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

Implementation of the third programme of EU action in the field of health in 2017

{SWD(2020) 52 final}

INTRODUCTION

This report presents the implementation of the annual work programme for 2017 (2017 AWP) of the third health programme 2014-2020 established by Regulation (EU) No 282/2014 of the European Parliament and of the Council ¹. In accordance with the Article 13 of the Regulation, the Commission must report to the health programme committee² on the implementation of all actions funded through the Programme, and keep the European Parliament and the Council informed. This report meets the latter requirement, providing information on the 2017 budget and how it was used.

The Commission staff-working document accompanying this report presents the key actions co-funded under the third health programme for which final results became available in 2017. It further includes information on the actions carried out under the main thematic priorities included in successive financing decisions (promotion of health and prevention of non-communicable diseases, including tobacco, nutrition and mental health; protection against cross-border health threats; patient safety; health technology assessment; results of operating grants). The document also provides the overview tables detailing all co-funded activities and contracts.

The 2017 AWP launched six Joint Actions totalling EUR 20.229.410,14 of EU co-funding:

- Joint Action Health Equity Europe (JAHEE),
- European Joint Action on vaccination (JAV),
- Joint Action supporting the eHealth Network(e-Health),
- Joint Action Information for Action (InfAct),
- Joint Action Innovative Partnership for Action Against Cancer (iPAAC), and
- Joint Action Preparedness and action at points of entry (Healthy Gateways).

These Joint Actions, along with other actions funded in 2017, addressed several of the health programmes objectives.

The new JA iPAAC and JAHEE, addressing cancer prevention and health inequalities, are tackling important determinants of health, such as tobacco, nutrition and alcohol, as well as access to screening programmes and cancer care and support, supporting objective 1 (*Health promotion and disease prevention*).

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 <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0282&from=EN>, Chapter V, art.17.

Under the objective 2 (*Protecting Union citizens from serious cross-border health threats*), the focus in 2017 was on addressing vaccination hesitancy and improving preparedness and response capacities to combat health threats at entry and exit points of the EU (ports, airports and ground crossings).

Under objective 3 (*Contributing to innovative, efficient and sustainable health systems*), two important Joint Actions were launched, on e-Health and on health information for Action, while a direct grant was used to step up the collaboration with the Council of Europe on pharmaceutical products.

The first communication and information campaign on the new medical devices Regulation (EU) 2017/745³ was launched in collaboration with DG GROW, in support of the health programme's objective 4 (*Facilitating access to better and safer healthcare for Union citizens*).

In 2017, the Consumers Health Agriculture and Food Executive Agency (Chafea) published the second call for proposals for a Framework Partnership Agreement for operating grants to non-governmental organisations, covering the period 2018-2021.

The Commission and Chafea ensure that program results are publicised widely through appropriate communication and dissemination activities. Member States and third countries participating in the Programme are also encouraged to engage in the dissemination of the results of the co-funded actions and to seek synergies with other EU funding programmes. This included the organisation of the national information days in collaboration with the National focal point network⁴.

In parallel to these initiatives, the Commission ensures that the implementation of the third health programme is monitored. Two evaluation tasks were launched in 2017: a “Data gathering study” to inform the health policy options in the Multiannual Financing Framework 2021-2027, and the 2nd external evaluation of Chafea.

³ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

⁴ The National Focal Points (NFP) are the national experts for the Health Programme in member states and participating countries. NFP representatives are appointed by their national health ministries. The specific role of the NFPs is to assist the Consumers, Health, Agriculture and Food Executive Agency (Chafea) in: Health Programme implementation at national level, Health programme dissemination of results, Information on the impact generated by the Health Programme in their respective countries.

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HIGHLIGHTS OF THE YEAR

The 2017 AWP addressed in a broad manner the four specific objectives of the Health Programme. The inclusion of six Joint Actions, mobilising more than EUR 20 million of EU contribution, supports the willingness of the competent authorities of the Member States and other countries participating in the programme to work together in key policy areas.

