

Brussels, 8 July 2022 (OR. en)

11211/22

SAN 448 PHARM 126 MI 565 **CADREFIN 125**

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director	
date of receipt:	8 July 2022	
To:	General Secretariat of the Council	
No. Cion doc.:	COM(2022) 328 final	
Subject:	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 2020	

Delegations will find attached document COM(2022) 328 final.

Encl.: COM(2022) 328 final

11211/22 EN LIFE.5



Brussels, 8.7.2022 COM(2022) 328 final

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 2020

{SWD(2022) 186 final}

EN EN

Table of contents

1. INTRODUCTION	2
2. HIGHLIGHTS OF THE YEAR	5
3. BUDGET IMPLEMENTATION	7
3.1 Priorities	9
3.2 Execution of the operational budget by financing mechanism	12
3.3 Beneficiaries	13
4. MAIN COMMUNICATION ACTIVITIES	13
5. CONCLUSION	14

1. INTRODUCTION

This report covers the implementation of the annual work programme for 2020 (the 2020 AWP) of the third Programme for the Union's action in the field of health ('the Programme'). Article 13(1) of the Regulation that established the programme¹ requires the European Commission to report to the Programme Committee on the implementation of all actions funded through the Programme, and to keep the European Parliament and the Council informed. This report meets the latter requirement and describes how the Programme was implemented and the budget was used in 2020.

The Commission staff working document accompanying this report presents the key actions cofunded under the Programme for which results became available in 2020, together with tables detailing all co-funded activities and contracts in the Programme's 2020 operational budget.

The 2020 AWP was built around a number of priority areas, but also addresses health inequalities as a cross-cutting issue.

Impact of COVID-19 pandemic on the implementation of the annual work programme

Following the COVID-19 outbreak in the first quarter of 2020, the Programme's running actions² in the area of health security were activated in an 'emergency mode' and steered to fight the pandemic. Key examples are the joint action 'Healthy gateways'³, which supported the coordination among EU countries to improve capacity for combating cross-border health threats at points of entry, including ports, airports and ground crossings; and the joint action on Strengthened International Health Regulations and preparedness (SHARP⁴), which saw the collaboration with the European Centre for Disease Prevention and Control's EVD-LabNet

¹ 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).

² These actions carried out by the health programme created synergy with and complemented the emergency measures for immediate response mobilized by the EU, under specific and dedicated instruments (such as the Union Civil Protection Mechanism, the Emergency Support Instrument and the EU Solidarity Fund, the Joint Procurement for Medical Countermeasures) an other programmes (e.g. Horizon 2020 Framework Programme for Research and Innovation).

³ www.healthygateways.eu

⁴ The JA SHARP (<u>www.sharpja.eu</u>) supports coordination among EU reference laboratories to prevent, detect and respond to biological outbreaks, chemical contamination and environmental and unknown threats to human health

(Emerging Viral Diseases-Expert Laboratory Network) to ensure quality control and capacity building for precise diagnostics for COVID-19 at an early phase of the pandemic, and demonstrated the importance of using laboratory networks as a preparedness and response tool.

Due to the orientation of human resources in DG SANTE to COVID-19 pandemic activities, other activities were reduced, such as the secretariat of the Scientific Committees, thus resulting in less Opinions adopted by the Committees, six adopted by the the Scientific Committee on Consumer Safety (SCCS) and one by the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER).

Due to restrictions on movement, the two conferences organised by the German and Portuguese Presidency of the EU Council, were held on line, as well as the Information days organised by the Consumers, health, agriculture and food executive agency (Chafea) to present the funding opportunities under the 2020 work programme. Several timelines to submit proposals for projects or joint actions had to be postponed due to the fact that health authorities of Member States were busy dealing with the COVID-19 pandemic. However, despite all these difficulties, the implementation of the 2020 annual work plan was not significantly affected, also in terms of budget consumption.

Under Objective 1 'Promote health, prevent diseases, and foster supportive environments for healthy lifestyles', the EU provided a total funding of **EUR 11 097 241.78** for 11 non-governmental organisations (NGOs)⁵, one joint action, one international organisation, two other actions and 10 service contracts. The 11 NGOs had submitted proposals for a specific grant agreement (SGA) under a framework partnership agreement signed in 2017. The joint action is for the exchange of best practices in the implementation of the Tobacco Products Directive (2014/40/EU)⁶ and for implementing and delegated acts relating to e-cigarette legislation.

