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EVALUATION

Final Evaluation of the Third Health Programme 2014-2020

{SWD(2023) 370 final}

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Glossary

Term or acronym	*Meaning or definition*
1HP	First health programme
2HP	Second health programme
Programme	Third health programme
AHEAD	Action for Health Equity Addressing Medical Deserts
AIR	Annual implementation report
AMR	Antimicrobial resistance
AWP	Annual work plan
Best-ReMaP	Joint Action on the implementation of validated best practices in nutrition
CARE	Common approach for refugees and other migrants' health (project)
CBA	Cost-benefit analysis
CEA	Cost-effectiveness analysis
CHAFEA	Consumers, Health, Agriculture and Food Executive Agency
CHRODIS+	Joint Action on chronic diseases
COMPASS	European Commission's IT-based workflow system for the Horizon 2020 Framework Programme for Research and Innovation and for other EU Programmes of the research family, including the Third Health Programme 2014-2020
CPMS	Clinical patient management system for European Reference Networks
CVD	Cardio vascular disease
DG	Directorate-General of the European Commission
DG SANTE	Directorate-General for Health and Food Safety
DGA	Direct grant agreement
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EHaction	Joint Action supporting the eHealth network

EHDS	European Health Data Space
ERDF	European Regional Development Fund
ERN PaedCan	European Reference Network on Paediatric Cancer paediatric cancer [1]
ERNs	European Reference Networks for rare and complex diseases
ERWS	Early warning and response system
ESF	European Social Fund
ESIF	European Structural and Investment Funds
EU-JAV	Joint Action on vaccination
EUDAMED	European Database on Medical Devices
EURIPID	European medicine price database
EUnetHTA	Joint Action European network for health technology assessment
FPA	Framework Partnership Agreement
GAPP	Joint Action Good practice guidelines on the authorisation and preparation process for blood, tissues and cells
GDP	Gross domestic product
GNI	Gross national income
HaDEA	The European Health and Digital Executive Agency
HCAIs	Healthcare-associated infections
HTA	Health technology assessment
IHR	International Health Regulations 2005
ImmuHubs	Innovative immunisation hubs (project)
IOM	International Organisation for Migration
iPAAC	Innovative partnership for action against cancer
JAHEE	Joint Action Health Equity Europe
JAMRAI	Joint Action on antimicrobial resistance and healthcare-associated infections
JANPA	Joint Action on nutrition and physical activity

[1] The list of the other 23 established ERNs is provided through the following link: Networks (europa.eu)

MFF	Multiannual financial framework
Mig-HealthCare	Strengthen community-based care to minimise health inequalities and improve the integration of vulnerable migrants and refugees into local communities (project)
MS	Member State
MyHealth	Models to engage vulnerable migrants and refugees in their health, through community empowerment and learning alliance (project)
NCA	National competent authority
NFP	National Focal Point
NGO	Non-governmental organisation
PC	Public consultation
ORAMMA	Operational refugee and migrant maternal approach (project)
RAHRA	Joint Action on reducing alcohol-related harm
SCIROCCO	Scaling integrated care in context (project)
SDGs	Sustainable development goals
SGA	Specific grant agreement
SH-CAPAC	Supporting health coordination, assessments, planning, access to healthcare and capacity building in Member States under particular migratory pressure (project)
SGPP	Steering Group on Health promotion and disease prevention and management of non-communicable diseases
SYGMA	European Commission' IT-based grant management system for the Horizon 2020 Framework Programme for Research and Innovation and for other EU Programmes of the research family, including the Third Health Programme 2014-2020
TFEU	Treaty on the Functioning of the European Union
VISTART	Joint Action on vigilance and inspection for the safety of transfusion, assisted reproduction and transplantation
WHO	World Health Organisation
WP	Work package

1. INTRODUCTION

Purpose and scope of the evaluation

1.1. Purpose of the evaluation

This staff working document sets out the final evaluation of the third programme for EU action in the field of health (2014-2020) (the Programme)[2]. It is supported by an external study carried out by a contractor of the Commission between July 2021 and October 2022. Its purpose is to assess the management and implementation of the Programme, including the follow-up to recommendations of past health programmes' evaluations. The evaluation complies with the financial rules[3] applicable to the general budget of the EU, which call on the Commission to monitor, evaluate and to report on the implementation of actions of spending programmes. It contributes to a better understanding of the strengths and weaknesses of Programme implementation and management and provides conclusions that can be used as a basis for improving subsequent EU health programmes.

1.2. Scope of the evaluation

The evaluation assesses the performance of the Programme, its main outcomes and achieved results and identifies the main problems and solutions with regard to its implementation, including recommendations from previous evaluations.

The evaluation covers the Programme's entire implementation period (2014-2020). It covers all EU Member States[4], EFTA countries and non-EU countries participating in the Programme (Moldova, Serbia and Bosnia and Herzegovina). It focuses on the five main evaluation criteria, namely: relevance, effectiveness, efficiency, coherence and EU-added value.

While assessing the functioning of the entire Programme, the external study supporting this evaluation concentrated on issues that were insufficiently explored in past evaluations, and provided conclusions that can be used as a basis to improve the implementation of future EU health programmes.

Following the outbreak, in the first quarter 2020, of the COVID-19 pandemic in the EU territory, relevant actions funded by the Programme (2014-2020) were switched to their emergency mode and geared towards combatting the pandemic.

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[2] The Programme was established by (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. 1–13

[3] Articles 34(1) and 34(3) of the Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union (Financial Regulation), OJ L 193, 30.7.2018, p. 1–222

[4] 27 Member States plus the UK before Brexit.
For ease of reference the Commission will refer in the rest of the document to Member States. However, where relevant, this shall be deemed to also include EFTA countries and other countries which participated in the Programme (i.e. Bosnia and Herzegovina Moldova, Serbia).

These actions were not included in the scope of the external study supporting the evaluation, since some of them were in early stage or in the middle of implementation at the time when the external study was launched. Nevertheless, the SWD mentions these actions, which were funded by the Programme in its last implementation year, as part of the EU response to the COVID-19. These emergency actions were mostly launched in the early stages of the pandemic, before the adoption of the EU4Health Programme (2021-2027)[5], which succeeded the Third Health Programme 2014-2020.

The comprehensive EU response to COVID-19 was evaluated through a continuous process of assessment of actions and measures and lessons learnt, which have been the subject of several Commission communications, including the Communication on drawing the early lessons from the COVID-19 pandemic[6], the Communication on short-term EU health preparedness for COVID-19 outbreaks[7], the Communication on EU Strategy for COVID-19 vaccines[8], the Communication on Preparedness for COVID-19 vaccination strategies and vaccine deployment[9], the Communication on EU Strategy on COVID-19 therapeutics[10], and the Communication on EU Global Health Strategy[11].
Lessons learnt from the pandemic led, notably, to the Commission proposals for establishing a Health Emergency and Response Authority[12] (HERA) and for building the European Health Union[13], a set of key actions and legal instruments which help[14]:

- better protecting the health of citizens,

[5] Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (*OJ L 107, 26.3.2021, p. 1–29*)
EUR-Lex - 32021R0522 - EN - EUR-Lex (europa.eu).

[6] European Commission, (2021), Communication on drawing the early lessons from the COVID-19 pandemic.

[7] European Commission, (2020), Communication on short-term EU health preparedness for COVID-19 outbreaks.

[8] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE EUROPEAN COUNCIL, THE COUNCIL AND THE EUROPEAN INVESTMENT BANK EU Strategy for COVID-19 vaccines, COM (2020) 245 final, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0245

[9] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL Preparedness for COVID-19 vaccination strategies and vaccine deployment, COM (2020) 680 final https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0680

[10] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS EU STRATEGY ON COVID-19 THERAPEUTICS COM/2021/355/final

[11] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS on EU Global Health Strategy COM/2022/675 final.

[12] Proposal for a Regulation of the European Parliament and of the Council establishing a European Health Emergency Response Authority (HERA)

[13] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS: Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats

[14] The European Health Union comprises a set of key actions, notably in the areas of: Crisis preparedness, reform of the EU pharmaceutical legislation, Europe's Beating Cancer Plan, A comprehensive approach mental health, the European Health Data Space, Global Health Security, together with accompanying legal acts. See European Health Union (europa.eu)

- equipping the EU and its Member States to better prevent and address future pandemics,
- improving the resilience of Europe's health systems.

In April 2020, the Emergency Support Instrument (ESI) was activated[15] to enable direct support to Member States through targeted measures, deployed strategically and in a coordinated manner, in order to provide a comprehensive and flexible response to the urgent, evolving and diverse needs emerging during the COVID-19 pandemic.

By its decision C(2020)2794[16], the Commission authorised the financing of emergency support actions under the ESI Regulation and cooperated closely with the Member States in the implementation of the instrument.

Measures implemented through the ESI have been the subject of a separate reporting and assessment by the Commission[17].

Methodology

The methodology[18] of the evaluation followed the five evaluation criteria of effectiveness, efficiency, coherence, EU added value and relevance and comprised three main aspects: (1) an assessment of the publicly-available health programme database[19] as well as other documents related to the Programme, in order to build an understanding of the functioning of the Programme; (2) consultations with stakeholders through interviews, focus groups, a targeted survey, a public consultation and the monitoring social media to understand their views on the Programme implementation; and (3) an in-depth analysis of a subset of funded actions on six areas of the Programme (nutrition, alcohol, health inequalities, antimicrobial resistance, health technology assessment and vaccination). The areas for in-depth analysis were selected through a comprehensive consultation of health policy units of DG SANTE, with a view to highlighting more prominent achievements and draw lessons from health policy themes that are the most relevant from health policy point of view and the most representative of actions implemented by the Programme.

The method of contribution analysis has been used in the case studies to identify links between inputs, outcomes, and impacts of specific actions of the Programme.

[15] Council Regulation (EU) 2020/521 activating emergency support under Council Regulation (EU) 2016/369 and amending its provisions to finance expenditure necessary to address the COVID-19 pandemic.
[16] Commission Decision C(2020)2794 of 24 April 2020 on the financing of Emergency Support under Council Regulation (EU) 2016/369.
[17] REPORT FROM THE COMMISSION TO THE COUNCIL on the implementation of Regulation (EU) 2020/521 on activating emergency support to finance necessary expenditure to address the COVID-19 pandemic
[18] Methodological information on how the evaluation was conducted is detailed in the Annex II to the staff working document.
[19] Health Programme DataBase - European Commission (europa.eu).

The evaluation study gathered feedback from stakeholders from seven groups/categories[20]. The participation of experts involved in the management and design of the Programme in interviews and focus groups was particularly important. This approach enabled insights from relevant stakeholder groups to be corroborated with feedback from the various consultations to ensure that the assessment underpinning the evaluation was based on reliable evidence and data.

An extensive document review[21] was conducted prior to the stakeholder consultations, providing a solid basis for the evaluation and a steer on useful lines of enquiry. The document review and desk research provided a sound basis for triangulation of information and confirming the findings of the subsequent consultation activities.

Limitations to the evaluation study include the fact that it was developed mainly by using the publicly-available database for the Programme, which only includes actions funded through grant agreements and does not include comprehensive information, such as detailed financial data and outputs of the actions.

The related data gaps were mitigated through the provision of additional documentation and specific data, such as a list of all procurement contracts concluded under the Programme. For the operating grants awarded to NGOs, the final technical reports were made available to the contractor, as were the final reports and detailed technical results of a sample of actions funded by the Programme.

These measures, combined with the triangulation of data from different sources, enabled evidence-based conclusions, confirmed by more than one information source.

2. WHAT WAS THE EXPECTED OUTCOME OF THE INTERVENTION ?

2.1 Description of the intervention and its objectives

According to the Treaty on the Functioning of the European Union (TFEU), a high level of health protection must be ensured in the definition and implementation of all EU policies (Article 168 (1) TFEU). EU action, complementing national policies, must be directed towards improving public health, preventing physical and mental illness and diseases, and preventing sources of danger to physical and mental health.

[20] Public authorities (central government/ministries of health, and public health authorities or agencies); academic/research organisations; NGOs; EU citizens; patients and service users and organisations representing them; Consumer organisations; company/business organisations; other (international organisations e.g. WHO, OECD; Healthcare service providers; Organisations presenting healthcare service providers; Healthcare professionals' associations; Independent experts).

[21] Such as annual Work Programmes, Annual Implementation Reports, work programmes, annual implementation reports, final reports of selected funded actions, final reports of relevant studies carried out under the Programme, guidance to call for proposals applicants, funding opportunities, programme dissemination strategy, reviews or assessments of the Programme by other organisations or institutions, DG SANTE and wider Commission policy documents.

The 2014-2020 health programme is the third programme of EU action in the field of health, established by Regulation (EU) No. 282/2014. With a budget of EUR 449.4[22] million over 7 years, it was the Commission's main tool to underpin and support EU policy coordination in the area of health during that timeframe.

Designed to help Member States improve the health of their population, the Programme contributed to the Europe 2020 objective of smart, sustainable and inclusive growth. While fully respecting Member States' responsibility for drawing up their own health policies and organising the delivery of health services and medical care, the Programme aimed to complement, support and add value to national policies, in order to improve the health of people across the EU and reduce health inequalities.

The Programme aimed to serve Member States' needs to meet the Commission's overarching priorities:

- the link between the health status of the population and its contribution to growth and jobs through labour market participation and labour productivity;
- investment in health as a source of economic prosperity and social cohesion;
- societal challenges (such as demographic ageing, inequalities, burden of chronic diseases, effectiveness, sustainability and resilience of health systems).

In line with the intervention logic diagram in Figure 1 below, the EU was faced, during the design of the Programme, with the following health challenges, (first column of the intervention logic):

- increasingly challenging demographic context (ageing population) threatening the sustainability of health systems;
- fragile economic recovery limiting the resources available for investment in healthcare;
- increase of health inequalities between/within Member States;
- increase in non-communicable disease prevalence.

To address these challenges and Commission's overarching priorities, the general objective of the Programme was (column 2 of the intervention logic):

> *'to complement, support and add value to the policies of Member States to improve the health of EU 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.'*[23].

As shown in column 3 of the intervention logic, the Programme's four specific objectives with related indicators covered by Article 3 of Regulation (EU) No 282/2014, were to:

(i) promote health, prevent diseases and foster supportive environments for healthy lifestyles;

[22] Budget expressed in 2014 prices; Programme budget in current prices is equal to EUR 452.3 million.
[23] Article 2 of Regulation (EU) No 282/2014).

(ii) protect EU citizens from serious cross-border health threats;
(iii) contribute to innovative, efficient and sustainable health systems; and
(iv) facilitate access to better and safer healthcare for EU citizens.

The 4 specific objectives are translated into 4 operational objectives that describe concretely and enable to identify the typology of operational actions to be considered for implementation.

The specific objectives of the Programme are achieved through actions in line with the 23 thematic priorities listed in Annex I and implemented via the annual work programmes referred to in Article 11 of the Regulation (EU) 282/2014[24] (column 5 of the intervention logic). See also Annex VI to this document.

The majority of actions relating to the specific objective 1 (promote health, prevent diseases and foster supportive environments for healthy lifestyles) consist of the exchange and implementation of evidence-based best practices geared at health promotion and disease prevention. They are complemented by the establishment of guidelines funded by the Programme on specific topics, such as cancer screening, nutrition, healthy lifestyles. These actions, including studies, are mainly directed to Member States health authorities and policymakers. Therefore, attainment of the specific objective 1 is measured by the increased use of evidence-based practices at national and sub-national levels. In-line with the Regulation (EU) No 282/14, relevant indicators for this specific objective should therefore relate to the number of Member States involved in health promoting and disease prevention and adopting the evidence-based practices and guidelines developed under the Programme.

Activities relating to the specific objective 2 (protection of citizens from serious cross-border health threats) evolve around: risk assessment, capacity building (notably through the establishment, regular assessment and strengthening of preparedness plans) against health threats in Member States and where appropriate cooperation with third countries, implementation of EU legislation on communicable diseases and other health threats, strengthening of health information and knowledge system for evidence-based decision-making. The natural stakeholders for actions undertaken by the Programme under the specific objective 2 are Member States health authorities at national and sub-national levels. The implementation of actions under the specific objective 2 should notably enable the integration of coherent approaches[25] in Member States' preparedness plans, as reflected by the indicator associated with this objective in the regulation establishing the Programme.

As regards the specific objective 3 (contribute to innovative, efficient and sustainable health systems) actions funded by the Programme relate, inter alia, to the support to EU cooperation in health technology assessment, to innovation and digital health and to

[24] Specific and operational objective 1 mapped with thematic priorities 1.1-1.6; Specific and operational objective 2, mapped with thematic priorities 2.1.-2.4; specific and operational objective 3 mapped with thematic priorities 3.1-3.7; specific and operational objectives 4 mapped with thematic priorities 4.1-4.6.

[25] ie. based on agreed guidelines and practices and compatible/compliant with relevant EU legislation and International Health Regulations

health workforce forecasting and planning. Other actions consisted of pooling expertise at EU level, supporting healthy and active ageing, implementing EU legislation (e.g. in medical devices, medicinal products and cross-border healthcare), developing a health information and knowledge system. The expected common result of these actions is the production of EU-level advice (in particular in the field of health technology assessment), tools (including the adoption and implementation of legislation) and mechanisms for use by Member States in the reform of their health systems.
Six types of actions are co-funded under the specific objective 4 (facilitate access to better and safer healthcare for EU citizens), relating to: the European Reference Networks; rare diseases; patient safety and quality of healthcare; measures to prevent antimicrobial resistance and control of healthcare-associated infections; implementation of Union legislation in the fields of tissues and cells, blood, organs; health information and knowledge system to contribute to evidence-based decision-making.
Although the six types of funded actions are important for achieving the specific objective 4, the creation of European Reference Networks (ERNs), including for rare diseases, and the increase in the number of healthcare providers and centres of expertise joining the ERNs are considered as the main and most representative results of this specific objective.

One of the over-arching rationales of actions implemented under the 4 specific objectives is to enable the use by Member States of the knowledge and results produced by the Programme, thereby helping to improve health and healthcare policies across the EU.
The indicators associated in the basic act establishing the Programme, the Regulation (EU) No 282/2014, therefore relate at least partly to the 'number of Member States' using the tools and knowledge produced under each of the 4 objectives into their policy-making process.
For the specific objective 3 (contribute to innovative, efficient and sustainable health systems), the basic act included an additional indicator concerning the advice produced, in particular the number of Health Technology Assessments (HTA) produced per year, taking into account the important part of HTA-related activities in this specific objective.
Likewise, taking into account the important role played by the European Reference Networks (ERNs), the basic act included 2 additional indicators relating to the 'number of European reference networks established in accordance with Directive 2011/24/EU' and to 'number of healthcare providers and centres of expertise joining European reference networks'.
These indicators[26] are relevant and instrumental for assessing the extent or degree of attainment of the expected outcomes described in the intervention logic.
The Programme was managed by the Commission and implemented through annual work programmes adopted following the positive opinion of a Programme Committee consisting of Member States' representatives. The implementation was entrusted to the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA).

[26] see sections 2.2 and 3 and annex VII for more information on the indicators used to assess the performance of the Programme

The executive agency CHAFEA was closed with effect on 31 march 2021[27]. Further to this winding up of the agency, the 'legacy activities (on-going activities, running projects)' of the Programme were transferred to the newly created European Health and Digital Executive Agency – HaDEA, which succeeded CHAFEA, with regard to the implementation of legacy/remaining activities of the Programme and which was also entrusted with the implementation of the successor health programme, the EU4Health Programme on the period 2021-2027.
Table 1 below shows the financial mechanisms used by the Programme.

Table 1: Financial mechanisms of the health programme

Financial mechanism	Description
Project grants	Used to fund collaborative efforts between organisations in various EU MS that join forces to perform tasks to achieve a common set of objectives for a defined period of time[28] [29]
Operating grants	Contribute to the core activities of non-governmental bodies or networks, over a period equivalent to their accounting year[30]
Direct grants to international organisations	Awarded to international organisations, such as the WHO, to equip them with the capacity needed to tackle relevant health priorities
Joint actions	Actions with a clear EU added value, co-financed either by competent authorities responsible for health in the Member States or the participating non-EU countries, or by public sector bodies and non-governmental bodies mandated by those competent authorities[31]
Procurement contracts	Also called service contracts or tenders) over specific needs related to the support of EU health policies (e.g. studies, development of IT tools, etc.)[32]
Presidency conferences	Thematic conferences on health topics (such as personalised medicine) to mark the Presidencies of Council of the EU
Others	For example: 'Payment of membership fee and reimbursement of expert mission costs', 'Reimbursement of auditor mission costs", "Cross sub-delegation to EUROSTAT'.

Figure 1: Intervention logic of the Programme

[27] Article 21 of COMMISSION IMPLEMENTING DECISION (EU) 2021/173 of 12 February 2021 establishing the European Climate, Infrastructure and Environment Executive Agency, the European Health and Digital Executive Agency, the European Research Executive Agency, the European Innovation Council and SMEs Executive Agency, the European Research Council Executive Agency, and the European Education and Culture Executive Agency and repealing Implementing Decisions 2013/801/EU, 2013/771/EU, 2013/778/EU, 2013/779/EU, 2013/776/EU and 2013/770/EU (OJ *OJ L 50, 15.2.2021, p. 9–28).*

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

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

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

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

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

THE CHALLENGES

- increasingly challenging demographic context threating the sustainability of health systems

- fragile economic recovery limiting the resources available for investment in healthcare

- increase of health inequalities between/within Member States

- increase in chronic diseases prevalence

GENERAL OBJECTIVES

Complement, - support and add value to the policies of Member States

- to improve the health of EU citizens *and*

-reduce health inequalities

Budget: €449.4 million (2014-2020)

Management mode: Centralised direct and indirect management

Programming and implementation on the basis of adoption of Annual Work Programmes through implementing acts

Monitoring and reporting Mid-term review in 2017

Annual implementation report sent to EP& Council

SPECIFIC OBJECTIVES

1) Promote health, prevent disease and foster supportive environments for healthy lifestyles

2) Protect citizens from serious cross-border health threats

3) Contribute to innovative, efficient and sustainable health systems

4) Facilitate access to better and safer healthcare for Union citizens

OPERATIONAL OBJECTIVES

1) Identify, disseminate and promote the up-take of evidence-based and good practices for cost-effective disease prevention and health promotion measures by addressing in particular the key lifestyle related risk factors with a focus on the Union added value.

2) Identify and develop coherent approaches and promote their implementation for better preparedness and coordination in health emergencies.

3) Identify and develop tools and mechanisms at Union level to address shortages of resources, both human and financial, and facilitate the voluntary up-take of innovation in public health intervention and prevention strategies.

4) Increase access to medical expertise and information for specific conditions also beyond national borders, facilitate the application of the results of research and develop tools for the improvement of healthcare quality and patient safety through, inter alia, actions contributing to improve health literacy.

ACTIONS *(see annex I of the Programme Regulation)*

1.1 *Risk factors such as use of tobacco and passive smoking, harmful use of alcohol, unhealthy dietary habits and physical inactivity.*
1.2. *Drugs-related health damage, including information and prevention.*
1.3. *HIV/AIDS, tuberculosis and hepatitis*
1.4. *Chronic diseases including cancer, age-related diseases and neurodegenerative diseases*
1.5. *Tobacco legislation*
1.6. *Health information and knowledge system to contribute to evidence-based decision making*
2.1 *Risk assessment additional capacities for scientific expertise*
2.2. *Capacity building against health threats in Member States, including, where appropriate, cooperation with neighbouring countries*
2.3. *Implementation of Union legislation on communicable diseases and other health threats, including those caused by biological, and chemical incidents, environment and climate change*
2.4 *Health information and knowledge system to contribute to evidence-based decision making*
3.1 *HTA*
3.2 *Innovation and e-health*
3.3 *Health workforce forecasting and planning*
3.4 *Setting up a mechanism for pooling expertise at Union level*
3.5 *European Innovation Partnership on Active and Healthy Ageing*
3.6 *Implementation of Union legislation in the field of medical devices, medicinal products and cross-border healthcare*
3.7 *Health information and knowledge system including support to the Scientific Committees set up in accordance with Commission Decision 2008/721/EC*

4.1 *European Reference Networks*
4.2 *Rare diseases*
4.3 *Patient safety and quality of healthcare*
4.4 *Measures to prevent antimicrobial resistance and control healthcare-associated infections*
4.5 *Implementation of Union legislation in the fields of tissues and cells, blood, organs*
4.6 *Health information and knowledge system to contribute to evidence-based decision making*

RESULTS

1. Increased use of evidence-based practices at the appropriate level in MS

2. Coherent approaches integrated in the MS preparedness plans

3. Increased production of advice and use of developed tools and mechanisms by MS in the reform of their health systems

4. Creation of the European Reference Networks including for rare diseases, and increasing number of healthcare providers and centres of expertise joining the ERNs

2.2 Point(s) of comparison

The final evaluation of the third health programme (the Programme) uses as a point of comparison, the results of the final evaluation of the second health programme (2008-2013)[33], combined with the findings of the Programme's mid-term evaluation[34].
According to the results of its final evaluation, the second health programme had very broad objectives and a large scope. This implied that the themes addressed by the funded actions were all relevant. This large scope and lack of focus meant that the programme's limited resources were thinly spread among a high number of funded actions, affecting the ability to reach a critical mass and to have a major impact.
To address this issue, the Programme focused on certain key objectives and on fewer actions with **proven EU added value** and with the following characteristics:

- a focus on fostering the exchange of best practices between Member States and supporting networks for knowledge sharing or mutual learning. (specific objectives 1, 3 and 4);
- addressing cross-border health threats to reduce risks and mitigate consequences (specific objective 2);
- addressing issues relating to the internal market where the EU has substantial legitimacy to ensure high-quality solutions across Member States and actions to unlock the potential of innovation in health (specific objectives 3 and 4);
- 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. (specific objectives 1, 3 and 4).

The mid-term evaluation of the Programme concluded that implementation was on track, 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. Compared to the second Health Programme, the 3rd Health programme demonstrated its value as an effective and flexible instrument. However, there was scope to further streamline the added-value criteria to focus on three key areas: addressing serious cross-border health threats, improving economies of scale, and fostering the exchange and implementation of best practices. The mid-term evaluation, notably recommended to keep the Programme focused, to improve the arrangements for the monitoring of the programme's implementation, to increase participation of low-GNI Member States and underrepresented organisations.

[33] Ex-post evaluation of the 2nd Health Programme 2008-2013 (europa.eu)
[34] Commission report - Mid-term evaluation of the 3rd Health Programme 2014-2020 (europa.eu)

2.2.1 Under specific objective 1 for promoting health and preventing diseases, the Programme aimed at identifying, disseminating and promoting the uptake of evidence-based best practices, including measures to address health inequalities.
According to Article 3(1) of Regulation (EU) No. 282/2014, the attainment of this specific objective is measured, in particular, through 'the increase in the number of Member States involved in health promotion and disease prevention, using evidence-based and good practices through measures and actions taken at the appropriate level in Member States'.
At implementation level, this indicator has been broken down into the two (proxy) following components or sub-indicators:

- number of Member States with a national initiative on reducing saturated fat in food;
- number of Member States implementing the European accreditation scheme for breast cancer services.

The baselines and targets for the two sub-indicators, established at the beginning of the Programme implementation, are presented in the box below.

Sub-indicator 1: Saturated fat
Baseline: 12 Member States have had a national initiative on the reduction of saturated fat in 2013.
Target: By 2020, all EU-28 should have had a national initiative on the reduction of saturated fat[35].

Sub-indicator 2: Implementation of the European accreditation scheme for breast cancer services
Baseline: 0 Member States implemented the European accreditation scheme for breast cancer services in 2013.
Target: by 2020 all EU-28 should have implemented the accreditation scheme for breast cancer services.

2.2.2 Under specific objective 2 on protecting citizens from cross-borderborder health threats, the Programme aimed at identifying and developing coherent approaches and support and promoting their implementation to contribute to a better preparedness and coordination in health emergencies.

Supported actions under this objective have identified gaps in Member States' capacities and helped prioritise actions and implement capacity building activities to fill in those gaps.

In line with Article 3(2) of Regulation (EU) No. 282/2014, the achievement of specific objective 2 is measured, in particular, through 'the increase in the number of Member States integrating coherent approaches in the design of their preparedness plans",

The integration by Member States of coherent approaches in the design of their preparedness plans means the inclusion, the taking into account and implementation by Member States, when designing their preparedness plans, of guidelines, protocols and tools concerning :

[35] including through the exchange and implementation of best practices co-funded by the Programme.

