

HEADING 3: Security and citizenship

Union action in the field of health (Health Programme)

Lead DG: SANTE

I. Overview

What the programme is about?

Good health is a major concern of European citizens. The European Union (EU) works for better health protection through its policies and activities, in accordance with Article 168 of the Treaty on the Functioning of the European Union. The EU does not define health policies, nor the organisation and provision of health services and medical care. Instead, its action serves to complement national policies and to support cooperation between member countries in the field of public health.

Regulation (EU) No 282/2014 established the third Programme for the Union's action in the field of health (2014-2020) as a financial instrument for policy coordination at EU level. The aim is to complement, support and add value to the policies of member States in improving the health of EU citizens and reducing health inequalities, encouraging innovation in health and increasing the sustainability of health systems. The Programme has four specific objectives:

- (1) promote health and healthy living and prevent diseases;
- (2) protect Europeans from serious cross-border health threats;
- (3) contribute to innovative, efficient and sustainable health systems; and
- (4) facilitate access to better and safer healthcare for Europeans.

While this document relates to the Health Programme activities carried out during the year 2019, it should be noted that when the Covid-19 outbreak started in the first quarter of 2020, the Programme's on-going actions have been urgently reoriented towards the fight against the pandemic. For example, the Healthy Gateways Joint Action ⁽¹⁾ organised training courses for trainers and specific webinars, providing guidance including questions and answers on points of entry and borders. The SHARP Joint Action ⁽²⁾ (Strengthened International Health Regulations and Preparedness in the EU) is supporting laboratory diagnostics for covid-19, and mapping the current existing facilities and clinical capacities.

In addition to the Health Programme's actions, and in the context of the Joint Procurement Agreement to procure medical countermeasures ⁽³⁾ signed by the Commission and Member States, DG SANTE launched, in emergency mode, joint procurements for gloves and coveralls (for a maximum amount of 1.402.836.634 euros); for eye and respiratory protection (for a maximum amount of 150.851.116 euros); for ventilators/respirators (for a maximum amount of 790.000.000 euros) and for laboratory equipment.

To complement the very limited resources of the Health Programme (approximately 60 million euros per year), the resources of other Directorates-General and of other EU instruments, among which, the Union Civil Protection Mechanism, the Emergency Support Instrument and the EU Solidarity Fund, the Horizon Europe 2020 Framework Programme for Research and Innovation, have been mobilised to finance the emergency response to the pandemic.

EU added value of the programme

As stated in Article 168 of the Treaty on the Functioning of the European Union, EU action must complement national policies and encourage cooperation between Member States. The programme contributes only where Member States cannot act individually or where coordination is the best way to move forward.

The programme focuses on fostering best practice exchange between Member States and supporting networks for knowledge sharing or mutual learning. Moreover actions are undertaken addressing cross-border health threats to reduce risks and mitigate consequences. The Health programme addresses issues relating to the internal market where the EU has substantial legitimacy to ensure high-quality solutions across Member States and targets actions unlocking the potential of innovation in health. Lastly it promotes actions that could lead to a system of benchmarking or improving economies of scale by avoiding waste due to duplication and optimising the use of financial resources.

Implementation mode

The Health Programme is implemented under direct management and is mainly executed through grants and procurement procedures focusing on Commission priorities. A major part of the Health Programme is implemented by the Consumers Health Agriculture and Food Executive Agency (CHAFEA).

II. Programme Implementation Update

⁽¹⁾ www.healthygateways.eu

⁽²⁾ www.sharpja.eu

⁽³⁾ https://ec.europa.eu/health/preparedness_response/joint_procurement_en

Implementation Status (2017-2019)

The Commission adopted the work programme for 2019 in the framework of the third Programme of the Union's action in the field of health (2014-2020) on 29 March 2019. This has focused on the following areas: (a) country specific and cross country knowledge; (b) cross-border health threats, (c) preparedness and response, focusing specifically on antimicrobial resistance and vaccination; (d) structural support to health systems and link to digital single market; (e) promotion of health and prevention of non-communicable diseases.

Grants

A Joint Action (part of AWP 2018) was signed in 2019 for EUR 9.9 million: twenty-six partners initiated on 2 July 2019 their collaboration to strengthen the implementation of Decision 1082/2013/EU on serious cross-border threats to health, support EU level preparedness and responses to health threats and reinforce the implementation of the International Health Regulations (2005), in fine, ensuring a safer environment for all EU citizens.

Three other Joint Actions were launched under the AWP 2019: two of them will focus on the implementation of best practices selected by the Steering Group on Health Promotion and Disease Prevention (SGPP) in the areas of nutrition and food reformulation, and digitally enabled integrated care models. The third one focuses on improving capacity and response of Member States' authorities against bioterrorism related threats.

In 2019, 3-year Specific Grant Agreements (SGAs) were signed covering the period March 2019-February 2022 with all 24 European Reference Networks (ERNs) for an amount of EUR 13.7 million. The funding for the coordination tasks of the networks was complemented under the AWP 2019, by a call for projects related to the setup of patient registries with an indicative amount of EUR 3 800 000. Nineteen proposals have been recommended for funding, with an expected signature in the 1st – 2nd quarter 2020.

A call for proposals was launched in the second quarter of the year in order to support stakeholders in the area of Anti-Microbial Resistance (AMR) for EUR 2 million. One project has been recommended for funding, with an expected signature in the 1st – 2nd quarter 2020. On the basis of a call for Operating Grants launched under the 2017 annual work programme and ensuing Framework Partnership Agreements signed with 17 Non-Governmental Bodies in 2018, specific grant agreements have been awarded on a competitive basis for the financial year 2018, 2019 and 2020. It is expected that the supported non-governmental bodies will assist the Commission with the information and advice necessary for the development of health policies and the implementation of the Health 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. The Commission also encourages these non-governmental bodies to work together with the European Solidarity Corps, where appropriate.