The launch of the **Joint Action on vaccination** (EU-JAV)⁵ complements and supports the Commission Communication regarding vaccine preventable diseases⁶ and Council Recommendation on strengthened cooperation against vaccine-preventable diseases⁷ as well as the Joint Procurement of medical countermeasures initiative⁸.

Background

Vaccination is a major tool of primary prevention of communicable diseases and the most cost-effective public health measure. Thanks to widespread vaccination, smallpox has been eradicated, Europe is polio-free and many other contagious, and for some lethal, diseases have almost been eliminated.

Despite this successful track record, several EU and neighbouring countries are currently facing unprecedented outbreaks of vaccine-preventable diseases due to low vaccination coverage rates. Unequal access to vaccines and the waning of public confidence in vaccine safety are a cause for concern and a major challenge for public health authorities.

Goal

Coordinated by INSERM (France) and involving 23 countries (among them 20 EU member states), the Joint Action on vaccination aims to build concrete tools to strengthen national responses to vaccination challenges in Europe and therefore improve population health..

Means

The Joint Action is currently working on the following areas:

⁵ <https://eu-jav.com/>

⁶ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Strengthened Cooperation against Vaccine Preventable Diseases, COM(2018), 26.4.2018 245 final.

⁷ Council Recommendation of 7 December 2018 on strengthened cooperation against vaccine-preventable diseases(OJ C 466, 28.12.2018, p. 1).

⁸ https://ec.europa.eu/health/preparedness_response/joint_procurement_en

- Establishing sustained cooperation of relevant Member State authorities
- Defining basic principles for vaccine demand forecasting
- Developing a concept and prototype for a data warehouse for EU-wide sharing of vaccine supply and demand data/information among dedicated stakeholders
- Defining common stages and criteria for priority-setting of vaccine research and development
- Developing a concept and prototype for a vaccine R&D priority setting framework
- Defining structural, technical and legal specifications as regards data requirements for electronic vaccine registries/databases/immunisation information systems
- Providing a framework to cooperate on confidence from research to best practices and implementation

The **Joint Action Health Equity Europe (JAHEE)**⁹ brought together 25 EU Member States to improve health and well-being of European citizens and achieve greater equity in health outcomes across all groups in society.

Background

The effects of health inequalities within and between European countries are widely recognized¹⁰, and reducing health inequalities is a crosscutting priority on the agenda of the EU¹¹ and many other countries. Despite an increasing awareness and concern on the impact of health inequalities, political response varies widely in Europe.

Goal

The Joint Action is currently working on the following areas :

- Improving the planning and development of the policies to tackle health inequalities at European, national, regional and local level;
- Implementing actions that provide the best opportunity to tackle health inequalities in each participating country;
- Strengthening a cooperative approach in tackling health inequalities and facilitate exchange and learning among participating countries (sharing and learning approach);
- Facilitating transferability of best practices among participating countries.

⁹ <https://jahee.iss.it/>

¹⁰ Health inequalities in the EU, Marmot report:

https://ec.europa.eu/health/sites/health/files/social_determinants/docs/healthinequalitiesineu_2013_en.pdf

¹¹ European Regional Development Fund (ERDF) for the period 2014– 20 identifies reducing health inequalities as one of a number of priorities.

Means

To achieve its goals the Joint Action is supporting participating countries in:

- Monitoring health inequalities through the development and uptake of health indicators for health policy evaluation and prioritization, adapted to the national context and sustainable over time;
- Identifying national strategies, policies and models of good practice for healthy living environments including advocacy guidance for decision-makers and stakeholders;
- Reducing health inequalities in access to health and social services, through the formulation of adapted regional, national and local strategies, policies and programs;
- Strengthening capacity of participating countries to develop and apply a “Health and Equity in all policies” approach.

Under health programme objective 3 (contributing to innovative, efficient and sustainable health systems), the **collaboration with the Council of Europe on pharmaceutical products** was supported through the signature of a three year direct grant agreement with an EU contribution of EUR 3 300 000.