- the improvement of risk assessment capacities as regard health threats,
- capacity-building against health threats, including where appropriate, cooperation with other Member States and neighbouring countries; taking into account, and coordinating with global initiatives; public health response coordination (notably through the promotion of the interoperability of preparedness systems); non-binding approaches on vaccination; addressing the increasing health threats resulting from global population movements; guidelines development on protective measures in an emergency situation; information and guides to good practice; the contribution to the framework for a voluntary mechanism, including the introduction of optimal vaccination coverage to effectively combat the resurgence in infectious diseases and for the joint procurement of medical countermeasures; development of coherent communication strategies.
- actions required by, or contributing to the implementation of Union legislation in the fields of communicable diseases and other health threats, including those caused by biological and chemical incidents, environment and climate change.
- fostering a health information and knowledge system to contribute to evidence-based decision-making,

These guidelines, protocols and tools are tailored to the specific needs and gaps of each Member State, which are identified through regular training sessions, workshops, round tables, simulations and command post exercises aimed at testing established procedures, tools and systems for reporting, monitoring and assessing risks and threats to people and communicating on these risks and threats. The command post exercises serve to test multi-sector arrangements for responding to an outbreak.
Through the identification of capacity gaps, these activities are aimed at contributing to a better preparedness of Member States and to their capacity to respond to health threats and at implementing EU legislation – Decision 1082/2013/EU - and international regulations (International Health Regulations - IHR[36] 2005) that seek to contribute to the development of an adequate management of serious cross-border health threats.

The coherent approaches adopted by Member States are therefore in line with the above-described guidelines, protocols and tools resulting from actions funded by the Programme and also compliant with international health regulations adopted by the WHO.

The baseline and target for this indicator, established at the beginning of the Programme implementation, are presented in the box below:

Baseline: in 2014, 0 Member States had integrated coherent approaches into the design of its preparedness plans.
Target: by 2020, all EU-28 Member States should have integrated coherent approaches into the design of their preparedness plans.

[36] International Health Regulations (2005) (who.int)

2.2.3 Under specific objective 3 on contributing to innovative, efficient and sustainable health systems, the Programme aimed to identify and develop tools and mechanisms at EU level to address shortages of human and financial resources, and facilitate the voluntary uptake of innovation in public health intervention and prevention strategies. The main ones are health technology assessment, eHealth, the European Innovation Partnership on active and healthy ageing, the Expert Panel on effective ways of investing in health and the Commission's scientific committees.

In line with Article 3(3) of Regulation (EU) No. 282/2014, the achievement of specific objective 3 is measured, in particular, through 'the increase in the advice produced and the number of Member States using the tools and mechanisms identified in order to contribute to effective results in their health systems'.

The indicator relates to HTA advice produced by the joint assessment actions undertaken and completed by the joint actions carried out under the Programme. The EUnetHTA JA3 (European Network for Health Technology Assessment Joint Action 3) was launched with the participation of 61 partners and 16 affiliated partners from 26 Member States, NO and the UK.

At implementation level, this indicator is broken down into the following sub-indicators:

- Advice produced by actions launched under the Programme (e.g., the EUnetHTA 3), in particular the number of health technology assessments produced per year.
- Number of Member States using the identified tools and mechanisms to contribute to effective results in their health systems. This indicator is measured by the number of Member States that have effectively integrated and implemented tools and mechanisms produced by HTA actions (advice, assessment results and recommendations) in their health systems.

The baselines and targets for these sub-indicators, established at the beginning of the Programme implementation, are presented in the box below.

Number of Member States using the identified tools and mechanisms (i.e. the joint HTA reports and recommendations)[37]to contribute to effective results in their health systems.
Baseline: 0 in 2013
Target in 2020: 18 Member States

Health technology assessment (HTA)
Baseline: 2 HTA per year in 2013 at EU level
Target in 2020: 50 HTA annually involving all EU-28 at EU level

2.2.4 Under specific objective 4 on facilitating access to better and safer healthcare, the aim was to increase access to medical expertise and information for specific conditions, also beyond national borders, to facilitate the application of research results[38]

[37] Advice, assessment and recommendations to support evidence-based, sustainable and equitable choices in healthcare and health technologies (see the following hyperlink for more information on the tools produced and the governance of EUnetHTA3 joint action: ev_20201027_co07_en_0.pdf (europa.eu)
[38] These refer to the results of health-related research activities carried out at EU and/or at national level

and to improve healthcare quality and patient safety through actions on health literacy.

In line with Article 3(4) of Regulation (EU) No. 282/2014, the achievement of specific objective 4 is measured, in particular, through 'the increase in the number of European Reference Networks (ERNs) established under Directive 2011/24/EU of the European Parliament and of the Council[39]', 'the increase in the number of healthcare providers and centres of expertise joining European Reference Networks', and 'the increase in the number of Member States using the tools developed'[40].

The baselines and targets for these indicators, established at the beginning of Programme implementation, are presented in the box below.

Number of European ReferenceReference Networks (ERNs) established in accordance with Directive 2011/24/EU
Baseline: 0 ERNs in 2014
Target in 2020: 30 ERNs

Number of healthcare providers and centres of expertise joining the ERNs
Baseline: 0 in 2014
Target in 2020: 1450

Number of Member States using the tools developed:
Baseline: 0 in 2014
Target in 2020: 28 Member States or 27, taking account of Brexit[41]

3. HOW HAS THE SITUATION EVOLVED OVER THE EVALUATION PERIOD?

At the end of 2020, 100% of the allocated budget (EUR 452.3 million[42] for 2014-2020) was committed for projects and other actions pursuing the Programme's objectives. 67% of the total budget (i.e. EUR 305.3 million) was paid to beneficiaries or used to procure services necessary for the implementation of the Programme. Outstanding payments (33% of the budget or EUR 147 million) account for projects or actions launched in the last 2-3 years which have not yet been completed and therefore have not led to final payments by the Commission.

Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).
[40] Tools developed within ERNs for diagnosis, clinical trials and treatment, such as the IT-based Clinical Patient Management System (CPMS)
[41] The transition period for the Brexit ended on 31/12/2020.
[42] The budget amounts to EUR 452.3 million in current prices and EUR 449.4 million in 2014 prices.

Table 2: Overview of financial programming over the implementation period

	Financial Programming (EUR million)							
	2014	2015	2016	2017	2018	2019	2020	Total Programme
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(*)**

(*) Figure in 2014 prices

The Programme addressed four specific objectives in line with the Commission's priorities, namely: the implementation of best practices for health promotion and disease prevention; crisis preparedness and risk management; contribution to innovative, efficient and sustainable health systems; and facilitation of access to better and safer healthcare.

Despite **a relatively small budget**[43], the Programme contributed to a better health protection through its policies and activities, in accordance with Article 168 TFEU.

A majority of indicators[44] and sub-indicators (except for one sub-indicator[45]) for assessing progress towards the Programme's general and specific objectives improved over the implementation period (2014-2020), with many of them meeting their 2020 targets.

A comprehensive list of Programme indicators is set out in Annex VII to this document.

3.1. Specific objective 1: promote health, prevent diseases, and foster supportive environments for healthy lifestyles

3.1.1. Indicators

28% (EUR 127 million) of the overall Programme budget was allocated to actions falling under specific objective 1. EUR 8 million was spent on cancer, including on supporting screening programmes in the MS, improving the quality of patients' lives, addressing survivorship issues, assessing the impact of cancer research and facilitating the uptake of innovative treatments. EUR 11 million was allocated to major risk factors of cancer and other chronic diseases, i.e. alcohol and tobacco control, physical activity and nutrition. Other activities aimed at preventing chronic diseases included promoting the EU-wide uptake of validated best practices in preventing cardiovascular disease and diabetes. The Programme also developed the EU-Compass for Action on **mental health** and wellbeing

[43] As compared to health-related expenditure under the European structural and investment funds or with the budget of the ongoing EU4Health Programme (2021-2027)

[44] The full list of indicators is presented in annex VII to this document

[45] **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, **Sub-indicator: Cancer**

which is a web-based mechanism used to collect exchange of best practices and analyse information on policy and stakeholder activities in mental health.

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

Saturated fat: The indicator on the number of Member States with an initiative on the reduction of saturated fat improved over the implementation period, reaching **24 Member States in 2020**.

European accreditation scheme for breast cancer: The indicator on the number of Member States implementing the EU scheme for breast cancer services improved in 2014-2018, reaching 10 Member States by the end of that period, before declining to **6 in 2020**.

3.1.2. Examples of actions implemented under Specific objective 1: promote health, prevent diseases, and foster supportive environments for healthy lifestyles:

(i) The online '**best practice** portal'[46] was launched in April 2018. Since then, it has had 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. Stakeholders can also submit a practice for evaluation.

As of 2020, more than 12 best practices selected by the Member States in the Steering Group on health promotion, disease prevention and management of non-communicable diseases (SGPP) have been taken up in 75% of EU Member States. Areas covered include integrated care, mental health and the fight against depression, nutrition and physical activity, the prevention of alcohol abuse and the prevention and management of chronic diseases.

(ii) The Programme developed in 2016, the 'EU Compass for Action on **mental health** and wellbeing', a web-based tool to collect and exchange best practices and analyse information on policy and stakeholder activities in mental health.

(iii) On **cancer**, the European Quality Assurance scheme has been developed (over the period 2015 to 2019), in a harmonised, evidence-based and flexible way to grant equal and quality-benchmarked treatment to patients. The activities of the European Network of Cancer Registries coordinated by the Joint Research Centre (JRC) provides a 'data-brokering' service to ensure the integrity of a single European dataset for different purposes. 128 Cancer Registries from 29 European countries regularly provide data to JRC with more than 25 900 000 records so far in the database.

[46] BP Portal (europa.eu)

3.2. *Specific objective 2: protect EU citizens from serious cross-border health threats*

3.2.1. Indicator

12% (EUR 52 million) of the overall budget[47] was allocated to this objective. Over EUR 14 million was allocated to projects aiming to contribute, to the extent possible, to Member States' preparedness to respond to possible major health threats. Projects included the organisation of simulations and other exercises on generic preparedness, capacity building - such a quality assurance for diagnostic capacity, and specific activities addressing the air transport and shipping sectors. Other actions aimed to support Member States in addressing the challenges of the migratory crisis of 2015-2016.

Indicator: number of Member States integrating coherent approaches into the design of their preparedness plans (see paragraph 2.2.2)

This indicator showed progress, increasing from 0 Member States in 2014 to 16 in 2015, and **22 in 2020**

Despite the positive trend of this indicator and, while the Programme continuously contributed to improve the EU and Member States' preparedness and response to cross-border health threats of usual magnitude (including outbreaks such as Zika and Ebola that occurred in third countries), the COVID-19 outbreak in the first quarter of 2020 uncovered weaknesses and fragilities in the Preparedness and response of the EU and of the Member States with regard to a major health threat such as the COVID-19 pandemic (see section 4.1.1, paragraph a).

3.2.2. Examples of actions implemented under *specific objective 2: protect EU citizens from serious cross-border health threats:*

(i) As response to the COVID-19 outbreak in the first quarter of 2020, running actions on health security, funded by the Programme, were steered to contribute to combating the pandemic, in particular in its early stages. Key examples are: the **Joint Action Healthy gateways** which supported coordination among EU Member States to improve capacity to combat 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 (SHARP)**[48],; which involved a collaboration with ECDC's EVD-LabNet (Emerging Viral Diseases-Expert Laboratory Network) to ensure quality control and capacity building for precise diagnostics at an early phase of the

[47] Note that apart from actions funded under the health programme, other EU-level actions, mechanisms, permanent structures and organisations. also address health threats, e.g., the early warning and response system (EWRS), the Health Security Committee, the Health Emergency Operation Facility and the European Centre for Prevention and Disease Control. This may partly explain the relatively smaller proportion of the Programme budget devoted to health threats.

[48] The Joint Action SHARP supports coordination among EU reference laboratories to prevent, detect and respond to biological outbreaks, chemical contamination and environmental and unknown threats to human health.

pandemic and demonstrated the importance of using laboratory networks as a preparedness and response tool.

Under the 3rd Health Programme, actions have been reoriented to specific needs related to the coronavirus threat, such as training for health professionals (including practical advice on isolation, waiting rooms and reception areas, cleaning, and appropriate personal protective equipment), and the provision of real-time RT-PCR tests to detect the virus, including shipment costs if needed.[49]

These emergency actions implemented by the Programme were complementary with other emergency actions carried out outside the health programme by DG SANTE (e.g. measures taken by the Health Security Committee, the Joint Procurement to purchase medical countermeasures, the Early Warning and Response System – EWRS, the Health Emergency Operation Facility - HEOF) and with emergency measures taken by a wide range of other Commission services as well as the ECDC, which were mobilised to combat the pandemic.

(ii) During the **Ebola** and **Zika** outbreaks, part of the Programme funding was used to support measures to limit the spread of these viruses by strengthening the preparedness and response of individual Member States working together under the Health Security Committee (entry screening, medical evacuations, preventing transmission in transport and hospital settings). The budget in 2014-2016 for strengthening EU response to health threats amounted to EUR 11 million. The budget for the remaining implementation period (2017-2020) amounted to EUR 41 million.

3.3. *Specific objective 3: support public health capacity building and contribute to innovative, efficient and sustainable health systems:*

3.3.1. Indicators

24% (EUR 109 million) of the overall budget was allocated to objective 3. EUR 30 million was spent on collaboration on **health technology assessment (HTA)** to develop commonly agreed tools and procedures and carrying out joint assessments or early dialogues taking a 'life cycle' approach to 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 (e.g. the Joint Action on implementation of digitally enabled integrated person-centred care – JADECARE that was launched in autumn 2020 and will run for 3 years) and supported the EU eHealth network in promoting the uptake of digital solutions. The **Joint Action on health information** helped to streamline and harmonise health information activities across

[49] EU response to the COVID-19 pandemic was carried out by a wide range of other Commission services, EU programmes and funding instruments, as referred to in the following non-exhaustive list: the Union Civil Protection Mechanism; the Emergency Support Instrument; the EU Solidarity Fund; the health programmes[49], the Joint Procurement for Medical Countermeasures; the European Centre for Disease Prevention and Control - ECDC, the Horizon 2020 Framework Programme for Research and Innovation (2014-2020), the Single Market Programme

Europe by developing a sustainable and solid infrastructure on EU health information, and to increase consistency and sustainability.

Indicator: advice produced and the number of Member States using the tools and mechanisms identified to contribute to effective results in their health systems

Number of Member States using the tools and mechanisms identified (i.e., advice, joint HTA reports and recommendations produced by the EUnetHTA Joint Action 3) to contribute to effective results in their health systems: Progress was made on this indicator, with the number of Member States increasing from 0 in 2014, to 5 in 2015, to 9 in 2017 and finally to **23 in 2020**.

Advice produced, in particular the number of health technology assessments (HTA) produced per year: This indicator, improved, increasing from 2 HTA at EU level in 2012, to 22 in 2018 and finally to **41 in 2020**

3.3.2. Examples of actions under specific objective 3: *support public health capacity building and contribute to innovative, efficient, and sustainable health systems*

(i) State of Health in the EU - (1) 2019 country health profiles and (2) Health at a Glance 2020: Europe

On 28 November 2019, the European Commission published **30 country health profiles** as part of the **State of Health in the EU** cycle. The accompanying 'companion report' (a Commission staff working document) and factsheet flagged five key challenges faced by 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 Programme and to the key priorities of the 2019-2024 Commission, as set out in the mission letter to Commissioner Kyriakides.

(ii) *Digital innovation – paving the way to a European health data space*

Building on past actions in the field of eHealth (e.g. inclusion of eHealth into health policies, better alignment of eHealth investments into health needs, as part of the implementation of the Digital Single Market Strategy), the Commission aims to support EU Member States in making the most of the potential of digital health to provide high-quality healthcare and reduce inequalities. Key to achieving this aim is the creation of a '**European Health Data Space' (EHDS)**, to promote health data exchange and support research, innovation and policymaking. The European Health Data Space will lead to better health outcomes for patients and the public, reduced costs, increased efficiency, more resilient health systems, new treatments and better policymaking. The Programme funded the **Joint Action TEHDAS** (The European Health Data Space) in 2020 and

started in 2021, with 25 participating countries, to help set up a European health data space, by developing principles for the cross-border secondary use of health data. This joint action shows continued relevance, with the adoption of the Commission proposal on EHDS[50] on 3 May 2022 and its potential impact for healthcare, research, innovation and policymaking.

3.4. *Specific objective 4: facilitate access to better and safer healthcare for EU citizens*

3.4.1. Indicators

19% (EUR 87 million) of the overall budget was allocated to objective 4. EUR 26 million was invested for setting up and coordinating of the European Reference Networks (ERNs)[51].

Actions included assessments of the networks and their healthcare provider members. Key priorities of Programme spending for this objective included the effort to jointly address the effects and challenges of increased antimicrobial resistance and healthcare acquired infections, support for Member States' collaboration on blood, tissues and cells, and rare diseases.

Indicators: number of ERNs set up in accordance with Directive 2011/24/EU; number of healthcare providers and centres of expertise joining the ERNs; number of Member States using the tools developed.

Number of ERNs set up in accordance with Directive 2011/24/EU: the number increased from 0 in 2014 to 23 in 2016, and finally to 24 in 2017.

Number of healthcare providers and centres of expertise joining the ERNs: the number increased from 0 in 2014 to 936 in 2016, and finally to 1 185 in 2020.

Number of Member States using the tools developed (i.e., diagnostic and treatment tools, Clinical Patient Management System - CPMS)**:** The number increased from 0 in 2014 to 25 in 2017 and to 27 in 2020.

3.4.2. Actions under specific objective 4: *facilitate access to better and safer healthcare for EU citizens*

(i) The **European Reference Networks (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.

The first ERNs were set up in 2017. Over the five subsequent years, as the ERNs reach higher capacity, thousands of EU patients suffering from a rare or complex condition

[50] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space COM/2022/197 final

[51] This amount does not include cost of IT tools for the Clinical Patient management System Clinical (CPMS) which are estimated at EUR 6 million.

have benefited from better diagnosis, better advice on specialised treatments, new or better clinical practice guidelines, while healthcare professionals involving in rare diseases were offered better training and support.

(ii) **Rare diseases:** the Joint Research Centre has developed in 2018 and is maintaining the **European Platform on Rare Diseases Registration** receiving specific financial support from the Programme. The Platform is promoting the interoperability of existing registries and has helped in the creation of new ones, including those developed by the ERNs. The migration of the two databases - the European Surveillance of Congenital Anomalies (EUROCAT) and the Surveillance of Cerebral Palsy in Europe (SCPE) – has been successfully implemented.

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

3.5. Examples of actions addressing horizontal/cross-cutting issues – health inequalities, legislation, the sustainable development goals - SDGs, dissemination of programme results

Finally, 8% (EUR 38 million) of the overall budget was devoted to horizontal and cross-cutting issues (health inequalities, dissemination of Programme results, SDGs, and legislation)[52].

(i) The Joint Action on health equity Europe (JAHEE) (2018-2021) enables Member States to work jointly to address **health inequalities** and achieve greater equity in health outcomes across all groups in society, in all participating countries and in Europe at large. The general objective of this initiative is to improve the health and well-being of people across the EU and across all societal groups. It also has a specific focus on vulnerable groups and migrants.

(ii) The programme provided resources for **implementing the EU's political commitments and legal obligations in health** (e.g. implementation of the tobacco control[53] cross borderand health threats[54] legislation, the EU regulatory framework for

[52] The percentages devoted to the 4 specific objective and to horizontal/cross-cutting issues do not add up to 100% since a small (residual) part of the overall Programme budget is allocated to administrative support and to the cost of functioning of the executive agency CHAFEA.

[53] 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. 1–38*)

[54] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (*OJ L 293, 5.11.2013, p. 1–15*), repealed by REGULATION (EU) 2022/2371 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 November 2022

medicinal products[55] and medical devices[56], for substances of human origin[57] and cross-border healthcare[58]), including through the development of common tools (e.g. the European Database on Medical Devices - EUDAMED[59] and European Medicine Price Database - EURIPID[60] database) which are necessary for the smooth operation of the internal market in the medical devices and medicines sectors.

More examples of actions implemented by the Programme are presented in Annex VIII to this document.

3.6. Current state of play:

Given that the majority of actions funded by the Programme through grant agreements have a typical duration of 3 years, the actions launched in 2020 and 2021[61] are still ongoing and should come to an end only in 2023 and 2024 respectively.

This is the case for example for the joint actions on implementing best practices in the field of nutrition (Best-REMAP); to strengthen health preparedness and the response to biological and chemical terror attacks (TERROR); on implementing digitally enabled, integrated, person-centred care (JADECARE), along with 20 projects that were launched in 2019.

Ongoing actions launched in 2020 include: the second Joint Action on tobacco control (JATC2)[62] to facilitate the exchange of good practices between the Member States in order to improve the implementation of the Tobacco Products Directive[63] and the delegated acts relating to e-cigarettes; the Joint Action on exchange and implementation of best practices in the field of mental health (ImplMENTAL), with particular focus on suicide prevention and the reform of mental health services; and the Joint Action

[55] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (*OJ L 136, 30.4.2004, p. 1–33*)

[56] 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*)

[57] Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (*OJ L 33, 8.2.2003, p. 30–40*)
and Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (*OJ L 102, 7.4.2004, p. 48–58*)

[58] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (*OJ L 88, 4.4.2011, p. 45–65*)

[59] EUDAMED database - EUDAMED (europa.eu)

[60] European medicine price database (EURIPID) | WHOCC PPRI (goeg.at)

[61] A number of actions under the Programme were launched in 2021, through a carry-over of their budget from 2020 to 2021.

[62] JAOTC2 is a 3-year joint action with EC co-funding of EUR 2.5 million

[63] 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. 1–38)

'increasing the capacity of National Focal Points to provide guidance, information and assistance to national applicants to the health programmes[64] and to other health-related EU programmes and funding instruments (NFP4Health)'[65].

Three projects to boost vaccination uptake were also funded in 2020, namely RISE-Vac[66], ImmuHubs[67] and ActToVAx4NAM[68] ('increased access to vaccination for newly arrived migrants').

Furthermore, due to the disruptions and delays caused by the COVID-19 outbreak in 2020, certain actions initiated in 2018 incurred additional delays and have not come to an end as originally planned in 2022.

Because of their ongoing/unfinished status, the results of the above actions could not be fully taken into account in this Programme evaluation.

4. EVALUATION FINDINGS (ANALYTICAL PART)

4.1. To what extent was the intervention successful and why?

4.1.1. Effectiveness

The Programme has been effective in meeting its own implementation objectives, by following up on the recommendations from previous evaluations, and applying the exceptional utility criteria to encourage participation of low-GNI countries. It has also made efforts to ensure the sustainability of the outcomes and results of its actions over time.

a) *to what extent have the Programme objectives been met*

a.1. ANALYSIS OF THE PROGRAMME INDICATORS

The effectiveness of funded actions has been measured using the indicators set under the Programme (see Section 3 and Annex VII[69]).

Although they do not cover all the implemented actions, progress on these indicators shows the extent to which the Programme has met its objectives.

[64] ie. The ending 3rd Health Programme (2014-2020) and its successor, the EU4Health programme (2021-2027).
[65] Health Programme DataBase - European Commission (europa.eu).
[66] Duration: 3 years, EU co-funding: EUR 951 120.
[67] Duration 3 years, EU co-funding: EUR 989 104.
[68] Duration: 3 years, EU co-funding: EUR 994 393.
[69] It was decided not to use the indicator '*Number of Healthy Life Years at birth*' in the analysis conducted in this document, since this indicator is shown to be influenced by several other factors beyond the health programme and since it was found difficult and technically challenging to separate or isolate the influence of the Programme implementation on the indicator.

(i) The specific objective 1 aimed at promoting health, preventing diseases and fostering supportive environments for healthy lifestyles. The implemented actions should result in an increased use of evidence-based practices at national level.
Associated with this specific objective, the indicator on the *number of Member States having a national initiative on reduction of saturated fat* showed a moderate increasing trend over the implementation period 2014-2020, reaching or exceeding the annual targets set out. The Programme contributed to increased initiatives put in place by Member States on reduction of saturated fat, which, in line with scientific evidence promotes health by reducing in the long-term the occurrence of diseases.
The second indicator ('*number of Member States in which the European accreditation scheme for breast cancer services is implemented*') saw a decrease from 10 in 2018 to 6 in 2020. This is explained by the fact that in 2019, developers of guidelines and/or national authorities of (only) six Member States had used, implemented or adapted in their national cancer plans, the guidelines or methodology developed by the European Commission initiative on breast cancer, coordinated by the Joint Research Centre. The reduction in the number of national implementations of the European accreditation scheme for breast cancer was due to the choice made by certain Member States to implement similar other schemes, taking into account country-specific factors and building on national know-how and practice. This reduction in the number of national implementations does not significantly affect the conclusion on the overall ability of the Programme to meet the objectives set out under the Specific Objective 1. Qualitative analysis demonstrates that other cancer-related actions funded by the Programme were taken up by Member States in their health policies. This was, notably the case for the accreditation schemes for cervical and for colorectal cancers.

Beyond cancer prevention and treatment, the stakeholder consultations showed that funded actions relating to health promotion and disease prevention actions were overall effective in reaching their objectives, particularly in the field of nutrition, alcohol[70], tobacco control, and more generally through further rationalised and more systematic organisation of the exchange of best practices, as enabled by the dedicated portal set-up under the Programme in 2018.

(ii) The specific objective 2 (protection of citizens from serious cross-border health threats) evolves around: risk assessment, capacity building (notably through the establishment, regular assessment and strengthening of national preparedness plans) against health threats in Member States and where appropriate cooperation with third countries, implementation of EU legislation on communicable diseases and other health threats, strengthening of health information and knowledge system for evidence-based decision-making. The natural stakeholders for actions undertaken by the Programme under the specific objective 2 are Member States health authorities at national and sub-

[70] see section below on stakeholders consultations

national levels. The implementation of actions under the specific objective 2 should notably enable the integration of coherent approaches[1] in Member States' preparedness plans, as reflected by the indicator associated with this objective in the regulation establishing the Programme.
The indicator showed a positive trend, starting from 0 in 2014, nearly reaching the annual targets or exceeding them in all years except in 2017 and 2020.
In 2020, 22 Member States integrated coherent approaches (as described in sections 2.1. and 2.2.2.) in their preparedness plans, as shown by the assessment of the reports on national preparedness plans transmitted to the Commission. The coherent approaches included, for instance, the implementation of International Health Regulations (IHR), the interoperability between the health sector and other sectors, business continuity plans to cope with outbreaks, setting up and testing standard operating procedures (SOP) for the coordination between the health sector and a number of other sectors, notification to the Commission of substantial revisions of national preparedness planning, testing, training and exercises to ensure that IHR core capacities are maintained and strengthened in the future.

Although actions on preparedness and response to cross-border health threats are also under the responsibility of other services, bodies and mechanisms[71] outside the health programme, actions funded by the Programme contributed to strengthen the preparedness and response of the EU and of Member States to cross-border health threats (see paragraph 3.2.2 Annex VIII, paragraph 2.). The funded actions contributed to improve the preparedness plans at EU and Member States levels for cross-border health threats, thereby enabling on the one hand to effectively respond to the frequent, moderate health threats that occurred during the Programme implementation period, and on the other hand to quickly gear the Programme-funded actions towards combating the COVID-19 outbreak from the first quarter of 2020 (see paragraph 3.2.2. (i))

As has been the case in other geographical areas, the COVID-19 pandemic revealed, however, weaknesses and fragilities in the preparedness and response of the EU and of Member States to health threats of big magnitude. As mentioned in the Communication on short-term EU health preparedness for COVID-19 outbreaks, the main weaknesses at the beginning of the pandemic were:

- the shortage of tests and testing materials; insufficient contact tracing, public health surveillance and rapid response to avoid further spread of the virus; insufficient trained laboratory personnel and some supplies of laboratory equipment;
- insufficient availability of medical countermeasures (personal protective equipment, medicines and medical devices) enabling to cope with increased demand;

[71] The Health Security Committee, the Early Warning and Response System – EWRS, the Joint Procurement to purchase medical countermeasures, the epidemiologic surveillance and rapid response activities carried out by the European Centre for Disease prevention and Control (ECDC)

- healthcare surge capacity (shortages of intensive care units, insufficient availability of healthcare staff).