In 2019, international cooperation was pursued through the signature of five direct grants with international organisations. These included the two grants implementing the State of Health in the EU cycle with the OECD and the European Observatory on Health Systems and Policies; the signature of a grant with the OECD on digitally enabled integrated care; and one with the WHO Secretariat of the Framework Convention on Tobacco Control (FCTC).

Procurement

The Health Programme included procurement procedures launched by CHAFEA, as well as DG SANTE. By the end of 2019, 12 procedures were launched and 8 service contracts were signed. From them, four contracts were signed based on Framework Contract CHAFEA/201/Health/36 with regard to tobacco legislation, to support the assessment of characterising flavours in tobacco products. They concern support services to the Technical Group of sensory and chemical assessors and the Independent Advisory Panel. These services are key to determining whether tobacco products placed on the EU market comply with the Directive's rules and hampering the tobacco industry efforts in making their products more enticing by adding different flavourings.

Another contract was signed for an expert study on the development and configuration of the automatic alerts ('alerts') that will be generated by the EU traceability system for cigarettes currently consisting of a set of primary and secondary data repositories. Its main objective is to establish a set of automatic alerts that can be used by competent authorities among Member States and by other law enforcement bodies at European level.

Regarding vaccination, two important tenders were launched in support of the policy actions of the recommendation of 7 December 2018 to strengthen the EU cooperation on vaccine-preventable diseases (2018/C 466/01), and the Commission communication of 26 April 2018 on Strengthened Cooperation Against Vaccine Preventable Diseases (COM(2018)245 final):

The first tender (signed for a value of EUR 2 220 000) is a feasibility study for a common vaccination card for EU citizens, that is interoperable with EU Member States' Immunisation information systems (IIS); and that can be common to all EU Member States and usable across borders.

The second tender (launched with an indicative budget of EUR 700 000) concerns a study which will: (i) explore the feasibility of and identify options for physical stockpiling of vaccines; and (ii) develop a concept for a mechanism for exchanging vaccine supplies from one EU Member State to another in case of an outbreak.

Regarding digital innovation and in view of the creation of a ‘European Health Data Space’ to promote health-data exchange and support research on new preventive strategies, a service contract has been signed (EUR 440 000) to assess the current situation on primary and secondary health data use and exchange in Europe and to identify enabling factors and barriers.

Key achievements

The below are examples of actions corresponding to main Commission priorities for (i) implementation of best practices for health promotion and diseases prevention, (ii) the establishment of 24 European Reference Networks, (iii) Crisis preparedness and risk management, (iv) Relevant information in the framework of the EU semester, (v) Mental health and (vi) Health and Innovation.

(i) Implementation of best practices for health promotion and diseases prevention:

The online ‘best practice portal’ was launched in April 2018. Since June 2018, it counted more than 6 650 visitors from all EU Member States as well as neighbouring countries. Portal visitors can access good practices collected by previous Health Programme actions, for example in the field of nutrition and physical activity, prevention of alcohol abuse, mental health and integrated healthcare. Stakeholders can also submit a practice for evaluation. The portal is always open for submissions, but it is also open for specific calls. The practices selected as ‘best’ are presented to Member States in so-called marketplace workshops. Afterwards, Member States prioritize among the presented practices for scale-up and country-to-country transfer. Those scoring highest can receive financial support for such transfer.

(ii) The establishment of 24 European Reference Networks (ERNs):

ERNs 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 are convening a ‘virtual’ advisory board of medical specialists across different disciplines, using a dedicated IT platform and telemedicine tools. This way, the medical knowledge and expertise travel rather than the patients.

Using the clinical patient management system (CPMS), the members of the ERNs have already been able to consult, explore, diagnose and decide on cases of particular complexity. In February 2019, the ERNs had used 458 panels to discuss 444 patient cases, and the number of cases opened in the CPMS regularly evolves (see for example <https://ec.europa.eu/avservices/video/player.cfm?sitelang=en&ref=1164244>).

Since 2018, with a help of a dedicated contract financed through the EU Health Programme, ensuring the funding of their coordination costs until March 2022, ERNs are cooperating in the development of a complete taxonomy of the different technical and informative documents that they are producing, such as training programmes, or patient information packages. The results of this cooperation will feed, for example, some of the necessary elements for the creation of the ERNs methodology for the development of clinical practice guidelines for rare diseases, expected for May/June 2020.

Furthermore, a first pilot group of 5 among the 24 ERNs, supported by grants under the EU Health Programme, has started in 2018 to develop and improve rare disease registries relevant for the diseases and conditions covered by their respective ERNs. In 2019, the EU awarded funding to the remaining 19 networks, allowing them to take forward methodologies and technical solutions already tested and validated by the first pilots. With additional health programme support, the Joint Research Centre (JRC) has developed and put at their disposal a dedicated EU Rare Diseases Registration Platform, as well as related tools and standards.

The first ERNs are up and running since March 2017. 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. In addition, several networks received co-funding to set up disease and patient registries, building on the clinical patient management system provided through the DG SANTE IT platform.

