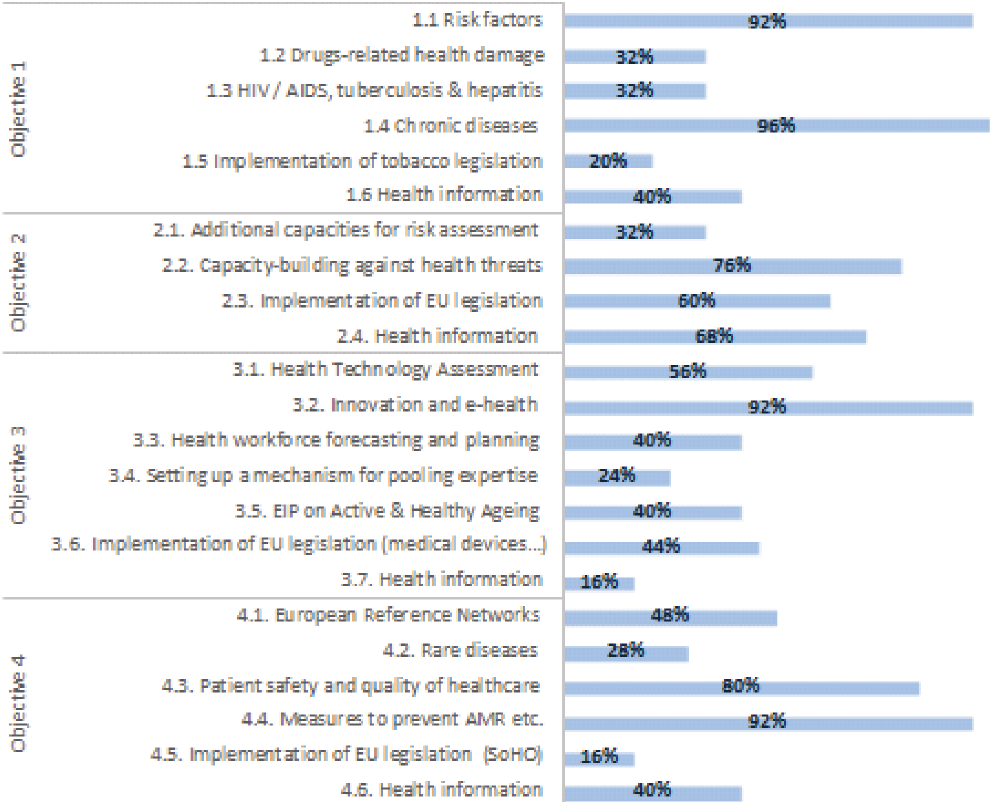
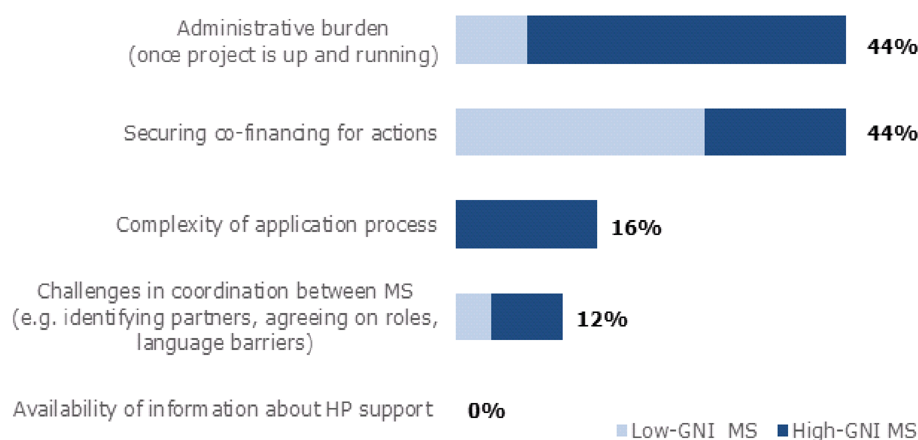


**Figure 1: Relative importance of potential barriers to participation (low and high-GNI Member States)**




## 2.3 Stakeholders Interviews

### 2.3.1 Interviews with Internal and external stakeholders

On the basis of the literature review and evaluation criteria, a questionnaire was prepared as guidance for semi-structured interviews with representatives of the European Commission (12 officials from DG SANTE, 4 officials from DG HOME, DG RTD, DG DEVCO, DG CONNECT, DG GROW and 6 staff members of CHAFEA including for the most project officers but also communication officer, coordinator of the Programme, etc.). The purpose of these interviews was to shed light on all aspects of the design and implementation of the Programme, particularly regarding new features such as the thematic priorities and multi-annual planning.

Interviews have also been organised with representatives from ECDC, WHO/Europe and independent experts involved as external evaluators in the selection procedure for the awarding of funding.

### 2.3.2 Interviews with Health Security Committee Members

Finally, given the political sensitivity of specific objective 2 (Protect citizens against cross-border health threats), the originally foreseen focus group was replaced with a series of in-depth interviews with members of the Health Security Committee (HSC). The interviews were conducted during November and December 2016 and included members of France, Malta and Spain. An additional interview with a representative from Croatia took place in early January.