According to the Communication on 'Drawing the early lessons from the COVID-19 pandemic', preparedness and planning have been exposed as being under-funded and under-developed and much of the EU response had to be ad hoc and temporary, implying that preparedness and response systems and cultures have to be strengthened.

The above analyses lead to the conclusion that, despite the increase of the number of Member States integrating coherent approaches in the design of their preparedness plans, the specific objective 2 (protecting EU citizens against cross-border health threats) has been met only partially by the Programme.

(iii) Under the specific objective 3, actions implemented by the Programme enabled to identify and develop tools and mechanisms at EU level to address shortages of human and financial resources, and to facilitate the voluntary uptake of innovation in public health intervention and prevention strategies. The main identified areas of action were: Health Technology Assessment (HTA), Digital health, Health Information and Knowledge system (the State of Health and the Health at a glance publications cycles), the setting-up and operation of the Health Policy Platform, implementation of Union legislation in the field of medical devices, medicinal products and cross-border healthcare. The results of these actions should be reflected in an increase of advice produced and of the use by Member States (in the reform of their health systems) of the tools and mechanisms developed by these actions.

The two indicators associated (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 and the Number of Member States using the tools and mechanisms identified in order to contribute to effective results in their health systems) showed positive trends falling short to reach their annual target (except in 2020) for the first indicator and exceeding the annual targets for several years for the second indicator.

The first indicator (e.g., 'number of health technology assessments') showed major progress in 2020, evolving from 29 in 2019 to 50 in 2020.

The above analysis of indicators, combined on the one hand with an assessment of a sample of actions funded under the specific objective 3 (e.g. the EUnetHTA series of joint actions, TEHDAS joint action, the Commission proposal on the European Health Data Space – EHDS, the State of Health in the EU publication cycle, the Health Policy Platform), and on the other hand with the results of stakeholders surveys enable to infer that the specific objective 3 has been met to a good extent by the Programme.

(iv) Concrete actions under the specific objective 4 (facilitate access to better and safer healthcare) aim at increasing access to medical expertise and information for specific conditions (such as rare diseases), also beyond national border. They also facilitate the

application of research results and develop tools for the improvement of healthcare quality and patient safety, through, inter alia actions to improve health literacy. Effective implementation of these actions should notably be reflected in the creation of European Reference Networks for rare and complex diseases (ERNs) and in an increase of healthcare providers and centres of expertise joining the ERNs.

Three indicators were defined to measure the attainment by the Programme of the specific objective 4: the number of European reference networks established in accordance with Directive 2011/24/EU, the number of healthcare providers and centres of expertise joining European reference networks, and the number of Member States using the tools developed. All the indicators exhibited overall increasing trends. 23 ERNs were established in 2016, and 1 more established in 2017. This figure continued to increase and fell short of the set out target of 30 in 2022.

As for the second indicator, (the number of healthcare providers and centres of expertise joining ERNs, it fell between 2018 and 2019, due to a cleaning of duplicate records; the number has increased again since then and reached 1185 in 2020.

Finally, the third indicator showed a steady increasing trend over the implementation period.

In addition, by the end of the Programme (2020), 23 Member States had deployed or were using patient summaries data/e-prescription, in line with the EU guidelines (the target was 18 Member States) and 24 ERNs had been established.

The above quantitative analysis indicates that the specific objective 4 has been met by the Programme. This indication is confirmed by stakeholders views and by in-depth analysis of a sample of funded actions under this specific objective.

(v) Attainment of targets set out for the indicators at the beginning of Programme implementation

Despite displaying significantly increasing trends (except the indicator on cancer) the analyses above show that certain indicators did not reach their intermediate targets and/or their final targets set out at the end of the Programme implementation period, in 2020[72]. The targets were not revised to take sufficiently into account the dynamic and complex implementation as well as unforeseen obstacles encountered.

[72] For instance, this is the case for the indicator for: the specific objective 1 ('saturated fat') which was 24 versus a target of 28 Member States set out in 2020, the indicator for the specific objective 2 ('number of Member States integrating coherent approaches in the design of their preparedness plans') which reached the value of 22, versus an initial target of 28 in 2020, the indicator for the specific objective 3 ('Advice produced, in particular the number of Health Technology Assessments – HTA produced per year') which reach 41 versus a target value of 50 in 2020, and the indicators for the specific objective 4 the 'number of European reference networks established in accordance with Directive 2011/24/EU' (which reached 24 versus an initial target of 30 ERNs in 2020) and the 'number of healthcare providers and centres of expertise joining European reference networks' (which reached 1180 versus a target value of 1450 in 2020).

a.2. RESULTS OF STAKEHOLDER SURVEYS AND QUALITATIVE ANALYSIS BY TYPE OF FUNDING INSTRUMENT

The available data from stakeholder surveys and qualitative analysis show that the most effective funded actions were joint actions and projects and, to a lesser extent, direct grants to international organisation and service contracts.

Over the implementation period, a number of health topics have been considered as particularly important, including **chronic diseases, lifestyle risk factors, HTA, rare diseases and vaccination**.

The effectiveness of joint actions and projects is supported by targeted stakeholder surveys, in which the respondents stated that two main actions which contributed the most to achieving Programme objectives were joint actions (79% of responses) and projects (61% of responses). Conversely, only 43% of respondents considered that operating grants contributed to the achievement of the Programme's objectives, with the corresponding figure being even lower for the Presidency conferences (23% of respondents).

According to stakeholders, examples of successful actions were the European Reference Networks for rare diseases, actions to promote vaccination, to address antimicrobial resistance (AMR), nutrition and alcohol consumption.

With regard to alcohol consumption, findings from the dedicated case study on alcohol included in the external study supporting the evaluation shows that the Programme contributed to addressing the objectives and priorities in the area of alcohol marketing. More specifically, it has addressed the sub-theme of reducing alcohol-related harm and alcohol marketing by supporting the Joint Action on reducing alcohol-related harm (RAHRA) under the second health programme (2HP). The **RAHRA** Joint Action aimed to support Member States in their work on common priorities, in line with the 2006 EU alcohol strategy, and to strengthen their capacity to reduce and address alcohol-related harm. RAHRA contributed to capacity building and strengthened the ability to deliver a survey methodology and monitoring instrument for alcohol-related-harm.

Although no joint action on alcohol consumption was funded under the Programme, outputs from the RAHRA Joint Action supported by 2HP were further developed using other funding mechanisms. These comprised the DEEP SEAS[73] service contract and the Presidency conference on alcohol marketing.

73 DEEP SEAS., 2014. About DEEP SEAS. Available at: About DEEP SEAS | Deep Seas (deep-seas.eu)

a.3. Factors hindering the achievement of the Programme objectives

The evaluation findings (desk research, corroborated by stakeholder views) identified the following factors at national level that may have hindered the achievement of the Programme objectives: insufficient resources, expertise and data, insufficient knowledge of population health needs, difficulties engaging with stakeholders, and lack of (or insufficient) political will.

EU action can address these factors through strengthened/enhanced cooperation and engagement to support the Member States.

Increased resources at EU level dedicated to health issues (such as under the the EU4Health programme) would help address national difficulties in participating in the health programmes. Furthermore, an even stronger role of the Commission in brokering the existing knowledge and pooling the existing data and resources being generated would contribute to closing the knowledge gaps where needed, while also steering national action.

a.4. Conclusion on the achievement by the Programme of its objectives

Taking into account the above quantitative analyses and the results of the stakeholders surveys, it can be concluded that the specific objective 1 (promote health and prevent diseases) was met to a good extent. The decrease of the number of Member States using the European accreditation scheme for breast cancer does not significantly affect this conclusion since other European guidelines (e.g., on colorectal and cervical cancers) had been developed and implemented by Member States. The qualitative analysis of funded actions under this specific objective (e.g., on alcohol, tobacco control, physical activity, exchange of best practices) demonstrate the effectiveness of the Programme in achieving its objectives.

With regard to the specific objective 2 (protect EU citizens against cross-border health threats), 22 Member States integrated coherent approaches in their Preparedness plans, which were reviewed by the Commission. The associated indicator exhibited an increasing trend over the implementation period. Through the implementation of actions aimed at reinforcing the laboratory capacities to respond to highly dangerous and emerging pathogens, and through regular tests and simulations exercises, the Programme contributed to protect the EU citizens against moderate health threats (e.g. ZIKA, Ebola outbreaks).

As response to the COVID-19 outbreak, the Programme steered its running actions to fight the pandemic, notably by switching these actions from an inter-epidemic to an emergency mode. Despite this response, the COVID-19 pandemic revealed fragilities and weaknesses in the preparedness plans at Member State and EU level.

It can therefore be inferred that the Programme only partially met its objectives on protecting EU citizens against serious cross-border health threats.

Under the specific objective 3 (support public health capacity building and contribute to innovative, efficient and sustainable health systems) the Programme met its objectives to a good extent. This is demonstrated by the increasing trends of the indicators associated with health technology assessment (HTA), further corroborated by in-depth analysis of the outcome of a sample of actions (such as the EUnetHTA Join Action 3; The proposal on the European Health Data Space as a result of the joint action on this issue) and by the results of the stakeholders surveys.

All indicators associated with the specific objective 4 (facilitate access to better and safer healthcare), and mainly relating to the ERNs showed a positive trend falling short or attaining the targets set out for 2020. The quantitative analysis is corroborated by stakeholders views who rated the ERNs as one of the most important achievements of the Programme. Other actions under this specific objective, such as the ones addressing AMR were positively assessed by stakeholders.
It can therefore be concluded that, under the specific objective 4, the Programme met its objectives to a good extent.

b) *contribution to improvements in health and healthcare at both EU and Member State level*

In addition to progress on the various indicators, the effectiveness of the Programme is demonstrated by the fact that knowledge produced by funded actions was used in policymaking, enabling the Programme to contribute to improvements in health and healthcare in the EU and at Member State level.

This is particularly the case for actions in the area of cancer, HTA, and blood, tissue and cells which influenced national practices and helped create and strengthen national legislation.

For instance, the iPAAC (Innovative Partnership for Action Against Cancer) Joint Action was very effective in terms of providing ready-made solutions that have been implemented in the Polish National Oncology Strategy.

The Programme also contributed to improving health and healthcare in the EU through the transfer and implementation of best practices. For example, the CHRODIS+ Joint Action enabled the transfer of good practices related to nutrition in schools between countries. Furthermore, following the successful pilot of an integrated multi-morbidity care model as part of CHRODIS+, Member States' health authorities decided to extend this project to other healthcare institutions, using resources from the European structural funds.

Additional examples include a Joint Action (RD-ACTION) that developed a toolset to help European countries implement the Orphanet nomenclature of rare diseases (ORPHA codes, standardised coding system); and a Joint Action that helped extend successful national initiatives on physical activity in primary schools (Active Schools Flag) to other Member States.

c) *effectiveness of the exceptional utility criteria in supporting and increasing participation of low-GNI countries in the Programme*

The exceptional utility criteria provided for a higher level of co-funding for actions that include a certain proportion of members from low-GNI countries. They applied to joint actions, project grants and operating grants**.** These criteria were introduced in the second Health Programme 2008-2013 (2HP) but have been further refined under the Programme.

To qualify for the exceptional utility criteria, a country needed a GNI of less than 90% of the EU average. A total of 16 countries met these requirements (BG, CY, CZ, EE, EL, ES, HR, HU, LT, LV, MT, PL, PT, RO, SI and SK).

The exceptional utility criteria were introduced at the beginning of the Programme in 2014, as they were included in the basic act, namely in Article 7(3) of Regulation (EU) No. 282/2014.

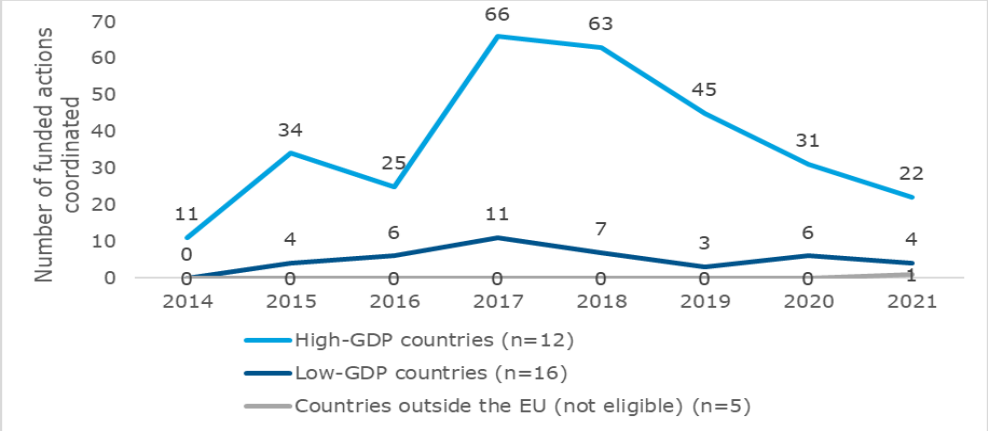
The exceptional utility criteria were used relatively often; between 2 and 212 funded actions met these criteria per year. In the targeted stakeholder survey organised as part of this evaluation, respondents often did not know whether their country had used this mechanism. Among the interviewed stakeholders who applied for funding using the exceptional utility criteria, a majority stated that their country's participation has been incentivised to a small or moderate extent.

Data from the public project database of HaDEA indicates that low-GNI countries were less likely on average to participate in funded actions as partners or coordinators than high-GNI countries.

A number of factors influenced the decision not to apply for funding under the exceptional utility criterion. These included a lack of administrative capacity to manage actions in the Member State, the administrative burden (once the project is up and running) and the complexity of the application processes.

Programme participation by low-GNI countries did not increase over time. Low-GNI countries did not coordinate more than 11 funded actions in one year, and in 2014 did not coordinate any actions at all. In contrast, the high-GNI countries coordinated between 11 and 66 actions per year. Some eligible countries (e.g., Czechia, Latvia, Lithuania and Poland) did not coordinate any funded action.

Figure 2- Number of funded actions coordinated per year



Source: HaDEA public project database of funded actions

Finally, Programme participation by low-GNI countries has not increased as compared to the 2HP according to data analysis conducted as part of the evaluation.

The reasons why the criteria did not greatly increase participation are not clear but may include administrative issues and costs. To improve participation of low-GNI countries, certain stakeholders suggested to raise the co-funding percentages from 60-80% to 70-90%.

d) *publication of Programme's actions, outcomes and results by the Commission services and by beneficiaries and stakeholders, and accessibility to the wider scientific and health community and to the public.*

Beneficiaries and stakeholders rated the Programme results as 'fair' but saw space for improvement in the dissemination of the publications resulting from it to a wider group of stakeholders and to the public.

The analysis of the HaDEA public project database identified 4 866 outputs related to 277 of the 339 funded actions under the Programme. In HaDEA's public database, outputs were classified as 'layman', 'newsletters' and 'others'. The most prevalent category was 'others', making up 79% of all outputs, compared with only 2% of outputs being 'newsletters' (2%) and 'layman' (2%). Some publications resulting from the Programme actions have been published in scientific journals.

The findings from the stakeholder surveys point to difficulties faced by the Programme's beneficiaries in developing and implementing dissemination activities for the funded actions. Furthermore, there is no systematic method in place to monitor the extent to which Programme beneficiaries disseminate findings after a project has ended.

The evaluation therefore concludes that improvements to the dissemination of results are needed. These could be attained through supportive actions by the Commission, such as

organising knowledge transfer activities (e.g. communities of practice, policy dialogues and other events). Lastly, although Programme results have been used by stakeholders, this could be further strengthened if limitations to dissemination are addressed.

For instance, the support provided by CHAFEA (and continued by HaDEA[74]) in promoting the tool developed under the SCIROCCO funded action was considered a concrete example of facilitating dissemination and thus the sustainability of Programme results. However, while the Commission could provide further support on the dissemination of results, as suggested above, the observed limitations to the dissemination of Programme results cannot be considered a shortcoming of the Programme alone, but rather a shared responsibility with Programme beneficiaries, in particular Member States competent authorities involved in funded actions.

The case study on the third EUnetHTA Joint Action (JA3) showed that the production and use of pharmaceutical assessments (both joint assessments and collaborative assessments) increased under JA3 as compared to the second EUnetHTA Joint Action (JA2) funded under the second health programme. When considering other technologies, there has been increased production of joint assessments and collaborative assessments but a slightly decreased use, which can be partly explained by limited national capacity and increased outputs under Joint Action 3, and by the fact that other HTA processes are not fully established in some countries. For both pharmaceuticals and other technologies there is an increased number of countries that have used joint assessments and collaborative assessments (JA/CA)[75] under JA3 compared to JA2[76]. Other EU funded actions that produced results used by stakeholders include the RARHA Joint Action[77] and the Oramma project[78].

According to stakeholder surveys, disseminating results has helped raised awareness among patients and healthcare providers in the field of digital health, tackling scepticism and helping realise a European health data space (EHDS). Likewise, the scientific publications resulting from funded actions helped prove to ministries of health that the interventions were effective.

[74] CHAFEA was closed with effect on 31/3/2021 by the Commission Decision (EU) 2021/173 of 12/2/2021 (*OJ L 50, 15.2.2021, p. 9–28*). Its legacy activities relating the Health Programme (2014-2021) were transferred to the newly created Health and Digital Executive Agency – HaDEA, which was also entrusted with the implementation of the successor EU health programme (EU4Health Programme) on the period 2021-2027.

[75] ie assessments carried out jointly by multiple HTA agencies

[76] EUnetHTA Work Package 7, Deliverable 7.2 – Final report. Available at: https://www.eunethta.eu/wp-content/uploads/2020/07/Final-Deliverable-7.2-report-after-consultation_FINAL.pdf?x69613

[77] The Joint Action on Reducing Alcohol Related reducing alcohol related harm [RARHA] aimed to support Member State cooperatecooperation on the uptake, exchange and development of common approaches relating to the priorities of the EU alcohol strategy.

[78] The ORAMMA project aimed to promote safe pregnancy and childbirth through efficient provision of, access to, and use of quality skilled care for all migrant and refugee women and their infants.

Despite those successes and considering the limitations to dissemination discussed above, it can be concluded that there is room for improvement in the use of Programme results if these minor limitations are addressed.

e) to what extent have the recommendations from previous evaluations been implemented?

Commission's Directorate General SANTE and CHAFEA have taken steps to address the 10 recommendations included in the Programme's midterm evaluation.

The evaluation shows that some of the recommendations set out in the midterm evaluation have been addressed successfully. These include maintaining a focus on thematic areas of strong EU added value, strengthening and building links between the Programme and the wider Commission and EU policy agenda to maximise impact, developing a broader strategy to increase participation from poorer Member States and underrepresented organisations, and improving dissemination of action results.

Conversely, some recommendations were not sufficiently taken up, including spelling out how actions targeting health promotion and health systems should generate EU added value and investing in the resources necessary to improve systems for monitoring Programme implementation. The latter recommendations, alongside those which were only partially met, should be followed up under subsequent EU health programmes. Similarly, despite progress in the dissemination of results and in the participation of low-GNI countries, there are still limitations that affect full uptake.

f) how are the results and effects of the Programme likely to last at the end of its implementation if funding ceases to exist (self-sustainability)?

According to the evaluation analyses the Programme was found sustainable overall.

This is the case for achievements in the field of HTA. The work developed under the EUnetHTA joint actions strengthened the collaboration of national HTA agencies, promoting coordination and increasing production of HTA joint work. EUnetHTA's activities laid a strong foundation for sustainable cooperation, which has been reflected in the permanent framework for joint work established by the HTA Regulation[79]. The Regulation replaces the current system based on a voluntary network of national authorities and project-based cooperation. (See the case study on HTA for more information).

Another area where funded actions were deemed sustainable is antimicrobial resistance (AMR). In the Joint Action on AMR (EU-JAMRAI) which ran from 2017 to 2021, , a work package focused on sustainability, thereby enabling the exploitation and further

[79] Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (OJ L 458, 22.12.2021, p. 1–32)
See also Judit Erdös et al. (2019), 'European Collaboration in Health Technology Assessment (HTA): goals, methods and outcomes with specific focus on medical devices",', Wien Med Wochenschr.

development of the joint action's results beyond the end of the project. The joint action identified two main ways to ensure sustainability: (i) ensure direct follow-up and cooperation between Member States (ii) continue action at EU level, and if necessary, making use of EU funding.

The ERNs established through the Programme also had sustainable impacts. One of the tools the Commission developed for the ERNs was the Clinical Patient Management System (CPMS), which allowed for cross-border virtual consultations. Another tool was the five first grants to support registry development for five ERNs started in 2018 and the 19 following started in 2020. They collect data at EU level for patients with rare diseases. Thanks to the progressive development and integration into the EU RD Platform, these registries linked to the 24 ERNs should progressively become more and more interoperable (using at minima the 'common data elements' provided by the EU RD platform) and also visible.[80].

Finally, the SCIROCCO[81] funded action has created sustainable outputs, as the tool is used in 35 countries by hundreds of thousands of users, and the users have reportedly found it very useful.

The evaluation found that there were common elements and aspects of the Programme itself which helped ensure that projects would be sustainable following their conclusion. For example, introducing an obligatory work package (WP)[82] exclusively on the sustainability of the funded action, and the relationships and connections built through the funded actions.

However, there were shortcomings in integrating the results of funded actions into policy making. Another challenge was related to the design of the Programme, with actions not lending themselves to increasing sustainability, either due to the limited duration of funded actions, or to a slight mismatch between their results and the ability to implement them directly at local level. Projects were found by certain surveyed stakeholders, too limited in scale and/or in ambition to be sustainable. These stakeholders gave recommendations on how to make the Programme or similar programmes more sustainable. These included the creation of an EU-level repository of outputs and outcomes of the funded actions, and of more opportunities or funding to continue and further develop existing projects or to disseminate their results to more Member States.

According to the various consultations, the opportunity to continue to fund critical actions that have proven successful and demonstrated strong EU added value would be welcome. For this, it would be useful to combine Health programme funding with other

[80] Academic and research organisation, in the focus group on project grants.
[81] SCIROCCO – Scaling Integrated Care in Context. The SCIROCCO project validated and tested a self-assessment tool to identify the maturity of the health and social care systems for the adoption and scaling up of integrated care solutions.
[82] This work package has been made mandatory for all grants

EU financial instruments (e.g. the cohesion policy funds, EU Framework Programmes for research and innovation, national funding programmes) that address health.

The sustainability of the actions funded under the Programme also depends on efforts made by the participating countries themselves to learn from and take up the results. Introducing strategies and approaches derived from the Programme into their national cancer plans is just one example.

A major challenge to sustainability is the limitation to Member States' or other beneficiaries' ability to take over the funding of completed projects. Lack of resources and reduced political will or interest to continue specific activities at national level constitute additional barriers to sustainability.

In conclusion, the results of the Programme were found to be sustainable overall. Challenges and barriers to sustainability mainly stem from insufficient integration of results into national policies, a lack of further resources and a lack of political will in the participating countries or by beneficiaries, and insufficient links with other programmes.

4.1.2 Efficiency

a) to what extent has the Programme been cost effective?

The evaluation found that the Programme achieved its objectives in a cost-effective way and within the allocated budget. According to stakeholders, the Programme produced high quality (and quantity of) outputs and work within the budget provided.

The flexibility of the management of the budget and the adaptability of the Programme to changing circumstances was an important success factor in achieving those impacts in a cost-effective way.

Moreover (as shown in Table 2, Section 3), the budget allocated to administrative support and to the functioning of the executive agency CHAFEA, amounted to EUR 10.5 million and EUR 30.3 million respectively, which makes a total of EUR 40.8 million of operational costs or 9% of the total Programme budget. This ratio is comparable to or lower than the operational cost ratios of other EU programmes[83] of similar size and demonstrates the efficiency of the Programme.

Several consulted stakeholders (particularly those involved in project grants and joint actions) expressed satisfaction with the fact that the budget allocated to actions could be changed within a certain limit, without having to make formal amendments to the underlying grant agreements. This avoided long administrative procedures linked with the preparation of amendments. Funding could be transferred across different cost

[83] Eg. the Consumer Programme (2014-2020) [Regulation (EU) No 254/2014 of the European Parliament and of the Council of 26 February 2014 on a multiannual consumer programme for the years 2014-20 and repealing Decision No 1926/2006/EC (OJ L 84, 20.3.2014, p. 42–56)] e.g., the Consumer Programme (2014-2020).

categories and partners, which was useful to many stakeholders, particularly given the uncertainty created by the COVID-19 outbreak.

b) to what extent are the costs associated with the Programme proportionate to the benefits it has generated?

The surveyed stakeholders found the management and operational costs of the Programme to be generally reasonable, whereas the costs relating to the administration, preparation and coordination of proposals, and the associated personnel costs, were generally seen as disproportionate, especially for countries with a lower GNI and smaller organisations involved in funded actions.

Although improved and simplified, administrative costs were still found high by most categories of stakeholders, who also perceived the level of detail required for monitoring and reporting as *'heavy'* and at times *'bureaucratic'.*

Funded actions which were found to be the most effective were also found to entail the highest efficiency.

Consulted stakeholders considered that the costs of specific actions were proportional to their benefits. These include the SCIROCCO Exchange Project[84] which developed a self-assessment tool for integrated care with a limited budget, which is now used by regional and national healthcare authorities in the EU and beyond[85]. ERNs were also mentioned as an area where the benefits were high, compared to related costs.

Considering the specific objective 1 (promote health, prevent diseases and foster supportive environments for healthy lifestyles), the total costs (for the Commission, the Member States and Project participants) for implementing these actions are estimated at EUR 200 million. The qualitative direct and indirect benefits include 24 Member States using evidence-based good practices in health promotion and disease prevention notably on nutrition (in particular in the area of saturated fat) and also in other areas such as physical activity, alcohol and tobacco, cardiovascular diseases and diabetes. As regard cancer, the qualitative benefit includes the fact that 6 Member States are using evidence-based good practices on EU guidelines and accreditation for breast cancer screening. Moreover, a database of 128 cancer registries from 29 European Countries has been established (including on breast, colorectal and cervical cancers) and provide data for more than 25 900 000 records. These registries, data and screening guidelines are accessible to researchers and specialised healthcare professionals, as tools for improving

[84] The SCIROCCO project had an estimated budget of EUR 2.2 million. Taking into additional cost (administrative and preparatory costs) incurred by beneficiaries and by the Commission, the total cost for implementing the Project is estimated at EUR 3.2 million. Although the benefits of the project have not been estimated in monetary terms, it is to be noted that has been positively evaluated, since it has generated short-term and longer-term results and tools that used in 35 countries by hundreds of thousands of users, and the users have reportedly found it very useful. It can thus be inferred that the qualitative results of the project exceed by several folds its total costs.

[85] This was mentioned by a government official/policymaker in the Project Grants focus group.

and accelerating diagnostics and for providing patients with more tailored treatments. The direct and short-term benefits from Programme are enhanced by longer term benefits due to positive changes of behaviour of the population (healthier eating habits, physical activity, reduced abusive consumption of alcohol and smoking) to which the Programme has contributed (see annex IV for more information).

Concerning specific objective 2 (protect EU citizens from serious cross-border health threats) the estimated total costs of funded actions amounted to EUR 70 million. Qualitative benefits from these actions include the production of new knowledge on health threats, the improvement of the diagnostics capacity of EU laboratory dealing with emerging pathogens. Funded actions contributed to the response to frequent (and moderate) health threats that occurred during the implementation period of the Programme, including outbreaks in third countries (Zika, Ebola). Twenty-two Member States integrated coherent approaches in the design of their prepared plans, even if the COVID-19 outbreak demonstrated weaknesses in preparedness and response to a major health threat of such magnitude at EU and Member States level. At the beginning of the COVID-19 outbreak, the Programme funded-actions were switched from inter-epidemic to emergency mode and geared at combatting the pandemic, particularly in its early stages, before adoption of the EU4Health Programme (2021-2027)[86]. Lessons learned from the COVID-19 pandemic enabled to design the EU4Health Programme, with actions aimed at strengthening the preparedness and response of Member States and of the EU to cross-border health threats[87].

As regards the specific objective 3 (contribute to innovative, efficient and sustainable health systems) the total costs of implemented actions is estimated at EUR 160 million. Significant qualitative benefits are derived from funded actions by Member States, Stakeholders and EU citizens (see annex IV for more information). Funded actions provided support to several EU policy developments:

- the joint action on secondary use of health data (TEDHAS) paved the way for the Commission proposal on the European Health Data Space (EHDS) by developing European principles for the secondary use of health data. The EHDS is expected to benefit not only citizens and health professionals by ensuring greater access and control by individuals to their health data collected (primary use) but also to researchers, regulators and policymakers by supporting access to health data for secondary purposes that would benefit the society such as research and innovation, patient safety, personalised medicine, policy-making or regulatory activities (secondary use).