Background

Directives 2001/83/EC on medicinal products¹² and 2001/82/EC on veterinary medicinal products¹³ assign a central role to the European Pharmacopoeia¹⁴ in ensuring the quality of medicines in the European Economic Area (EEA). The European Union is a party to the “Convention on the elaboration of a European Pharmacopoeia” of the Council of Europe, in line with the Council Decision 94/358/CE¹⁵. The Council of Europe/European Directorate for the Quality of Medicines and Health care¹⁶ ensures the secretariat for the European Pharmacopoeia.

Goal

The action aims at:

¹² Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

¹³ Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

¹⁴ <https://www.edqm.eu/en/european-pharmacopoeia-ph-eur-9th-edition>

¹⁵ Council Decision 94/358/E of 16 June 1994 accepting, on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia (OJ L 158, 25.6.1994, p. 17).

¹⁶ The European Directorate for the Quality of Medicines & Health Care is a Directorate of the Council of Europe, <https://www.edqm.eu/>

- Ensuring the use of harmonised quality standards and reference materials for biologicals in line with the EU efforts for protection of animals;
- Ensuring an adequate and effective surveillance of the quality of marketed medicines in Europe; and
- Maintaining and further improving the harmonised identification of medicinal products in Europe and globally.

Means

This action supports:

- The Biological Standardisation Programme by making available new methods for the quality control of biologicals as well as reference standards that are needed to perform the quality assessment methods in the European Pharmacopoeia.
This 2018-2020 programme will work on the establishment of such reference standards. These are needed because stocks of previously established standards are depleted or new/revised monographs of the European Pharmacopoeia have been created and require them¹⁷.
- The Official Medicines Control Laboratories (OMCLs) in their role for monitoring the quality of medicinal products on the European market through the dedicated OMCL Network.
During 2018-2020, the OMCL Network will take into account newly authorised medicinal products, medicinal products with a complex formulation or manufacturing process, products produced using novel manufacturing or control technology or where difficulties in the testing methodology have been encountered previously.
- The implementation of Quality Management System in all OMCLs, promoting the sharing of work, experience, equipment and cost for surveillance of medicines.
- The role of OMCLs in the detection of falsified medicines as required by the EU legislation (Directives 2001/83/EC and 2001/82/EC).
- The "Terminology" project, which underpins the identification of medicinal products in a harmonised way across the globe, primarily for pharmaco-vigilance purposes. By maintaining the Standard Terms database of harmonised terms and definitions (for pharmaceutical dose forms, routes and methods of administration, packaging and units of presentation), the action strengthens post-marketing safety activity and the global monitoring of suspected adverse events caused by medicinal products.

¹⁷ Special emphasis is given to the development of such methods that can replace, reduce and refine animal experiments for the quality control of biologicals, in line with the Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes Text with EEA relevance (OJ L 276, 20.10.2010, p. 33).

Under health programme objective 4 (facilitating access to better and safer healthcare for Union citizens), the **communication campaign on the new medical devices Regulation** (EU) 2017/745 was launched in collaboration with DG GROW. The three-year campaign covers the adaptation phase for the enforcement of the said medical devices regulation and is investing circa EUR 1 600 000 for the period 2017-2019.

Background

This campaign resulted from the adoption in April 2017 of the two new Regulations on medical devices - Regulation (EU) 2017/745 - and on in vitro medical devices – Regulation (EU) 2017/746¹⁸. The purpose of the campaign is to make sure that all actors, and first of all the manufacturers, are well aware of the changes, new requirements and timelines of the new Regulations. The date of application is May 2020 for medical devices and May 2022 for in vitro diagnostics but there are several transitional provisions for earlier implementation that all interested parties need to fully understand.

The adoption of these Regulations shows that the EU takes action to ensure that medical devices on the market will be safer for patients and healthcare professionals. The information and communication campaign fitted into the European Commission's President Jean-Claude Juncker priorities for 'Jobs, growth and investments' and 'Internal Market'.

Goal

The communication initiative aims at avoiding a disruption in the medical devices market following the latest legislative modifications. There is a need to provide information to all the actors concerned by the modifications brought by these new Regulations. This is relevant to EU and global manufacturers but also to importers, distributors, authorised representatives, notified bodies, re-processors of single-use devices, health institutions, healthcare professionals, and competent authorities.