(iii) Crisis preparedness and management:

In 2018, the Joint Action EMERGE – Efficient response to highly dangerous and emerging pathogens at EU level – has delivered on its work for the improvement of capabilities for rapid laboratory diagnosis of new or emerging pathogens (e.g. sample sharing). It completed three rounds of external quality assurance exercises (EQAEs), improving detection methodologies and response capabilities of the participating laboratories on high risk (re)emerging pathogens such as *Bacillus anthracis*, *Yersinia pestis*, Crimean-Congo haemorrhagic fever (CCHF) and Lassa virus. The Joint Action also contributed to combating the outbreaks of ZIKA and Ebola.

The Health Programme is also playing a crucial role in addressing Antimicrobial Resistance (AMR), by defining common approaches to fight AMR and to control healthcare-associated infections in line with ongoing EU and international policies.

Funded under the AWP 2017 (EU contribution of EUR 6.9 million) the Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI) supports EU Member States in developing and implementing effective one health action plans against antimicrobial resistance (AMR) and healthcare associated infections (HCAI). Its main results are:

- It completed the mapping of the National Action Plans (NAPs); the mapping of the implementation of the One Health strategy; and a self- assessment by the EU Member States of the implementation of their NAPs.
- It implemented ten pilot peer review visits with ‘One health’ delegations, in order to share best practices, and discuss future policy options.

- It launched a social media campaign that reached 2.7 million people in just one month.
- It held an AMR webinar for journalists, followed by more than 90 organisations and media from 33 countries, to provide clear and accurate scientific information for journalists to be able to correctly inform national audiences about AMR.
- The JA also designed a Universal Infection Control Framework (UICF) currently tested in 5 countries. It also developed an implementation model (Breakthrough Series) to improve safety and infection control in Catheter Associated Urinary Tract Infections (CAUTI) management, also currently tested in pilot hospitals from 11 countries. It also performed a mapping of research priorities and identified gaps in research.
- Finally, EU-JAMRAI is working to develop a simple surveillance system of antibiotic use and resistance including rapid feedback mechanisms for a shorter time lag in both human and animal.

(iv) State of Health in the EU and Country Profiles (European semester):

On 28 November 2019 the European Commission published the 30 country health profiles delivered under the State of Health in the EU Europe Cycle. The accompanying companion report and factsheet flagged five key challenges facing the EU health systems:

- Tackling the decline in vaccination confidence across the EU,
- Harnessing the digital transformation of health promotion & disease prevention,
- Strengthening the evidence base on access to healthcare,
- Shifting tasks and changing the skill mix to explore new ways of providing care,
- Breaking down silos for safe, effective and affordable medicines.

Several of these are closely linked to objective 3 of the health programme as well as to the key priorities of the incoming Commission as set out in the mission letter to Commissioner Kyriakides and are supported by specific actions co-funded under the 3rd health programme (see below sections on health and innovation, vaccination and access to medicines).

(v) Accessible and affordable medical technologies:

The companion report raised the issue of access to affordable medical technologies whether pharmaceutical products or medical devices, as being essential for the sustainability and resilience of health systems. This is a challenging area, combining implementation of legislation (notably for medical devices); common if not harmonized life-cycle based assessment methods; shared information and expertise on pricing and procurement methods, including joint procurement or other collaboration mechanisms.

The contribution of the health programme is important in this area, through the following:

- It supports the work of civil society and the contribution to the EU level policy dialogue in this field of stakeholder organisations, through the operating grants awarded to Health Action International; the European Public Health Alliance; and the European Organisation of Rare Diseases Associations.
- It provides continuing financial support to the work of the EUnetHTA 3 Joint Action: The piloting of the EU cooperation on Health Technology Assessment has proven successful. By the end of 2019, the EUnetHTA 3 Joint Action carried out 27 joint reports (13 assessments and 14 early dialogues).

vi) Digital innovation – paving the way to a European health data space

The Commission aims to support EU Member States in making the most of the potential of e-health to provide high-quality healthcare and reduce inequalities. Key to achieving this aim is the creation of a ‘European Health Data Space’, to promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes.

In this context, CHAFEA used the newly signed experts’ meeting framework contract to set up an expert network on primary and secondary health data use and exchange in Europe with the aim to identify enabling factors and barriers. The first workshop of Member States’ representatives and experts has already taken place and the results of this technical and legal analysis will feed into the programme of the upcoming German presidency in this area and a possible legislative initiative.

In parallel, the joint action on eHealth (eHAction) continues supporting the work of the eHealth Network for the period 2018-2021 for the delivery of Cross Border eHealth information Services (CBeHIS. These services (the patient summary for unscheduled care, ePrescriptions and eDispensations) are delivered through the National Contact Points for eHealth, while the health programme will in addition reinforce their capacity through a service contract (currently under evaluation for an indicative budget of EUR 920 000) providing training and other capacity building activities.

vii) Supporting the implementation of the new medical devices regulations

In 2019, through service contracts, the first communication and information campaign on Medical Devices was implemented, informing stakeholders about the legislative changes brought by the new EU legislation on Medical Devices and in-vitro Diagnostic

Medical Devices which will enter into force in May 2020. The campaign mapped all relevant stakeholders, numbering more than 2000 contacts in and outside the EU. It produced eight informative factsheets translated in all EU languages, as well as in Chinese, Japanese and Arabic. The campaign also comprises the organisation of webinars addressed to stakeholders as well as other information material in a layman language.

A new hub on the DG GROW website ('New regulations') was created, with information addressing the main target stakeholders: manufacturers of medical devices and in-vitro diagnostic medical devices; authorised representatives, importers and distributors; healthcare professionals and health institutions; as well as institutions in charge of procurement of medical devices and in-vitro diagnostic medical devices. Finally, a social media campaign on Twitter and LinkedIn produced over 6000 link clicks (to the Medical Devices website), as well as 2 million impressions and 800 000 video views.