⁵ European Public Health Association (EUPHA), European Public Health Alliance, Smoke Free Partnership, European Network for Smoking and Tobacco Prevention, Obesity Training And Information Services in Europe - phase 2, Schools for health in Europe Foundation, TBEC: strengthening TB response in the WHO Europe region, AIDS Action Europe - Stronger together, Correlation - European Harm Reduction Network, Alzheimer Europe, European Cancer Leagues -Collaborating for impact in cancer control.

Under Objective 2 'Protect Union citizens from serious cross-border health threats', the EU provided a total funding of **EUR 3 933 955.42** for four projects that focus on improving vaccination access and uptake. One of the projects is IMMUNION (Improving IMMunisation cooperation in the European UNION) focuses on increasing vaccine uptake and is thus part of the response to the 2018 Council Recommendation on vaccination, while also adding value to EU and national initiatives, particularly the Coalition for Vaccination.

Under Objective 3 'Contribute to innovative, efficient and sustainable health systems', the EU provided a total funding of EUR 31 850 207,93 to support the operating of one NGO (Health Action International) and for several actions fostering innovative, efficient and sustainable health systems. One joint action concerned the exchange and implementation of best practices in the field of mental health, with a particular focus on suicide prevention and the reform of mental health services. Moreover, a joint action, 'Towards the European Health Data Space' (TEHDAS) was launched to help establish a European Health Data Space⁷ – an important advance in the sharing of health data. A direct grant was awarded to the European Directorate for the Quality of Medicine and Healthcare to help it establish harmonised quality standards and reference materials for substances of biological origin in line with the EU's initiatives on animal protection.

Under Objective 4 'Facilitate access to better and safer healthcare for Union citizens', the EU provided total co-funding of **EUR 7 710 843.21** to support 3 NGOs⁸ contributing to EU health objectives, to fund the presidency conference on "Availability, Accessibility and Affordability of Medicines and Medical devices", organised under the Portuguese Presidency of the Council of the European Union, and to fund service contracts.

The total expenditure for cross-cutting activities related to all objectives, including the joint action to support the Programme National Focal Points, the 2020 EU Health Award,

⁶ Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1).

⁷ EUR-Lex - 52022PC0197 - EN - EUR-Lex (europa.eu)

⁸ Thalia: action against thalassemia, EURORDIS, SAVDON: World Marrow Donors Association.

communication activities, information communication technology (ICT) and expert evaluators was EUR 13 595 548.80.

The Commission and the Consumers, Health, Agriculture and Food Executive Agency (Chafea) ensured that the programme's results were publicised widely through appropriate communication activities. Those activities focused on the key communication priorities indicated by the Commission's Directorate-General for Health and Food Safety (DG SANTE) - for example, vaccination, COVID-19, promoting healthy lifestyles, health workforce, health technology assessment and digital health. Promotional activities were organised in cooperation with the National Focal Points (NFPs) network⁹, including two information days in the format of webinars to promote the funding opportunities available under the 2020 AWP.

2. HIGHLIGHTS OF THE YEAR

The 2020 AWP broadly addressed the four specific objectives of the Programme.

Under Objective 1 'Promote health, prevent diseases and foster supportive environments for healthy lifestyles', a Joint Action on Tobacco Control (JATC2)¹⁰ was launched to facilitate the exchange of good practices between the Member States, thereby improving the implementation of the Tobacco Products Directive and of implementing and delegated acts relating to e-cigarette regulation. One of JATC2's aims is to ensure greater consistency in the Directive's application and thereby ensuring a fair single market for tobacco and related products, with a particular focus on market surveillance and enforcement. It will assess the existing legal framework for tobacco advertising and the advertising of emerging products.

Among the several NGOs receiving an operating grant, there was the Association of European Cancer Leagues (ECL), a unique platform bringing together various cancer leagues active at regional, national and international level to achieve a cancer-free Europe. The ECL supports the cancer leagues in the implementation of the Council Recommendation on Cancer Screening, while also uniting them to advocate for equal access to treatment, support, and rehabilitation for

5

⁹ The NFPs are designated by EU Member States and other countries participating in the programme to help the EC promote the programme and to communicate its results and information on its impact.