[86] REGULATION (EU) 2021/522 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014

[87] Although not in the scope of this document, other measures resulting from the lessons learned from the COVID-19 pandemic are, for example, the setting-up of the Health and Emergency Response Authority (HERA) and the revision and strengthening of the EU legislation on cross-border health threats: REGULATION (EU) 2022/2371 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU

- the adoption of a legislation on permanent EU cooperation in health technology assessment (HTA) which resulted from the series of EUnetHTA joint actions; improvement of country knowledge in the field of health through the State of Health in the EU publication cycle and the related Country Profiles.

Concerning the specific objective 4 (facilitate access to better and safer healthcare for EU citizens) the total costs of funded actions are estimated at EUR 100 million. Qualitative benefits include, inter alia, the establishment of 24 ERNs which enable access to healthcare concerning 6000-8000 rare diseases affecting the daily lives of around 30 million people in the EU, with 1185 healthcare providers, and 2100 virtual expert panels opened in the clinical patient management system (CPMS). 1.7 million patients were treated by ERN members, and patient participated in 732 clinical trials within the ERNs. (See annex IV). The total amount spent should also be put in perspective with the less than EUR 60 per patient targeted expert diagnosis which otherwise would not be accessible to those patients.

Evaluating the above qualitative benefits of funded actions, against their total costs and also weighing the qualitative benefits stemming from cross-cutting (horizontal) actions relatively to their total costs (estimated at EUR 20 million) it can be inferred that the benefits generated by the Programme are proportionate with its total costs of implementation. These benefits can be further magnified by positive longer-term effects that the Programme may have contributed to create, such as the establishment of contacts and knowledge sharing and learning networks among health professionals, policymakers and health authorities of different Member States, change of the behaviour of the population towards healthier habits and lifestyles.

c) to what extent do factors linked to the Programme influence the efficiency with which the observed achievements were attained?

The type of funding mechanism, and the availability of financial and human resources are the main factors influencing the efficiency with which results were attained. The evaluation also analysed the influence of additional factors, such as the right balance of actors involved in the funded actions. The limited sustainability also affected the efficiency of a funded action. Finally, outside factors affected the efficiency of the Programme, for example internal budgetary and accounting rules and procedures for hiring staff in participating organisations.

d) to what extent was the distribution of Programme credits among the four specific objectives efficient?

The distribution of Programme credits among the four specific objectives was found efficient, since it addressed the key health needs identified during the implementation

period. Analyses conducted showed that the Programme provided funding in a way that met the key health needs in the EU over the Programme implementation period.

Surveyed stakeholders found funding critical to achieving the expected results for both the four specific objectives and the 23 thematic priorities. Two thirds of respondents to the targeted survey considered that the thematic priority structure of the Programme fostered efficiency.

e) if there are significant differences in costs (or benefits) between participating countries, what is causing them? How do these differences link to the Programme?

Desk research undertaken as part of this evaluation indicates that the distribution of funding and actions has not been evenly spread across participating countries.

An analysis of HaDEA's database of funded actions revealed that across the Programme, there were 25 coordinating countries. Overall, countries in Western Europe were much more likely to coordinate a funded action than countries in Northern or Eastern Europe.

These disparities in EU funding and in the number of actions coordinated led to some differences in costs and benefits between participating countries.

The factors identified as being responsible for the differences in costs and benefits between the Programme's participating countries included different financial resources, an uneven organisational capacity to deliver funded actions, and the administrative burden of applying for and receiving Programme funding.

f) to which extent did the simplification measures contribute to the efficiency of the Programme? Was there further scope for simplification to make the Programme implementation more efficient?

As identified in the midterm evaluation, a wide range of systems and processes were simplified and digitised to streamline the Programme's administration. The main simplifications to systems and processes were the following:

- Application and grant management procedures were simplified and digitised.
- Procedures for awarding joint actions and grants were simplified.
- The rules of the Programme were made less complex, i.e., by harmonising the co-financing rates to 60% (or up to 80% in cases of exceptional utility).
- Operating grants were allowed to be funded through framework agreements (which run for up to 3 years).
- 2016 ERN grants had been made longer-term (5 years) to 'establish a partnership procedure for important actors at EU level, offer a clearer financial perspective for ERNs and provide more stability and efficiency gains for all involved'. The procedure for this was the signing of an FPA and insurance of annual co-funding through an SGA. It was acknowledged that having these two consecutive steps (and repeating annual SGAs) entailed more administration for applicants, but it was expected that the process would simplify awarding of ERNs in the future.
- A quality assurance process was introduced for joint actions.

- The requirements for amendment procedures were simplified, most importantly by allowing beneficiaries to transfer resources between different cost categories without the need for an amendment.
- Electronic tools were introduced for the submission of proposals, management of grants and e-reporting and monitoring. In 2015, electronic monitoring and reporting were introduced to save time; beneficiaries and CHAFEA became paperless[88].
- All electronic tools were centralised on the Participant Portal.
- Simplification measures relating specifically to the exceptional utility criteria were introduced.
- Conditions were simplified and made less restrictive, especially for joint actions where the list of five criteria was reduced to two, one of which concerned the proportion of funding that had to be allocated to staff.
- The explicit upper limit on the proportion of funded projects that can be awarded exceptional utility (under 2HP: 'No more than 10% of funded projects should receive EU co-funding of over 60%') was discontinued.

Efforts were made to improve the efficiency of the Programme by simplifying and streamlining procedures. In 2015, the EU saw a large migration flux in its territory. In response, the Agency quickly launched direct grants and call for proposals for projects addressing the refugee crisis and was able to sign the selected grant agreements within less than 3 months of the 2015 AWP amendment. This was made easier by the simplified administrative procedures introduced in 2014 as well as the portal for online submissions and the online evaluation and electronic signature of grant agreements used for the Horizon 2020 programme.

These simplifications reduced administrative costs and improved the efficiency of the Programme. They also reduced paperwork. They helped reduce costs and made the application processes smooth. The funding portal played a key role by providing manuals and useful links.

However, according to a minority of stakeholders, simplification measures did not reduce administrative burden/costs which they still found unreasonable. These respondents suggested ways to further reduce costs (e.g. by using unit costs and lump sums, and by further simplifying the information requested in the application forms).

g) to what extent were the monitoring processes and resources (at the Commission and MS level) cost-effective?

Monitoring processes were found to be fairly efficient and reasonable. Key factors enabling their efficiency were the relevance and clarity of indicators along with the digitalisation of the processes. The monitoring (and reporting) process helped Programme participants to plan their work effectively and understand the expectations, thereby improving the quality of their deliverables.

[88] European Commission. (2018), Report from the Commission to the European Parliament and the Council: Implementation of the third Programme of the Union's action in the field of health in 2015. Available from: https://ec.europa.eu/health/sites/default/files/funding/docs/ implementation2015_en.pdf

Although they improved throughout the Programme implementation period, mainly thanks to digitalisation, the monitoring processes could be further simplified to achieve more efficiency gains, for example through further centralisation of the information.

The monitoring processes are still found 'too heavy' and 'too detailed', especially for smaller organisations and individual experts brought in, who call for further simplification. Furthermore, there is still a need for more measurable and comprehensive monitoring indicators.

h) what are the benefits of the reporting systems against their costs and how could they be effectively implemented?

The reporting systems provided several benefits, including the possibility of tracking the progress of actions against the original plan. Factors that made reporting more efficient included the Compass and SYGMA reporting systems, which enabled beneficiaries to report back to the Commission with less administrative burden and to track projects from start to end. Another benefit was the portal which made reporting more efficient.

Stakeholders consulted as part of this evaluation had mixed views as to whether the costs associated with the reporting were proportionate in relation to the benefits. The Commission's 4-step reporting cycle was praised, while others highlighted the need for better guidance to avoid that the costs of the reporting systems outweigh the benefits.

i) summary of costs and benefits identified in the evaluation

	Table 3. Summary of costs and benefits identified in the evaluation									
Relevant stakeholders / **Costs and benefits**	EU Citizens		Businesses/Contractors awarded Procurement contracts		Project participants/NGOs/Stakeholders other than National Authorities		Member States Authorities / National Administrations		European Commission (DG SANTE, CHAFEA, Other Commission services	
	Quantitative	Qualitative	Quantitative	Qualitative	Quantitative	Qualitative	Quantitative	Qualitative	Quantitative	Qualitative
Cost or Benefit description										
Specific objective 1: promote health, prevent diseases and foster supportive environments for healthy lifestyles										
Costs:										
Direct Costs: Monetary input into implementation of best practices and other actions under specific objective 1 Recurrent	N/A	N/A	N/A	N/A	MEUR 30 of co-funding for Projects and Direct Grant		MEUR 32 of co-funding of Joint Actions		Estimated MEUR 139	
Direct benefits			procurement MEUR 46		EU co-funding of grants MEUR 56		EU co-funding Joint Actions: MEUR 36		N/A	
Direct benefits						A prize for NGOs is organised annually	24 MS using evidence-based good practices	6 MS using evidence-based good practices on breast cancer screening		

Direct benefits								Online best-practices portal 6 6650 visitors	On cancer: 128 cancer registries from 29 European Countries, Data on 25 900 000 records		
Other direct benefits									Uptake of best practices on: cancer, tobacco control, physical exercise, nutrition, cardiovascular disease and diabetes		
Indirect benefits			Better health outcomes for population benefiting from implementation of best practices:		Productions of knowledge and tools at EU level:						
Specific objective 2: protect Union citizens from serious cross-border health threats											
Costs											

Direct costs linked with Programme implementation		N/A		N/A		Co-funding from another organisation: MEUR 11		Co-funding from MS MEUR 7		MEUR 41 specific objective 2	
Benefits											
Direct benefits						During the COVID-19 outbreak actions of the Programme have been geared, in their 'emergency mode', towards combating the pandemic	Examples Healthy Gateways Joint Action, the JA on Strengthened International Health Regulations and Preparedness (SHARP), Training for Health Professionals on isolation, waiting rooms and reception areas, cleaning, appropriate PPE, real time RT-PCR testing for COVID-19	During the COVID-19 outbreak actions of the Programme have been geared, in their 'emergency mode', towards combating the pandemic	During the COVID-19 outbreak actions of the Programme have been geared, in their 'emergency mode', towards combating the pandemic		

Direct benefits		N/A		Procurement MEUR 14			Production of new knowledge on health-threats at EU level	22 Member States integrated coherent approaches in the design of their preparedness plan	Production of new knowledge on health-threats related issues at EU level		Production of new knowledge on health-threats related issues at EU level
Direct benefits								JA EMERGE improved the capabilities for rapid laboratory diagnosis for new or emerging pathogens	Feasibility study launched for the developmen t of a common EU vaccination card		
Direct benefits								Support to interventions in 2014-2016 to limit spread of Zika and Ebola			
Indirect benefits		Better protection of the population against cross-border health threats	Better protection from vaccine-preventable diseases through interventions to improve vaccine uptake								

Specific objective 3: contribute to innovative, efficient and sustainable health systems											
Costs											
Direct Costs linked with implementation of the Programme		N/A		N/A		Contribution from other participating organisations: MEUR 30		Contribution of MS participating in Joint Actions: MEUR 19		Total appropriations MEUR 110	
Benefits											
Direct benefits				Procurement MEUR 37				41 HTAs per year produced per year	23 MS using identified tools and mechanisms, contribute to effective results in their health systems		

Direct benefits		Organ database which has helped 34000 transplants in 2017				Setting up of the EU Health Policy Platform (HPP) a collaborative on-line tool		Successful implementation of EUnetHTA JA3 which led to a permanent regulation on EU cooperation on HTA	Launching of THEDAS JA (The European Health Dataspace) to develop principles for cross-border secondary use of health data		Improvement of country knowledge in the field of health through regular publication of The State of Health in the EU, the Country Profiles and Health at a Glance series
Direct benefits								JA on Market Surveillance on Medical Devices reinforced the market surveillance system for these devices and improving cooperation among all MS			
Indirect benefits			Strengthening of Health Systems of the Member States for the benefit of EU citizens and patients					Cost savings for health systems by use of tools such as HTA and digitalisation policies			

Specific objective 4: facilitate access to better and safer healthcare for Union citizens											
Costs											
Direct costs for implementing the Programme						Contribution of other organisations: MEUR23		Contribution of MS in Joint Actions: MEUR 15		Total appropriations MEUR 85	
Benefits											
Direct benefits				Procurement : MEUR 27		24 European Reference Networks (ERNs) established		24 European Reference Networks (ERNs) established			
Direct benefits		1.7 million patients treated by ERN members Patients participated in 732 clinical trials				1185 healthcare providers and centre of expertise joined the ERNs 2,100 virtual expert panels opened in the CPMS		27 MS using the tools developed			
Indirect benefits		Easier access to treatment for patients with rare diseases									
Cross-cutting issues and overall Programmes costs and benefits											

Overall Administrative Cost for the implementing the Programme										MEUR 10	
Cost for functioning of the executive Agency CHAFEA										MEUR 30	

4.1.3 *Coherence*

a) are the actions implemented under the Programme coherent with its objectives? How has the coherence of the Programme influenced its effectiveness?

The evaluation's analysis showed that the actions funded by the Programme were coherent with each other and aligned with the Programme's objectives and with DG SANTE's activities. This is evidenced by a review of DG SANTE's annual activity reports for 2014-2020 and the mapping of its fields of activity to the specific objectives and thematic priorities of the Programme, for each year.

The coherence between the actions facilitates synergies, complementarities and mutually reinforcing mechanisms between actions launched under the same or different thematic priorities.

b) to what extent have the priorities of the Programme led to more synergy, focus and coherence between the EU-funded actions in delivering on similar objectives? Did the Programme encourage cooperation with the European Structural and Investment Funds and other EU financial instruments? To which extent is the Programme coherent with wider EU policy and with international obligations?

Links with other EU financial instruments were built into the design of the Programme. Regulation (EU) No. 282/2014 states that the Programme should promote synergies with other EU programmes funding actions in the field of health, such as the Framework Programme for Research and Innovation 2014-2020 (Horizon 2020) and the European Structural and Investment Funds (ESIF).

Synergies were built with the Horizon 2020, for example, in the area of rare diseases and ERNs. The Programme's actions were complementary to Horizon 2020 projects such as the European Joint Programme co-fund on Rare Diseases (EJP RD) and the Coordination and Support Action for the 24 ERNs (ERICA), as well as EU-funded collaborative research projects (e.g. Solve-RD, Conect4Children).

Direct links between the Programme and Horizon 2020 are established for cancer and for specific thematic priorities (e.g. AMR, chronic diseases, rare diseases, …). This is also the case for action on HTA under objective 3 (Contribute to innovative, efficient and sustainable health systems). The Programme aimed to facilitate the uptake of the results stemming from research projects supported under Horizon 2020[89], including within the feedback to policy (F2P) framework developed by the Research and Innovation Directorate-General of the Commission (DG RTD) in 2020. Similarly, the Programme

[89] In areas such as personalised medicine, one health/antimicrobial resistance, infectious diseases (Ebola, Zika), COVID-19 related projects

aimed to facilitate the uptake of Horizon 2020 projects' results in the area of effective and efficient investment and innovation in public health and health systems (objective 3 – Thematic thematic priority 3.4 Setting up a mechanism for pooling expertise at EU level)[90].

Moreover, Horizon 2020 and the ESI Funds directed funding to health-related activities over the Programme implementation period (2014-2020).

When considering EU action in the field of research and innovation, the Regulation establishing Horizon 2020 included health, demographic change and well-being as a specific objective under the priority 'Societal challenges'[91]. Research priorities included topics such as personalised medicine, health promotion and disease prevention, innovative health and care systems, non-communicable and infectious diseases, rare diseases, antimicrobial resistance, global health and the digital transformation in health and care.

Interlinkages and synergies between the Programme and ESIF were sought and created during the Programme implementation period, as results from Programme-funded actions served as a basis for actions financed through ESIF. Examples of health-related actions financed by ESIF include the promotion of digital public services through the deployment of digital health solutions and the provision of accessible medical services to vulnerable groups[92].

Programme-funded actions contributed to the EU's wider policies and wider international obligations.

In particular, DG SANTE's specific objectives for Programme spending were aligned with and built on wider EU policy priorities: the Europe 2020 strategy for smart, sustainable and inclusive growth in 2014-2015; the Juncker Commission's priorities in 2016-2019; and the Von der Leyen Commission's priorities in 2020.

For instance, in 2016-2019 the Programme's thematic priority 1.3 'Cost-effective health promotion and disease prevention' and 1.4 'Effective, accessible and resilient healthcare systems in the EU' contributed to the Commission priority *A new boost for jobs, growth and investment in the EU*, and in 2020 the thematic priority 2.2 'Patients' access to safe, innovative and affordable medicines and medical devices' contributed to the Commission priority *Promoting our European Way of Life.*

On the alignment of the Programme with wider international obligations that share common objectives with the Programme, information reviewed shows that the

[90] European Union., 2014. Regulation (EU) No 282/2014: https://eurlex.europa.eu/legalcontent/EN/TXT/PDF/?uri=CELEX:32014R0282&from=EN.

[91] European Union., 2013. Regulation (EU) No 1291/2013 of the European Parliament and of the Council establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC (OJ L 347, 20.12.2013, p. 104–173).

[92] European Commission, European Structural and Investment Funds 2014-2020. 2020 Summary report of the programme annual implementation reports covering implementation in 2014-2019.

Programme was aligned for instance with the WHO common policy framework Health 2020[93].

In conclusion, the Programme encouraged cooperation and was aligned with other EU financial instruments that support health-related activities. However, such alignment and cooperation cannot be considered as fully achieved, despite efforts made to forge links and synergies with other financial instruments.

c) *to what extent has the Programme proved complementary to other EU or Member States targets, interventions, and initiatives in the field of health?*

The evaluation demonstrates that the Programme has been coherent with other EU health policies during its timeframe (up to 2020) and that there has been alignment between the relevant Commission departments and the different EU policies in the area of health. The Programme was also coherent with Member State health-related strategies and initiatives.

A mapping exercise of selected EU health-related initiatives adopted up to 2020 (including EU legislation on medicinal products for human use, medical devices and tobacco control) showed that those initiatives are aligned with the Programme objectives. In particular, initiatives such as the 2012-2020 eHealth action plan, the action plan for the EU health workforce[94], the 2014-2020 EU action plan on childhood obesity and the One Health action plan against Antimicrobial Resistance[95], AMR, were aligned with the Programme objectives.

Furthermore, a review of the documentation demonstrated alignment between different Commission services on the direction of health policies. This coherence is also reflected in the policy coordination between relevant Commission departments and between the different EU policies and mechanisms involving health. A key example is the *European Semester*, the Commission's annual cycle of policy coordination, which includes health-related priorities among its recommendations. Similarly, the activities of DG REFORM through the structural reform support programme and of DG REGIO and DG RTD have been found to be overall aligned with the Programme objectives.

[93] World Health Organisation (2013), 'Health 2020. A European policy framework and strategy for the 21st century'. Available from: https://www.euro.who.int/__data/assets/pdf_file/0011/199532/Health 2020-Long.pdf

[94] The 2012-2020 eHealth Action plan and the Action plan for the EU Health workforce were both adopted before the entry into force of the Programme and covered the Programme's implementation period.

[95] COMMUNICATION FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT A European One Health Action Plan against Antimicrobial Resistance (AMR) - COM/2017/0339 final, see also amr_2017_action-plan_0.pdf (europa.eu)

4.2. How did the EU intervention make a difference and to whom?

a) what is the additional value resulting from the Programme, compared to what could reasonably have been expected from Member States acting at national and/or regional levels, and compared to what the EU would have achieved without the Programme?

In accordance with Article 168(7) TFEU, Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. However, the importance of EU action in the field of public health is acknowledged in the Treaty on the Functioning of the European Union (e.g., Articles 6 and 168 TFEU), which refers to the Union's role in complementing, supporting, and coordinating national actions. Within the remit of its competences, EU action in the field of health can add value to national efforts and support Member States in achieving common objectives and tackling common challenges such as serious cross-border health threats, preventing and managing non-communicable diseases, promoting good health, improving access to care and supporting health systems.

From the analysis, it emerged that the Programme-funded actions provided EU added value according to the definition in Section 2.2.

Regarding the specific thematic areas, the Programme's midterm evaluation identified the added value of Programme actions in areas such as capacity building against health threats, pooling expertise and resources across the EU to reduce health inequalities, collaboration in the field of health technology assessment (HTA) and eHealth, and exchange and implementation of best practices for promoting health and preventing diseases.

On the EU added value of the Programme's funding mechanisms, stakeholders mentioned that procurement contracts led to the production of EU-wide studies that provided valuable information on the public health situation and issues across EU. This was perceived to go beyond what would have been achieved by individual Member States, acting alone.

The Programme strongly supported the sharing of best practices. This can be seen in DG SANTE's online 'best practice portal', launched in 2018. The sharing of best practices and networking across Member States is seen as an example of the Programme's EU added value[96]. Examples of actions on sharing best practices include the EU Compass for action on mental health and wellbeing, the CHRODIS+ Joint Action and the Young50[97]

[96] LOMBA, N., 2019. The benefit of EU action in health policy: The record to date.

[97] The YOUNG50 project aims to transfer the Italian best practice CARDIO50 project in Lithuania, Romania, Luxembourg among 50 years old.
The objectives of CARDIO 50 were to estimate cardiovascular risk among the 50 years old population, identify persons with inadequate lifestyles, new cases of hypertension, hyper-glycemia and hyper

project. The Programme also delivered EU added value by encouraging cooperation and coordination on specific policy issues among Member States. This is especially the case in areas such as rare diseases, alcohol consumption.

HTA is another area of strong EU added value. The EUnetHTA Joint Action 3 funded under the Programme created a collaborative infrastructure for national and local HTA authorities and enabled sustainable cooperation, which was reflected in the recently adopted HTA Regulation. EUnetHTA Joint Action 3 builds on the lessons of earlier EUnetHTA joint actions funded under previous health programmes. The overall objective of EUnetHTA JA3 was to establish a model for joint work on HTA that would continue after its completion. It also set out to increase the amount of high quality HTA joint work, promote its uptake and implementation at national, regional and local level, and support evidence-based, sustainable and equitable choices in healthcare and health technologies.

EUnetHTA JA3 (and its predecessors) has achieved its overarching objective and laid a strong foundation for sustainable cooperation which is reflected in the permanent framework for joint work set up by the HTA Regulation. This regulation aims to tackle the remaining barriers to EU-wide HTA collaboration. While it is acknowledged that the longer-term benefits (i.e. the sustainability of health systems, a more efficient allocation of resources in healthcare, greater innovation and transparency, and a higher level of human health protection) depend on a variety of factors that go beyond the contribution of EU action on HTA, it can be reasonably assumed that the outcomes achieved under the Programme on HTA are conducive to reaching those impacts.

The setting up of 24 ERNs is considered a flagship achievement of the Programme, as ERNs provide undisputable EU added value. The ERNs involve healthcare providers across Europe, and are an example of how the EU can add value to Member States' actions by enabling them to coordinate efforts, pool resources and take advantage of expertise across Europe.

Another area where EU action made a difference by supporting coordination and cooperation among Member States was the establishment of several EU-wide data systems. These included an EU quality register to ensure the safety of medical devices, a platform to facilitate organ transplants, an EU-wide tobacco tracking and tracing system to combat the trafficking of illicit tobacco products.

Lastly, the Programme provided EU added value by enabling mutual learning and the development of new knowledge. Many respondents to the evaluation surveys considered one of the most important examples of EU added value of the Programme to be the 'supporting networks for knowledge sharing or mutual learning'. The Programme

cholesterolemia, activate an integrated model of assistance to help modify or reduce risk factors among healthy subjects, promote interventions to change unhealthy lifestyles and increase knowledge and perceptions of CVD risks among the general population.

enabled mutual learning and synergies between multiple stakeholders (national authorities, healthcare providers, patient organisations, regulators and NGOs) and Member States.

b) how far have the EU added value criteria led to the development of proposals that better addressed these aspects? Are all of these criteria still relevant? Which criteria have been most/least addressed?

Seven criteria set out in the Programme Regulation identify areas where Programme-funded actions should provide added value. These are[98]:

- the exchange of good practices between Member States;
- support networks for knowledge sharing or mutual learning;
- addressing cross-border threats to reduce their risks and mitigate their consequences;
- addressing certain issues relating to the internal market where the EU has substantial legitimacy to ensure high-quality solutions across Member States;
- unlocking the potential of innovation in health;
- benchmarking to allow informed decision-making at EU level; and
- improving efficiency by avoiding a waste of resources due to duplication and optimising the use of financial resources[99].

Evidence from the evaluation's consultation activities shows that these seven criteria were used in funding proposals to sufficient extent. The criteria which were considered the most important were the exchange of best practices, support networks for mutual learning and avoiding inefficient duplication of work.

Survey respondents who were involved in the management and administration of a Programme action mentioned that the criteria were well-defined, at least to a moderate extent. However, a large proportion of respondents stated that they did not know. Of those who did provide an answer, 30% said the criteria were used, at least to a moderate extent.

This suggests that the process of integrating the EU added value criteria into proposals could be made clearer and more systematic.

The EU added value criteria remained relevant throughout the Programme implementation period and are considered useful for future health programmes.

[98] Regulation (EU) No 282/2014 of the European Parliament and the Council 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. Available from:https://eurlex.europa.eu/legalcontent/EN/TXT/PDF/?uri=CELEX:32014R0282&from=EN [Accessed November 2021]].

[99] European Commission. n.d. Funding under the third Health Programme 2014-2020: The European Added Value. Available from: https://ec.europa.eu/chafea/health/programme/documents/factsheets-hp-av_en.pdf [Accessed July 2022].

A large proportion (65%) of survey respondents who were involved in the management and administration of a Programme action stated that the criteria remained relevant, at least to a moderate extent.

Moreover, the important developments and revisions initiated by CHAFEA helped increase the relevance of these criteria during the Programme's lifespan. Its guide for applicants for project grants released in 2018[100], expanded on the list of EU added value criteria, with the following additions:

- Impact on target groups;
- Long-term effect and potential multiplier effect such as replicable, transferable, and sustainable activities;
- Contribution to complementarity, synergy, and compatibility with relevant EU and Member State policies and programmes, including compatibility with the European Platform on Rare Disease registration and the Commission's ERN Platform.

Furthermore, the guide included the following ways to achieve added value:

- Implementing EU legislation;
- Promoting best practice;
- Benchmarking for decision-making;
- Reducing cross-border threats;
- Strengthening free movement of persons;
- Strengthening networking activities.

As regards the future relevance of the EU added value criteria, most survey respondents indicated that the seven added value criteria should be retained in future health programmes. A minority (20%) stated that the criteria should be modified. Suggestions for improving these criteria included:

- Ensuring the involvement of civil society actors (NGOs) throughout the programme;
- Putting a stronger focus on health equity, health promotion and education;
- Including evidence-based work (activities, policies);
- Allocating funding to areas of unmet needs where EU action has particular added value, such as rare diseases including childhood cancers.

Further improvements to help strengthen the EU added value of EU action in health, included enhancing cooperation across the wider Commission services, notably across Directorate-Generals of the Commission (DGs) and involvement of agencies and other related organisations that would be beneficial in addition to DGs.

[100] Third Health Programme (2014-2020) Project Grants (HP-PJ) Guide for Applicants, European Commission.

4.3. Is the intervention still relevant?

OVERALL MATCHING WITH MEMBER STATES' HEALTH STRATEGIES

The Programme's midterm evaluation identified a set of public health and healthcare needs and problems at the time when the Programme was established in 2014[101]. A majority of those needs remained relevant throughout the Programme's lifespan (2014-2020) and were identified as priority areas for participating countries and highlighted by all consulted stakeholders.

During the Programme implementation, the main EU-wide health needs related to health promotion and better and safer healthcare. A mapping of national health strategies set out in the participating countries at the beginning of the Programme was conducted as part of the evaluation. This mapping revealed that the most common priority area indicated in country-level health strategies was objective 4: better and safer healthcare. Key health needs relating to this objective included rare diseases, patient safety and quality of healthcare.

The second most common priority area was objective 1: health promotion. This was confirmed by stakeholders who consider the promotion of healthy behaviours to be a key health need in the EU.