In 2019, the Joint Action on Market Surveillance of Medical Devices (JAMS) came to its end, yielding significant added value by reinforcing the market surveillance system for medical devices and improving coordination and cooperation among all European Union's countries. The joint action developed methods, tools and guidance for a consistent and proactive approach to manufacturers' inspections by national competent authorities, also by strengthening capacity through the training courses for inspectors. It further established specific inspection scopes and objectives to complement those conducted by conformity assessment bodies. A high level Conference on the Health Programme was organised on 30 September 2019. The event presented the results of the current and previous EU Health Programmes, highlighting achievements in fighting cancer; enhancing health security in support of the free movement of persons; innovation in delivering care; and access to better care through the European Reference Networks (ERNs).

Finally, a roundtable discussion, brought together high-level representatives of 5 different DGs (DG EMPL, DG RTD, DC CNECT, SG and DG REGIO) to present the new approach in the future Multiannual Financial Framework for 2021-2027.

Evaluation/studies conducted

The key findings of the latest evaluation (Mid-Term evaluation of the 3rd Health Programme https://ec.europa.eu/health/funding/programme/2014-2020/midterm_evaluation_en) have been presented in the Programme Statements of 2018.

The Mid-term evaluation of the 3rd Health programme 2014-2020 was published in the Commission Report to the European Parliament and to the Council COM(2017) 586 final. The conclusion was that implementation of the Programme was on track, in alignment with the Commission's main priorities under Article 168 TFEU and the SDG, striving to maximise synergies with other EU policies and financial instruments such as Horizon 2020. All thematic priorities remained valid and most actions delivered useful outcomes with high EU-added value, in particular for crisis management and for the safety and security in Europe.

The open public consultation provided strong support for continued cooperation through the Programme, particularly in areas such as health promotion, disease prevention and eHealth.

The Staff Working Document SWD(2017) 331 final accompanies the Commission's report on the mid-term evaluation. It presents the main findings based on an independent external study conducted from May 2016 to May 2017. The conclusions of the evaluation were used to improve the implementation of the Health Programme in 2018-2020 and serve as a basis for the new Health Programme.

The evaluation indicated that major achievements were:

- establishing 24 European Reference Networks;
- supporting Member States to increase their capacity-building to respond to outbreaks (e.g. Ebola and Zika viruses);
- contributing to the EU's migration policy by supporting Member States to respond to the health needs of high influx of migrants and refugees;
- training health professionals and other front-line staff.

Other achievements of the health programme included exchanges of good practice in areas as diverse as alcohol reduction, cancer screening, HIV/AIDS and TB prevention, additional support for EU health legislation on medicinal products and medical devices, the eHealth Network activities and Health Technology Assessment.

A significant progress represented the joint work with the OECD and the European Observatory on Health Systems and Policies. This collaboration brought together internationally renowned expertise in the State of Health in the EU cycle to strengthen country-specific and EU-wide knowledge on health issues.

Compared to the second Health Programme, the 3rd Health programme design took a more strategic view of a mid-term perspective and has demonstrated its value as an effective and flexible management tool capable of covering unforeseeable needs (refugees' crisis).

The external evaluation of the 3rd Health programme 2014-2020 ('3HP') concluded that the programme complemented and supported to the policies of Member States, in terms of improving the health of EU citizens and reducing health inequalities. The 3HP represented a major improvement. The new structure has increased the Health Programme's ability to target important health needs where it can add value (such as anti-microbial resistance and 'e-Health' in the context of the digital single market to name

just a few). It demonstrated efforts to identify common, structural challenges facing Member States. The mechanisms for pooling expertise at EU level and supporting MS in their health reforms have been set up (namely the Expert Panel on Health and the Expert Group on Health Systems Performance Assessment) and the 3HP was providing direct financial support to the OECD and WHO to produce country profiles, giving a clear understanding of country specific needs. This focus was recognised by Member States: the consultation of Programme committee members and national focal points representing Member States' interests confirmed the 3HP structure matches the main health challenges in their country.

Forthcoming implementation

The AWP 2020 was adopted on 28 January 2020 ⁽⁴⁾. It includes different kind of actions (grants for projects and joint actions, operating grants, service contracts, etc.) and focuses on the following main topics:

Implementation of best practices in the area of mental health; tobacco control; vaccination; health technology assessment cooperation; GDPR implementation in the health sector; innovation and e-health; health workforce reforms; healthcare procurement; international cooperation on pharmaceuticals; patient-reported measures and prioritisation for the implementation of best practices.

The expected results of the work programme include: (a) the exchange and adoption of best practices in various areas of health; (b) enhanced understanding of properties and regulatory implications of novel tobacco products and e-cigarettes; (c) increased vaccination uptake among disadvantaged groups and migrants; (d) enhanced knowledge base for the conception and implementation of reforms on retention policies, medical deserts and task-shifting related to the health workforce (e) a GDPR-compliant data governance model and code of conduct for health(care)-related data; (f) knowledge-sharing and discussion on public procurement in the healthcare sector; (g) an NGO contribution to achieving the objectives of the EU health programme.