Means

In order to achieve its objectives, the campaign includes, inter alia:

- The preparation of a Communication strategy for the campaign.

¹⁸() Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC , and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).).

- The establishment of a database of actors to serve the campaign, including competent authorities, professional and trade organisations as well as patient organisations.
- Assistance to selected key stakeholders for the preparation of conferences on the new Regulations on medical devices (Regulation (EU) 2017/745 and Regulation (EU) 2017/746).
- Production of tailored sets of information material for each type of actor targeted.
- Preparation of a bi-annual newsletter on the information campaign.
- Preparation of a media package, complemented with the media mapping and tailored media packages.
- Organisation of online webinars and/or online trainings.

BUDGET IMPLEMENTATION

The overall budget for the third health programme 2014-2020 is EUR 449.4 million. This includes EUR 30 million for the operating costs of the Consumer, Health, Food and Agriculture Executive Agency (Chafea), mandated by the Commission to manage the health programme 2014-2020. Chafea has been providing the Commission with technical, scientific and administrative assistance in implementing the health programme since 2005¹⁹. It 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 many procurement procedures.

The budget set out in the work plan for 2017²⁰ was EUR 61.904.085,00 broken down as follows:

- Operational expenditure: EUR 60.404.085,00 corresponding to third programme for the Union's action in the field of health (2014-2020) 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*);
- Administrative expenditure: EUR 1.500.000,00; corresponding to the expenditure to support the third programme for the Union's action in the field of health (2014-2020) budget line 17 01 04 02.

The operational budget totalled EUR **60.404.085,00** including EUR 1.574.508,00 of EFTA/EEA credits.

From that, under the 2017 annual work programme, EUR 60.386.800,00 were committed. Chafea committed EUR 46.764.719,17 of this budget while DG SANTE committed EUR 13.622.080,83 covering part of procurement and other actions. From the overall commitment, the budget implemented was EUR 60.063.178,12 with EUR 323.621,88 of not used credits (0,54%).

1. Priorities

In 2017, the total operational budget implemented (EUR 60.063.178,12) was divided among the four specific Programme objectives as follows:

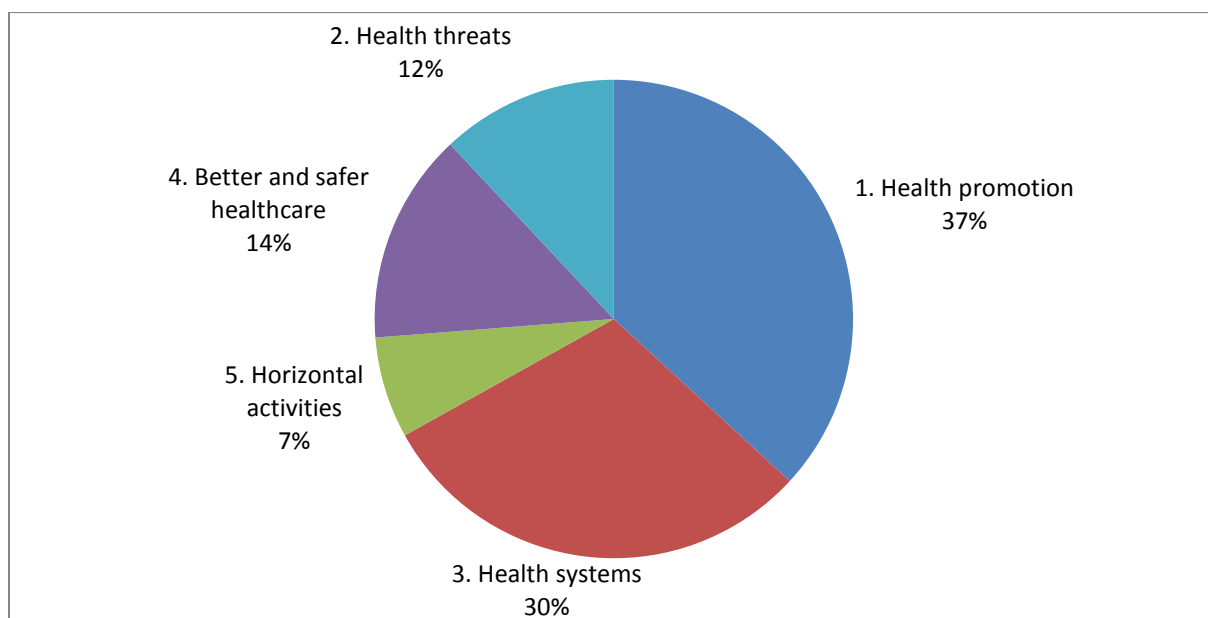
¹⁹ Commission Implementing Decision of 17 December 2013 establishing the Consumers, Health and Food Executive Agency and repealing Decision 2004/858/EC (OJ L341, 18.12.2013 p. 69);

