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# REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

Implementation of the third Programme of Union Action in the field of health in 2019

{SWD(2021) 311 final}

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#### 1. INTRODUCTION

This report covers the implementation of the annual work programme for 2019 (2019 AWP) of the third health programme 2014-2020<sup>1</sup> (hereafter 'the programme'). Under Article 13(1) of the Programme Regulation, the European Commission (EC) must report to the Health Programme Committee on the implementation of all actions funded through the programme, and must keep the European Parliament and the Council informed. This report meets the latter requirement and describes how the programme was implemented and the budget used in 2019.

The Commission staff working document accompanying this report presents the key actions co-funded under the programme for which results became available in 2019, together with tables detailing all co-funded activities and contracts in the programme's 2019 operational budget.

The 2019 AWP was built around a number of priority areas, while addressing health inequalities as a cross-cutting issue.

Under Objective 1 (*Promote health, prevent diseases and foster supportive environments for healthy lifestyles*), the EU provided total funding of EUR 20 752 505.10 to five projects and one joint action. This included a joint action on implementing best practices in the field of nutrition, which aimed to increase the offer of healthier processed foods and/or to reduce salt, sugar and saturated fats in the processed foods available in EU supermarkets.

Under Objective 2 (*Protect Union citizens from serious cross-border health threats*), the EU provided total funding of EUR 8 058 630.32 to three projects, which included organising the global summit on vaccination. There was also a joint action to strengthen health preparedness and the response to biological and chemical terror attacks; this aimed to detect threats and assess risks of health-related terrorism acts, while bridging gaps between partners from public health, security and civil protection.

Under Objective 3 (*Contribute to innovative, efficient and sustainable health systems*), the EU provided total funding of EUR 15 473 042, 80 to several actions supporting innovative, efficient and sustainable health systems. A service contract was concluded to identify ways to enhance

<sup>&</sup>lt;sup>1</sup> Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC (OJ L 86, 21.3.2014, p. 1).

the cross-border exchange of health data in the EU, in line with the EC's priority for a 'EU health data space' to map, analyse and assess Member States' rules governing the processing of health data. A joint action on implementing digitally-enabled, integrated, person-centred care was also launched to help authorities reform their healthcare systems. This aimed to develop the capacity to transfer best practices and implement integrated care, using a bottom-up approach and following the main design principles and building blocks identified by the expert group on Health Systems Performance Assessment (HSPA)<sup>2</sup>.

Under Objective 4 (*Facilitate access to better and safer healthcare for Union citizens*), the EU provided total co-funding of EUR 14 044 589, 5 to support: (a) coordination activities and registries of the European Reference Networks (ERNs) for rare diseases; (b) non-governmental organisations contributing to EU health objectives; (c) networking of national authorities to transfer best practices; and (d) cooperation with international organisations.

The Commission and the Consumers, Health, Agriculture and Food Executive Agency (Chafea) ensured that the programme results were publicised widely through appropriate communication and dissemination activities. These focused on the key communication priorities indicated by DG SANTE, such as vaccination, ERNs for rare diseases, fighting against anti-microbial resistance, health technology assessment and digital health. These promotional activities included organising seven information days to promote the funding opportunities under the 2019 AWP, in cooperation with the National Focal Points (NFP) network<sup>3</sup>.

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<sup>&</sup>lt;sup>2</sup> Expert group on Health Systems Performance Assessment: https://ec.europa.eu/health/systems\_performance\_assessment/policy/expert\_group\_en

<sup>&</sup>lt;sup>3</sup> The NFPs are designated by EU Member States and other countries participating in the programme to help the EC promote the programme and disseminate its results and information on its impact.

#### 2. HIGHLIGHTS OF THE YEAR

The 2019 AWP broadly addressed the four specific objectives of the health programme.

Under Objective 1 (*Promote health, prevent diseases and foster supportive environments for healthy lifestyles*), a number of studies were launched to support EU legislation on tobacco products, related to the assessment of characterising flavours, and support the EC in applying Directive 2014/40 on tobacco products (TPD). Studies on alcohol were also funded to help Member States reduce alcohol-related harm and to map their fiscal measures and pricing policies applied to food, non-alcoholic drinks and alcoholic beverages.

Under Objective 2 (*Protect Union citizens from serious cross-border health threats*), a study was launched to examine the feasibility of developing a common vaccination card for EU citizens<sup>4</sup>.