Stemming from what was discussed with the HSC experts during the interviews, it is possible to identify some strengths and areas for improvement of how the Programme addresses health security:

*Strengths:* Objective 2 is clear and covers the most important aspects of the protection of citizens from serious cross-border health threats. Thematic priorities related to risk assessment, capacity building, and coordination/cooperation between relevant stakeholders were considered the most relevant for EU action. They are also the areas were the most remarkable achievements have been realised. In this respect, the EWRS was mentioned by

one expert as an example of a tool developed by the EU that works very well and that is being used extensively by Member States. The creation of an EU network of reference laboratories was also cited as a very important initiative, as well as the joint procurement of medical counter-measures.

*Areas for improvement:* The formulation of objective 2 could be improved by emphasising the ways in which the protection of citizens will be accomplished, and there was agreement that this related to enhancing coordination and networking between Member States, but also with the EC, international organisations and third countries. Moreover, developing Member States capacities to define and disseminate messages to the public during an outbreak was considered to be not sufficiently addressed by the current thematic priorities and a relevant area where the EU could play a more important role.

### 2.3.3 Interviews with beneficiaries (case study interviews)

Based on the assessment of the results from the desk study and questionnaires, several stakeholders were identified to be interviewed for the eight case studies. Mainly these were project coordinators from the around 30 actions examined for the case studies. Names and details for interviews under each case study are provided in Annex B (case studies report) of the Evaluation Report.

The case study interviews overall confirmed the findings from the targeted on-line questionnaire, but allowed a more in-depth insight through the specific actions.

## 3. Open Public Consultation

The purpose of the consultation was to allow stakeholder to provide views on different aspects of the evaluation questions mainly

- The objectives and priorities of the Programme, and the extent to which these are appropriate and in line with health needs in the EU;
- The way the Programme is implemented, and the extent to which this is effective and efficient; and
- The overall added value and usefulness of the Programme

  (1)

In total, 133 responses to the OPC were received, covering the countries listed in below. The vast majority of respondents listed a country in the EU-15 MS (which corresponds to the older MS of the EU and also MS which are typically more involved in the Programme.

**Table 1: Main country of residence / establishment of OPC respondents (as stated)**

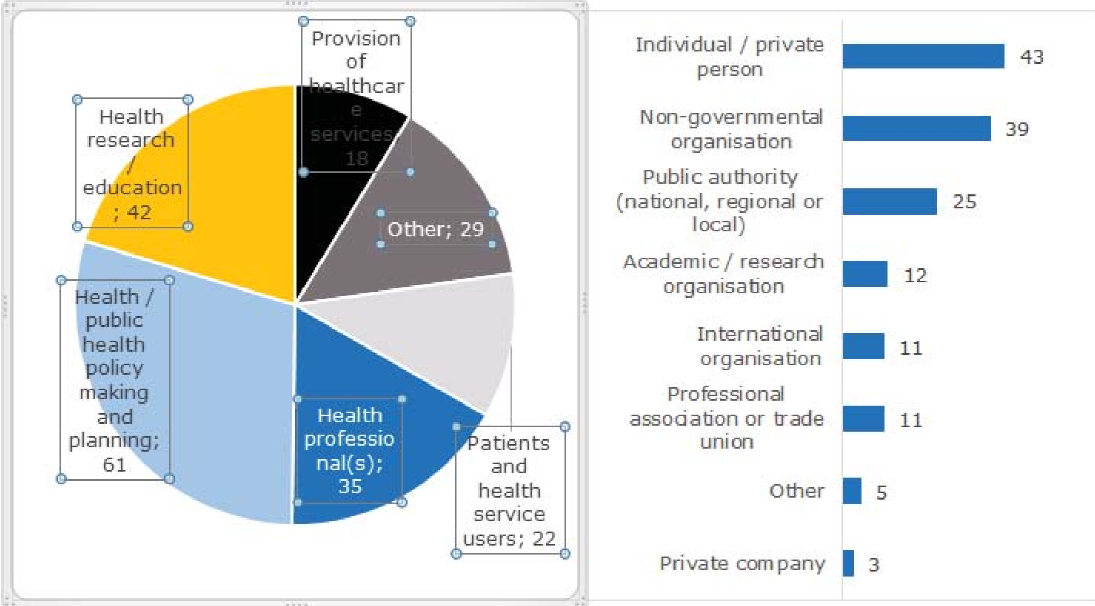
| | EU-15 Member States | EU-13 Member States | Associated countries | Other |
|---|---|---|---|---|
| **Respondents** | Austria (5) | Bulgaria (3) | Norway | Global (offices in US, South Africa and representation in Brussels) |
| | Belgium (29) | Croatia | Switzerland | |
| | Denmark (2) | Cyprus (3) | | Ukraine |
| | Finland (5) | Czech Republic | | |
| | France (5) | Hungary | | |
| | Germany (4) | Latvia | | |
| | Greece | Lithuania (4) | | |
| | Ireland (4) | Poland (2) | | |
| | Italy (12) | Romania | | |
| | Luxembourg | Slovakia (6) | | |
| | Netherlands (10) | Slovenia (1) | | |
| | Portugal (3) | | | |
| | Spain (13) | | | |
| | Sweden (3) | | | |
| | United Kingdom (7) | | | |
| **TOTAL** | 104 | 24 | 2 | 3 |

Half of the participants reported having some knowledge on EU health policy and the Programme, the number of individuals aware of (general) EU health policy being slightly more important.