²⁰ Commission implementing decision of 26.1.2017 concerning the work programme for 2017 in the framework of the third Programme of the Union's action in the field of health (2014-2020) and the EU financial contribution to the WHO Framework Convention on Tobacco Control, serving as a financing decision, C(2017) 316 final: https://ec.europa.eu/health/sites/health/files/programme/docs/wp2017_en.pdf .

1. **Health promotion** - EUR 22.282.477,74 (*37% 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 7.198.549,97 (*12% of the operational budget*) for protecting Union citizens from serious cross-border health threats;
3. **Health systems** - EUR 18.059.351,37 (*30% of the operational budget*) for contributing to innovative, efficient and sustainable health systems;
4. **Better and safer healthcare** - EUR 8.560.567,66 (*14% of the operational budget*) for facilitating access to better and safer healthcare for Union citizens.

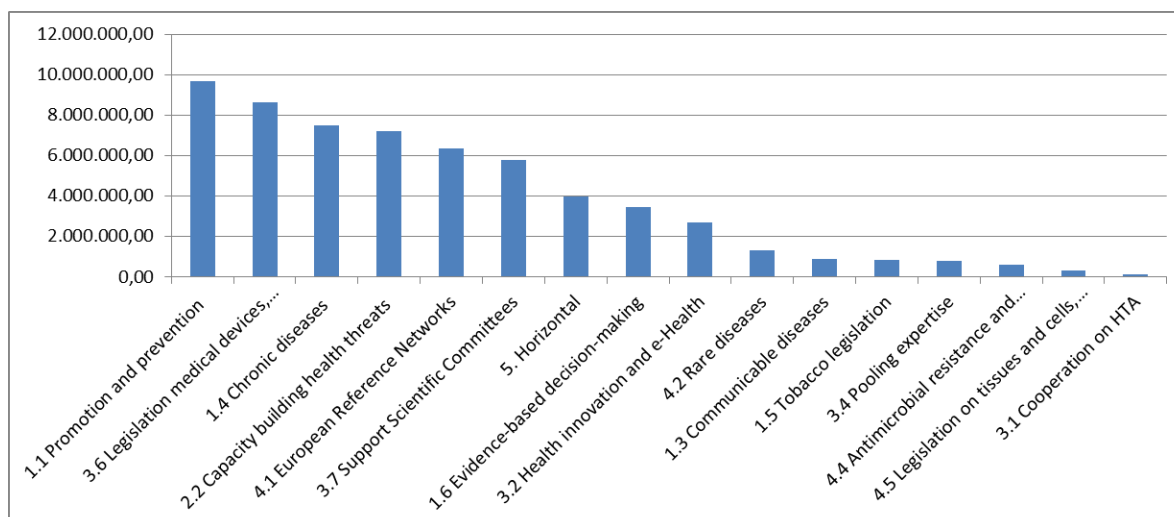
In addition, **horizontal activities** (IT, communication) and transversal actions amounted to EUR 3.962.231,38 (*7% of the operational budget*).

Figure 1: Operational budget by third Health Programme objective in 2017



The figure below provides information about the Health Programme credits invested as EU contribution through the different thematic priorities in year 2017.