The objective of the study is two-fold:

- Firstly, to carry out a mapping exercise to examine and compare the form and content
  of existing vaccination cards to identify features that could be included in an EU
  citizens' vaccination card.
- Secondly, to develop, test and evaluate three different templates for an EU citizens' vaccination card, taking interoperability into account. The templates should be in both electronic and physical format.

A future EU citizens' vaccination card would, first of all, be a self-empowerment tool, helping citizens to get their vaccines and those of their children at the right moment, particularly when

<sup>&</sup>lt;sup>4</sup> On 7 December 2018, EU Health Ministers adopted a Council Recommendation on strengthened cooperation against vaccine-preventable diseases

<sup>(</sup>https://ec.europa.eu/health/sites/health/files/vaccination/docs/14152\_2018\_en.pdf). The Recommendation was accompanied by a Commission Communication (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:245:FIN).

While the organisation of vaccination programmes is the responsibility of Member States, the Recommendation and the Communication call for a multitude of actions at EU level to fight vaccine-preventable diseases. One of these actions is to examine the feasibility of developing a common EU citizens' vaccination card/passport, with the main purpose of improving vaccination coverage by addressing the issues caused by cross-border movement of people and differences in vaccination programmes across the EU. Such a vaccination card/passport is also in line with the 'participatory approach' in the way individuals engage in health-related decisions and with the citizencentred approach adopted in the EC's eHealth Action Plan 2012-2020 (<a href="https://eur-lex.europa.eu/legalcontent/EN/TXT/?qid=1550061597950&uri=CELEX:52012DC0736">https://eur-lex.europa.eu/legalcontent/EN/TXT/?qid=1550061597950&uri=CELEX:52012DC0736</a>).

moving between EU Member States. It is proposed to test the dual templates in at least 10 volunteer Member States.

Under Objective 3 (*Contribute to innovative, efficient and sustainable health systems*), several actions were launched to support innovative, efficient and sustainable health systems, and a number of activities were funded to run campaigns supporting the implementation of the new regulations on medical devices ((EU) 2017/745) and in vitro medical devices ((EU) 2017/746). These campaigns address market players, healthcare professionals, health institutions, and citizens as patients. Their overall purpose is to inform and raise awareness among stakeholders about the regulations on medical devices (MD) and in vitro medical devices (IVD) and their requirements, before they enter into force in May 2021 and 2022 respectively, to avoid disruption to MD and IVD markets.

Under Objective 4 (*Facilitate access to better and safer healthcare for Union citizens*), a call was launched to support the development of rare disease (RD) registries for the ERNs<sup>5</sup>. The planned activities concern the building and development of RD patient registries for ERNs and further development and quality control of existing registries.

#### The main objectives are:

- to enable building, upgrading, linking and making interoperable registries covering the
  diseases and conditions relating to each ERN. This will help link and make patient
  cohorts visible at European level, so as to follow the natural course of diseases with
  sufficient patient data; in addition, all of the ERNs' individual RD registries will be
  registered on the EU RD Platform.
- to develop a comprehensive approach for RD registries that covers all the ERNs, following the standards and tools provided by the EU RD Platform.

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<sup>&</sup>lt;sup>5</sup> Twenty-four ERNs approved by the ERN Board of Member States were launched in March 2017, including more than 900 highly specialised healthcare units from around 300 hospitals located in 25 EU Member States and in Norway covering major disease groups, from bone disorders to haematological diseases, and from paediatric cancer to immunodeficiency. One member of each network acts as a coordinator.

Furthermore, a contract was awarded to provide services and technical assistance to the EC for an integrated assessment, monitoring, evaluation and quality improvement system (AMEQUIS) for the ERNs. Specifically, it will:

- examine all existing tools and indicators for assessing, monitoring and evaluating the ERNs:
- analyse the lessons learned from the use of existing tools and methods, while conducting a review of state-of-the-art tools and methodologies developed and tested by other organisations at national or international level, in the same and similar contexts.

This action helps the EC to fulfil its obligations under the cross-border Directive 2011/24/EU on patients' rights in cross-border healthcare and the 2014 Commission Implementing<sup>6</sup> and Delegated Decisions<sup>7</sup> in relation to the establishment and evaluation of ERNs.