Over 90% of all respondents reported working on health issues that are closely related to the ones supported by the third Health Programme and three in four were aware of activities funded by the Programme relevant to their work.

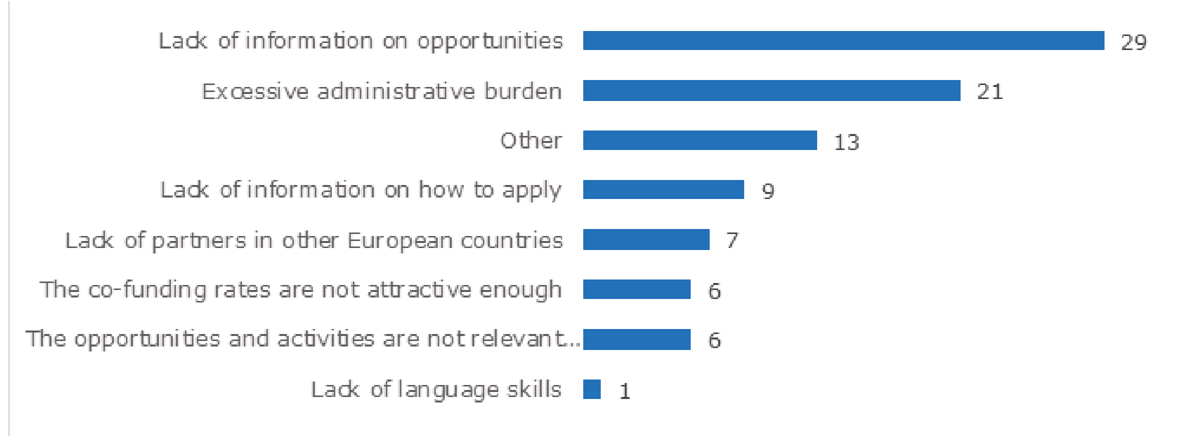
A majority of respondents were individuals, followed closely by representatives of non-governmental organisations. Almost one fifth of respondents were representatives of national, regional or local public authorities. Representatives from academia, international organisations and professional associations were less numerous to participate.

**Figure 4: Profile of respondents to OPC**[51]




However, almost half of the respondents noted they have never applied for funding from the Programme and one in 10 was unsure if they had applied. The reasons for not have done so are depicted in the below graphic.