Addressing health and social inequalities is also a key health need in the EU, with major health differences across regions and socio-economic groups reported by several of the stakeholders interviewed[102]. This issue was also prioritised by some participating countries at the beginning of the Programme (2014-2016). Specific groups or specific inequalities within the EU were identified, including women and children, children with cancer and cancer survivors.

The Programme has been overall relevant to the key health needs identified in the EU. This is reflected in the allocation of the Programme funding, which appears proportionate to the priority areas expressed by participating countries, under each of the four specific objectives and with regard to health inequalities/health determinants and to other cross-cutting issues.

[101] An ageing population, threatening the financial sustainability of health systems and causing health workforce shortages; A fragile economic recovery, limiting the availability of resources to invest in healthcare; An increase in health inequalities between and within Member States; An increase in the prevalence of chronic disease; Pandemics and emerging cross-border health threats; The rapid development of health technologies; Increase in mental health problems (particularly among the young); Other specific emergency situations which expose EU health professionals to unprecedented challenges (for example, dealing with the repercussions of the large increase in refugees); and Threats to environmental health such as air quality and pollution monitoring.

[102] Including an academic / research stakeholder, a governmental public health organisation, and an organisation representing patients and services users.

INCREASED RELEVANCE OF PREPAREDNESS AND RESPONSE TO CROSS-BORDER HEALTH THREATS

Preparedness and response to health threats (objective 2) was not highlighted as priority by many countries. However, health threats are perceived as a challenge best addressed at EU and/or international level because of their cross-border and fast changing nature.

This was due to the fact that health strategies of participating countries were defined at the beginning of the Programme over the period 2014-2016, at a time when cross-border health threats were not perceived as a first priority.

The need to strengthen preparedness to health threats increased over time because of the frequent (but moderate) outbreaks that occurred at the beginning of the implementation period and because of the Ebola and Zika outbreaks which were more significant, even if they originated in countries outside the EU territory.

According to the stakeholders surveyed, the specific objective 2 (health threats) became more relevant over time, also because of the severity of communicable diseases (such as HIV/AIDS, hepatitis, resurgence of tuberculosis in certain countries). Other factors justifying the increase relevance of preparedness to health threats were: migrations/population movements, globalisation and environmental threats.

The implementation of the Decision No 1082/2013 (EU)[103] on serious cross-border threats to health, contributed to more awareness on the need to strengthen preparedness and response to cross-border health threats. The tools provided by the Decision No 1082/2013 (EU) were complemented by the work of Health Security Committee, the Early Warning and Response System – EWRS, the Health Emergency Operation Facility – HEOF and the Joint Procurement to purchase medical countermeasures, epidemiologic surveillance.

The COVID-19 outbreak in the first quarter of 2020, revealed weaknesses in the preparedness and response to a major cross-border health threat of such magnitude. As a consequence of the lessons learned from the pandemic, preparedness and response to cross-border health threats became the first health priority at EU and Member States levels.

FLEXIBILITY AND ADAPTABILITY TO CHANGING AND UNFORESEEN NEEDS

The Programme has been flexible and relevant to ongoing and changing health needs.
For example, it has effectively adapted and responded to the migrant/refugee crisis in 2015.

[103] Now repealed by Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health

To adapt the Programme to evolving health needs, Article 14 of Regulation (EU) No 282/2014 establishing the Programme states that following the midterm evaluation, the list of thematic priorities in its Annex I may be updated, where relevant, by removing certain thematic priorities from the list and adding new ones. This provision integrated flexibility and adaptability into the Programme from the beginning.

In addition to the thematic priorities, the Programme's midterm evaluation aimed to assess the continued relevance of all the Programme objectives.

However, the midterm evaluation did not recommend any change to the list of thematic priorities as it considered them to be still relevant to the health needs of the EU.

The major health challenge during the Programme's lifespan was COVID-19 outbreak in the first quarter of 2020. Although, this evaluation does not cover the comprehensive EU response to COVID-19, it should be noted that following the outbreak of the pandemic, the relevant actions funded by Programme were reoriented to the greatest extent possible from an 'inter-epidemic mode' to their '*emergency/pandemic mode*' (see Section 3.2.2 for more information), with a view to contributing to combat the pandemic, in particular in its early stages.

Stakeholders considered the work on COVID-19 as an example of how the Programme has remained relevant to public health changes in Europe. They highlighted the new comprehensive approach to mental health adopted by the Commission in June 2023[104] also as a consequence of COVID-19, and considered DG SANTE's recent call for proposals on this topic as highly relevant.

COMMISSION WIDER POLICIES, CITIZENS NEEDS AND CROSS-CUTTING PRIORITIES

The actions funded under the Programme were found to be relevant and aligned with the Commission's wider policies (see Section 4.1.3.b).

Regarding citizens, the evaluation shows that the Programme has been largely relevant to their needs, as confirmed by stakeholder consultations (PC, interviews), even if a minority of respondents stated that most thematic priorities were not directly relevant to people's needs as they were too broad, and because the practical problems faced by many patients (such as long waiting lists to receive medical care) are not in the remit of EU health programmes.

Certain topics (e.g. childhood cancers – despite the establishment of ERN PaedCan for paediatric cancers) were seen to be insufficiently addressed by the Programme, given the magnitude of the issues at stake in these areas. These are concrete areas where EU-level action could further increase the relevance of the health programme to citizens' needs.

[104] The Communication of the Commission on a comprehensive approach to mental health has been adopted on 7 June 2023 – COM(2023) 298 final

Progress is being made in this area thanks to the EU4Health programme, which funds dedicated measures under Europe's Beating Cancer Action Plan.

Finally, the Programme addressed health inequalities, which while not a specific objective of the Programme, were to be addressed across all thematic priorities. The box below presents relevant findings of the case study on this topic.

The Programme has supported the following six main actions:

- the **Joint Action Health Equity Europe**, (see 3.5.(i))**;**
- the project **AHEAD** which aims to address the challenge of medical deserts and medical desertification in Europe to help reduce health inequalities;
- the **European network to reduce vulnerabilities in health** which aimed to bring together NGOs and academic partners from different European countries and to contribute to the reduction of EU-wide health inequalities and to better equipped health systems to deal with vulnerability factors;
- the project **Mig-HealthCare**, which aimed to promote effective community-based care models to improve physical and mental health care services, support the inclusion and participation of migrants and refugees in Europe and reduce health inequalities;
- the project **MyHealth**, which aimed to improve the healthcare access of vulnerable immigrants and refugees newly arrived in Europe and focused on women and unaccompanied minors;
- **SH-CAPAC**, which aimed to support Member States in coordinating, assessing and planning their public health response to the challenges posed by migratory pressure.

Despite these positive results and the significant resources invested by the Programme on this policy area, overall, the theme of health inequalities is not perceived by consulted stakeholders as sufficiently addressed by the Programme. This might be partly explained by the fact that reducing health inequalities was a general, cross-cutting objective of the Programme, rather than a specific objective or thematic priority. Therefore, stakeholders might be less aware of the role the Programme played in addressing health inequalities.

The positive results of the funded actions in terms of increased cooperation and coordination between different actors, improved knowledge and exchange, can contribute in the long-term to building capacity and creating infrastructures able to address health inequalities and social determinants of health.

CONSEQUENCE OF THE COVID-19 PANDEMIC AND FUTURE HEALTH NEEDS IN THE EU

Despite the adaptability and flexibility of the Programme described above, the COVID-19 pandemic has demonstrated that health systems need to be ready to provide state-of-the-art services and care and to be prepared to cope with epidemics and other unforeseeable challenges.

The pandemic showed the importance of testing, contact tracing and public health surveillance as essential aspects of preparedness and response. It also demonstrated the need for a smooth functioning single market and access to personal protective equipment,

medicines, and medical devices. Another key lesson learned was that, while physical infrastructure could be expanded, the most pressing need became the availability of healthcare staff that were competent within intensive care units. In some instances, healthcare service reservists and medical students were called in and, where needed, rapid training was provided.

Overall, the crisis demonstrated the fragility of national and local health systems and the need for strong and coordinated action at EU level to complement Member State health policies to improve the health of people across the EU and ensure that public health protection is taken into account in all EU policies.

These new challenges and health needs were fully taken into account and addressed in the design of the EU4Health programme[105] (2021-2027) which succeeds the Programme.

The EU4Health programme, adopted as a response to the COVID-19 pandemic, is one of the main instruments paving the way to a stronger European Health Union. It has a total budget of around EUR 5.3 billion over the whole 2021-2027 multiannual financial framework.

5. WHAT ARE THE CONCLUSIONS AND LESSONS LEARNED?

5.1. Conclusions

Effectiveness

The Programme produced an array of positive effects during its implementation.
Knowledge produced by the Programme was used in policymaking, helping to improve health and healthcare policies across the EU. This was especially the case for cancer, AMR, HTA, alcohol and tobacco control. The Programme also helped improve health and healthcare through the implementation of best practices, the coordination of efforts across Member States and changes to policy and practices at EU level. For example, joint actions as a funding mechanism enabled important collaboration, fostered coordination efforts among Member States, facilitated the sharing of good practices and capacity building on a number of pertinent topics. Similarly, the setting up of 24 ERNs allowed for a high level of coordination between healthcare providers across Europe to tackle complex or rare diseases conditions and will also allow to boost clinical research on rare diseases in the long run.

[105] Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (*OJ L 107, 26.3.2021, p. 1–29*)
see also: EU4Health programme 2021-2027 – a vision for a healthier European Union (europa.eu)

Funded actions contributed to achieving the Programme objectives to a good extent, in particular for objective 1 (promote health, prevent diseases, and foster supportive environments for healthy lifestyles), objective 3 (increase of health inequalities between/within Member States) and objective 4 (facilitate access to better and safer healthcare for EU citizens).

This is evidenced by the overall positive trend of the indicators associated with the specific objectives of the Programme, even if these indicators did not cover comprehensively all funded actions under the 23 thematic priorities of the Programme.

The available data shows that the most effective funding mechanisms were joint actions and project grants. According to the evaluation results, factors hindering the achievement of the Programme objectives were limited resources, limited capacity, insufficient political will at national level, difficulties in engaging with stakeholders. There is therefore room for strengthened and more effective EU action to address those limitations and further support Member States.

As regards objective 2 (protect EU citizens from serious cross-border health threats), the relevant indicator ('*number of Member States integrating coherent approaches in the design of their preparedness plans'*) showed an increasing trend, indicating the ability of the Programme to effectively meet this objective. Complementary qualitative analyses confirmed that funded actions contributed to strengthen the preparedness and response of the EU and Member States, as they contributed (in coordination with other tools set up in DG SANTE and in the Commission) to respond to and mitigate the moderate health threats[106] that frequently emerged during the implementation period.
Despite active contribution of the Programme funded actions to combatting the COVID-19 pandemic, particularly in its early stages, the pandemic uncovered weaknesses on several aspects of the preparedness and response to a major cross-border health threats at EU and at Member States level. It can therefore be concluded that the objective 2 was met only partially or to a moderate extent by the Programme.

The exceptional utility criteria intended to facilitate higher participation of low-GNI countries in the Programme; and stakeholders did perceive the criteria as having a positive impact. However, low-GNI countries had a lower overall participation rate in Programme actions as coordinators and partners when compared with high-GNI countries. Furthermore, programme participation by low-GNI countries did not increase over time.

An important measure of effectiveness concerned the sharing and dissemination of Programme results. The evaluation conclusions suggest that the Programme results have, to varying extents, been published by the Commission services and by other stakeholders

[106] among which: the avian influenza H7N9 in human beings (2013-2014); resurgence of polio and tuberculosis in certain countries; hepatitis; Ebola outbreak in west Africa and later in Democratic Republic of Congo – DRC; Zika virus outbreak; influenza; measles; dengue; yellow fever, West Nile fever, chikungunya viruses.

in scientific journals, and that publications resulting from the Programme have been used by stakeholders. However, it emerged that Programme beneficiaries faced difficulties in publishing and disseminating the results of funded actions. There is therefore scope for the Commission to provide further support to the dissemination of Programme results by way of organising knowledge transfer activities.

The midterm evaluation was an important milestone in the implementation of the Programme. The Commission, and notably DG SANTE and the executive agency, CHAFEA have taken steps to address its 10 recommendations. Evidence suggests that some of the recommendations have been addressed successfully. Conversely, some recommendations were not sufficiently taken up, including spelling out how actions targeting health promotion and health systems should generate EU added value and investing in the resources necessary to improve systems for monitoring Programme implementation. The latter recommendations, alongside with those which were only partially met, should be followed up under the new EU4Health programme (and beyond).

Lastly, the results of the Programme were found to be sustainable overall, with HTA, the Joint Action on AMR and ERNs identified as areas of high sustainability. Sustainability was supported by the addition of an obligatory work package on sustainability in the funded actions' workplans, as well as through strong connections built between key stakeholders jointly working on a funded action or through adoption of legislation (or a similar permanent framework) resulting from the funded action. Challenges to sustainability were found to be linked with a lack of political will in participating countries or beneficiaries, insufficient integration of actions' results in national/local policymaking, insufficient synergy and complementarity with other funding sources undermining the scaling up and further development of the results of an action.

Efficiency

The data assessed shows that the Programme was relatively cost-effective considering changes in the health landscape over its implementation period, and the size and scope of actions undertaken. In particular, the Programme's operational costs (administrative costs plus the costs allocated to the functioning of the executive agency CHAFEA) were found to be reasonable and comparable to those of other EU programme of similar size. Consulted stakeholders highlighted the positive impacts of work achieved with the resources allocated, even in cases where funding was not deemed to be wholly sufficient. Flexibility of funding allocation was particularly efficient and underlines a strong success factor of the Programme as a whole.

An analysis of the total implementation costs[107] of actions funded under the 4 specific objectives and on cross-cutting issues, against the qualitative outcome of these actions enables to conclude that the total costs were proportionate to the results and outcomes of

[107] i.e., the total costs incurred by the Commission, Programme beneficiaries, Member States and relevant stakeholders.

the funded-actions, even if the latter are not expressed in monetary terms. The benefits of the funded actions potentially outweigh to a significant extent their total implementation costs. This potential is further enhanced if longer-term effects[108] of the actions are taken into account.

While operational and management costs were reasonable, administrative costs were considered by stakeholders as sometimes disproportionately heavy, increasing workload of those involved in actions and potentially putting countries with low GNI or smaller organisations off becoming involved, or being involved in future work.

The distribution of Programme credits among the four specific objectives was efficient in that it addressed the key health needs identified during the implementation period, with funding allocation deemed critical to achieve expected results. A particular strength of the Programme was the flexibility of funding allocation, which for example allowed the Programme to respond to key emerging health threats.

There were significant differences in costs and benefits between participating countries, as countries with lower GNI were less able to participate in the Programme (especially in coordinating roles) and Western European countries led the most actions and received the most funding for actions. Accordingly, countries with less capacity and funding did not feel the same benefits as other countries. Although the exceptional utility criteria intended to increase the participation of low GNI countries, differences in capacity still prevented these countries from participating more fully. Further support to these countries may be needed in order to improve the situation.

Over the implementation period, significant efforts were made to improve the efficiency of the Programme by simplifying and streamlining its procedures. This included the introduction of electronic monitoring and reporting mechanisms via the IT tools SYGMA[109] and COMPASS[110], which were also used for the Horizon 2020 programme. However, according to certain beneficiaries, there was scope to further simplify the processes, especially for applications for funding, monitoring and reporting.

The cost-effectiveness of actions could have been improved by introducing a more centralised information system (either using systems already in place in the Programme portal or adding a new one) dedicated to disseminating information about different funding possibilities to ensure synergies across projects, to better disseminate the results of implemented actions, to coordinate projects and to allow direct communication with project officers of the executive agency CHAFEA or of DG SANTE.

[108] e.g., establishment of lasting knowledge/expertise sharing networks; contribution to progressive changes in population behaviour, through the implementation of health promotion and disease prevention actions
[109] European Commission' IT-based grant management system
[110] European Commission's IT-based workflow system for the Horizon 2020 Framework Programme for Research and Innovation and for other EU Programmes of the research family, including the Third Health Programme 2014-2020

Coherence

The actions funded by the Programme were aligned with its objectives and coherent with each other. Funded actions were found to be focused on thematic priorities while also complementing and building on one another, thereby demonstrating high internal coherence.

Overall, the Programme encouraged cooperation and was aligned with other instruments financing health-related activities, in particular the European Structural and Investment Funds and Horizon 2020[111]. Moreover, actions funded by the Programme contributed to the EU's wider policies and priorities (i.e. the Europe 2020 strategy for smart, sustainable and inclusive growth in 2014-2015, the Juncker Commission's priorities in 2016-2019 and the von der Leyen Commission's priorities in 2020), and were aligned with wider international obligations, in particular the WHO common policy framework 'Health 2020' and the European action plan for strengthening public health capacities and services. Lastly, the Programme was coherent with other health-related EU policies and was largely aligned with Member States' relevant strategies and initiatives.

EU-added value

The Programme provided added value in comparison with what could have been achieved by the EU without the Programme and by Member States acting alone. In particular, it funded multiple actions which demonstrated strong EU added value by encouraging Member States to exchange best practices and cooperate and coordinate with each other on pertinent policy issues. Furthermore, it enabled mutual learning and knowledge exchange in areas such as health promotion, HTA, rare diseases, AMR, alcohol and tobacco policy.

The seven added value criteria were well-defined and used in the assessment of funding proposals. A significant proportion of stakeholders were not aware of the extent to which the criteria were defined or used, suggesting that there is scope for making the process of integrating the EU added value criteria into proposals, clearer and more systematic. The criteria that were considered the most important were 'sharing of best practices' and 'supporting networks for mutual learning', which corresponds to some of the areas where the Programme-funded actions provided stronger EU added value. Finally, the EU-added-value criteria remained relevant throughout the Programme's implementation period and are considered useful for developing future health programmes and establishing health policies and priorities at EU-level.

[111] EU Framework Programme for Research and Innovation 2014-2020.

Relevance

During the third Health Programme (2014-2020), the main health needs identified across the EU related to health promotion and better and safer healthcare. However, there were also additional new and emerging needs related to health systems and health and social inequalities.

An analysis of participating countries' priorities and action plans indicates that the Programme was relevant in that it addressed the national health needs. This was particularly the case for objectives 1 (promote health, prevent diseases and foster supportive environments for healthy lifestyles) and 4 (facilitate access to better and safer healthcare for EU citizens). The involvement of participating countries in the design phase was instrumental in ensuring the Programme's relevance.

The Programme has for the most part remained relevant to changes in health needs over time, and was flexible enough to respond to emerging health needs such as the migrant/refugee crisis in 2015 and the COVID-19 pandemic in 2020, even if this pandemic showed, at EU level and in the Member States, weaknesses in preparedness plans and in the ability to respond to a major health threat.

A number of factors limited the relevance of the Programme. For example, stakeholders felt that higher budgets could have helped address the problems better (e.g. health inequalities, mental health, and child and infant health, including paediatric cancers). There were, however, funded actions that covered mental health and health inequalities, even if these themes were not always perceived by surveyed stakeholders as adequately addressed. This is likely because they were not named as specific thematic priorities, so they did not receive proper emphasis.

The Programme was also relevant in that funded actions were clearly aligned with its specific thematic priorities. The funded actions were also aligned with the Commission's wider priorities, which enabled them to respond to the needs of EU citizens, in particular in areas such as the reduction of alcohol consumption, tobacco control, rare diseases, cancer screening, and implementation of best practices in nutrition, physical activity and the prevention of chronic diseases.

During the Programme implementation period, the relevance of preparedness and response to health threats significantly increased because of infectious diseases and the moderate (or less severe) outbreaks[112] that originated either within the EU territory or in third countries. With the COVID-19 outbreak at the beginning of 2020 the protection of EU citizens from serious cross-border health threats became the highest health priority.

[112] e.g., avian influenza H7N9 in human beings; resurgence of polio and tuberculosis; measles; hepatitis; Ebola outbreak in west Africa and in Democratic Republic of Congo; Zika virus; influenza; dengue; yellow fever, West Nile fever, chikungunya viruses.

The COVID-19 pandemic demonstrated the need for the health systems to be ready to provide state-of-the-art services and care and to be prepared to cope with epidemics and other unforeseeable challenges. Lessons learned from the pandemic in terms of emerging challenges and new health needs were considered and addressed in the design of the EU4Health programme (2021-2027) which succeeded the third health programme (2014-2020).

5.2. Lessons learned

Conclusions and recommendations

This evaluation assessed the Programme's effectiveness, efficiency, coherence, EU added value and relevance so as to learn lessons and pave the way for future EU action in health. The Programme has been largely relevant in addressing the health needs expressed by European countries and citizens over the period of its implementation and has adapted to changes in health needs over time, being flexible enough to respond to emerging health needs such as the migrant/refugee crisis and the COVID-19 pandemic.

It has been effective in achieving its objectives, as shown by the progress made on the indicators designed to measure the Programme's performance. It has also been effective in enabling more cooperation and coordination among Member States and overall improvements in health policy developments across the EU. Its' funded actions demonstrated added value and created synergies with other national, EU and international policies addressing health. Despite its overall success, there have been limitations to what the Programme could have achieved, as outlined above. To address those limitations and ensure that EU action in health is fit for the complex and ever-evolving health landscape, this evaluation sets out recommendations for EU action structured under four headings, summarised below.

Further building on the midterm evaluation recommendations

Building on the midterm recommendations, continued focus should be placed on areas of EU added value that have clearly emerged from this analysis.

- Future EU action in the area of health should continue to encourage cooperation and coordination among Member States in areas such as preparedness and response to cross-border health threats; rare diseases, HTA and eHealth, while also fostering exchanges and implementation of best practices in health promotion and disease prevention, in particular sub-themes that have become increasingly important (such as cardiovascular diseases, diabetes, mental health, cancer, physical activity, alcohol, tobacco control and nutrition).

Design of Programme and funding frameworks

Improving the outcomes and impacts of funded actions begins at the design stage. A number of key findings on the main evaluation criteria suggest that improvements could be made to the Programme's funding structures.

- Rethinking how cross-cutting policy issues can be integrated into the Programme's priority areas. Any significant health needs should be given explicit attention and funding, rather than being included as a 'cross-cutting issue'. For example, although actions were funded on mental health and health inequalities, stakeholders did not always perceive these topics to be adequately addressed. This was probably because they were not named as specific thematic priorities, even though at certain moments during the Programme's lifespan, funding and emphasis was provided.
- The flexibility and adaptability of the Programme was one of its key strengths, and this aspect should continue and be further developed to help face sudden emergencies or changes in health needs.

Facilitating and strengthening participation of all countries

Having all EU Member States participate contributes to strengthening the Programme's outputs, outcomes and impacts. Full participation also increases the added value of funded actions and should remain a key factor for improvement.

- Structures should be put in place to remove barriers to full participation by countries with fewer resources through additional support and relevant mechanisms, schemes and incentives.
- Increased EU-level resources dedicated to health issues could contribute to addressing national difficulties in participating in the Health Programme.
- Furthermore, an even stronger action at EU level in brokering the existing knowledge and pooling the existing relevant information would contribute to closing the knowledge gaps, where needed, while also steering national action.
- Support to the dissemination of Programme results by way of organising knowledge transfer activities (e.g. communities of practice, policy dialogues and other events) should be strengthened.

Ensuring sustainability

The sustainability of funded actions has a profoundly positive effect on EU and national health policies and systems.

Guiding and actively supporting beneficiaries in conceptualising and implementing actions to foster sustainability is a key element to consider during future planning.

Mechanisms and support should be provided to ensure sustainability measures are planned or negotiated with beneficiaries at the start of the funded actions.

Joint actions have been particularly successful at this, due to the obligation to ensure the sustainability of the work and should be considered as good practice.

ANNEX I: PROCEDURAL INFORMATION

- *[Lead DG, Decide reference and, if relevant, Work Programme reference.*
- *Derogations granted and justification.*
- *Organisation and timing.*
- *Consultation of the Regulatory Scrutiny Board (if relevant).*
- *Evidence used together with sources and any issues regarding its quality (i.e. has the information been quality assured?);*
- *Use of external expertise.]*

Lead DG

The European Commission's Directorate-General (DG) for Health and Food Safety (DG SANTE) is the lead DG for this evaluation (PLAN/2020/9070).

Organisation and timing

The Commission published a roadmap on the final evaluation of the 3rd Health Programme 2014-2020 on 20 October 2020 and was open for feedback until 17 November 2020.

A public consultation ran for 13 weeks from 11 March 2022 to 10 June 2022 with 68 responses received in total.

An interservices steering group (ISSG) was established in September 2020 involving representatives from: Secretariat-General, DG AGRI, DG INTPA, DG RTD, DG EAC, ESTAT, DG REGIO and JRC.

The ISSG contributed to the evaluation and ensured that it met the necessary standards for quality, impartiality and usefulness. Five meetings of the IISG were held.

Exceptions to the Better Regulation Guidelines

None. This evaluation was not selected for scrutiny by the Regulatory Scrutiny Board.

Evidence, sources and quality

This evaluation report drew on the following sources of evidence:

- Study supporting the final evaluation of the 3rd Health Programme 2014-2020
- Study supporting the mid-term evaluation of the 3rd Health Programme 2014-2020
- Study supporting the final evaluation of the 2nd Health Programme 2008-2013
- Data-gathering study on the common financial framework for the management of expenditure under Regulation (EU) No. 282/2014
- Annual Implementation Reports, of the 3rd Health Programme for the years 2014 to 2020

- Report from the Commission to the European Parliament and the Council on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare and the staff working document (SWD) accompanying this report
- Study of the European Parliament 2019, on the Benefit of EU action in health policy: The record to date
- Special report of the European Court of Auditors, 2019 addressing antimicrobial resistance: progress in the animal sector, but this health threat remains a challenge for the EU
- Special report of the European Court of Auditors, 2019: EU actions for cross-border healthcare: significant ambitions but improved management required.
- Health for the EU: a selection of actions funded under the Third EU Health Programme – Special Edition for the EU Health Programme Conference 30 September 2019
- Submissions to the online public consultation from March to June 2021 and the factual summary report of these as well as the synopsis report of all consultation activities in Annex V
- Submissions to the targeted stakeholder survey, and the factual summary report of these, as well as the synopsis report of all consultation activities in Annex V
- Submissions to the focus groups conducted for each main type of funding instruments implemented by the Programme (actions grants, joint actions, operating grants, procurement contracts, direct grants to international organisations), and factual summary reports of these, as well as the synopsis report of all consultation activities in Annex V
- Results of stakeholder interviews, and case studies

ANNEX II. METHODOLOGY AND ANALYTICAL MODELS USED

In order to assess the Programme according to the 22 evaluation questions, a three-phase approach was devised:

- starting with an in-depth understanding of the programme and its implementation
- then consultation with stakeholders
- analysis and synthesis

1. Building an understanding of the Programme

The first phase of the study involved gathering contextual information on the background, structure, functioning and implementation of the Programme. The steps taken under this phase are outlined below.

- Searching and checking data availability and making and overview of the functioning of Programme
- **Identification of relevant stakeholders** within seven stakeholder groups,[113] to be consulted with in later phases of the study. Relevant stakeholder groups were identified for this study to ensure a varied and robust response to the evaluation questions and full understanding of the programme. A stakeholder engagement strategy was prepared to detail how stakeholders were to be involved in the evaluation.
- An **analysis of the Programme database** was carried out. Which enabled the development of a single output database containing relevant collated information on the main funded actions, participating entities, and the geographical and temporal scope of actions falling within this evaluation, in the form of all publicly available information about all funded actions in the database.
- **In-depth review of 61 preliminary documents**[114] relating the context, legal and financial basis of Programme.

- **Main document review** covering documents that confirm the implementation status of Programme activities, and strategic documents which shed light on the evolution of the Programme to evolving needs and priorities. Through this review, the national health strategies and plans, as well as specific health strategies such as HIV/AIDS action plans, of all countries in the scope of the present study were reviewed and the priorities were extracted and mapped to the objectives of the Programme.

[113] Public authorities (central government/ministries of health, and public health authorities or agencies); Academic/research organisations; Non-governmental organisations; EU citizens; Patients and service users and organisations representing them; Consumer organisations; Company/business organisations; Other (international organisations e.g. WHO, OECD; Healthcare service providers; Organisations presenting healthcare service providers; Healthcare professionals' associations; Independent experts)

[114] Consisting of previous evaluations of the European Commissions' health programmes, as well as relevant EU health strategy documents and legal texts on the functioning of the health programmes

- Five **scoping interviews** were carried out within DG SANTE and with Programme Committee members, to better understand differing perspectives of Programme, including successes and gaps, administrative issues, and the varied funding mechanisms

- An **in-depth analysis of a sample of 18 funded actions** relating to the case study topics[115] was carried out. Relevant documents were reviewed, and discussions were held with key stakeholders within DG SANTE and HaDEA to inform the development of the case studies.