Outlook for the 2021-2027 period

Given the Covid-19 crisis, the Health Programme will be expanded in the Commission proposal for the new MFF as a stand-alone Health Programme. The Health Programme should bring together two strands of activities. A longer-term vision of continuously improving health conditions across the Member States, through better disease prevention, health promotion, access, diagnosis and treatment – objectives which have already been pursued through the currently existing programme. And a second strand on health security that would endow the EU and Member States with the preparedness and responses capacities to swiftly react to health emergencies. Both strands would contribute to tackling structural weaknesses of European health systems. Its objective is to ensure a high level of health protection in the Union by preventing health risks and promoting public health and access to medical products. This will help reduce health inequalities and help address health challenges identified in the European Semester. The main operational objectives of the Health Programme are (a) strengthening crisis preparedness and response against cross border-health threats; (b) empowering health systems; (c) supporting EU health legislation and (d) supporting integrated cross-national work. Actions include policy analysis and implementation; capacity building of networks and partners; communication and dissemination.

The focus will be on key areas and priorities where Europe can deliver added value and make a real difference to the life of citizens. It will build on actions and achievements under the current EU Health Programme, and better coherence, complementarity and synergy in close cooperation with other EU programmes such as the Horizon Europe will be ensured. From a post-crisis recovery perspective, the Health Programme will make an important contribution to ensuring that the EU will be better prepared to face future health threats affecting the whole or large parts of its territory.

The Health Programme is currently under development and the negotiations are ongoing.

III. Programme key facts and performance framework

1. Financial programming

Legal Basis	Period of application	Reference Amount (EUR million)
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	2014 – 2020	449,4

	Financial Programming (EUR million)							Total Programme
	2014	2015	2016	2017	2018	2019	2020	
Administrative support	1,5	1,5	1,5	1,5	1,5	1,5	1,5	10,5
Operational appropriations	52,9	54,0	56,5	58,8	60,5	62,3	63,6	408,5
Executive Agency	4,2	4,2	4,2	4,2	4,4	4,6	4,6	30,3
Total	58,6	59,8	62,2	64,5	66,4	68,3	69,7	449,4

⁽⁴⁾ https://ec.europa.eu/health/funding/adoption_workplan_2020_en

2. Implementation rates

	2019				2020			
	CA	Impl. Rate	PA	Impl. Rate	CA	Impl. Rate	PA	Impl. Rate
Voted appropriations	68,308	100,00 %	63,129	98,42 %	97,254	39,22 %	87,098	36,14 %
Authorised appropriations (*)	70,815	99,92 %	66,180	97,21 %	98,990	39,20 %	90,385	37,06 %

(*) Authorised appropriations include voted appropriations, appropriations originating from assigned revenues (internal and external) as well as carried-over and reconstituted appropriations; the execution rate is calculated on 15 April 2020

3. Performance information

Programme performance

In line with the results of the mid-term evaluation of 2017, the Commission (DG SANTE) considers that the Health Programme is performing well and has been effectively implemented, 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. The programme addresses efficiently the Commission priorities on the implementation of best practices for health promotion and diseases prevention, crisis preparedness and risk management, relevant information in the framework of the EU semester, mental health, and health and innovation.

In the period 2014-2020, the Court of Auditors published several reports assessing the implementation of the Health programme. In the Special report no 07/2019 ⁽⁵⁾ on Cross-border healthcare access, the Court of Auditors mentioned: 'EU actions in cross-border healthcare enhanced cooperation between Member States. The Commission has overseen the implementation of the Cross-border Healthcare Directive well'. This Special report (SR 07/2019) also identified certain shortcomings and improvements to be made in terms of administrative burden reduction and long-term financial sustainability of the European Reference Networks (ERNs). In the ECA's Special report no 21/2019 on Addressing Antimicrobial resistance ⁽⁶⁾ it is emphasized that 'Fighting against antimicrobial resistance is complicated. The Commission and ECDC support to strengthen Member States One Health approach to AMR was valuable'. However, the Court observed challenges, particularly with regard to the sustainable implementation of the results in the Member States.

The performance indicators linked to the programme's specific objectives are relevant, measurable and realistic. The Commission (DG SANTE) makes significant efforts in order to reach the targets.

Objective 1: promoting health and preventing diseases: 34 % of the overall Programme budget (EUR 96 million). From those EUR 8 million were spent on cancer, inter alia to support screening programmes in MS, improve the quality of patients' lives, address survivorship issues, look into the impact of research in cancer and the uptake of innovative treatments; EUR 11 million were channelled towards the prevention of major risk factors i.e. on alcohol and tobacco control, physical activity and nutrition. Other activities addressed the prevention of chronic diseases, including through the promotion of uptake of validated best practices across the EU in cardiovascular disease or diabetes prevention.

Indicator: 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

Objective 2: protecting from cross-border health threats: 10 % of the overall budget, EUR 29 million; more than EUR 14 million for projects to ensure that EU Member States are well prepared to respond to a possible major health threat. These included several table top or other types of exercises addressing generic preparedness; capacity building actions such a quality assurance for diagnostic capacity, as well as specific activities addressing the air transport and shipping sectors. They also included several actions supporting Member States in addressing the challenges of the migratory crisis of 2015-2016.

Currently on going actions have been re-orientated as to provide coverage for specific needs regarding the Coronavirus threat (such as training for health professionals including practical advice- isolation, waiting rooms and reception areas, cleaning, appropriate PPE etc; as well as an offer for real-time RT-PCR for detection including coverage of costs for shipment of the samples, if needed).

Indicator: number of Member States integrating coherent approaches in the design of their preparedness plans

Objective 3: contributing to innovative, efficient and sustainable health systems (27 % EUR 95 million). From those EUR 30 million were invested in the collaboration on Health Technology Assessment, to develop commonly agreed tools and procedures, as well as carrying out joint assessments or early dialogues, in an approach recognizing the full life cycle of health technologies. Other actions supported the exchange of experience and best practices in addressing the ageing of the population, promoted integrated care models and practices or supported the EU eHealth network in promoting the uptake of digital solutions.