¹⁰ JAOTC2 is a 3-year joint action with EC co-funding of MEUR 2.5

cancer patients. Finally, ECL advocates for the European Guide for quality improvement in cancer control to be better established and considered in national cancer plans. The active involvement of the ECL in fighting cancer has been of great significance particularly in the case of the EU Pharmaceutical Strategy, on which the ECL has issued a position paper, sharing its views and reinforcing the proposed patient-centred approach. This involvement is also linked with the implementation of the Europe Beating Cancer Plan.

Under Objective 2 'Protect Union citizens from serious cross-border health threats', three projects to boost vaccination uptake were funded. Projects RISE-Vac¹¹, ImmuHubs¹² and ActToVAx4NAM¹³ 'Increased Access To Vaccination for Newly Arrived Migrants' aim to increase access to vaccination for disadvantaged, isolated and difficult-to-reach groups and for newly arrived migrants (taking a life course approach). In particular, ActToVAx4Nam targets exclusively newly arrived migrants – in first-line, transit and destination countries – and aims to ensure fair access to vaccination.

Under Objective 3 'Contribute to innovative, efficient and sustainable health systems', Chafea launched a service contract¹⁴ for the provision of joint health technology assessment (HTA) work to support ongoing EU cooperation on HTA. This service will address existing methodological issues in order to promote joint work on HTA, while also supporting EU cooperation on HTA beyond the end of the EUnetHTA joint action. It will therefore provide relevant input to the development of a new legal framework on HTA. Given that Regulation (EU) 2021/2282¹⁵ on HTA entered into force in January 2022 and will become applicable in January 2025, this service contract is expected to actively support the implementation of the new Regulation which is currently in its preparatory phase.

In particular, the service contract will lead to the:

¹¹ duration: 3 years, EU co-funding: EUR 951 120.

¹² duration 3 years, EU co-funding: EUR 989 104

¹³ Duration: 3 years, EU co-funding: EUR 994 393

¹⁴ for an amount of MEUR 3, and a duration of 3 years

¹⁵ EUR-Lex - 32021R2282 - EN - EUR-Lex (europa.eu)

- further development of HTA methodology to be applied when carrying out joint clinical assessments (JCAs) and joint scientific consultations (JSCs). It will address those areas where opinions still diverge with a view to further developing the methodology for joint work and making it easier to reach a common approach when carrying out JCAs and JSCs;
- completion of eight parallel JSCs for medicinal products or a minimum of six JSCs, enabling one of the most successful products of the EUnetHTA joint action to continue;
- completion of two JCAs for medicinal products and four JCA/CAs for medical devices if
 possible, but in any event at least one JCA for medicinal products and two JCA/CAs for
 medical devices;
- coordination of the above-mentioned joint activities, including interaction with stakeholders' representatives (patients, health professionals, industry), academia, relevant EU and international organisations and HTA initiatives.

Under Objective 4 'Facilitate access to better and safer healthcare for Union citizens', a study was launched to support the impact assessment for the reviews of Directive 2002/98/EC on safety and quality of human blood and blood components and of Directive 2004/23/EC on safety and quality of human tissues and cells, as well as of these two directives' implementing acts. The contract duration was nine months and helped the Commission prepare an impact assessment to support its proposal to amend existing EU legislation on blood, tissues, and cells.

The specific objectives are to:

- provide a description of the baseline situation, summarise the key elements of the
 evaluation, and complement problem definition by gathering and analysing evidence on
 the impact and other aspects of borderline technologies/therapies together with the
 lessons learned from the COVID-19 pandemic;
- measure the likely significant economic, social and environmental impacts of each of the policy options;
- analyse and compare the effectiveness, efficiency and consistency of policy options.

3. BUDGET IMPLEMENTATION

The overall budget for the Programme was EUR 449 000 000. This included EUR 30 600 000 for the operating costs of Chafea which assisted the Commission in the Programme implementation. Chafea provided the Commission with technical, scientific and administrative assistance in implementing the Programme and its predecessor programmes since 2005¹⁶.

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

The budget set out in the 2020 AWP was EUR 71 556 963. This can be analysed as follows:

- operational expenditure funded by the EU: EUR 63 624 000 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';
- operational expenditure funded by EFTA/EEA¹⁷ and other non-EU countries¹⁸ participating in the programme: EUR 1 882 963;
- administrative expenditure: EUR 1 500 000 corresponding to budget line 17 01 04 02;
- Chafea's operating costs: EUR 4 550 000 corresponding to budget line 17 01 06 02.