Finally, Chafea launched a contract<sup>8</sup> to design, plan and manage the implementation of a programme to facilitate the exchange of visiting professionals between clinical centres in the ERNs for rare or low prevalence and complex diseases. The goal of the visits/exchanges is to share expertise, experiences and highly specialised knowledge within the scope and framework of the 24 ERNs. This programme will help to increase the overall level of highly specialised knowledge, deepen and facilitate cooperation among hospitals, and strengthen professional relationships within and between the different networks. In addition, the visits/exchanges will help to lay the foundations for creating and developing highly specialised training programmes.

<sup>&</sup>lt;sup>6</sup> https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL 2014 147 R 0007

<sup>&</sup>lt;sup>7</sup> https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL\_2014\_147\_R\_0006

<sup>&</sup>lt;sup>8</sup> Service contract for the provision of services on capacity and knowledge sharing through short-term mobility and exchanges of healthcare professionals for ERNs.

#### 3. BUDGET IMPLEMENTATION

The overall budget for the third health programme 2014-2020 was EUR 449.4 million. This includes EUR 30.6 million for the operating costs of Chafea, which the EC mandated to manage the programme. Chafea has been providing the EC with technical, scientific and administrative assistance in implementing the health programme since 2005<sup>9</sup>.

Chafea organises annual calls for proposals, coordinates the evaluation of submissions, negotiates, signs and manages grant agreements, and disseminates the results of the actions. It is also responsible for most procurement procedures.

The budget set out in the 2019 AWP was EUR 70 424 862, which was broken down as follows:

- Operational expenditure: EUR 62 258 000, corresponding to budget line 17 03 01 (Encouraging innovation in health, increasing the sustainability of health systems and protecting Union citizens from serious cross-border health threats);
- EFTA/EEA<sup>10</sup> and other third countries<sup>11</sup> participating in the programme made additional contributions of EUR 2 116 862;
- Administrative expenditure: EUR 1 500 000, corresponding to budget line 17 01 04 02;
- Budget for the operating costs of Chafea: EUR 4 550 000, corresponding to budget line
   17 01 06 02.

The operational budget totalled EUR **64.614.759,55**. DG SANTE and Chafea committed in total EUR **63 862 709,64** under the 2019 AWP (99%). Chafea committed **EUR 46 888 723,23** while DG SANTE committed **EUR 16 973 986.41**, covering part of the **procurement** commitments and other actions. From the overall commitment, unused appropriations amounted to EUR **752 050,11**, corresponding to **1.2%** of the total.

<sup>&</sup>lt;sup>9</sup> Commission Decision 2004/858/EC of 15 December 2004 setting up an executive agency, the 'Executive Agency for the Public Health Programme', for the management of Community action in the field of public health – pursuant to Council Regulation (EC) No 58/2003 (OJ L 369, 16.12.2004, p. 73) amended by Commission Decision 2008/544/EC of 20 June 2008 amending Decision 2004/858/EC in order to transform the 'Executive Agency for the Public Health Programme' into the 'Executive Agency for Health and Consumers' (OJ L 173, 3.7.2008, p. 27). From December 2014, the Executive Agency for Health and Consumers (EAHC) was replaced by the Consumers, Health, Agriculture and Food Executive Agency (Chafea) by Commission Implementing Decision 2014/927/EU of 17 December 2014 amending Implementing Decision 2013/770/EU in order to transform the 'Consumers, Health and Food Executive Agency' into the 'Consumers, Health, Agriculture and Food Executive Agency' (OJ L 363, 18.12.2014, p. 183).

Norway and Iceland.Serbia, Bosnia and Herzegovina, and Moldova.

#### 3.1 Priorities

In 2019, the total operational budget that was implemented **EUR 63 862 709,44** was assigned to the four specific programme objectives as follows:

- 1. **Health promotion EUR 20 752 505,10** (32% of the operational budget) for promoting health, preventing diseases and fostering supportive environments for healthy lifestyles, taking into account the 'health in all policies' principle;
- 2. **Health threats EUR 8 058 630.32** (13% of the operational budget) for protecting Union citizens from serious cross-border health threats;
- 3. **Health systems EUR 15 473 042,80** (24% of the operational budget) for contributing to innovative, efficient and sustainable health systems;
- 4. **Better and safer healthcare EUR 14 044 589,5** (22% of the operational budget) for facilitating access to better and safer healthcare for Union citizens.