Indicator: 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

⁽⁵⁾ https://www.eca.europa.eu/Lists/ECADocuments/SR19_07/SR_HEALTH_CARE_EN.pdf

⁽⁶⁾ https://www.eca.europa.eu/Lists/ECADocuments/SR19_21/SR_Antimicrobial_resistance_EN.pdf

Objective 4: ensuring access to better and safer healthcare (27 % EUR 75 million). From those EUR 26 million was invested for set up cost and coordination of the European Reference Networks, including through the assessment of the networks and their healthcare provider members. The effort to jointly address the effects and challenges of increased anti-microbial resistance and healthcare acquired infections; the support to the Member States' collaboration in the area of blood, tissues and cells; and rare diseases were key priority areas of the health programme spending.

Indicator: number of European reference networks established in accordance with Directive 2011/24/EU; number of healthcare providers and centres of expertise joining European reference networks; number of Member States using the tools developed

Main key achievements of the Health programme:

- In April 2018 DG SANTE launched the online 'best practice portal'. Since June 2018, it counted more than 6 650 visitors from all EU Member States as well as neighbouring countries.
- Efficient response to highly dangerous and emerging pathogens at EU level (Joint Action EMERGE) and improvement of capabilities for rapid laboratory diagnosis of new or emerging pathogens (e.g. Ebola, Zika).
- The establishment of 24 European Reference Networks (ERNs), which are providing greater access to high quality healthcare and information, accurate diagnosis and appropriate treatment to patients affected by rare or low prevalence diseases. In this first phase (2017-2018), ERNs include more than 900 highly specialised healthcare providers in 300 hospitals across the EU.
- Effective evaluations and studies conducted: in 2019, DG SANTE undertook an extensive evaluation of the Regulations on orphan medicines (141/2000) and paediatric medicines (1901/2006), including a study, a staff working document, and outreach to stakeholders; DG SANTE also launched a feasibility study for a monitoring system on reformulation initiatives for salt, sugars and fat in support of the EU framework for national initiatives on selected nutrients; a Staff Working Document to finalise the evaluation of the Directives on blood (2002/98/EC) and tissues and cells (2004/23/EC) was also adopted.
- Establishment of an EU quality register ensuring the safety of medical devices.
- Establishment of an Organ Database, which has helped 34 000 transplants only in 2017.
- Set up of an EU-wide tobacco tracking and tracing system to combat illicit tobacco products trafficking.
- Finally, a majority of indicators for assessing the performance of the Programme's general and specific objectives showed positive trends over the implementation period 2014-2019. Furthermore, as detailed below, in the sections 'General objectives' and 'Specific objectives' 5 indicators out of 8 ⁽⁷⁾ reached their milestone figures defined at the beginning of the implementation and in certain cases were above these milestones (implying that they should reach their defined targets at the end of the programme).

The decrease of 'the number of Member States (MS) in which the European accreditation scheme for breast cancer services is implemented' indicator is explained by the fact that in 2019, guidelines developers and/or national authorities of (only) six Member States have used, implemented or adapted in their national cancer plans the European Guidelines, evidence base or methodology developed by the European Commission Initiative on Breast Cancer, coordinated by the Joint Research Centre (JRC). The other 2 indicators which did not reach their milestones in 2019 are, the indicator on the Number of Health Technology Assessments (HTA) produced per year reached (27 in 2019, versus the foreseen milestone of 29) and the indicator on the number of healthcare providers and centres of expertise joining European reference networks (ERNs). The stabilisation of this indicator around 950, after reaching in 2017 the milestone set out for that year, can mainly be explained by the fact that subsequent annual milestones were set at too ambitious levels, with regard to external factors linked with the ERNs' infrastructure, capacity and resources.

The weak aspects of the programme:

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

- improve monitoring, reporting and dissemination efforts
- encourage participation of all Member States and other participating countries, and to work with all Member States, particularly those with greater public health needs; and
- develop synergies with the Commission's main priorities and other programmes.

These points are still valid and the Programme will continue to work on these areas. In particular for the dissemination of results and implementation of best practices in close cooperation with other Programmes investing in health.

The experience from the ongoing Covid crisis has demonstrated that the EU must improve health systems ready to provide state of the art services and care and to be prepared to cope with epidemics and other unforeseeable challenges. An ambitious self-standing Health Programme can support Member States in the transition to better preparedness and stronger health systems. The Programme should bring together two strands of actions. A longer-term vision of continuously improving health conditions across the Member States, through better disease prevention, health promotion, access, diagnosis and treatment – objectives which have already been pursued through the currently existing programme. The second strand on health security would endow the EU and Member States

⁽⁷⁾ Out of 10 programme indicators, 2 indicators (i.e. Number of Healthy Life Years of Men and of Women) did not have defined milestones and targets

with the preparedness and responses capacities to swiftly react to health emergencies. Both strands would contribute to tackling structural weaknesses of European health systems. The new Health Programme’s objective is to ensure a high level of health protection in the Union by preventing health risks and promoting public health and access to medical products. The main operational objectives are (a) strengthening crisis preparedness and response against cross border-health threats; (b) empowering health systems; (c) supporting EU health legislation and (d) supporting integrated cross-national work. Actions include policy analysis and implementation; capacity building of networks and partners; communication and dissemination.