The total budget for operational expenditure was **EUR 65 506 963**. DG SANTE and Chafea between them committed a total of **EUR 68 187 797.40** under the 2020 AWP (105% of the operational expenditure budget). Chafea committed **EUR 40 430 042.00** and DG SANTE committed **EUR 27 657 755.14** – covering some of the procurement commitments and other actions.

8

¹⁶ 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, 16.12.2005, 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).

¹⁷ Norway and Iceland.¹⁸ Serbia, Bosnia and Herzegovina, and Moldova.

The EUR 2 680 834, 14 difference between the voted operational budget and the final committed

budget is due to internal transfers that occurred during the global transfer exercise resulting from

the COVID-19 pandemic.

3.1 Priorities

In 2020, the total operational expenditure commitment of EUR 68 187 797.14 was assigned to

the following four specific Programme objectives:

1. promotion of health - EUR 11 097 241.78 (16% of the total 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 3 933 955.42 (6% of the total operational budget) for protecting EU

citizens from serious cross-border health threats;

3. health systems – EUR 31 850 207.93 (47% of the total operational budget) for promoting

innovative, efficient and sustainable health systems;

4. better and safer healthcare – EUR 7 710 843.21 (11% of the total operational budget) for

facilitating access to better and safer healthcare for people in the EU.

In addition, cross-cutting activities (IT activities, communication, reimbursement of expert

evaluators) and other activities (e.g. Scientific Committees, Expert Panel and other expert group

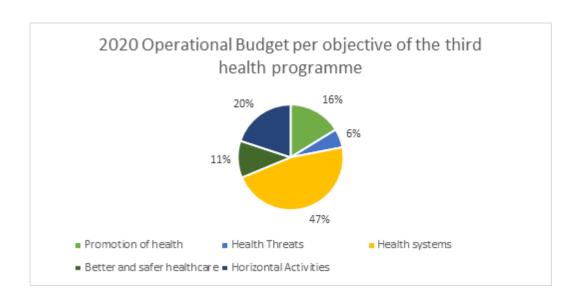
activities, studies to assist in developing health policies), amounted to EUR 13 595 248.80

(20% of the operational budget).

Chart 1 below shows the allocation of the budget among the different objectives.

Chart 1: 2020 operational budget per objective of the Programme

9



In relation to the 2020 budget allocation for each of the Programme's thematic priorities, Chart 2 below shows that activities under thematic priority 3 – to contribute to innovative, efficient and sustainable health systems – were allocated the largest share of the budget, followed by horizontal or cross-cutting activities, health promotion and vaccination initiatives.

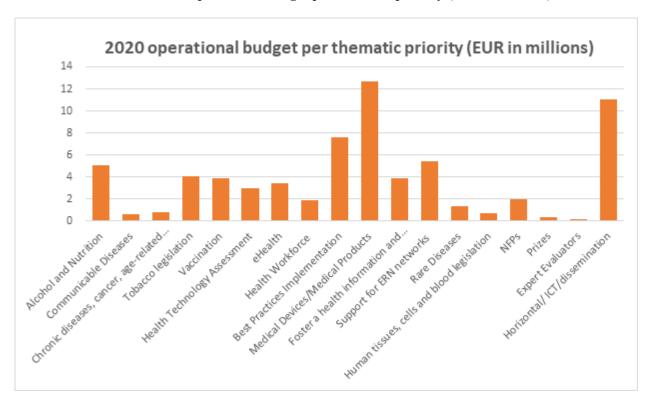


Chart 2: 2020 operational budget per thematic priority (in EUR million)

The programme was implemented through a wide range of funding instruments. These included:

- project grants,
- operating grants in support of NGOs,
- actions co-financed with Member State authorities (joint actions),
- direct grant agreements with international organisations,
- public procurement,
- other actions, such as support for the scientific committees, administrative agreements with the Joint Research Centre and Eurostat, and grants for conferences organised by Council presidencies.

Competitive calls were used to select actions for funding, for example for projects and procurement. Joint actions, grants to international organisations and conferences organised by presidencies of the Council of the EU are direct grant agreements because there is a monopoly situation (*de jure or de facto*), meaning that there is only one possible service provider.

External reviewers (joint actions), DG SANTE and Chafea officials evaluate proposals to ensure the quality of these co-funded actions.