**Figure 5: Reasons for not applying for funding through Programme, n= 51**

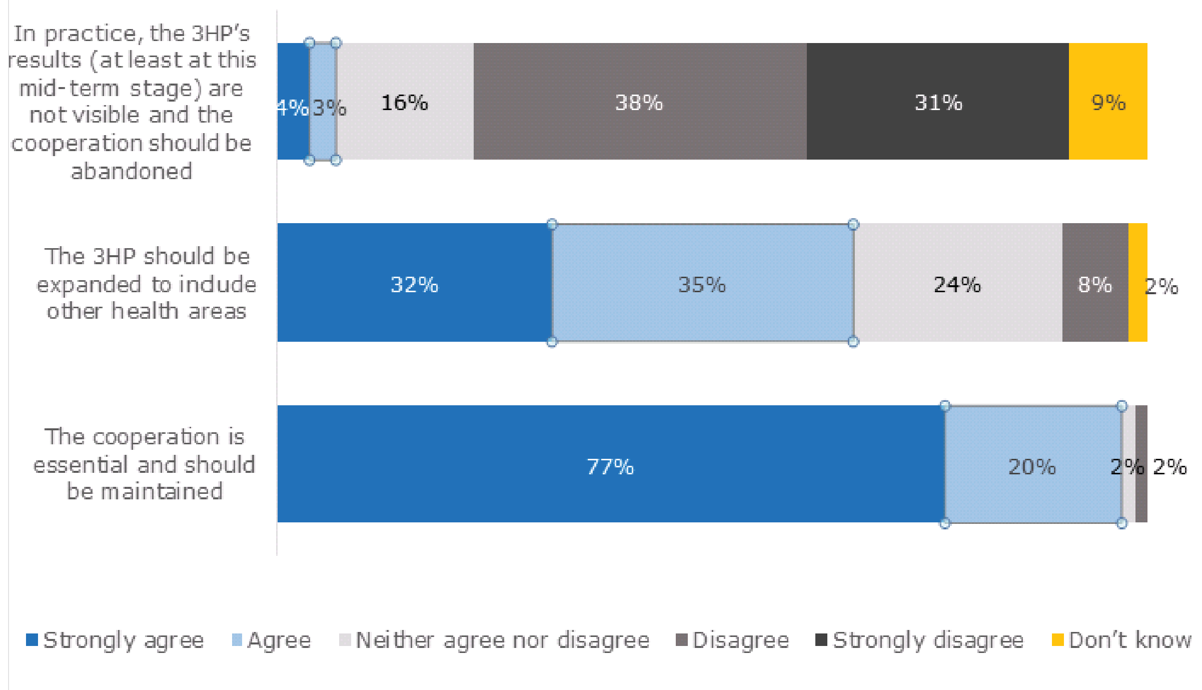



### *3.1 Respondents' views on EU cooperation*

The respondents appeared largely supportive of the activities funded under the Programme in the context of EU level cooperation between actors of the health sector, as over two thirds stated that the cooperation is essential and should be maintained. Respondents also appeared to share the view that the Programme should be maintained as less than one in 10 agreed that it should be abandoned. The responses of survey participants were more nuanced on whether the scope of the Programme should be expanded to include other health areas. Here, the number of neutral respondents and those who disagreed with this statement were higher.

[51] As respondents were able to select more than one answer to describe the two profile questions, the total number of responses adds up to more than 133.

**Figure 6: Opinions on the support of cooperation at EU level, n=133**

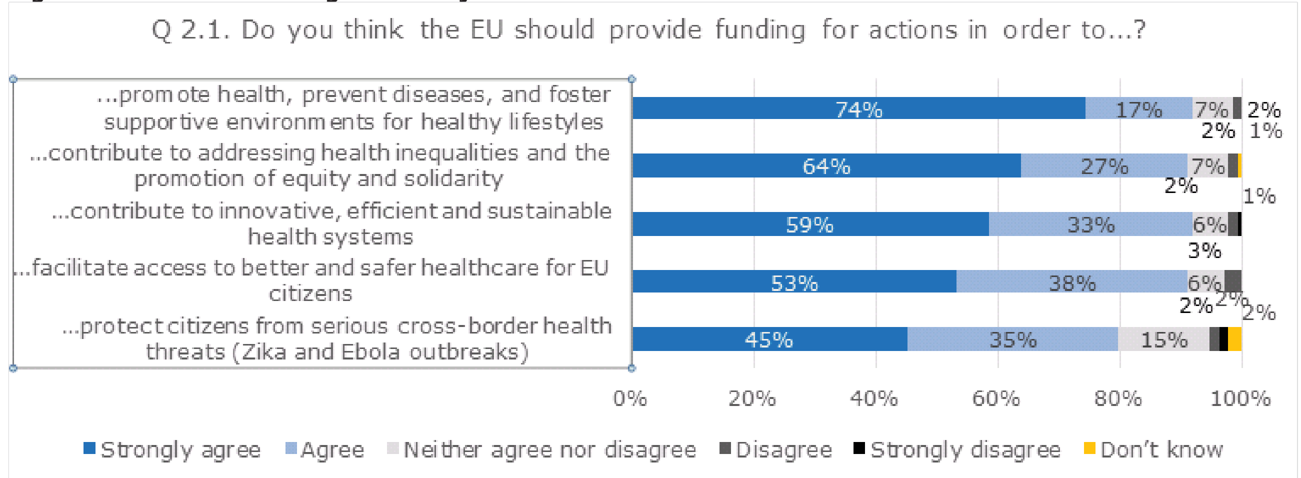



### *3.2 Respondents' views on the Programme's objectives and priorities*

The respondents were overwhelmingly of the view that the EU should continue supporting the important health-related challenges facing EU citizens, governments and health systems reflected in the formulation of the Programme's objectives. The areas considered as most important for EU action were to:

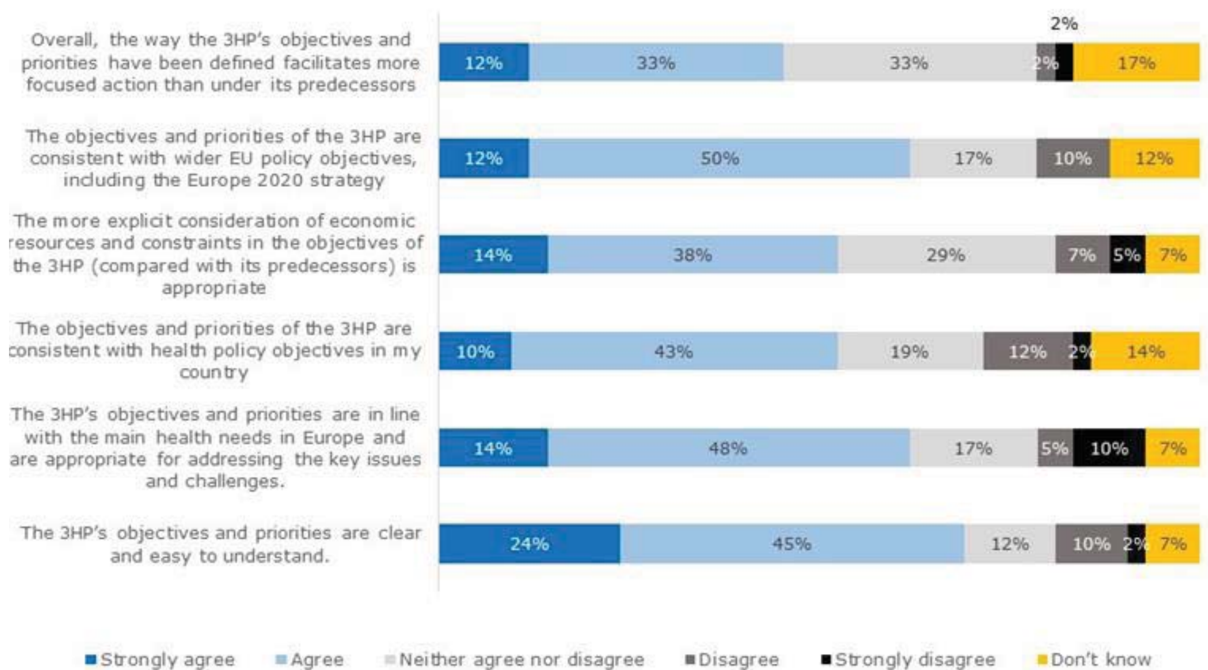
- promote health, prevent diseases, and foster supportive environments for healthy lifestyles (Specific Objective 1)
- contribute to innovative, efficient and sustainable health systems (Specific Objective 3), and
- contribute to addressing health inequalities and the promotion of equity and solidarity (General Objective).
- The respondents were slightly more uncertain on the relevance of EU support for the protection of citizens from serious cross-border health threats (Specific Objective 2) and for the facilitation of access to better and safer healthcare for EU citizens (Specific Objective 4).

**Figure 7: Relevance of Programme objectives**




The majority of respondents agreed that the Programme's objectives and priorities are clear and easy to understand, as well as consistent with wider EU policy objectives (more than 60% agreed or strongly agreed with these statements). Similar numbers were also of the opinion that the Programme's objectives and priorities are in line with the main health needs in Europe and are appropriate for addressing the key issues and challenges. Just over one in two respondents agreed or strongly agreed with the remaining statements. Overall, the outlook was slightly less positive when it came to the definition of the Programme objectives and priorities and their consistency with national health policy objectives.