2. Consulting with stakeholders

In-depth stakeholder consultations were carried out over the course of the study: an Public consultation, a targeted survey, interviews, focus groups and social media listening as elaborated below.

- The **Public consultation (PC)** (11 March to 10 June 2022) provided the general public, and all interested parties, with the opportunity to provide information and opinions on the matters to be addressed in this study. The PC was targeted at all those who have an interest in the 3rd Health Programme but who had not necessarily been directly involved in the Programme design or implementation. Questions were therefore relatively high-level, exploring the overall perception of the Programme, and its relevance to broader health needs and objectives. A total of 69 responses were received.[116]
- The **targeted stakeholder survey** (10 March to 13 May 2022) collected further evidence on the views and perceptions of those with direct experience of the Programme regarding its relevance and implementation and performance. The survey was targeted at all those who have been directly involved in the Programme design and/or implementation (including those having received funding from the Programme) and who were therefore able to answer relatively specific and more detailed questions on the implementation and performance of the Programme.
- 34 **Stakeholder interviews** were carried out from April to July 2022 to help the study team to understand in more depth the design and implementation of the Programme. They were also used to triangulate findings drawn from other data collection tasks and to fill gaps in evidence collected through other tasks.
- Five online focus groups were conducted (May to June 2022) to gain further insights into the main funding mechanisms of the Programme[117]. Between three and 10 stakeholders took part in each focus group, which lasted for up to 4 hours.
- **Social media listening[118]** was conducted to extract data from Twitter between July 2020 – July 2022 to understand coverage and trends of discussions on the six case study topics of the study.[119]

[115] Alcohol, Antimicrobial resistance (AMR), health inequalities, nutrition, Health Technology Assessment (HTA), and vaccination;

[116] Three responses were identical (including responses to open-ended questions), and so they have been considered as one response. The analysis therefore focused on 67 responses;

117 Project Grants, Operating Grants, Joint Actions, Procurement contracts, and a final focus group on all funding mechanisms. Due to a lack of participation and availability of DG SANTE and HaDEA staff, the fifth focus group was ended early, and follow-up interviews were scheduled instead.

[118] Social media listening is the process of tracking social media platforms for mentions and conversations related to a topic, then analysing these for insights.

[119] Alcohol, Antimicrobial resistance (AMR), health inequalities, nutrition, Health Technology Assessment (HTA), and vaccinations

3. Analysis and synthesis

Once all data from desk research and consultations with stakeholders was gathered, in-depth analysis and synthesis was undertaken, detailed below.

The purpose of the analysis and synthesis phase was to draw together the data sources generated from the study, to allow for the identification of patterns, divergences and convergences in findings per evaluation criteria. Data sources were analysed separately to identify key findings per evaluation question. The findings were compared per evaluation question across the study activities, noting divergence and convergence of evidence and accounting for differences in views per stakeholder group. In preparation for analysis, data was organised into useable formats, e.g., writing up interview notes and focus group notes, cleaning and organising PC and targeted survey data files. Then, data was analysed as below.

Qualitative data analysis

The following steps were carried out to utilise qualitative data gathered through the document review and stakeholder consultations:

- Key findings were drawn from the document review to provide documentary evidence relating to each relevant evaluation question.
- Relating to the funded actions database, qualitative information including abstract, priority area, and coordinator, was analysed related to each relevant evaluation question.
- Open-ended questions from the PC and targeted stakeholder survey were manually reviewed and coded for key themes.
- The notes from the focus groups were reviewed and key findings were summarised by evaluation criteria.
- The notes from the interviews were reviewed and coded into a master file showing key issues by stakeholder group. This was then reviewed by evaluation criteria and trends were summarised into the final report.

Quantitative data analysis

The following steps were carried out to utilise quantitative data gathered through the document review and stakeholder consultations:

- Responses to close-ended questions within the PC and targeted stakeholder survey were processed using univariate analysis (proportions, averages), disaggregated by question and key variables. Responses were also processed using bivariate analysis, including cross-tabulations.
- Tables and graphs of key points were created for the social media listening and further explanatory text was drafted to provide insights into these findings.

Case studies

The case studies provide a deep dive on a specific theme within Programme. The approach of contribution analysis[120] was used to enable the identification of concrete links between thematic objectives and their specific outcomes and impacts. The level of contribution from the Programme

[120] Contribution analysis involves unpacking the intervention logic for specific activities of Programme, isolating the hypothesis (or hypotheses) underpinning the various steps involved – e.g., from outputs to outcomes, or from outcomes to impacts – and exploring to which extent the evidence available supports the hypothesis.

at each of these steps was considered based on a thorough review of the evidence; as well as other contributing factors in influencing the outcomes.

The case studies were used to provide evidence to answer certain questions, related to the effectiveness of the Programme. Additionally, findings from the case studies were used to provide evidence to answer other evaluation questions as needed.

Limitations and robustness of study findings

Key strengths of the evaluation include the identification of links between inputs, outcomes and impacts of specific actions of the Programme, which was achieved through the use of contribution analysis and presented in the case studies of the Programme. Furthermore, despite challenges in engaging stakeholders as outlined below, the study engaged with a rank of stakeholders from across the main groups identified through the study. Engagement with those involved in the management and design of the Programme was particularly high through the interview and focus group consultations. It was therefore possible to corroborate insights from such relevant stakeholder groups across the multiple consultations to yield reliable evidence and data to produce a thorough assessment underpinning the evaluation. Additionally, the extensive document review provided a solid basis for the study and generated key line of enquiry to be investigated through the stakeholder consultations.

However, some limitations related to the fact that the evaluation study was developed mainly using the publicly available database and limited participation from stakeholders.

The Health Programme database[121], contained only actions funded through grant agreements and did not include comprehensive information such as detailed financial data and outputs of the actions.

Thus, the analysis of the database may be limited or may not be representative due to the types of funded actions which are included. For instance, half of the actions included were half a year long, and over one third of them were still ongoing when finalising this evaluation report. As not all of the actions of the Programme are included in the database, this means the analysis may be biased to include more short-term actions and not consider longer ones. However, through the consultations undertaken as part of this study, stakeholders were able to provide feedback on all ongoing actions as well as completed actions, regardless of their implementation maturity, as long as they fell under Programme funding.

This shortcoming and related data gaps were mitigated by the provision of separate complementary documents and specific data, such as the list of all procurement contracts concluded under the Programme. For the operating grants awarded to Non-governmental Organisations the final technical reports were made available to the contractor, as well as the final reports and detailed technical deliverables and outputs of a sample of actions funded by the Programme.

These measures, combined with triangulation of data from different sources, enabled to arrive at evidence-based results confirmed by more than one information source.

[121] Health Programme DataBase - European Commission (europa.eu)

Moreover, due to the timing of the study (being undertaken after the commencement of the EU4Health Programme) and the number of other public-health priorities being faced by all relevant stakeholder groups during the study period (COVID-19, war in Ukraine), the stakeholders' engagement was limited.

The online targeted survey and PC yielded fewer replies than anticipated, despite a dissemination campaign and several targeted reminder emails. This may be due to a lack of engagement by stakeholders and other contextual factors (including delays to the overall study timeline, the study being run after the launch of the new health programme- and thus a risk of de-prioritisation of the previous programme). A larger number of survey responses would have provided greater depth to the qualitative analysis, however an equal representative response from all relevant stakeholders was received and allowed for an assessment to be made.

Similarly, for the stakeholder interviews, despite multiple communications to stakeholders, the targets per stakeholder group were not fully met for two groups: 'government policymakers' and 'healthcare service providers and organisations representing them'. While the target was to have 45 participants in the interviews, despite substantial attempts to engage with stakeholders, 34 stakeholders participated in total.

ANNEX III. EVALUATION MATRIX

	Evaluation questions	Judgment criteria	Quantitative and qualitative indicators	Research methods	Sources for document review
	Relevance				
1	**To what extent have the Programme's scope, including its objectives and priorities been relevant to health needs across the EU, considering their evolution over the evaluation period?**				
1a	To what extent did the objectives and priorities of the Programme, its actions and other activities, address health and healthcare needs and problems at EU-level over the evaluation period?	• Problems, needs and their drivers identified as part of the Programme were correctly defined. • No relevant problems or needs were left out of the Programme at the time. • The implementation mode of the Programme was relevant given needs and context at the time.	• [Quantitative] A majority of stakeholders agree that problems/needs/drivers were correctly defined • [Qualitative] Expert stakeholders' recollection of problems at the time • [Qualitative] Available literature from 2014-2020 reflects the problems/needs/drivers of the Programme	• **Document review** looking at sources from 2014-2020 that address problems, needs and drivers related to health and healthcare • **PC** • **Targeted stakeholder surveys** • **Stakeholder interviews** • **Social media analysis** • **Focus groups**	• Programme Implementation documentation • Strategic Documents (policies/reports) to understand relevance of the Programme
1b	To what extent have each of the objectives and priorities remained relevant to health and healthcare needs and problems at EU-level over time and up until 2020?	• The problems and drivers that led to the choice of the Programme's objectives are still relevant. • Each of the objectives and actions have remained relevant considering changes in: • science and technological progress in the area of health and healthcare • solutions developed at national level, by public, private and not-for-profit actors • changes in prevalence & severity of NCDs & CDs	• [Quantitative] A majority of stakeholders agree that problems/needs/drivers remain relevant defined • [Qualitative] Expert views on extent to which there is still a need to focus on each of the Programme's priority areas • [Qualitative] Extent to which Member States still require support in the areas identified by the Programme • [Qualitative] Extent to which: • EU knowledge needs to be improved and in which domains • health officials and healthcare providers use new knowledge	• **Document review**, particularly: • review of data on prevalence and severity of NCDs & CDs • literature reviews on the state of play in health & healthcare research & innovation • **Mapping of project database** • **PC** • **Targeted stakeholder surveys** • **Stakeholder interviews**, • **Social media analysis** • **Focus groups**	• Programme Implementation documentation • Strategic Documents (policies/reports) to understand relevance of the Programme • EU-level collected data on health indicators to help understand the relevance of the Programme

		• *The implementation mode of the Programme remains relevant given evolving needs and context.*	*developed through the Programme* • *[Qualitative] Overview and assessment of health and healthcare solutions (technologies, therapies, products) developed between 2014-2020* • *[Quantitative & qualitative] Changes in prevalence, incidence and severity of NCDs and CDs*		
2	***To what extent were the Programme's thematic priorities sufficiently covered by the funded actions to achieve the Programme's objectives and Commission's wider priorities?***				
2a	*To what extent were the Programme's funded actions aligned with the thematic priorities of the Programme?*	• *There is a clear alignment between funded actions and the specific thematic priorities set out by the Programme.*	• *[Qualitative] Available information from the Programme period reflects alignment between funded actions and Programme priorities* • *[Quantitative] A majority of stakeholders agree that funded actions align with thematic priorities* • *[Quantitative] % of total number of funded actions that align with specific Programme themes*	• ***Document review*** • ***Mapping of project database*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews*** • ***Focus groups***	• *Programme Implementation documentation* •
2b	*To what extent were the funded actions aligned with the Commission's wider priorities?*	• *There is a clear alignment between funded actions and wider Commission priorities.*	• *[Qualitative] Available information from the Programme period reflects alignment between funded actions and wider Commission priorities* • *[Quantitative] A majority of stakeholders agree that funded actions align with wider Commission priorities*	• ***Document review*** • ***Mapping of project database*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews,*** *particularly with SANTE & CHAFEA and NFPs & PCs* • ***Focus groups***	• *Programme Implementation documentation* • *Strategic Documents (policies/reports) to understand relevance of the Programme*
3	***How relevant is the Programme to EU citizens, and in particular, is the Health Programme close to citizens and responding to their needs?***				
3a	*How relevant is the Programme to EU citizens?*	• *Each of the objectives and actions have remained relevant considering changes in public/citizens' expectations and behaviours in relation to health and healthcare*	• *[Quantitative] A majority of stakeholders agree that funded actions are relevant to public/EU citizens' expectations and behaviours in relation to health and healthcare* • *[Qualitative] Available information from the*	• ***Document review****, particularly: review of existing data on public/citizens' expectations & behaviours* • ***PC*** • ***Social media analysis***	*Strategic Documents (policies/reports) to understand relevance of the Programme* *EU-level collected data on health indicators to help understand the relevance of the Programme*

			Programme period demonstrates that funded actions are relevant to public/citizens' expectations and behaviours in relation to health and healthcare	• ***Stakeholder interviews***		
3b	*Is the Programme close to citizens and responding to their needs?*	• *Actions funded under the Programme are directly relevant/responding to the needs of EU citizens*	• *[Quantitative and Qualitative] Survey data & other research on public/citizens' expectations & behaviours in relation to health & healthcare* • *[Qualitative] Available information on the extent to which funded actions directly address the needs of citizens*	• ***Document review**, particularly: review of existing data on public/citizens' expectations & behaviours* • ***Targeted stakeholder survey*** • ***Social media analysis***	*Strategic Documents (policies/reports) to understand relevance of the Programme* *EU-level collected data on health indicators to help understand the relevance of the Programme*	
	Effectiveness					
4	***What have been the (quantitative and qualitative) effects of the Programme?***					
4a	*To what extent has the Programme contributed to a more comprehensive and uniform approach to health and healthcare in the EU?*	• *Measures implemented by Member States are aligned with the Programme* • *National programmes and actions reflect evidence and evidence-based approaches developed through Programme funding* • *Health data is more robust, timely and comparable across EU Member States*	• *[Qualitative] Level of alignment or divergence between national level actions in relation to Programme priorities and actions* • *[Qualitative] Level or degree of MS use of evidence and evidence-based approaches developed under the Programme* • *[Qualitative] Extent to which health data is more robust, timely and comparable across EU Member States*	• ***Document review*** • ***Mapping of project database*** • ***PC*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews*** • ***Focus groups*** • ***Case studies***	• *Programme Implementation documentation* • *Strategic Documents (policies/reports) to understand relevance of the Programme* • *EU-level collected data on health indicators to help understand the relevance of the Programme*	
4b	• *To what extent has the Programme contributed to improvements in health and healthcare in the EU and at Member State level?*	• *Programme actions that have led to new knowledge and evidence have been used in the development of policy and decision-making* • *Programme actions have led to improvements in health and healthcare in the EU and at MS level in terms of:* • *Implementation of best practices by MS* • *Coordination of efforts across MS*	• *[Quantitative & Qualitative] Number and content of scientific studies and best practice, guidance, etc. developed as part of the Programme* • *[Qualitative] Extent of implementation of best practices by EU MS* • *[Qualitative] Coordination efforts by EU MS* • *[Qualitative] Changes in EU policy and practice* • *[Qualitative] Stakeholder views*	• ***Document review*** • ***Mapping of project database*** • ***PC*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews*** • ***Focus groups*** • ***Case studies***	• *Programme Implementation documentation* • *Strategic Documents (policies/reports) to understand relevance of the Programme* • *EU-level collected data on health indicators to help understand the relevance of the Programme*	

		• *Changes in policy and practice at EU level*	*on how studies, reports and evidence produced through the Programme contributed to decision making at EU or national level* • *[Qualitative] Extent to which stakeholders attribute improvements to the Programme* • *[Qualitative] Extent to which documentation corroborates stakeholder views on relationship between new knowledge and policy-making or decision-making* • *[Qualitative] Extent to which factors other than the Programme can explain any improvements*		
4c	• *To what extent has the Programme contributed to the EU's influence on health and healthcare standards, policies and practices at international level?*	• *Programme outputs have been used at an international level* • *The EU's coordination with international bodies in the field of health has been strengthened in Programme priority areas*	• *[Qualitative] Expert views on how the Programme contributed to the EU's influence on standards, policies and practices at global level (WHO, SDGs)* • *[Quantitative &Qualitative] extent to which documentation and other stakeholder interviews confirm expert views*	• ***Document review*** • ***Mapping of project database*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews*** • ***Focus groups*** • ***Case studies***	• *Programme Implementation documentation* • *Strategic Documents (policies/reports) to understand relevance of the Programme* •
5	***To what extent have the Programme's objectives (general and specific) been met? To what extent can factors influencing the observed achievements be linked to the EU intervention?***				
5a	*To what extent have the funded actions contributed to achieving the objectives of the Programme?*	• *There is a clear indication that funded actions meet the Programme's objectives* • *The actions funded by the Programme have led to high-quality, publicised and influential outputs that support Programme objectives*	*For a subset of the actions:* • *[Qualitative] Available information from the Programme period demonstrates that funded actions meet the Programme's objectives* • *[Qualitative] Quality of outputs from funded actions* • *[Quantitative] A majority of stakeholders agree that funded actions meet the Programme's objectives* • *[Quantitative &Qualitative] Information on publication & dissémination efforts*	• ***Document review*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews*** • ***Mapping of project database*** • ***Focus groups*** • *Results of analysis under EQ4 on Programme effects*	• *Programme Implementation documentation* • *Strategic Documents (policies/reports) to understand relevance of the Programme*

			• *[Qualitative] Influence of actions on decision-making* • *[Qualitative] Impact on achieving strategy objectives*		
5b	*Regarding the objectives partially met or unmet, which factors hindered the achievement of the objectives?* •	• *The cause and effect chain for achieving the objectives was effective* • *The explanatory factors that hinder and enable achieving Programme objectives can be identified*	• *[Qualitative] For question 5a, where objectives have not been met, assessment of what has contributed to objectives not being met*	• *Review of evidence gathered in support of question 5a* • ***Focus groups***	• *Programme Implementation documentation* • *Strategic Documents (policies/reports) to understand relevance of the Programme*
6	***How effective was the introduction of "exceptional utility" criteria in the Regulation establishing the Programme in order to incentivise the participation of low GDP countries?***				
6a	*To what extent did the 'exceptional utility' criterion incentivise participation of low GDP countries?* •	• *Programme participation by low GDP countries has increased:* • *over time* • *as compared to participation in the 2nd HP* • *As compared to participation during the first half of the Programme period (i.e. since the mid-term evaluation)*	• *[Quantitative] Trends in participation of low GDP countries over the Programme period and compared to 2HP* • *[Quantitative] Success rates of applicants seeking to benefit from the criterion, and as compared to success rates for regular funding* • *[Quantitative & Qualitative] Number of low GDP countries participating, levels of funding provided* • *[Qualitative] Stakeholder views on extent to which low GDP country participation was incentivised by the criterion* • *[Qualitative] Stakeholder views on any changes or improvements made since the mid-term evaluation that improved or might have led to improved participation (even if this is not directly reflected in the quantitative results)* • *[Qualitative] Stakeholder views on any factors leading to lower participation by low GDP countries that is specific to the criterion and Programme in general (e.g. awareness / understanding of the criterion)* • *[Qualitative] Stakeholder views*	• ***Document review*** • ***Mapping of programme data**, particularly:* • *Participation by low GDP countries/ organisations (number & geographic distribution)* • *Projects (number and types) funded under the criterion in comparison to regular funding* • *Funding allocations (proportions and amounts) to low GDP countries/ organisations overall and under the criterion* • ***Targeted stakeholder surveys*** • ***Stakeholder interviews***	• *Programme Implementation documentation* •

			on wider factors that may influence participation external to the criterion (e.g. securing co-financing, administrative capacity to manage actions in the MS)		
7	***To what extent are the Programme's actions/outcomes/results published by Commission services, by Programme beneficiaries and other stakeholders? To what extent are they made accessible to the international scientific and health community and to the wider public in the EU?***				
7a	*To what extent are Programme results published?* •	• *Programme results have been published by:* • *Commission services* • *Programme beneficiaries* • *Other stakeholders*	• *[Quantitative & Qualitative] Number, type and source of publications*	• ***Document review,*** *including programme monitoring & reporting data* • ***Mapping of project database-*** *focus on outputs and outcomes*	• *Programme Implementation documentation* • *Strategic Documents (policies/reports) to understand relevance of the Programme*
7b	*To what extent are publications made accessible to the wider scientific and health community and to the public?*	• *Publications are available to wider stakeholders and the public*	• *[Quantitative & Qualitative] Number & type of publications available Open Access (green & gold)*	• ***Document review,*** *including programme monitoring & reporting data* • ***Mapping of project database***	• *Programme Implementation documentation* • *Strategic Documents (policies/reports) to understand relevance of the Programme*
7c	*To what extent are the results used by stakeholders?*	• *Publications have been used by other stakeholders in research or other activities*	• *[Qualitative] Stakeholder views on quality of deliverables and dissemination efforts*	• ***Document review*** • ***Mapping of project database*** • ***Social media analysis***	• *Programme Implementation documentation* • *Strategic Documents (policies/reports) to understand relevance of the Programme* •
8	***To what extent have the recommendations from previous evaluations been implemented?***				
8a	*To what extent has SANTE maintained a focus on thematic areas of strong EU added value*	• *SANTE has undertaken activities that focus on areas identified as having the most EU added value since the mid-term evaluation* • *SANTE has identified MS needs where the Programme can provide added value and acted on these*	• *[Qualitative] Documented priorities and actions reflect a focus on areas of greatest added-value* • *[Qualitative] Stakeholder views on extent to which areas of greatest added value have been prioritised and acted upon*	• ***Document review*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews,*** • *Results of analysis under EQ18 on EU added value of the Programme*	• *Document review supporting EQ18* • *Strategic Documents (policies/reports) to understand relevance of the Programme* •
8b	*To what extent has SANTE strengthened and built links between the HP and wider Commission & EU policy agenda to maximise impact?*	• *SANTE has learned from experiences of successful coordination and extended these efforts where they have worked and/or undertaken new such*	• *[Qualitative] Programme actions indicate an effort to coordinate with wider Commission & EU policy agenda* • *[Qualitative] Stakeholder views*	• ***Document review*** • ***Targeted stakeholder surveys*** • ***PC*** • ***Stakeholder interviews,*** • *Results of analysis under*	• *Document review supporting EQ21* • *Programme Implementation documentation* • *Strategic Documents (policies/reports) to understand relevance of the Programme*

		efforts	*on extent to which coordination has occurred*	*coherence EQs*		
8c	*To what extent has SANTE spelt out how action targeting health promotion & health systems should generate EU added value?*	• *SANTE has defined in detail the mechanisms by which best practices should be taken up in practical terms and timescales for doing so since the mid-term evaluation* • *This information has been shared with key stakeholders* • *Operational objectives for the next Programme have been revised to detail how the Programme should generate added value*	• *[Qualitative] Guidance has been created which details how actions generate added value* • *[Qualitative] Operational objectives for the next Programme have been clearly revised to take this into account* • *[Qualitative] Stakeholder views on extent to which this information has been shared with stakeholders and reflected in the next Programme's objectives*	• ***Document review*** • ***Stakeholder interviews,*** • *Results of analysis under EQ18 on EU added value of the Programme*	• *Document review supporting EQ18* • *Programme Implementation documentation* • *Strategic Documents (policies/reports) to understand relevance of the Programme*
8d	*To what extent has SANTE refined Programme thematic priorities and streamlined them in EU4Health to focus spending on areas with the greatest potential impact?*	• *Thematic priorities have been refined since the mid-term evaluation to reflect more concretely their anticipated results* • *Thematic priorities have been streamlined for the next Programme to avoid overlap or ambiguity as well as any redundancies*	• *[Qualitative] Documented refinements to existing priorities to reflect anticipated results* • *[Qualitative] Documented efforts to streamline priorities in the EU4Health programme* • *[Qualitative] Stakeholder views on extent to which existing priorities have been refined and streamlined for the future*	• ***Document review*** • ***Stakeholder interviews***	• *Programme Implementation documentation* • *Strategic Documents (policies/reports) to understand relevance of the Programme*
8e	*To what extent have SANTE & CHAFEA refined the EU-added value criteria and fully integrated these into the application process?*	• *The EU-added value criteria have been refined & their use integrated more fully into the application process*	• *[Qualitative] Stakeholder views on the extent to which the EU added value criteria have improved & been used in a more integrated way in the application process* • *[Qualitative] Stakeholder views on the extent to which applicants & assessment panellists understand the EU added value criteria & how to apply them* • *[Qualitative] Review of Programme documents demonstrate these changes, including development of 'how to guides' or other guidance*	• ***Document review*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews,*** • ***Mapping of project database*** • *Results of analysis under EQ19 on the EU added value criteria*	• *Document review supporting EQ19* • *Programme Implementation documentation*
8f	*To what extent has SANTE*	• *Multi-annual planning has*	• *[Qualitative] Stakeholder views*	• ***Document review***	• *Programme Implementation*

	integrated multi-annual planning with existing programme processes?	*been integrated with the formal priority setting process since the mid-term evaluation*	*on the extent to which multi-annual planning has become more formally incorporated into priority setting* • *[Qualitative] Stakeholder views on the extent to which they feel more connected to the multi-annual planning processes* •	• ***Targeted stakeholder surveys*** • ***Stakeholder interviews,***	*documentation* • *Strategic Documents (policies/reports) to understand relevance of the Programme*
8g	*To what extent have SANTE & CHAFEA developed a broader strategy to increase participation from poorer MS & underrepresented organisations?*	• *A broader strategy to increase participation from poorer MS & underrepresented organisations has been developed since the mid-term evaluation* • *Low-GDP MS are participating in the Programme at higher rates or granted greater proportions of funding since the mid-term evaluation* • *The exceptional utility criterion is being used more since the mid-term evaluation*	• *[Qualitative] A strategy from increasing participation has been developed and/or implemented* • *[Quantitative] Resources allocated/dedicated to increasing participation from low GDP MS over the Programme period & compared with mid-term evaluation*	• ***Document review*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews*** • *Results of analysis under EQ6 on exceptional utility criterion*	• *Document review supporting EQ6* • *Programme Implementation documentation* • *Strategic Documents (policies/reports) to understand relevance of the Programme* •
8h	*To what extent have SANTE & CHAFEA invested in the resources necessary to improve systems for monitoring programme implementation?*	• *Additional resources have been allocated to monitoring systems since the mid-term evaluation* • *Real-time, accurate information about HP implementation is available to programme managers*	• *[Quantitative] Resources allocated/dedicated to Programme monitoring & trends in resource levels so allocated over the Programme period* • *[Qualitative] An electronic monitoring system has been developed and/or implemented* • *[Qualitative] Stakeholder views on the extent to which additional resources have been focused on monitoring* • *[Qualitative] Stakeholder views on the extent to which monitoring data has become more accurate / easier to access / less fragmented*	• ***Document review*** • ***Stakeholder interviews*** • *Results of analysis under EQ16 on monitoring processes & resources*	• *Document review supporting EQ16* • *Programme Implementation documentation*
8i	*To what extent have SANTE & CHAFEA implemented and used*	• *Programmatic and action specific monitoring*	• *[Qualitative] Programme documents demonstrate*	• ***Document review*** • ***Stakeholder interviews***	• *Document review supporting EQ16* • *Programme Implementation*

	programmatic and action specific monitoring indicators?	*indicators have been introduced and used since the mid-term evaluation* • *Existing programme monitoring indicators have become more comprehensive since the mid-term evaluation* • *A system for reporting on, collecting and presenting data on action specific indicators has been put in place*	*implementation of more specific monitoring indicators* • *[Qualitative] Programme documents demonstrate that a system for monitoring action specific indicators has been put in place* • *[Qualitative] Stakeholder views on the extent to which programme & action specific monitoring indicators have been implemented & used, as well as a system for monitoring action indicators has been put in place*	• *Results of analysis under EQ16 on monitoring processes & resources*	*documentation*
8j	*To what extent has dissemination of action results been improved?*	• *Dissemination of action results has clearly increased and the quality of dissemination efforts has improved since the mid-term evaluation*	• *[Quantitative & Qualitative] Trends in number, type and source of publications since the mid-term evaluation and comparison with mid-term results* • *[Qualitative] Stakeholder views on quality of dissemination efforts since the mid-term evaluation and comparison with mid-term results*	• ***Document review*** • ***Mapping of project database*** • ***Stakeholder interviews*** • *Results of analysis under EQ7*	• *Document review supporting EQ7* • *Programme Implementation documentation*
9	***How are the results and effects of the Programme likely to last at the end of its implementation if funding ceases to exist (self-sustainability)?***				
9a	*To what extent are the Programme results and effects likely to be sustainable?* •	• *Programme results and effects demonstrate evidence of being continued regardless of Programme funding (utilising sustainability plans where they have been requested in projects)* •	• *[Qualitative] Stakeholder views on the sustainability of Programme results* • *[Qualitative] Reviewing specific levers and barriers to sustainability of how the work funded by Programme has been sustained.*	• ***Document review*** • ***Mapping of project database*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews*** • ***Case studies*** • *Results of analysis under effectiveness EQ4*	• *Document review supporting EQ4* • *Project documentation in database* • *Strategic Documents (policies/reports) to understand relevance of the Programme* • *EU-level collected data on health indicators to help understand the relevance of the Programme*
	Efficiency				
10	***To what extent has the Programme been cost effective?***				