General objectives

General Objective 1: to complement, support and add value to the policies of the Member States to improve the health of Union citizens and reduce health inequalities by promoting health, encouraging innovation in health, increasing the sustainability of health systems and protecting Union citizens from serious cross- border health threats

Indicator 1: Number of Healthy Life Years at birth								
Baseline	2014	2015	2016	2017	2018	2019	2020	Target
2010	Milestones foreseen							2020
Men: 61.8	Actual results							
	61.4	62.6	63.5	63.5				
2010	Milestones foreseen							2020
Women: 62.6	Actual results							
	61.8	63.3	64.2	64.0				

Narrative: Baseline: Men 2012: 61.5 %, Women 2012: 62.6 %

Comment: The above indicator is taken directly from the 3rd Health Programme Regulation. The 2 indicators below are an operationalization. NB: the guidelines on breast cancer services were published in July 2017. Plus 3 announced in 2017 but not approved by the end of the year.

The above indicator is taken directly from the 3rd Health Programme.

Availability of Data: Data not available for 2018, 2019

Source: Eurostat. Data for 2017 will be made available by Eurostat in May 2019, and for year 2018 in May 2020, and so on.

Unit of measure: Healthy years

Specific objectives

Specific Objective 1: identify, disseminate and promote the uptake of evidence-based and good practices for cost-effective health promotion and disease prevention measures by addressing in particular the key lifestyle related risk factors with a focus on the Union added value

Indicator 1: 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								
Baseline	2014	2015	2016	2017	2018	2019	2020	Target
2012	Milestones foreseen							2020
Fat: 12	16	18	20	22	24	25	28	28
	Actual results							
	21	21	21	22	24	24		
2012	Milestones foreseen							2020
Cancer: 0				10			28	28
	Actual results							
	0	0	0	10	10	6		

Comment: (relevant for Cancer sub-indicators): In 2019, Guideline developers and/or national authorities from six EU countries have used, implemented or adapted the European Guidelines, evidence base or methodology developed or applied by the European Commission Initiative on Breast Cancer, coordinated by the Joint Research Centre (JRC). In 2019, guidelines developers and/or national authorities of six Member States have used, implemented or adapted in their national cancer plans the European Guidelines, evidence base or methodology developed by the European Commission Initiative on Breast Cancer, coordinated by the Joint Research Centre (JRC).

Unit of measure: Member States having a national initiative on reduction of sauterd fat & MS in which the European accreditation scheme for breast cancer services is implemented – establishment of the scheme

Expenditure related outputs

Outputs	Budget line	Budget 2020	
		Number	EUR million
Number of actions granted that plan to deliver validated best practices for cost effective prevention measures	17 03 01	5	15
Number of grants and contracts provided contributing to promoting health and fostering supportive environments	17 03 01	10	3
Total		15	18

Outputs		Number of outputs foreseen (F) and produced (P)						
		2014	2015	2016	2017	2018	2019	2020
Number of actions granted that plan to deliver validated best practices for cost effective prevention measures	F	4	5	3	12	11	5	5
	P	4	5	9	9 (all the actions below contribute with evidence-based interventions)	9		
Number of grants and contracts provided contributing to promoting health and fostering supportive environments	F	35	25	14	19	30	20	10
	P	35	23	20	9 (4 SC + 2 x JA on Health inequalities and on Cancer + 3 Direct grant to IGOs)	10		

Specific Objective 2: identify and develop coherent approaches and promote their implementation for better preparedness and coordination in health emergencies

Indicator 1: number of Member States integrating coherent approaches in the design of their preparedness plans

Baseline	2014	2015	2016	2017	2018	2019	2020	Target
2013	Milestones foreseen							2020
0	0	4	18	20	22	24	28	28
	Actual results							
	0	16	16	16	22			

Comment: Actual results on the indicators will be available after the next reporting exercise by Member States on preparedness and response planning under Article 4 of Decision 1082/2013/EU. The next reporting exercise takes place in 2020.

Unit of measure: Member States

Expenditure related outputs

Outputs	Budget line	Budget 2020	
		Number	EUR million
Number of grants and contracts provided to protect citizens from serious cross-border health treats	17 03 01	5	12
Total			

Outputs		Number of outputs foreseen (F) and produced (P)						
		2014	2015	2016	2017	2018	2019	2020
Number of grants and contracts provided to protect citizens from serious cross-border health treats	F	4	7	4	6	5	5	5
	P	4	7	5	6	1		

Specific Objective 3: identify and develop tools and mechanisms at Union level to address shortages of resources, both human and financial, and to facilitate the voluntary uptake of innovations in public health intervention and prevention strategies

Indicator 1: 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

Baseline	2014	2015	2016	2017	2018	2019	2020	Target
2012	Milestones foreseen							2020

Advice produced, in particular the number of Health Technology Assessments (HTA) produced per year: 2	11	6	12	18	22	29	50	50
	Actual results							
2012	6	9	0	4	22	27		2020
Number of Member States using the tools and mechanisms identified in order to contribute to effective results in their health systems:	Milestones foreseen							18
	Actual results							
2012	0	5	10	9	22			2020

Methodology: Annually

Comment: (relevant for the second sub indicator): In 2019, EUnetHTA Joint Action carried out 27 joint reports (13 assessments and 14 early dialogues). This is an increase from 22 joint reports in 2018-15 are on pharmaceutical products (2 Assessments and 13 Early Dialogues) and 7 on other technologies (6 Assessments and 1 Early Dialogue).