**Figure 2: Opinions on the Programme's objectives and priorities, n=133**



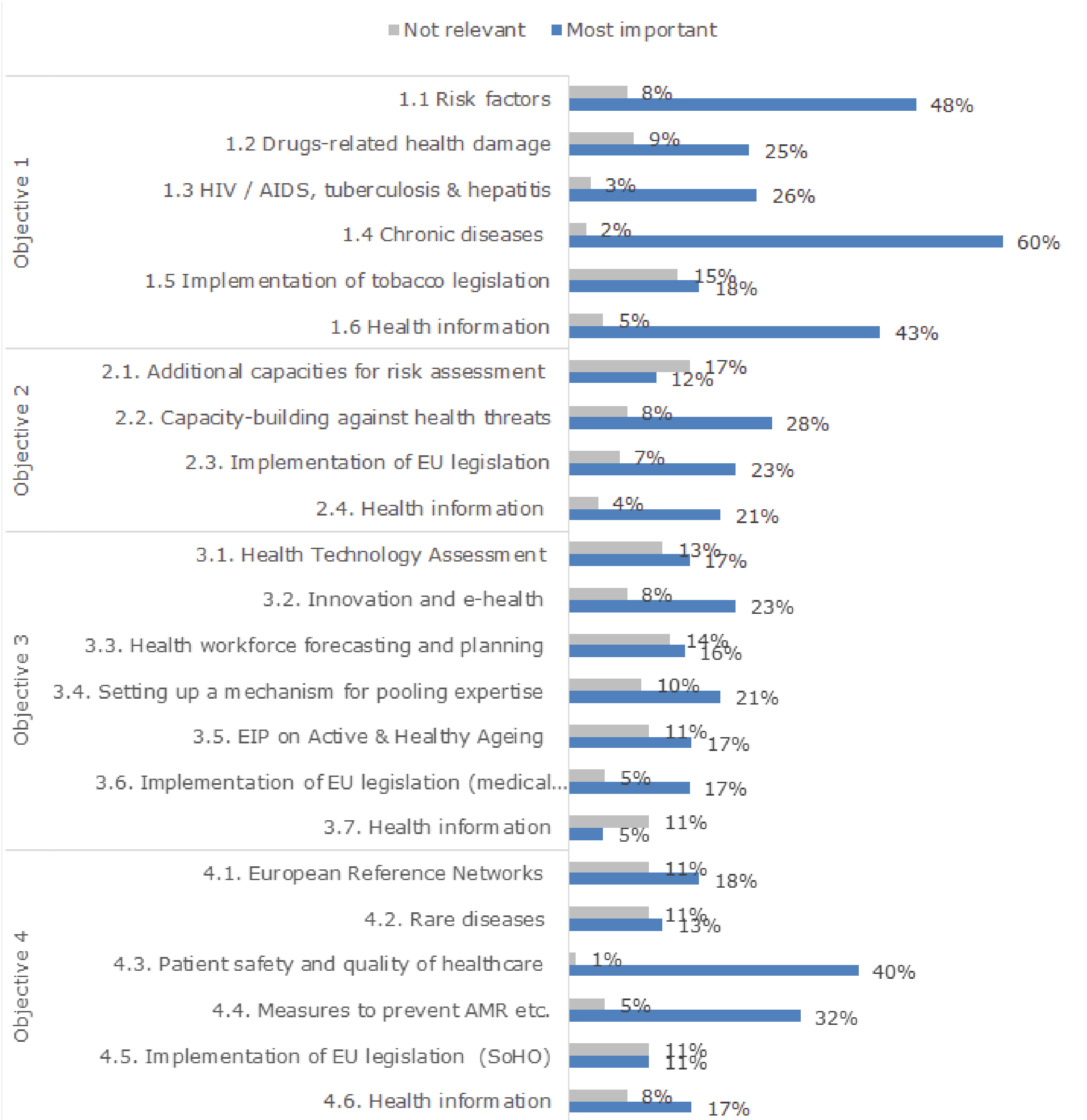

The OPC respondents were then invited to summarise any concerns about the relevance and coherence of the Programme and its objectives. A total of 46 respondents opted to provide comments. Often, the comments were very specific and it was difficult to identify trends or

shared concerns. Examples of comments are provided in the full synthesis report in Annex A of the Study Report[52].

The OPC respondents were invited to select up to five priorities that they consider to be the most important, and up to five that they consider to be not relevant.

Figure 3 presents the answers provided by the OPC respondents on the respective importance of the Programme's 23 thematic priorities, which are gathered under its four specific objectives.

**Figure 3: Respective importance of the Programme's 23 thematic priorities, n=133**




52 Mid-term Evaluation of the Third Health Programme (2014 – 2020) - Final report (Annex A), written by Coffey International Development, SQW and Economisti Associati, ISBN 978-92-79-68450-0 doi: 10.2875/292289

The respondents were also asked to list any other important thematic priorities they believe the Programme should support in the future, or to suggest amendments to the existing priorities. As many as 51 open replies were given, but the responses were very diverse. They included areas such as diabetes, hepatitis C and cancer prevention were cited which are anyway covered by the Programme. In addition, they have provided as additional items for inclusion in the Programme the endocrine disruptors in air, soil and water pollution.

### *3.3 Respondents' views on the implementation of the Programme*

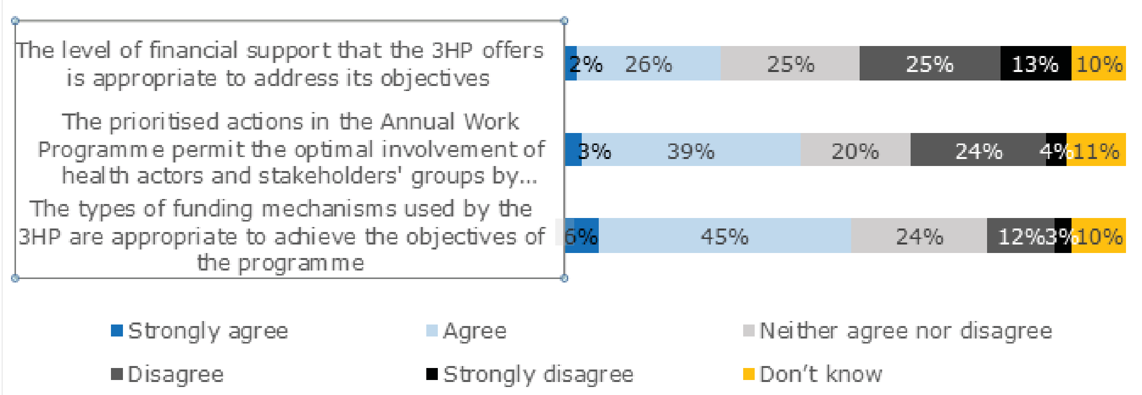
The OPC respondents were then asked to share their opinions in relation to statements about the implementation of the Programme (2014 – 2020) to date (i.e. 2014 – 2016).

- **Opinions on the Programme's funding mechanisms**

Figure 4 summarises the respondents' level of agreement with three statements regarding the suitability of the Programme's funding mechanisms. About a quarter of the OPC respondents were neutral on the three statements. Half of the respondents agreed that the types of funding mechanisms used by the Programme are appropriate to achieve the objectives of the programme. They were slightly less numerous to think that prioritised actions in the Annual Work Programme permit the optimal involvement of health actors and stakeholders' groups by making appropriate use of the different funding mechanisms. Less than one in three respondents agreed that the level of financial support that the Programme offers is appropriate to address its objectives and the respondents were more numerous to disagree with this statement.

One in 10 participants was unsure how to respond to the question.