Figure 2: Operational budget per thematic priority in 2017



To reach the described objectives, the Programme is implemented through a wide range of funding instruments. These are:

- Project grants, including the specific mono beneficiary grant agreements for the European Reference Networks;
- Operating grants in support of non-governmental organisations;
- Actions co-financed with Member State authorities (Joint Actions);
- Direct agreements with international organisations;
- Public procurement; and
- Other actions, such as support to the Scientific Committees, administrative agreements with the Joint Research Centre, sub-delegated budget to Eurostat and transversal actions, such as grants for Presidency Conferences.

Competitive criteria and award procedures were used to select the actions for funding. The exception to this rule were Joint Actions, direct grant agreements and conferences organised by Council presidencies because of specific rules or, for instance, monopoly situations. In the case of Joint Actions, the quality of the co-funded actions is ensured by the organisation of a peer-review process, whereby the draft proposals are evaluated using the AWP award criteria by external reviewers, SANTE Policy officers and Chafea.

Administrative credits covered expenditure such as studies (including the external evaluation of Chafea and the Impact assessment of the Health Programme), meetings of experts, information and publication costs and translations, and technical and administrative assistance for IT systems.

2. Execution of the Operational budget by financing mechanism

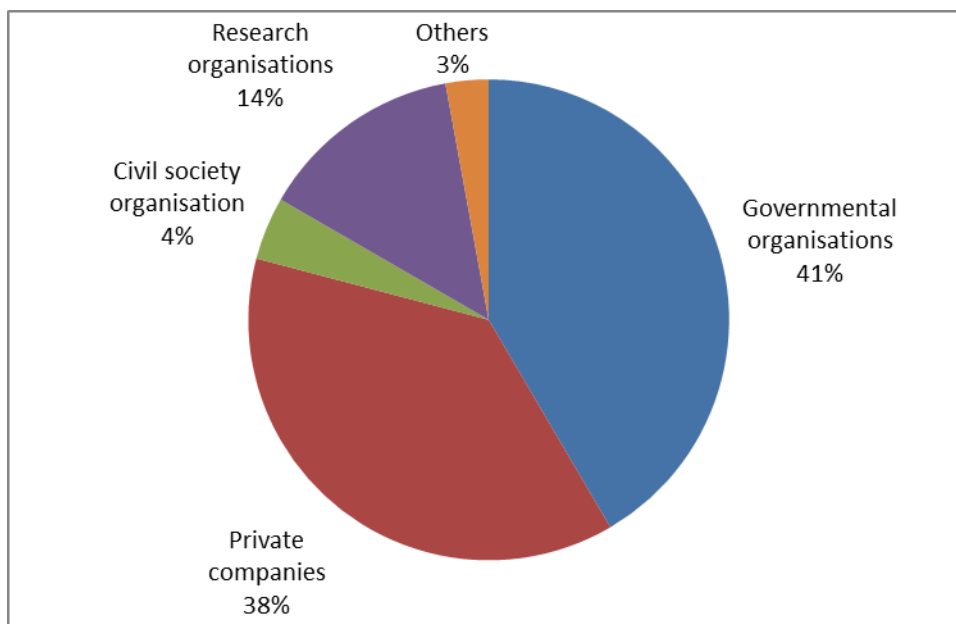
Type of financing mechanism	Implementation (EUR)	Share of mechanism in total implemented budget
Calls for proposals:	10.316.224,31	17,18%
Project grants	0,00	0,00%
European Reference Network (ERN) actions SGAs under FPA by objective	4.504.311,91	7,50%
Operating grants	5 811.912,40	9,68%
Grants for Joint Actions	20.229.410,14	33,68%
Conference grants to the Member States holding the presidency of the EU	210.059,00	0,35%
Direct grant agreements	9.300.000,00	15,48%
Procurement (service contracts), prizes and horizontal actions	14.580.482,75	24,28%
<i>Managed by CHAFEA</i>	5.863.073,68	9,76%
<i>Managed by DG SANTE</i>	8.717.409,07	14,51%
Other actions, and transversal actions, except Presidency conferences	5.427.001,92	9,04%
<i>Managed by CHAFEA</i>	663.836,33	1,11%
<i>Managed by DG SANTE</i>	4.763.165,59	7,93%
Budget implemented of AWP 2017	60.063.178,12	99,46%
Total available budget of AWP 2017	60.386.800,00	
Credits not used	323.621,88	0,54%
<i>by CHAFEA</i>	182.115,71	56,27%
<i>by DG SANTE</i>	141.506,17	43,73%