10a	*To what extent could the same results have been achieved with fewer resources?*	• *Programme actions have deviated from their planned resource budgets* • *Presence of Programme actions which had high costs but low impacts*	• *[Quantitative] Comparison of planned vs actual implementation budgets* • *[Qualitative] Expert opinion on planned and actual budgets and factors influencing deviations (including reasons)* • *[Quantitative / Qualitative] Action and causal chain effectiveness* • *[Quantitative] Actual implementation budgets* • *[Qualitative] Assessment of effectiveness of the Programme*	• ***Document review*** • ***Mapping of project database*** • ***Stakeholder interviews*** • *Responses to effectiveness questions*	• *Programme Implementation documentation* • •
10b	*Regarding Programme objectives partially met or unmet, what have been the opportunity costs?*	• *The degree to which the impacts foreseen for the Programme have matched the impacts achieved, and where there are discrepancies, an assessment of the opportunity costs of these*	• *[Quantitative & Qualitative] Degree of objective achievement (e.g. assessment of Programme effectiveness)* • *[Quantitative & Qualitative] Typology of benefits anticipated for each of the objectives* • *[Qualitative] Assessment of any discrepancies between the expected and achieved impacts*	• ***Document review**, namely considering:* • *Response to effectiveness question EQ5* • *Impacts anticipated for Programme* • ***Stakeholder interviews*** • ***Cost-effectiveness analysis***	• *Programme Implementation documentation* •
11	***To what extent are the costs associated with the Programme proportionate to the benefits it has generated? What factors are influencing any particular discrepancies? How do these factors link to the Programme?***				
11a	*To what extent are the Programme*	• *Costs associated with*	• *[Quantitative & Qualitative]*	• ***Document review***	• *Programme Implementation*

	costs proportional to the expected results?	*the Programme are reasonable and kept to the minimum necessary in order to achieve the expected results, including:* • *Programme operational costs (design & implementation)* • *Management costs for funding* • *Administrative costs for applicants & CHAFEA* • *Monitoring & reporting costs for MS and the Commission*	*Typology and accounting of costs associated with the implementation of the Programme* • *[Quantitative & Qualitative] Typology and (where possible) accounting of benefits associated with the implementation of the Programme* • *[Qualitative] Stakeholder views on the extent to which costs are reasonable given the objectives and expected results*	• ***Mapping of project database*** • ***PC*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews*** • ***Cost-effectiveness analysis*** • *Analysis of efficiency EQs, especially 14-17*	• *documentation* •
11b	*What factors influence any disparities between Programme costs and expected results?*	• *Identification of factors, both internal and external to the Programme related to any disproportionate costs found*	• *[Qualitative] Stakeholder views on factors that disproportionately affect costs relative to expected benefits*	• ***Document review*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews*** • ***Cost-effectiveness analysis*** • *Analysis of efficiency EQ12*	• *Programme Implementation documentation* •
11c	*To what extent are these factors linked to the Programme?*	• *The degree to which factors identified as creating disproportionate costs can be directly linked to the Programme*	• *[Qualitative] Stakeholder views on the extent to which identified factors are directly linked to the Programme*	• ***Document review*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews*** • ***Cost-effectiveness analysis*** • *Analysis of efficiency EQ 12*	• *Programme Implementation documentation* •
12	***To what extent do factors linked to the Programme (e.g. the number of priorities, available financial and human resources, various financial mechanisms, established procedures, intended results, political focus) influence the efficiency with which the observed achievements were attained? What other factors influence the costs and benefits?***				
12a	*How does the design and implementation of the Programme influence the efficiency with which achievements were attained?*	• *Identification of factors relating to the implementation of the Programme resulting in discrepancies in the efficiency of achieving its objectives* • *Identification of the magnitude to which factors related to the implementation of the Programme influence*	• *[Quantitative & Qualitative] Typology and accounting of costs associated with the implementation of the Programme* • *[Quantitative & Qualitative] Typology and (where possible) accounting of benefits associated with the implementation of the Programme* • *[Quantitative / Qualitative]*	• ***Document review*** • ***Mapping of project database*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews*** • ***Cost-effectiveness analysis***	• *Programme Implementation documentation* •

		the efficiency of achieving its objectives	*Action and causal chain effectiveness* • *[Quantitative] Actual implementation budgets* • *[Qualitative] Stakeholder assessment of factors influencing the effectiveness of the Programme*			
12b	*What other factors influence the costs and benefits of the Programme?*	• *Identification of factors external to the implementation of the Programme resulting in discrepancies in the efficiency of achieving its objectives* • *Identification of the magnitude to which factors external to the implementation of the Programme influence the efficiency of achieving its objectives*	• *[Quantitative & Qualitative] Typology and accounting of costs associated with the implementation of the Programme* • *[Quantitative & Qualitative] Typology and (where possible) accounting of benefits associated with the implementation of the Programme* • *[Quantitative / Qualitative] Action and causal chain effectiveness* • *[Quantitative] Actual implementation budgets* • *[Qualitative] Stakeholder assessment of factors influencing the effectiveness of the Programme*	• ***Document review*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews*** • ***Cost-effectiveness analysis***	• *Programme Implementation documentation* •
13	***To what extent was the distribution of Programme credits among the four thematic priorities efficient?***					
13a	*To what extent were the four thematic priorities allocated Programme credits in line with EU health priorities?*	• *Identification of the degree to which Programme funding was distributed across the four thematic priorities* • *Identification of EU health priorities*	• *[Quantitative] Actual implementation budgets* • *[Qualitative] Mapping of EU health priorities onto the Programme's four thematic priorities* • *[Qualitative] Stakeholder assessment of the alignment of the four thematic priorities and EU health priorities*	• ***Document review*** • *Mapping of project database* • ***Stakeholder interviews*** • ***Cost-effectiveness analysis***	• *Strategic Documents (policies/reports) to understand relevance of the Programme* • *Programme Implementation documentation* •
13b	*To what extent was the funding allocation considered to be critical to achieve the expected results?*	• *Assessment of whether the allocation of resources under the four thematic priorities is proportional to the expected results* •	• *[Quantitative] Actual implementation budgets* • *[Quantitative & Qualitative] Typology and accounting of costs associated with the implementation of the Programme*	• ***Document review*** • ***Stakeholder interviews*** • ***Cost-effectiveness analysis*** • ***Secondary data analysis of relevant health indicators*** *(i.e. Eurostat, Eurobarometer, OECD,*	• *Programme Implementation documentation*	

			• *[Quantitative & Qualitative] Typology and (where possible) accounting of benefits associated with the implementation of the Programme* • *[Qualitative] Stakeholder assessment of the role of the distribution of funding allocation in the achievement of Programme objectives* • *[Quantitative] Analysis of MS/EU level health trends and wider macroeconomic indicators*	*WHO)*	
14	***If there are significant differences in costs (or benefits) between participating countries, what is causing them? How do these differences link to the Programme?***				
14a	*What if any differences in costs (or benefits) occurred between participating countries?*	• *Assessment of the distribution of Programme funding across Member States* • *Identification of the costs incurred by Member States in the implementation of the programme* • *Identification of the benefits accrued by Member States in the implementation of the programme* •	• *[Quantitative] Actual implementation budgets* • *[Quantitative & Qualitative] Typology and accounting of costs associated with the implementation of the Programme* • *[Quantitative & Qualitative] Typology and (where possible) accounting of benefits associated with the implementation of the Programme* • *[Qualitative] Stakeholder assessment of the role of the distribution of funding allocation, type of funding mechanism, thematic priorities, and thematic objectives in the achievement of Programme objectives* • *[Quantitative] Analysis of MS/EU level health trends and wider macroeconomic indicators*	• ***Document review*** • ***Mapping of project database*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews*** • ***Cost-effectiveness analysis*** • ***Secondary data analysis of relevant health indicators*** *(i.e. Eurostat, Eurobarometer, OECD, WHO)*	• *Programme Implementation documentation* • *Strategic Documents (policies/reports) to understand relevance of the Programme* • *EU-level collected data on health indicators to help understand the relevance of the Programme* •
14b	*What factors resulted in any differences observed (where significant)?*	• *Assessment of the significance of factors relating to programme design and implementation (i.e.*	• *[Quantitative] Actual implementation budgets* • *[Quantitative & Qualitative] Typology and accounting of costs associated with the*	• ***Document review*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews*** • ***Cost-effectiveness analysis***	• *Programme Implementation documentation* • *Strategic Documents (policies/reports) to understand relevance of the Programme*

		funding mechanism, thematic objective, thematic priority, funding levels) in creating differences in the costs and benefits experienced by Member States • *Assessment of the significance of factors external to the programme (i.e. wider health trends, country-level factors) in creating differences in the costs and benefits experienced by Member States* •	*implementation of the Programme* • *[Quantitative & Qualitative] Typology and (where possible) accounting of benefits associated with the implementation of the Programme* • *[Qualitative] Stakeholder assessment of the role of the distribution of funding allocation, type of funding mechanism, thematic priorities, and thematic objectives in the achievement of Programme objectives* • *[Quantitative] Analysis of MS/EU level health trends and wider macroeconomic indicators*	• ***Secondary data analysis of relevant health indicators*** *(i.e. Eurostat, Eurobarometer, OECD, WHO)*	• *EU-level collected data on health indicators to help understand the relevance of the Programme* • •
14c	*To what extent can the differences be linked to the Programme itself?*	• *Assessment of the significance of factors relating to the programme in determining differences in the cost and benefits observed in Member States, relative to factors external to the programme*	• *[Quantitative] Actual implementation budgets* • *[Quantitative & Qualitative] Typology and accounting of costs associated with the implementation of the Programme* • *[Quantitative & Qualitative] Typology and (where possible) accounting of benefits associated with the implementation of the Programme* • *[Qualitative] Stakeholder assessment of the role of the distribution of funding allocation, type of funding mechanism, thematic priorities, and thematic objectives in the achievement of Programme objectives* • *[Qualitative] Stakeholder assessment of the role of external factors in the achievement of Programme objectives*	• ***Document review*** • ***Stakeholder interviews*** • ***Cost-effectiveness analysis*** • ***Secondary data analysis of relevant health indicators*** *(i.e., Eurostat, Eurobarometer, OECD, WHO)*	• *Programme Implementation documentation* • *Strategic Documents (policies/reports) to understand relevance of the Programme* • *EU-level collected data on health indicators to help understand the relevance of the Programme*

			• *[Quantitative] Analysis of MS/EU level health trends and wider macroeconomic indicators*		
15	***To which extent did the simplification measures contribute to the efficiency of the Programme? Was there further scope for simplification to make the Programme implementation more efficient?***				
15a	*To what extent did the simplification measures reduce administrative costs for applicants and CHAFEAh?*	• *The simplification measures led to a reduction in the administrative costs for applicants and CHAFEA*	• *[Qualitative] Programme information indicating the extent to which simplification measures reduce administrative costs* • *[Qualitative] Stakeholder assessment of the extent to which simplification measures reduce administrative costs*	• ***Document review*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews***	• *Programme Implementation documentation*
15b	*To what extent is there scope to further reduce costs?*	• *Assessment of potential improvements to the simplification measures to further reduce costs*	• *[Qualitative] Programme information indicating the extent to which simplification measures can be improved to further reduce administrative costs* • *[Qualitative] Stakeholder assessment of the extent to which simplification measures can be improved to further reduce administrative costs*	• ***Document review*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews***	• *Programme Implementation documentation*
16	***To what extent were the monitoring processes and resources (at the Commission and MS level) cost-effective? How the role and benefits of the monitoring systems [i.e. to plan and promote the results of the Health Programme and finally to incite stakeholders (internal and external) to make use of them] are assessed, against the costs of these monitoring systems (also considering any administrative burden involved)?***				
16a	*To what extent do the monitoring processes enable efficient management of supported actions?*	• *Monitoring resources are adequate to support the established processes* • *The monitoring framework includes indicators, targets, and objectives that enable effective measurement of results* • *Monitoring processes are effective across all MS* • *Monitoring processes enable effective dissemination and promotion of*	• *[Qualitative] Programme information indicating the effectiveness of monitoring processes* • *[Qualitative] Stakeholder assessment of the effectiveness of monitoring processes in the management of supported actions and the dissemination and promotion of results* •	• ***Document review*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews*** • ***Cost effectiveness analysis***	• *Programme Implementation documentation*

		Programme results			
16b	*To what extent are the monitoring costs proportional to the expected results?*	• *Monitoring does not entail resources beyond the minimum necessary to achieve the expected results*	• *[Quantitative] Data on monitoring costs across the implementation period at Commission and (if available) Member State level* • *[Qualitative] Stakeholder assessment of the proportionality of monitoring costs relative to the effectiveness of the monitoring processes* •	• ***Document review*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews*** • ***Cost effectiveness analysis***	• *Programme Implementation documentation*
17	***What are the benefits of the reporting systems against their costs and how could they be effectively implemented?***				
17a	*What benefits have resulted from the reporting system?*	• *Identification of benefits to stakeholders resulting from the reporting system*	• *[Qualitative] Programme information identifying benefits of the reporting system* • *[Qualitative] Stakeholder assessment of the benefits resulting from the implementation of the reporting system*	• ***Document review*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews***	• *Programme Implementation documentation*
17b	*What are the costs of the reporting system and are these proportionate in relation to the benefits?*	• *Identification of costs to stakeholders resulting from the reporting system*	• *[Qualitative] Programme information indicating the costs resulting from the reporting system* • *[Qualitative] Stakeholder assessment of the costs resulting from the implementation of the reporting system*	• ***Document review*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews***	• *Programme Implementation documentation* •
17c	*Are there any ways in which the reporting systems could be more effectively implemented?*	• *Assessment of improvements in the implementation of the reporting system*	• *[Qualitative] Programme information indicating ways the reporting systems could be effectively implemented* • *[Qualitative] Stakeholder assessment of the scope for potential improvements to be made to the reporting system*	• ***Document review*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews***	• *Programme Implementation documentation* •
	EU-added value				
18	***What is the additional value resulting from the Programme, compared to what could reasonably have been expected from Member States acting at national and/or regional levels, and compared to what the EU would have achieved without the Programme?***				
18a	*Why has action at EU-level been the most appropriate? To what extent have the results produced*	• *Improvements cannot be viewed as a result of Member States efforts and*	• *[Qualitative] Stakeholder views on the extent to which EU level action (i.e. the Programme)*	• ***PC*** • ***Document review*** • ***Targeted stakeholder***	• *Programme Implementation documentation* • *Strategic Documents*

	under the Programme gone beyond what Member States would have achieved in its absence (considering public and private initiatives at international, national and local levels)?	*initiative alone, i.e. Member States took actions as a result of the Programme that would otherwise not have taken place, or would have occurred more slowly or to a lesser extent* • *There is a clear link between the characteristics of health and healthcare challenges and the need for action at EU-level* • *There was no detrimental impact on existing Member State actions in respect of health and healthcare (i.e. the EU Strategy did not disrupt or slow existing activity or activity that was already planned)* • *Areas for EU action are appropriate in view of EU and national competencies*	*provided added-value* • *[Qualitative] EU dimension vs national dimension of the problems the Programme has aimed to resolve* • *[Qualitative] Evidence that MS actions have been helped/incentivised (and not harmed) by the Programme*	• ***surveys*** • ***Stakeholder interviews*** • ***Focus groups*** • *Synthesis of evidence collected through other EQs*	*(policies/reports) to understand relevance of the Programme* • *EU-level collected data on health indicators to help understand the relevance of the Programme*
18b	*To what extent have the results produced under the Programme gone beyond what the EU would have achieved in its absence?*	• *The Programme has led to results that go beyond what the EU would have achieved in its absence*	• *[Qualitative] Stakeholder views on the potential impact of discontinuing the Programme* • *[Qualitative] Expert views on what if scenarios involving the discontinuation of the Programme*	• ***Document review*** • ***Stakeholder interviews*** • ***Social media analysis*** • ***Focus groups*** • *Synthesis of evidence collected through other EQs*	• *Programme Implementation documentation* • *Strategic Documents (policies/reports) to understand relevance of the Programme* • *EU-level collected data on health indicators to help understand the relevance of the Programme*
19	• ***How far have the EU added value criteria led to the development of proposals that better addressed these aspects? Are all of these criteria still relevant? Which criteria have been most/least addressed?***				
19a	*To what extent have the EU added value criteria led to proposals that better address the*	• *The eight added-value criteria are well-defined and evidenced in funding proposals*	• *[Qualitative] Extent to which each of the criteria are assessed to be well-defined* • *[Qualitative] Extent to which*	• ***Document review*** • ***Mapping of project database*** • ***Targeted stakeholder***	• *Programme Implementation documentation*

	need for added value?	• *The cause-effect chain can be established between the added value criteria as applied in proposals and the extent to which the Programme has produced results with added value*	*each of the criteria have been evidenced in funding proposals* • *[Qualitative] Evidence of linkages between added value as applied in proposals and Programme results* • *[Qualitative] Stakeholder views on the added value criteria, including their definition, and the relationship between their use in proposals and Programme results*	• ***surveys*** • ***Stakeholder interviews***	
19b	*To what extent are the added value criteria still relevant?*	• *The added value criteria are relevant in light of current added-value needs & priorities*	• *[Qualitative] Extent to which each of the criteria are assessed to be aligned with added value needs & priorities for health* • *[Qualitative] Stakeholder views on the relevance of added value criteria in relation to current needs & priorities*	• ***Document review*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews***	• *Programme Implementation documentation* • *Strategic Documents (policies/reports) to understand relevance of the Programme*
19c	*To what extent have the added value criteria been addressed in funding proposals?*	• *The added-value criteria have all been addressed in funding proposals, and in proportion to their relative importance*	• *[Qualitative & Quantitative] Measurement of the extent to which each of the criteria have been applied in funding proposals* • *[Qualitative] Stakeholder views on the relevance of added value criteria in relation to current needs & priorities*	• ***Document review*** • ***Targeted stakeholder surveys*** • ***Stakeholder interviews*** • *Analysis of added value EQ19a*	• *Programme Implementation documentation*
	Coherence	•	•	•	•
20	***Are the actions implemented under the 3rd Health Programme coherent with its objectives? How has the coherence of the Programme influenced its effectiveness?***				
20a	*How well have the actions implemented under the Programme aligned with its objectives, over time and up until 2020? Conversely, are there any gaps, areas of tension or inconsistencies?* *Where there have been inconsistencies or gaps, what has caused these? What have been the impacts?*	• *The actions undertaken as part of the Programme have appropriately addressed its objectives* • *The actions undertaken have been aligned with each other where possible* • *There have been no tensions between the actions undertaken as part of the Programme and no gaps in terms of actions taken in relation to Programme objectives*	• *[Qualitative] Extent to which each of the actions have supported the objectives of the Programme* • *[Qualitative] Extent to which actions have been aligned with one another where relevant* • *[Qualitative] Evidence of tensions between different objectives or actions undertaken as part of the Programme* • *[Qualitative] Evidence of*	• ***Document review****, including outputs and deliverables associated with actions undertaken* • ***Mapping of programme database*** • ***Stakeholder interviews*** • ***Focus groups*** • *Intervention logic mapping to identify potential synergies, complementarities or tensions*	• *Programme Implementation documentation* • *Strategic Documents (policies/reports) to understand relevance of the Programme* •

			sufficient uptake of opportunities so that objectives are well-covered in relation to actions • *[Qualitative] Stakeholder insights on factors leading to inconsistencies and gaps* • *[Qualitative] Stakeholder insights on impacts of inconsistencies and gaps*		
20b	*How has the coherence of the Programme influenced its effectiveness?*	• *Programme effectiveness (as assessed in effectiveness EQs) was influenced by Programme coherence (as assessed in other coherence EQs)*	• *[Qualitative] Evidence of Programme coherence influencing effectiveness* • *[Qualitative] Stakeholder insights on factors leading to coherence influencing effectiveness (or a lack thereof)* • *[Qualitative] Stakeholder insights on impacts of coherence (or lack thereof) on Programme effectiveness*	• ***Document review*** • ***Stakeholder interviews*** • *Analysis of effectiveness EQs* • *Analysis of other coherence EQs*	• *Programme Implementation documentation*
21	• ***To which extent have the priorities of the Programme led to more synergy, focus and coherence between the EU-funded actions in delivering on similar objectives? Did the health Programme encourage cooperation with the European Structural and Investment Funds and other EU financial instruments? To which extent is the Programme coherent with wider EU policy and with international obligations?***				
21a	*To what extent have the Programme priorities led to more synergy, focus and coherence between the funded actions over time and up until 2020? Where there have been inconsistencies or a lack of focus and coherence, what has caused this? What have been the impacts?*	• *Programme priorities are reflected in the coherence of funded actions (and with reference to the assessment of coherence in EQ20).* • *Programme actions are clearly focused in relation to the priority areas.* • *Programme actions clearly exhibit synergies with one another and in relation to priority areas.*	• *[Qualitative] Evidence of the alignment of priorities with funded actions* • *[Qualitative] Evidence of focus and synergies between priorities and funded actions* • *[Quantitative] Analysis of planned and realised funding for actions in relation to Programme priorities* • *[Qualitative] Expert stakeholders agree that that coherence, focus and synergies exist between funded actions and priorities* • *[Qualitative] Insights from stakeholders on factors leading to any lack of coherence, focus and/or synergy.*	• ***Document review*** • ***Targeted stakeholder surveys**, particularly with NCAs* • ***Stakeholder interviews*** • ***Focus groups***	• *Programme Implementation documentation* • *Strategic Documents (policies/reports) to understand relevance of the Programme*
21b	*Did the health Programme encourage cooperation with the*	• *Provisions for cooperation were established within the Programme*	• *[Qualitative] Evidence of provisions being made in Programme documentation to*	• ***Document review*** • ***Stakeholder interviews*** • ***Focus groups***	• *Programme Implementation documentation* • *Strategic Documents*

	European Structural and Investment Funds and other EU financial instruments?	• *Cooperation activities were undertaken with the European Structural and Investment Funds and other EU financial instruments*	*cooperate with other EU financial instruments* • *[Qualitative] Evidence of cooperation activities being undertaken with other EU financial instruments* • *[Quantitative] Analysis of planned and realised funding for actions where cooperation was undertaken* • *[Qualitative] Insights from stakeholders on factors leading to cooperation and/or any areas where there was a lack of cooperation and reasons for this.*		• *(policies/reports) to understand relevance of the Programme*
21c	*To what extent has the Programme been aligned with wider EU policy and international obligations with common objectives?* *Where there have been inconsistencies or gaps, what has caused these? What have been the impacts?*	• *Wider EU policies incorporate, are aligned with, and/or do not contradict the Programme, in particular:* • *Research & Innovation framework programmes* • *EU Cohesion Policy* • *Food and food safety* • *International obligations with common objectives are aligned with and/or do not contradict the Programme, in particular:* • *WHO European Action Plan (EAP-PHS)* • *Sustainable development goals*	• *[Qualitative] Comparison of wider EU policies between 2014-2020 against Programme objectives* • *[Qualitative] Comparison of international obligations with common objectives between 2014-2020* • *[Qualitative] Expert assessment of how EU Programme objectives are reflected in wider EU policies and vice versa* • *[Qualitative] Expert assessment of how EU Programme objectives are reflected in meeting international obligations with common objectives* •	• ***Document review,*** *including mapping of wider EU policies and international obligations related to health and healthcare, to be compiled based on:* • *Expert/DG SANTE recommendations* • *NCA survey* • *Complementary document review* • ***Stakeholder interviews***	• *Programme Implementation documentation* • *Strategic Documents (policies/reports) to understand relevance of the Programme* • *EU-level collected data on health indicators to help understand the relevance of the Programme*
22	• ***To which extent has the Programme proved complementary to other EU or Member States targets/interventions/initiatives in the field of health?***				
22a	*To what extent has the Programme been coordinated and complementary with* ***other EU-level policies in the field of health*** *over time and up until 2020?* *Where there have been inconsistencies or gaps, what has*	• *Other EU policies and related activities in the field of health incorporate and/or do not contradict the Programme, in particular:* • *EU Framework on mental health & well-being* • *Directive 2011/21/EU on patients' rights to cross-*	• *[Qualitative] Comparison of other relevant EU-level policies and interventions from 2014-2020 against Programme objectives* • *[Qualitative] Expert assessment of how Programme objectives are reflected in other relevant EU-level health policies* • *[Qualitative] Insights from DG*	• ***Document review,*** *including mapping of EU interventions related to health to be compiled based on:* • *Expert/DG SANTE recommendations* • *Survey of NCAs* • *Complementary document review*	• *Strategic Documents (policies/reports) to understand relevance of the Programme*

	caused these? What have been the impacts?	*border healthcare* • *Decision 1082/2013/EU on serious cross-border health threats* • *ECDC Early Warning & Response System* • *EU legal frameworks for medical products & medical devices* • *Tobacco legislation*	*SANTE, other DGs and EU Agencies, as well as other stakeholders on factors leading to inconsistencies and gaps* • *[Qualitative] Insights from stakeholders on impacts of inconsistencies and gaps*	• ***Stakeholder interviews*** • ***Focus groups***	
22b	*To what extent has the Programme been coordinated and complementary* ***with Member State interventions/initiatives in the field of health*** *over time and up to 2020?* *What have been the drivers for this?* *Where there have been inconsistencies or gaps, what has caused these? What have been the impacts?*	• *Member State interventions/initiatives developed between 2014-2020 in the field of health incorporate and/or do not contradict the Programme*	• *[Qualitative] Comparison of relevant Member State policies and interventions from 2014-2020 in relation to Programme objectives* • *[Qualitative] Expert assessment of how Programme objectives are reflected in Member State health policies and interventions* • *[Qualitative] Insights from Member State representatives and other stakeholders on factors leading to inconsistencies and gaps* • *[Qualitative] Insights from stakeholders on impacts of inconsistencies and gaps*	• ***Document review,*** *including mapping of EU interventions related to health to be compiled based on:* • *Expert/DG SANTE recommendations* • *Survey of NCAs* • *Complementary document review* • ***Stakeholder interviews*** • ***Focus groups***	• *Documents on MS-level policies in the field of health and related analysis and commentaries, e.g., MS health strategies* • *Strategic Documents (policies/reports) to understand relevance of the Programme*

ANNEX IV. OVERVIEW OF BENEFITS AND COSTS

Table 1a. Overview of costs and benefits identified in the evaluation

Relevant stakeholders / Costs and benefits		EU Citizens		Businesses/Contractors awarded Procurement contracts		Project participants/NGOs/Stakeholders other than National Authorities		Member States Authorities / National Administrations		European Commission (DG SANTE, CHAFEA, Other Commission services	
		Quantitative	Qualitative	Quantitative	Qualitative	Quantitative	Qualitative	Quantitative	Qualitative	Quantitative	Qualitative
Cost or Benefit description											
Specific objective 1: promote health, prevent diseases and foster supportive environments for healthy lifestyles											
Costs:											
Direct Costs: Monetary input into implementation of best practices and other actions under specific objective 1	Recurrent	N/A	N/A	N/A	N/A	MEUR 30 of co-funding for Projects and Direct Grant		MEUR 32 of co-funding of Joint Actions		Estimanted amount of MEUR 139 of operaional appropriation	
Direct Cost: Administrative costs	One-off and recurrent	N/A	N/A		Costs linked with preparation or response to call for tenders	Administrative Costs linked with participation of Actions implemented by the Programme (provision of information		EU co-funding for Joint Actions: MEUR		Overall administrative costs for running the entire Programme are presented for all	

						nomination and coordination with national entities participating in Joint actions)				specific objectives and cross-cutting actions	
Direct benefits				Total amount of awarded procurement contracts: MEUR 46		EU co-funding of grants MEUR 56		EU co-funding for Joint Actions: MEUR 36		N/A	
Direct benefits							A prize for NGOs is organised annually to encourage the organisations which make significant contributions in the field of health	24 MS using evidence-based good practices on nutrition and in particular in the area of saturated fat	6 MS using evidence-based good practices on EU guidelines and accreditation for breast cancer screening		
Direct benefits								Online best-practices portal launched in 2018: 6 6650 visitors	On cancer: 128 cancer registries from 29 European Countries provide data to the		