In addition, **horizontal activities** (IT activities, communication, reimbursement of expert evaluators) and transversal actions amounted to **EUR 5 533 943, 24** (9% of the operational budget).

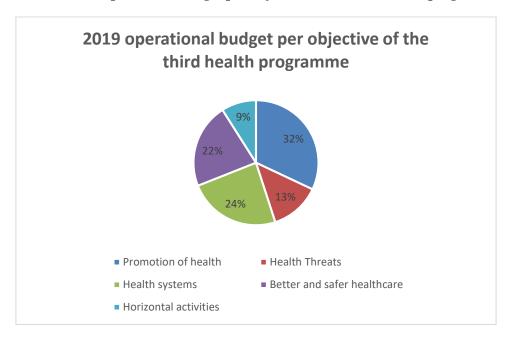


Chart 1: 2019 operational budget per objective of the third health programme

In relation to the 2019 budget allocation for each of the programme's thematic priorities, Chart 2 below shows that activities under thematic priority 1 to promote health, prevent diseases and foster supportive environments for healthy lifestyles rank highest, followed by vaccination, medical devices and rare diseases.

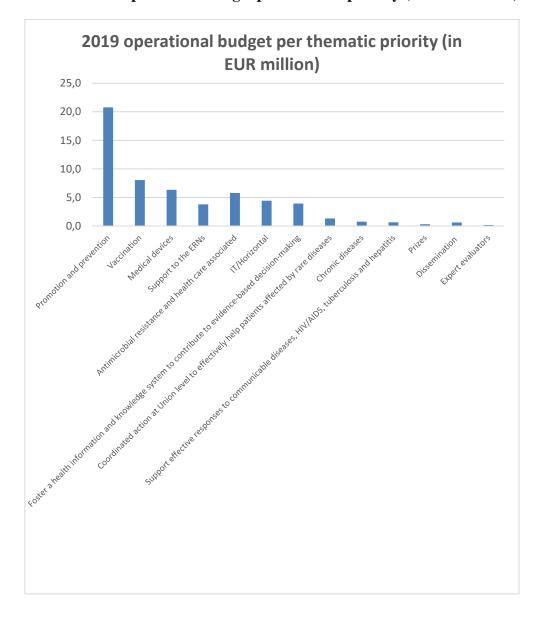


Chart 2: 2019 operational budget per thematic priority (in EUR million)

To achieve its objectives, the programme was implemented through a wide range of funding instruments. These included:

- project grants;
- operating grants in support of non-governmental organisations;
- actions co-financed with Member State authorities (joint actions);

- direct grant agreements with international organisations;
- public procurement; and
- other actions, such as support for the Scientific Committees, administrative agreements with the Joint Research Centre and EUROSTAT, and grants for Presidency conferences.

Competitive calls were used to select actions for funding, e.g. for projects and procurement. Joint actions, grants to international organisations and conferences organised by EU Council Presidencies are direct grant agreements because of their monopoly situations (*de facto* or *de jure*). External reviewers (joint actions), DG SANTE and Chafea officers ensure the quality of these co-funded actions through the evaluation of proposals.

The administrative budget covered expenditure such as studies, meetings of experts, communication and technical and administrative assistance for IT systems.

# 3.2 Execution of the operational budget by financing mechanism

Type of financing mechanism	Implementation	Share of mechanism
	(EUR)	in total implemented
		budget (%)
1. Grants under calls for	26 314 180.36	41%
proposals or by invitation:		
1.1 Project grants, including other	5 774 147.36	9%
DGA projects		
1.2 Operating grants for NGOs	5 434 283	8.4%
1.3. Joint action grants	14 992 063	23%
1.4. Conference grants to the	113 687	0.17%
Member States holding the		
Presidency of the EU		
2. Direct grant agreements with	5 750 000	9%
international organisations		
TOTAL GRANTS	32 064 180,36	50%
3. Procurement (service	24 359 690,04	38%
contracts), prizes and horizontal	21255 050,01	2070
actions		
Managed by Chafea	14 149 296,55	22%
Managed by DG SANTE	,	16%
4. Other actions	7 438 839,29	12%
Managed by Chafea	·	1%
Managed by DG SANTE		11%
5. Budget implemented under 2019	,	
AWP		
Managed by Chafea	46 888 723,30	72,6%
Managed by DG SANTE	16 973 986,41	26.2%
	63 862 709,44	