**Figure 4: Opinions on the funding mechanisms of the Programme, n=133**

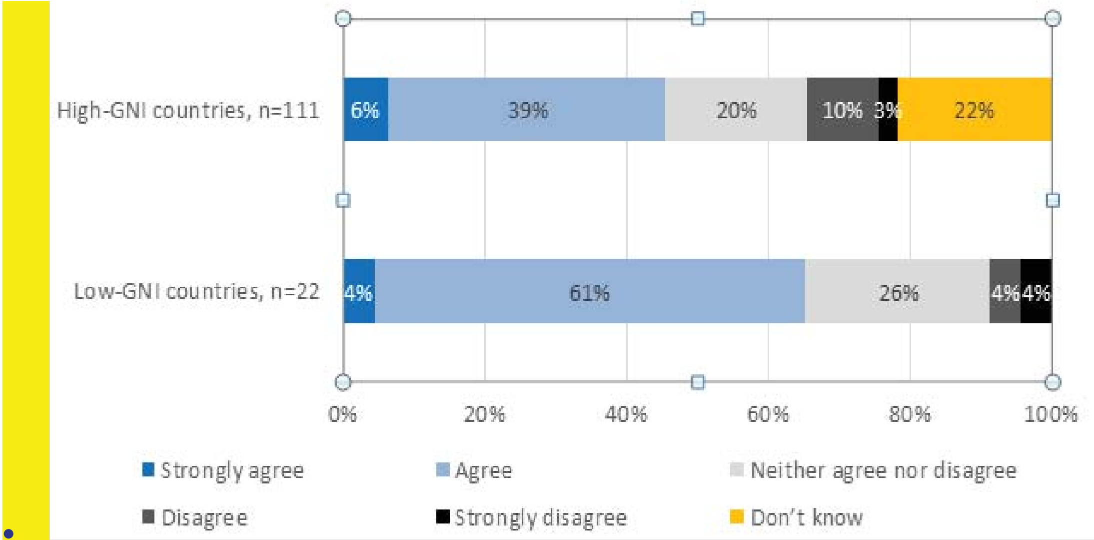



The participants were also asked whether they agreed or disagreed that the Programme includes appropriate measures to involve all Member States, including those with lower incomes. Figure 51 summarises the responses of the participants, by low-GNI (Bulgaria, Croatia, Czech Republic, Greece, Hungary, Latvia, Lithuania, Poland, Slovakia, Slovenia, Romania and Ukraine) and high-GNI countries (Cyprus, EU-15 except Greece and associated countries Norway and Switzerland).

The opinions of respondents from low- and high-GNI countries were broadly similar. A majority of respondents from low-GNI countries agreed with the statement, and one in four were neutral. Only less than 10% of low-GNI country respondents considered that the Programme does not include appropriate measures to involve lower income Member States. A

quarter of the respondents from high-GNI countries were unsure how to answer the question, but almost half thought that the Programme includes appropriate measures to involve all Member States, including those with lower incomes.

**Figure 5: Suitability of Programme measures to involve all MS, including those with lower incomes, n=133**

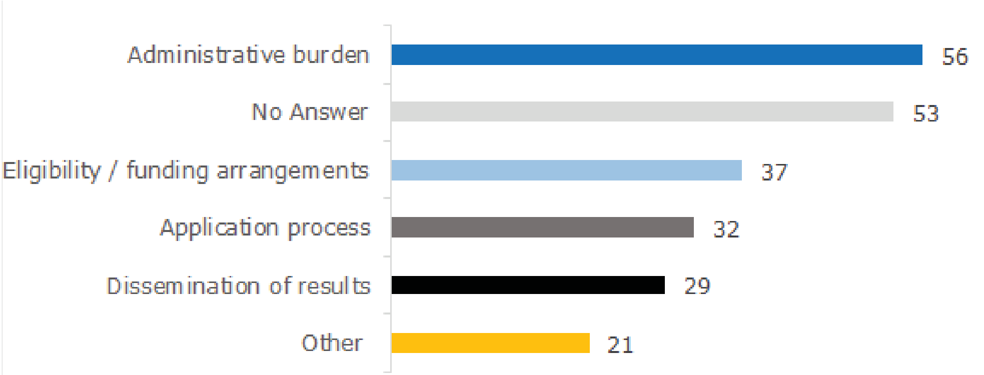



- **Additional concerns of respondents about the Programme and its implementation**

The participants were invited to share any additional concerns about the Programme and the way in which it is implemented, in the areas suggested in Figure 6. The respondents were able to select all the areas of concern relevant to them. Over a third of the participants did not provide an answer.

The participants to the OPC answering this question appeared to be mainly concerned with the administrative burden, as well as the eligibility and funding arrangements.