The administrative budget relates to expenditure on items 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 (EUR)	Share of mechanism in total implemented budget (%)
1. Grants under calls for proposals or by invitation:		
1.1 Project Grants / HP-PJ	7 452 705.51	11.30%
1.2 Operating grants / SGAs	5 852 209.00	8.90%
1.3 Joint action grants	12 408 994.17	18.90%
1.4. Conference grants to the Member States holding the Presidency of the EU	162 984.92	0.24%
1.5 Direct grant agreements with international organisations	5 730 000.00	8.74%
TOTAL GRANTS	31 606 893.60	48%
2. Procurement(service contracts, prizes, horizontal)	26 708 292.21	40%
Managed by Chafea	8 273 148.40	13%
Managed by DG SANTE	18 435 143.81	27%
4. Other Actions	9 872 611.33	10.90%
Managed By Chafea	650 000.00	0.90%
Managed by DG SANTE	9 222 611.33	10%
5. Budget implemented under 2020 AWP	68 187 797.14	105%
Managed by Chafea	40 530 042.00	62%
Managed by DG SANTE	27 657 755.14	37.47%
Total available budget under 2020 AWP	65 506 963.00	100.00%
Additional Credits -	2 680 834.14	5%
By Chafea	-	

By DG Sante	2 680 834.14	
Total with transferred credits		68 187 797.14

3.3 Beneficiaries

In 2020, Chafea and DG SANTE signed over 80¹⁹ grants and contracts with beneficiaries and service providers: governmental organisations, academic institutions, NGOs, private companies, and individual experts²⁰. Other beneficiaries included international organisations and EU departments. Around 286 beneficiaries and economic operators 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 ACTIVITIES

In 2020, Chafea organised communication activities to raise the visibility of results and successes achieved under the Programme, to promote DG SANTE's specific communication priorities and to boost efforts to reach out to potential Programme beneficiaries. Extensive information on these activities can be found in Chafea's 2020 activity report for the programme²¹.

The information webinars held on 4 and 5 March 2020 were the main events of the year, with over 350 attendees. The webinars highlighted the programme's success stories and presented EU health-funding opportunities under the 2020 AWP (for example, calls for projects, joint actions and tenders).

Moreover, in cooperation with the programme's NFPs, Chafea organised two information days in Italy and Sweden with over 100 participants on topics connected with national policy priorities. In addition, 60 people participated in an online information day meeting on joint actions on 8 June 2020.

¹⁹ Joint actions (4), project grants (10), operating grants /specific grant agreements (SGA) (15), direct grant agreement (4), prizes (3), presidency conferences (2), tenders (37) and other actions (10).

²⁰ This figure does not include contracts with individual experts participating in scientific committees, evaluators of calls for proposals, etc.

annual-activity-report-2020-chafea_en.pdf (europa.eu) or Annual activity report 2020 - Consumers, Health, Agriculture and Food Executive Agency | European Commission (europa.eu)

The two following events enabled to further communicate on the Programme implementation and results.

- 2020 European Public Health Conference, 20-23 November 2020, online event with two sessions and a virtual stand.
- 16th World Congress on Public Health 2020, 12-17 October 2020, online event with two sessions and a virtual stand.

Online communication activities in 2020 exceeded the set target (150 news items a year). Over 220 news items on Chafea's website were cross-linked with social media promotion, webinars on funding opportunities, communication guidance for beneficiaries and an upgrade of the database's download features. In addition, cross-linking with DG SANTE's website and the Health-EU Newsletter improved the communication of Commission measures to fight the COVID-19 pandemic.

Chafea produced a number of electronic publications, publicly available on its website and on the EU bookshop website, which can be printed on demand. These include three information sheets on cancer²², integrated care²³ and substances of human origin (SoHO)²⁴. They are available in all 23 of the EU's official languages.

5. CONCLUSION

While reorienting and gearing a proportion of its activities and resources towards fighting the COVID-19 pandemic, the programme continued the implementation of its actions under the programme with a view to enhancing and further consolidating key achievements over the entire implementation period 2014-2020. Under exceptional circumstances due to the COVID-19 outbreak, the programme performed well and has been effectively implemented in 2020, thereby contributing to better health protection through its policies and activities, in accordance with Article 168 of the Treaty on the Functioning of the European Union.

²³ Integrated care - Publications Office of the EU (europa.eu)

²² Cancer - Publications Office of the EU (europa.eu)

²⁴ Substances of human origin (SoHO) - Publications Office of the EU (europa.eu)