Availability of Data: Information is not available, due to time-lag between end of reference period and the availability of validated data

Unit of measure: For second sub indicator: Member States with patient summaries data/ePrescription in line with the EU guidelines

Expenditure related outputs

Outputs	Budget line	Budget 2020	
		Number	EUR million
Number of grants and contracts to address shortages of resources, both human and financial, and to facilitate the voluntary uptake of innovations in public health intervention and prevention strategies	17 03 01	15	8
Others of horizontal nature	17 03 01	5	3
Total		20	11

Outputs	Number of outputs foreseen (F) and produced (P)							
		2014	2015	2016	2017	2018	2019	2020
Number of grants and contracts provided concerning obj. 3	F	19	16	11	26	19	40	20
	P	19	11	13	32	17		

Specific Objective 4: increase access to medical expertise and information for specific conditions beyond national borders, facilitate the application of the results of research and develop tools for the improvement of healthcare quality and patient safety

Indicator 1: number of European reference networks established in accordance with Directive 2011/24/EU

Baseline	2014	2015	2016	2017	2018	2019	2020	Target
Milestones foreseen								2020
0	0	0	10	24	24	24	30	30
	Actual results							
	0	0	23	24	24	24		

Comment: Networks can only be formally established as provided in Commission Implementing Decision 2014/287/EU setting out criteria for establishing and evaluating European Reference Networks and their Members. The implementing decision was adopted later than forecasted in 2013 (when the goals were defined in the Health programme) and therefore the milestones and goals should be adapted to reality. The establishment of ERNs is a complex procedure, which involves several steps and tools. The first call for ERN has been launched in the second half of 2016, the result was the establishment of 24 ERNs. Target reduced from 33 to 30 based on the SANTE strategic plan 2016-2020. Revised target more likely to be reached by the end of the Programme.

Indicator 2: number of healthcare providers and centres of expertise joining European reference networks

Baseline	2014	2015	2016	2017	2018	2019	2020	Target
Milestones foreseen								2020
0	0	0	120	936	1 136	1 342	1 450	1 450
	Actual results							
	0	0	936	956	956	953		

Comment: The difference with regard to 2019 and 2018 is due to cleaning of duplicate records. The stabilisation of this indicator around 950, after reaching in 2017 the milestone set out for that year, can mainly be explained by the fact that subsequent annual milestones were set at too ambitious levels, with regard to external factors linked with the ERNs' infrastructure, capacity and resources.

Indicator 3: number of Member States using the tools developed								
Baseline	2014	2015	2016	2017	2018	2019	2020	Target
	Milestones foreseen							2020
0	0	0	0	18	20	24	28	28
	Actual results							
	0	0	0	25	25	25		

Expenditure related outputs

Outputs	Budget line	Budget 2020	
		Number	EUR million
Number of functioning European Reference Networks	17 03 01	24	0
Number of grants and contracts to facilitate access to better and safer healthcare for Union citizens	17 03 01	40	14
Total		66	14

*This is the number of actions to facilitate access to better and safer healthcare for Union citizens financed for the Draft Budget 2019. The number of functioning ERNs is independent from this total.

Outputs		Number of outputs foreseen (F) and produced (P)						
		2014	2015	2016	2017	2018	2019	2020
Number of functioning European Reference Networks	F	0	0	15	15	24	24	24
	P	0	0	0	24			
Number of grants and contracts to facilitate access to better and safer healthcare for Union citizens	F	9	10	22	30	30	40	40
	P	9	10	32	25 (23 ERNs + JA on AMR + assessment of ERN HCP)	39		

4. Contribution to Europe 2020 Strategy and mainstreaming of policies

Contribution to Europe 2020 headline targets

Table Contribution to Europe 2020 headline targets

75 % of the population aged 20-64 should be employed
20 million less people should be at risk of poverty

Gender mainstreaming

DG SANTE has developed a questionnaire for all beneficiaries to be completed at the time of the interim and final report, operating grant recipients will only provide a final report and complete the questionnaire then. One question targets gender mainstreaming and how it was performed in the actions. DG SANTE can already report on the first data from the beneficiaries/reports for the operating grants (budget of EUR 4.6 million), whereas information from project grants and Joint Actions will only be available later.

As regards the operating grants, the first replies from recipients indicate that on average an amount of about 2 % of their budget, i.e. EUR 86.000, is spent to finance activities targeting the gender issue related to health.

5. Programme contribution to the Sustainable Development Goals

SDG 3 Ensure healthy lives and promote well-being for all at all ages

The Health Programme contributes to EU efforts to achieve the Sustainable Development Goals in health and well-being by supporting actions to implement the EU’s political commitments and legal obligations in health and work towards Sustainable Development Goal 3 on health. Examples of such support included funding for operating grants to NGOs. Specific Grant Agreements were signed with 15 NGOs in 2019.

In order to maximise collective EU work towards the WHO's nine voluntary targets on non-communicable disease and the UN Sustainable Development Goals for health and well-being, DG SANTE works through the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases.

In 2019, mental health good practices identified by the Steering Group were selected for scale-up and transfer (Suicide Prevention in Austria, Mental healthcare delivery system reform in Belgium, and European Alliance Against Depression).

At the Steering Group's formal meeting in June 2019, childhood immunisation (and the uptake of the second dose of measles vaccination in particular) was identified as a priority area for best practices and screening of implementable research results in 2020. DG SANTE, in close collaboration with the Joint Research Centre, organised expert meetings to select potential best practices in this area.

Other projects on health promotion and disease prevention launched included projects on cardiovascular disease prevention; the prescription of physical activity; and on the promotion of whole grain consumption.