**Figure 6: Areas of additional concern on the implementation of the Programme, n=133**



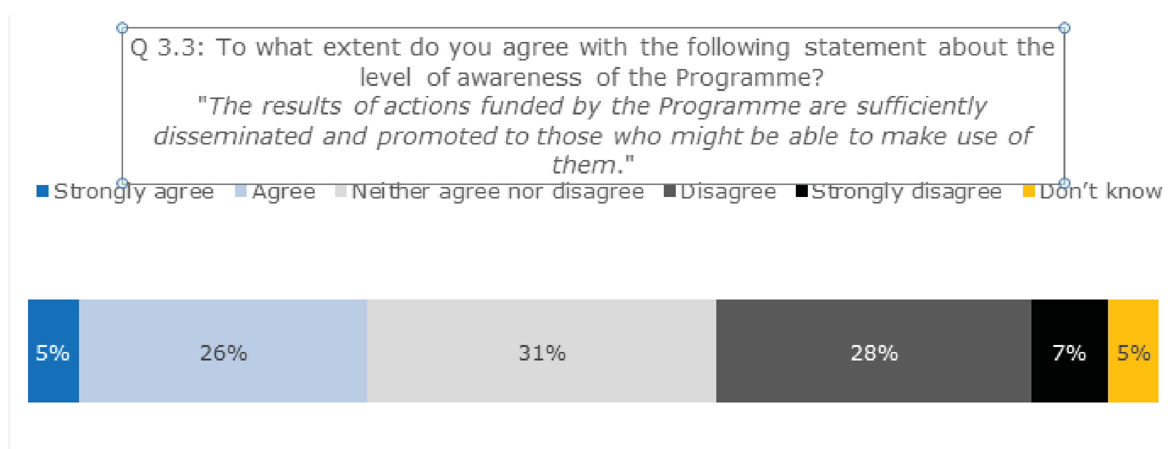

The respondents were able to briefly summarise any concerns other than the suggested areas in an open response. A few examples of relevant quotes from the 21 open replies received are provided below:

- *"More specialised programmes are needed, mainly by disease and another, a general one for rare diseases."*
- *"Opportunities for young public health professionals"*
- *"Civil society participation must be more explicit, even further - each member state should have one civil society organization working on national and international level included in the joint action. Only that will ensure greater performance and a greater added value for the EU citizens."*

- **Dissemination of results from actions funded by the Programme**

The respondents were also asked whether they agree that the results of actions funded by the Programme are sufficiently disseminated and promoted to those who might be able to make use of them. Figure 72 presents a summary of the responses collected. The same proportion of respondents agreed and disagreed with the statement, which suggests that their views are ambivalent on the promotion of the Programme to potential beneficiaries. This is also reflected in the fact that a third of the respondents remained neutral.

**Figure 72: Opinions on adequacy of dissemination of results, n=133**




- **Final comments**

Finally, the respondents to the OPC were able to share views on issues they considered had not been covered by the consultation. 44 respondents provided further details in their open replies. Often, the comments were very specific and it was difficult to identify trends or shared concerns. A snapshot (and relevant quotes) of the key aspects discussed in the open replies is provided in the full synthesis report in Annex B of the Evaluation Report. .

Comments were also made on the most relevant areas for EU action:

*"EU added value is clearest in a focus on internal market measures to tackle cross-border health threats, not only including communicable diseases and pandemics, and especially a stronger focus on AMR, but also recognising that all member states face the same threats from cross-border determinants including unhealthy dietary environments, alcohol, environmental health threats (including air quality, climate change), consumer safety, tobacco, sedentary work and mobility, and the impacts of employment and social precarity on (mental) health."*

*"The importance of prevention (of chronic diseases, communicable diseases and AMR) in economic and health system sustainability should be highlighted in Health contributions to EU economic, budget, taxation, social and employment policies and programmes. Much closer coordination is needed to respect the Health in all Policies requirement"*

- **Summary of main findings**

Overall, the respondents to the open public consultation provided a positive feedback on the EU's Health Programme and appeared largely supportive of the activities funded under the Programme. EU support is critical to EU level cooperation between actors of the health sector and respondents emphasised the role of the Programme for:

- The collection of best practices, dissemination of results and development of guidelines
- The provision of the necessary funding for campaigns and research
- The support to address systemic challenges such as health inequality.

The Programme's objectives are broadly agreed, in line with the main health needs and consistent with wider EU policy objectives and other EU programmes. But respondents suggested reconsidering the scope of the programme – to include such issues as diabetes, hepatitis C and cancer, but also endocrine disruptors in air, soil and water pollution – as well as the coordination and coherence with national health policy objectives.

From an implementation perspective, respondents raised a number of issues which should be monitored and addressed to enhance the cost-effectiveness of the Programme:

1. Administrative burden appears to remain a concern, especially when co-funding rates are not systematically considered attractive enough for individual organisations;

2. Awareness and information on the Programme remain relatively limited, even amongst stakeholders: more emphasis should be put on the communication and dissemination on the Programme, the opportunities created and its results, while the support to the networking of stakeholders could also be strengthened.

## 3. Feedback To Stakeholders

The results of the open public consultation have been published with a synthesis report on factual data and all the contributions received made public on http://ec.europa.eu/health/programme/consultations/midterm_evaluation_en.

A full synthesis report is annexed to the Study Report as Annex B[53] and will also be publicly available after the adoption of the Commission Report on Mid-term evaluation.

The participants to the open consultation and targeted consultation have been informed about the nature and set-up of the evaluation, and that the findings would be used for analysis, and that the EU would communicate about the results of the study.

[53] Mid-term Evaluation of the Third Health Programme (2014 – 2020) - Final report (Annex B) written by Coffey International Development, SQW and Economisti Associati; ISBN 978-92-79-68449- 4 doi: 10.2875/16031