3. Beneficiaries

In 2017, Chafea and DG SANTE signed more than 238 different grants and contracts with diverse beneficiaries and service providers: governmental, academic institutions, non-governmental organisations, private companies, and individual experts ²¹. Other beneficiaries include international organisations and EU services (via direct agreements). The total number of beneficiaries is 450, with the two main categories being private consultant companies (procurement) and governmental organisations (Joint Actions).

Figure 3 provides an overview of the different groups of beneficiaries.

Figure 3: Types of beneficiaries of the third Health Programme in 2017



²¹ The partial total of 238 does not include the contracts with individual experts participating in Scientific Committees, evaluators of calls for proposals, etc.

OTHER MAIN FEATURES

The 2017 work programme aimed to contribute –in the field of health– to the priorities of the Commission as outlined in the political guidelines of the President Juncker²² and the mission letter of the Commissioner responsible for Health and Food Safety²³.

Actions co-funded with the Member States' competent authorities (six Joint Actions) were selected to support key policy actions. These Joint Actions²⁴ brought together 217 beneficiaries, including their affiliated entities, and reflect the interest of member states to actively engage in common action in the areas of cancer control, health inequalities, vaccination and preparedness, eHealth and health information.

Following the adoption of the dissemination strategy for the 3rd health programme (in June 2017) and of its annual dissemination plan for the same year, Chafea and DG SANTE agreed on an improved method to plan and prepare dissemination activities. To support this objective, Chafea produced:

- A revamped project database, allowing stakeholders to have an organised access to project deliverables.
- A set of visual depictions illustrating the different topics covered by the health programme.
- Online tutorials (videos posted on its website to assist applicants and beneficiaries).
- Regular news items for the web or social media to inform stakeholders of projects' activities and results.
- Chafea has also participated in the Europe Day in Luxembourg, organised in cooperation with SANTE.

Focusing on the key communication priorities indicated by DG SANTE, and in addition to several other events, Chafea prepared:

- A Rare Disease Registries workshop and stand exhibition in Madrid, Spain attracting the interest of 160 participants in March
- A workshop and stand exhibition in the framework of the International Integrated care conference in Dublin, Ireland, in May (211 participants)

²² https://ec.europa.eu/commission/publications/president-junckers-political-guidelines_en

²³ https://ec.europa.eu/info/departments/health-and-food-safety/what-we-do-health-and-food-safety_en

²⁴ In 2017 there were six Joint Actions with a total of 160 nominated competent authorities, reaching 217 beneficiaries, after inclusion of the affiliated entities. The average number of participants for Joint Actions in 2017 was 36 partners.

- A cluster meeting titled "Migration and Health: paths for integration", in Brussels, Belgium, in September
- A Cluster meeting on non-communicable diseases, in Odense, Denmark, in October.

Concerning the monitoring of the programme implementation, Chafea reviewed the operating grants awarded under the Framework Partnership Agreements 2014-2017 with the help of external experts.

The review concluded that the objectives set out in the Framework Partnership Agreements were relevant to the health programme objectives, as well as to the objectives of EU public health policy; that the beneficiary organisations implemented the multi-annual work programmes set out in the agreements with minor deviations; and that high-quality reports and tools were produced. It also identified areas for improvement: administrative processes, links between the selection of NGOs and the priorities of the program, and the monitoring framework.

More information on the results of the Framework Partnership Agreements can be found at the Health Programme database²⁵.

²⁵ https://webgate.ec.europa.eu/chafea_pdb/health/search?context=HOME&texttosearch=operating+grant