Total available budget under 2019	64.614.759,55	
AWP		
Credits not used	752 050,11	1.20%
by Chafea <sup>12</sup>	752 046,35	
by DG SANTE	3.76	

### 3.3 Beneficiaries

In 2019, Chafea and DG SANTE signed over 273<sup>13</sup> grants and contracts with beneficiaries and service providers: governmental organisations, academic institutions, non-governmental organisations, private companies, and individual experts<sup>14</sup>. Other beneficiaries included international organisations and EU services. Around 479 beneficiaries and contractors received EU funding, with the two main categories being private companies (for procurement and other actions) and governmental organisations (for joint actions and for projects).

# 4. MAIN COMMUNICATION ISSUES

In 2019, Chafea organised dissemination activities to raise the visibility of results and successes achieved under the third health programme, to promote DG SANTE's specific communication priorities and to continue expanding outreach to potential programme beneficiaries. Extensive information on these activities can be found in Chafea's 2019 Activity Report for the third EU health Programme.

The EU Health Programme Conference on 30 September 2019 was the major event of the year, with over 350 targeted participants in attendance. The aim of the event was two-fold: to highlight the success stories of the third health programme and to present EU health funding under the post-2020 multiannual financial framework. In cooperation with the Health Programme NFPs, Chafea organised several information days (in Bosnia and Herzegovina, Czechia, Greece, Ireland, Italy, Malta, Poland and Sweden) with over 250 participants, on topics connected with national policy priorities.

<sup>&</sup>lt;sup>12</sup> The contract on the feasibility options for physical stockpiling was not awarded following the change of DG Sante policy needs for an expected total amount of 700 000 EUR.

<sup>&</sup>lt;sup>13</sup> Joint Actions (3), project grants (20), operating grants SGA (14), Direct Grant agreement (4), prizes (3), presidency conferences (2), tenders (21), horizontal actions (186) and other actions (20).

<sup>&</sup>lt;sup>14</sup> This figure does not include contracts with individual experts participating in Scientific Committees, evaluators of calls for proposals, etc.

Chafea also actively participated in other major European public health conferences, where scientists and health professionals were the target audience:

- the 19th International Conference on Integrated Care, 1-3 April 2019, San Sebastian, Spain<sup>15</sup>.
- the 22nd European Health Forum Gastein, 2-4 October 2019, Austria<sup>16</sup> (Chafea organised a stand).
- the 12th European Public Health Conference, 20-23 November 2019, 'Building bridges for solidarity and public health', Marseille, France<sup>17</sup> (lunch symposium on 'How can we join forces to engage in multiple stakeholder actions to reach optimal influenza vaccination coverage rates in Europe?').

Other web communication and web dissemination activities included the publication of over 120 cross-linked news items on the Chafea website and partly via social media, the publication of webinars on funding opportunities, the development of dissemination guidance for beneficiaries and the upgrade of the database download features.

In terms of producing and promoting web publications (and print-on-demand), Chafea produced a booklet on 'Health for the EU' presenting the programme's success stories<sup>18</sup>, and two info-sheets on 'e-health'<sup>19</sup> and 'frailty'<sup>20</sup>. They are available in 24 EU languages.

<sup>&</sup>lt;sup>15</sup> https://integratedcarefoundation.org/events/icic19-19th-international-conference-on-integrated-care-san-sebastian-basque-country

<sup>16</sup> https://www.ehfg.org/archive/2019/programme

<sup>&</sup>lt;sup>17</sup> https://ephconference.eu/conference-2019-marseille-271

<sup>18</sup> https://op.europa.eu/en/publication-detail/-/publication/98986869-e049-11e9-9c4e-01aa75ed71a1

<sup>19</sup> https://op.europa.eu/en/publication-detail/-/publication/08e68564-67fe-11e9-9f05-01aa75ed71a1/language-en?WT.mc\_id=Selectedpublications&WT.ria\_c=19980&WT.ria\_f=3171&WT.ria\_ev=search

<sup>&</sup>lt;sup>20</sup>https://op.europa.eu/en/publication-detail/-/publication/b3cbce3e-5ccd-11e9-9c52-01aa75ed71a1/language-en?WT.mc id=Selectedpublications&WT.ria c=19980&WT.ria f=3171&WT.ria ev=search