Specific objective 2: protect Union citizens from serious cross-border health threats								from all EU	Commission with more		
								Member States	than 25 900 000 records so far		
Other direct benefits									Implementation of and uptake of best practices at national leve in the fields of: cancer, tobacco control, physical exercise, nutrition, cardiovascular disease and diabetes		
Indirect benefits			Better health outcomes for population benefiting from implementation of best practices:		Productions on knowledge and tools at EU level: e.g., study on alcohol-related harm in the EU						

Costs											
Direct costs linked with Programme implementation		N/A		N/A		Co-funding from another organisation: MEUR 11		Co-funding from Member States: MEUR 7		MEUR 41 devoted to specific objective 2	
Direct Cost: Administrative costs	One-off and recurrent	N/A	N/A		Costs linked with preparation or response to call for tenders	Administrative Costs linked with participation of Actions implemented by the Programme (provision of information nomination and coordination with national entities participating in Joint actions)		EU co-funding for Joint Actions: MEUR		Overall administrative costs for running the entire Programme are presented for all specific objectives and cross-cutting actions	
Benefits											
Direct benefits						During the COVID-19 outbreak actions of the Programme have been geared, in their 'emergency mode', towards	Key examples of actions are the Healthy Gateways Joint Action, the Joint Action on Strengthen	During the COVID-19 outbreak actions of the Programme have been geared, in their 'emergency mode',	Key examples of actions are the Healthy Gateways Joint Action, the Joint Action on Strengthened International Health		

						combating the pandemic	ed International Health Regulations and Preparedness (SHARP), Training for Health Professionals on isolation, waiting rooms and reception areas, cleaning, appropriate PPE, real time RT-PCR testing for COVID-19	towards combating the pandemic	Regulations and Preparedness (SHARP), Training for Health Professionals on isolation, waiting rooms and reception areas, cleaning, appropriate PPE, real time RT-PCR testing for COVID-19		
Direct benefits		N/A		Procurement contracts awarded: MEUR 14			Production of new knowledge on health-threats related issues at EU level	As of 2202, 22 Member States integrated coherent approaches in the design of their preparedness plan	Production of new knowledge on health-threats related issues at EU level		Production of new knowledge on health-threats related issues at EU level
Direct benefits								Joint Action EMERGE	Feasibility study launched for		

								improved the capabilities for rapid laboratory diagnosis for new or emerging pathogens	the development of a common EU vaccination card		
Direct benefits								Support to interventions in 2014-2016 to limit spread of Zika and Ebola			
Indirect benefits		Better protection of the population against cross-border health threats	Better protection from vaccine-preventable diseases through interventions to improve vaccine uptake								
Specific objective 3: contribute to innovative, efficient and sustainable health systems											
Costs											
Direct Costs linked with implementation of the Programme		N/A		N/A		Contribution from other participating organisations		Contribution of MS participating in Joint		Total appropriations under specific	

						: MEUR 30		Actions: MEUR 19		objective 3: MEUR 110	
Direct Cost: Administrative costs	One-off and recurrent	N/A	N/A		Costs linked with preparation or response to call for tenders	Administrative Costs linked with participation of Actions implemented by the Programme (provision of information nomination and coordination with national entities participating in Joint actions)		EU co-funding for Joint Actions: MEUR		Overall administrative costs for running the entire Programme are presented for all specific objectives and cross-cutting actions	
Benefits											
Direct benefits				Procurement contracts awarded to contractors: MEUR 37				As of 2020, 41 Health Technology Assessments (HTAs) produced per year	23 MS using identified tools and mechanisms, in order to contribute to effective results in their health systems		
Direct benefits		Establishement of an organ database				Setting up of the EU Health Policy Platform		Successful implementation of the 3rd Joint	Launching of the THEDAS Joint Action (The		Improvement of country knowledge

		which has helped 34000 transplants in 2017				(HPP) a collaborative on-line tool which makes it easier for health-related interest groups, stakeholders and Commission services to cooperate		Action of HTA (EUnetHTA) which led to a permanent regulation setting up cooperation framework between MS on HTA	European Health Dataspace) to facilitate the European Health Data Space by developing principles for cross-border secondary use of health data		in the field of health through regular publication of Health information, in particular: The State of Health in the EU, the Country Profiles and Health at a Glance publication series
Direct benefits								The joint action on Market Surveillance on Medical Devices has yield significant added value by reinforcing the market surveillance system for these devices and improving cooperation among			

								all MS			
Indirect benefits			Strengthening of Health Systems of the Member States for the benefit of EU citizens and patients					Achieving cost savings for the benefit of health systems through appropriate use of tools such as HTA and through digitalisation policies			
Specific objective 4: facilitate access to better and safer healthcare for Union citizens											
Costs											
Direct costs for implementing the Programme						Contribution of other organisations: MEUR23		Contribution of MS in Joint Actions: MEUR 15		Total amount of appropriations MEUR 85	
Direct Cost: Administrative costs	One-off and recurrent	N/A	N/A		Costs linked with preparation or response to call for tenders	Administrative Costs linked with participation of Actions implemented by the Programme (provision of information nomination		EU co-funding for Joint Actions: MEUR		Overall administrative costs for running the entire Programme are presented for all specific	

						and coordination with national entities participating in Joint actions)				objectives and cross-cutting actions	
Benefits											
Direct benefits				Procurement contract awarded: MEUR 27		24 European Reference Networks (ERNs) established		24 European Reference Networks (ERNs) established			
Direct benefits		1.7 million patients treated by ERN members Patients participated in 732 clinical trials within the ERNs				1185 healthcare providers and centre of expertise joined the ERNs 2,100 virtual expert panels opened in the CPMS		27 MS using the tools developed			
Indirect benefits		Easier access to treatment for patients with rare diseases									
Cross-cutting issues and overall Programmes costs and benefits											

Overall Administrative Cost for implementing the Programme										MEUR 10	
Cost for functioning of the executive Agency CHAFEA										MEUR 30	

ANNEX V. STAKEHOLDERS CONSULTATION - SYNOPSIS REPORT

1 INTRODUCTION

This document provides a synopsis or summary of the consultation activities conducted under the *Study to support the ex-post evaluation of the European Commission's 3rd Health Programme 2014-2020*. It was prepared in accordance with the Better Regulation Guidelines Tool 55.[122]

This report is structured as follows:

Section 2 presents the approach to the consultations
Section 3 provides an overview of the results.

2 APPROACH TO THE CONSULTATION

The objective of the consultations was to collect qualitative and quantitative information from stakeholders on their views of the 3rd Health Programme (Programme).

2.1 Stakeholder selection

Eight stakeholder groups (policymakers, governmental public health organisations, international public health organisations, academic and research organisations, non-governmental organisations, healthcare service providers and organisations representing them, healthcare professionals' associations, and patients and services users and organisations representing them) were identified by the study team. The study team then aligned these categories with the groups set out in the Public consultation (PC) typology, which are already set by DG SANTE, to ensure comparability during the analysis and reporting phase of the study.

Stakeholders were identified using the public-facing database[123] for the Programme. The study team exported all stakeholder organisations from this database using a web scraper developed by the team and cleaned the dataset. This enabled us to get a longlist of stakeholder organisations who participated in the Programme. DG SANTE also shared the contact details of the National Focal Points and of some Programme Committee members who had agreed to be contacted for the study. While the study team web scraped the organisations of all those who received funding through grants, there may have been gaps in the list for stakeholders who received other types of funding (e.g. via Procurement Contracts). This was because such information was not stored in the public facing database nor was there a list that could be shared with us for the purposes of the consultation exercise. Further, specific named contacts were not available in the public-facing database. Therefore, the team conducted desk research to collate publicly available contact names and email addresses from the websites of the identified organisations and through other

[122] https://ec.europa.eu/info/sites/default/files/file_import/better-regulation-toolbox-55_en_0.pdf
[123] European Commission (2022) Health Programme Database. Available at: https://webgate.ec.europa.eu/chafea_pdb/health/

desk review sources. In some cases, the study team asked for assistance from HaDEA and DG SANTE to review the list to ensure it complied with their understanding of the Programme's stakeholders, to identify missing stakeholders and/or fill gaps in the contact details.

The lists of stakeholders contacted can be found in Annex 1. An overview of the stakeholder groups invited to participate in the consultations is show in Table 2a.

Table 2a Summary of stakeholders contacted through the consultations

Cross-cutting stakeholders contacted for all consultations		
Additional stakeholders	603[124]	9
Group-specific contact for individual consultations		
Type of organisation	**Targeted survey and PC**	**Interviews**
Policymakers (EU institutions, national government representatives)	100[125]	43
Governmental public health organisations		83
International public health organisations	23	5
Academic and research organisations	15	6
Non-governmental organisations	53	7
Healthcare service providers and organisations representing them	14	4
Healthcare professionals' associations	22	9
Patients and services users and organisations representing them	0	7
TOTAL	**830[126]**	**173**

2.2 Consultation activities

2.2.1 Advertising the consultations

The study team created and used a Stakeholder Network[127] on the Health Policy Platform[128] to disseminate information on the consultation activities. The study team copied key information

[124] The "additional stakeholders" from the survey were: companies/business organisations; consumer organisations; lead or partner organisations of funded actions; EU citizens; independent thematic experts; and public authorities.

[125] Stakeholders for the survey were identified as "public authorities"

[126] This figure does not include a generic mailing sent from our survey software tool to 143 general stakeholder contacts. These contacts were gathered as part of the general stakeholder mapping.

127 Network gathering health stakeholders on specific health policy areas

onto the AGORA network[129] so that all stakeholders could have the chance to participate in the consultation activities. This information was mirrored in the weekly Health Policy Platform newsletters.

In order to increase the number of responses, communication around the consultations was brief and informative, clearly outlining the importance of the consultations and encouraging participation, as well as clearly illustrating how to participate. The communications asked respondents to share the information amongst their own network, encouraging their peers to participate in the consultations.

The first email sent to stakeholders included an explanation on key details including: (a) details of the study; (b) consent procedures for taking part in the study (it was clearly stated that taking part in this research was voluntary); (c) attribution of information (information and quotes were not attributed to individuals, unless explicitly approved); and (d) audio-recording of the interviews and focus groups (for accuracy and note-taking purposes, and only with specific consent). This was also accompanied by an accreditation letter from DG SANTE.

As the PC and the survey were launched simultaneously, communications around these activities sought to clearly highlight the difference between the PC and the targeted survey (to ensure participants were aware of the most appropriate method for them to provide their views). In addition, to make sure that participants responded to the most relevant questionnaire (either PC or target survey), there was a filtering question at the start of both questionnaires on whether the participant (or their organisation) had been directly involved in the Programme design or implementation. If it became apparent that the respondent was using the wrong questionnaire, a prompt appeared encouraging them to switch to the other consultation activity.

Table 3a details the activities undertaken to boost the response rate to the consultations.

Table 3a – Activities undertaken to advertise the consultations

Consultation method	Activities undertaken to advertise the consultation
PC	- Emails from ICF to all contacts in the database collated by ICF - Emails from DG SANTE to their stakeholders (including all members of the Programme Committee) and the contact database collated by ICF - The Health Programme webpage: https://ec.europa.eu/chafea/health/funding/index_en.htm - DG SANTE webpage: https://ec.europa.eu/info/departments/health-and-food-safety_en - The Health Policy Platform: https://webgate.ec.europa.eu/hpf/ (and the HPP newsletter)
Survey	- Emails from DG SANTE to their stakeholders and the contact database collated by ICF

[128] European Commission (2022) Health Policy Platform. Accessible : https://webgate.ec.europa.eu/hpf/#:~:text=The%20EU%20Health%20Policy%20Platform%20is%20an%20interactive%20tool%20to,actions%20among%20a%20wide%20audience.

[129] Online space accessible to all users of the Health Policy Platform

	- Advertisements on the Health Policy Platform including the Stakeholder Network for the study and the Agora Network which were mirrored in the Health Policy Platform newsletter
Interviews	- Emails from ICF to selected contacts in the database collated by ICF - Asking interviewees to advertise the study to their network
Focus groups	- Emails from ICF to selected contacts in the database collated by ICF - Focus group participants sharing the invitation email with contacts who were involved in their funded action - Focus group participants were given the opportunity to do a follow-on interview if they had further feedback to provide - ICF worked with DG SANTE to identify the most suitable stakeholders for the focus group with EU institutions on Procurement contracts and all funding mechanisms

2.2.2 Targeted survey

The purpose of the targeted survey was to collect evidence on the views and perceptions of those with direct experience of the Programme regarding its relevance and implementation and performance. The survey was targeted at those who were directly involved in the Programme design and/ or implementation (including those who received funding from the Programme) and could therefore answer specific questions about Programme implementation and performance.

Identification and recruitment of participants

The identification and recruitment of participants was in line with section 2.2.1 on contacting stakeholders.

Conducting the targeted survey

The targeted survey was implemented using ICF's survey platform (Qualtrics). Before participating in the survey, respondents were provided with a privacy statement to ensure they were informed of their rights under the General Data Protection Regulation (GDPR)[130] in relation to the collection and retention of their data and that they understood that their participation was on a voluntary basis. The collected personal data and all information related to the consultation were recorded in a secured and protected database hosted at ICF's secure data centre within the European Union. The database is not accessible from outside ICF. Inside ICF, the database can be accessed using a User-ID/Password. Any data transferred between ICF and DG SANTE was done using the secure file-sharing system OneDrive, which is produced and maintained by Microsoft.

[130] https://gdpr-info.eu/

The study team kept the survey open from 10 March to 13 May 2022. The survey was originally planned to be kept open from 10 March to 21 April. Despite multiple email reminders, there was a lack of response from stakeholders, and so the survey deadline was extended to 6 May. The study team sent out two email communications to stakeholders, one to all contacts notifying them of the extension and encouraging their participation, and another tailored to those who had started but not completed the survey. For this latter group, the study team offered tailored support including organising a phone call to fill in the survey with them, or to organise an interview instead. The study team also provided Word versions of the questionnaire when requested so that multiple people within an organisation could contribute to the survey submission. The survey deadline was then extended again to 13 May to encourage more participants to take part. All stakeholders were informed of this including those who had started but not completed the survey. DG SANTE also emailed all stakeholders identified in the ICF contacts file to encourage participation.

Analysis

The questions asked in the survey covered the following themes: effectiveness, efficiency, relevance, coherence, and EU added value. Analysis included: cross-tabulations of closed answer questions and qualitative analysis of additional textual feedback provided by respondents in open answer questions and through position papers uploaded to support their responses. Manual qualitative analysis was used to provide insight into the themes being discussed.

2.2.3. Public consultation

A Public consultation (PC) was undertaken to provide the general public and all interested parties with the opportunity to provide information and opinions on the matters to be addressed in the study. The PC was targeted at all those who have an interest in the Programme but who had not necessarily been directly involved in the Programme design or implementation. Questions were therefore relatively high-level, exploring the overall perception of the Programme, and its relevance to broader health needs and objectives. The PC asked respondents to give their view on the effectiveness, efficiency, relevance, EU added value and coherence of the Programme.

Identification and recruitment of participants

Steps taken to identify stakeholders can be found in section 2.2.1.

Conducting the PC

The PC was carried out using the EU Survey tool. The PC was made accessible from the Health Policy Platform site of the European Commission: https://webgate.ec.europa.eu/hpf/.

The PC was launched on 10 March 2022. The PC was originally planned to close on 3 June 2022. However, during the last 2-3 days before closure of the PC, DG SANTE's server was

down, and the online questionnaire was inaccessible to respondents. DG SANTE therefore extended the deadline by 1 week to 10 June.

Analysis

The analysis of the PC included: cross-tabulations of closed answer questions and qualitative analysis of additional textual feedback provided by respondents in open answer questions and through position papers uploaded to support their responses. Manual qualitative analysis was used to provide insight into the themes being discussed.

2.2.4. Interviews

Targeted telephone interviews aimed to help the study team to understand in more depth the design and implementation of the Programme. The interviews were also used to help us triangulate findings drawn from other data collection tasks and fill gaps in evidence collected through other tasks or where the study team identified contradictory evidence.

Identification and recruitment of participants

The study team selected potential interviewees based on their field of knowledge and expertise, their level of involvement with the Programme and on their likely ability to provide information on key issues of the evaluation. Accordingly, interviewers tailored the questions for each interview to explore specific points, rather than aiming to cover all aspects of the evaluation with each interviewee. In this way, the study team aimed to make maximum and efficient use of the time-constrained consultation period and of the resources available.

The study team planned to carry out up to 45 interviews and anticipated speaking with representatives from eight stakeholder groups to ensure the consultation activity was representative of different perspectives. The study team proposed to conduct the most interviews with government policymakers since these include the national focal points who were pivotal in shaping Programme priorities. The study team also proposed to conduct many interviews with national public health organisations as they also played a vital role in bringing health-specific knowledge and understanding at MS level. For the remaining stakeholder groups, the study team allocated two or three interviews each. The study team also allocated a few interviews to be used as needed across the stakeholder groups based on response rate and gaps in the study.

Once a stakeholder responded to the invitation, the study team followed up with a short questionnaire to facilitate tailoring of the topic guides. The study team also followed up by email to schedule a telephone call or virtual meeting (as preferred by the stakeholder) and find a suitable date and time for an interview.

After being invited to interview, each stakeholder that did not respond to the invitation was contacted up to three additional times. A detailed log of all invited interviewees, contacts and consent was systematically stored on password protected computers, which helped ensure effective and efficient interview scheduling.

Conducting the interviews

The interviews followed a semi-structured topic guide, tailored to the involvement of the stakeholder in the Programme. Each interview was conducted by phone or Microsoft Teams. Each interview lasted approximately 40-60 minutes. The working language of the interviews was English.

A high-level summary of topics to be covered in the interviews (in the form of an abridged topic guide) was sent to interviewees in advance, to allow time for interviewees to prepare.

Interviews were recorded upon interviewee's consent. Recordings were stored on secure servers during the study to ensure the completeness and accuracy of qualitative and quantitative data collected.

Analysis

A summary of key points was drafted by the interviewer after each interview using the audio-recording to identify specific details and obtain direct quotes where needed. Interview write-ups were analysed thematically in order to match points discussed in each interview to the questions in the study's analytical framework. This was done per stakeholder group to allow analysis per group.

2.2.5. Focus groups

The objective of the focus groups was to gain further insight into the main funding mechanisms of the Programme.

The study team conducted five focus groups, covering each of Project Grants, Operating Grants, Joint Actions, Procurement contracts, and a final focus group on all funding mechanisms. Due to a lack of participation and availability of DG SANTE and HaDEA staff, the fifth focus group was concluded early, and follow-up interviews were scheduled instead.

Identification and recruitment of participants

There is no fixed ideal number of participants for a focus group, as this depends on the level of experience of the participants, how sensitive the topic is, how complex the questions are, and how long the team has for the discussion. For each focus group, the study team aimed to recruit between 5 and 12 participants. Recruiting a minimum of five participants meant that the study team had enough participants to engage in a meaningful discussion and gather sufficient feedback from a variety of stakeholders. Limiting the focus groups to a maximum of 12 participants meant that participants would be more comfortable and willing to speak, that each participant could have an opportunity to share insights and observation, and facilitators could more efficiently moderate the discussion so that it stayed on topic.

When a stakeholder responded to the invitation, the study team followed up with an email with further information including an agenda for the focus group and asking for the name and contact email of any colleagues who may want to attend with them. The link to join the focus group and a guidance note was then shared in advance with all attendees. For each focus group, the study team kept a detailed log of all invited participants responses. After being invited to the focus group, each stakeholder that did not respond to the invitation was contacted up to three additional times.

Conducting the focus groups

The focus groups took place virtually, online. The benefit of this was that more individuals were able to participate and from different locations. The study team conducted the focus groups via Microsoft Teams and used tools such as Sli.do which allowed for instant polls, word-clouds and quantification of stakeholder feedback.

In advance of the focus groups, the study team provided a guidance note to participants so they could consider the topics of the focus group in advance.

The focus groups started with a presentation on the Programme with emerging findings from the study to date, a plenary session to discuss overall views of the Programme and the specific funding mechanism in question, followed by sub-groups to discuss specific evaluation criteria, and finally a plenary session to share views as a group. Each focus group lasted for up to 4 hours depending on the topics to be covered and the participation of attendees.

Analysis

Notes about the discussions in the plenary sessions and breakout rooms were summarised in a report for each focus group. These reports were organised by evaluation question to enable findings to be easily integrated into the main report.

Limitations

The **online survey** and **PC** yielded fewer replies than anticipated, despite a dissemination campaign and reminder emails. This may be due to a lack of engagement by stakeholders and other contextual factors (including delays to the overall study timeline, the study being run after the launch of the new health programme, and thus a risk of de-prioritisation of the previous programme). A larger number of survey responses would have provided greater depth to the qualitative analysis, but the coverage of stakeholder interests was good, with no obvious gaps (see section 3 for further details).

Similarly, for the **stakeholder interviews**, multiple invitations were sent to stakeholders from 30 March 2021 to 27 June2021, however targets per stakeholder group were not met for two groups: government policymakers, and healthcare service providers and organisations representing them. The target for government policymakers was 20 and 10 interviews were conducted; the target for healthcare service providers and organisations representing them was 2-3, and 1 interview was

conducted. While the target was to have 45 participants in the interviews, despite substantial attempts to engage with stakeholders, 34 stakeholders participated in total. This figure includes follow-up interviews which were scheduled to compensate for a focus group with DG SANTE staff on 'Procurement contracts' and 'All funding mechanisms'. This is because the participation from DG SANTE was limited due to lack of staff availability.

3 OVERVIEW OF CONTRIBUTIONS

The sample of organisations consulted with covered a range of sectors, engagement with the Programme and geographic areas. All the key stakeholder groups were covered by at least one activity.

Targeted Survey

While no specific quota was set, the study team aimed to receive at least 70 responses (the number received in the mid-term evaluation). Due to a limited engagement by stakeholders and other contextual factors, a total of 32 fully completed responses were received. Most of these came from public authorities (20 responses, 62%), half of which were from central government or a ministry of health (10 responses, 50%) and the other half were public health authorities or agencies (10 responses, 50%). Seven responses were also received from non-governmental organisations (22%), and five from academic/research organisations (16%). No responses were received from consumer organisations, or from company/business associations.

Almost three quarters of survey respondents (23 responses, 72%) worked for an organisation focused on only one country, while the rest (9 responses, 29%) worked for an organisation with a pan-European or international focus.

Almost all survey respondents were either directly involved in the implementation of the Programme (16 responses, 50%), or stakeholders who benefited from the Programme (14 responses, 44%). Only one stakeholder directly involved in the design of the Programme responded to the survey (3%), and only one respondent said they were not directly involved in the Programme but only had an interest in it (3%). No responses were received from stakeholders directly involved in the evaluation of the Programme.

Respondents who said they were directly involved in the Programme or benefited from it were asked about their awareness of the different types of funding instruments. Almost all said they were aware of Joint Actions (30 responses, 97%). Most respondents were also aware of Project Grants (20, 65%) and Operating Grants (13, 42%). However, less than a third of respondents were aware of the Health Policy Platform and Health Award/Health Prizes (11, 35%), and even fewer knew about Direct Grants to international organisations (8, 26%) and Procurements Contracts (7, 23%).

Out of the 32 respondents, a majority (20 responses, 63%) had been involved in the management and administration of an action from the Programme (e.g. filled in an application form).

Public consultation

Whereas no specific quota was set, the study team aimed to receive at least 133 responses (the number received in the mid-term evaluation).

Due to a limited engagement by stakeholders and other contextual factors, a total of 69 responses were received to the PC. Three responses were identical (including responses to open-ended questions), and so they were considered as one response. Analysis therefore focused on 67 responses. More than a quarter of these came from public authorities (18 responses, 27%). These public authorities were mostly national (14 responses), but a few answers were also received from local public authorities (2 responses), as well as regional or international authorities (1 response each). Eleven of these were public health authorities or agencies, and seven were central governments or ministries of health. Responses were also received from EU citizens and academic/research institutions (16 responses each, 24%), and from NGOs (15 responses, 22%). In addition, a few responses were received from companies/business organisations (2 responses, 3%).

Respondents came from 22 different countries (AT, BE, BG, CH, CY, CZ, DE, DK, EL, ES, FI, FR, HR, IE, IT, LT, PL, PT, SE, SI, SK, UK). The most commonly represented countries were Spain (11 responses, 16%), Belgium and Italy (7 responses each, 10%) and Poland (6 responses, 9%).

Just over half of respondents said that they had applied for funding from the Programme (34 responses, 51%). Just over a third said that they had not applied for funding through the Programme (23 responses, 34%) and the rest either said they were not aware, or that the question was not applicable to them (10 responses, 14%). More than four in ten respondents said that they had received funding from the Programme (28 responses, 42%). Almost half of respondents said they had never received funding (30 responses, 45%) and the rest said they did not know (9 responses, 13%).

The type of funding instruments that were most familiar to respondents was Joint Actions (26 responses, 39%), followed by Project Grants (20 responses, 30%) and Operating Grants (8 responses, 12%). Only five or fewer respondents said they were familiar with the Health Policy Platform and Health Award/Health Prize (5 responses, 7%), Direct Grants to international organisations (3 responses, 4%) or Procurement Contracts (1 response, 1%). More than half of respondents did not provide an answer to this question. Unsurprisingly, when asked about what types of funding instruments they benefited from, respondents cited the same instruments: Joint Actions (20 responses, 30%), Project Grants (13 responses, 19%), and Operating Grants (3 responses, 4%).

Interviews

An overview of the type of stakeholders who participated in the interviews is shown in 0.

Table 4a Stakeholder interview participants

Types of stakeholders	Number of participants
Policymakers (EU institutions, national government representatives)	10
Governmental public health organisations	7
International public health organisations	2
Academic and research organisations	4
Non-governmental organisations	4
Healthcare professionals' associations	4
Healthcare service providers and organisations representing them	1
Patients and service users and organisations representing them	2
Totals	**34**

Focus Groups

There were between 3-10 participants at each focus group (Table 5a). Overall, the groups tended to be somewhat homogenous, however this was intentional as only certain groups have used certain mechanisms under the Programme. For example, Operating Grants were given to NGOs, so NGO representatives comprised most of the focus group participants on this topic.

Table 5a. Focus group participants

	1: Project Grants	2: Operating Grants	3: Procurement contracts	4: Joint Actions	5: Procurement mechanisms	Total
Government policymakers	1		8	2	3	**11***
Governmental public health organisations	1			4		**5**
International public health organisations						**0**
Academic and research organisations	1			4		**5**
Non-governmental organisations	2	8		0		**10**
Healthcare service providers and organisations representing them	2	1				**3**
Healthcare professionals' associations						**0**

Patients and services users and organisations representing them						**0**
Total	**7**	**9**	**8**	**10**	**3**	**37**

**Note the three participants in focus group 5 were also present at focus group 3, therefore the totals do not sum*

There were no stakeholders at any focus groups from the following stakeholder groups: international public health organisations, healthcare professionals' associations, and patients and services users and organisations representing them. Further information about the distribution of participants by focus group is given below:

- 1 (Project Grants): Attendees worked for seven different organisations and had taken part in seven projects.
- 2 (Operating Grants): Three of the participants were from the same NGO.
- 3 (Procurement Contracts): All but one participant were from DG SANTE. The remaining participant was from HaDEA.
- 4 (Joint Actions): Attendees were from seven organisations (three organisations had two representatives each). Attendees represented seven Joint Actions.
- 5 (All funding mechanisms): All attendees were from DG SANTE.

4 ANALYSIS OF THE REPLIES

The following subsections summarise the evidence collected and analysed across the consultation activities.

Relevance

During the implementation of the Programme, the main health needs in the EU related to health promotion and better and safer healthcare. An interviewed academic / research stakeholder, as well as a few NGOs, reported that the promotion of healthy behaviours (objective 1) was a key health need in the EU.[131] There were also some reported key health needs which related to objective 4 (better and safer healthcare), for example an academic / research stakeholder reported that visibility of rare diseases was a key healthcare need. Some interviewed

[131] For example, a stakeholder from an organisation representing patients and services users reported the main healthcare needs included a lack of accessibility of PrEP (a preventative drug for HIV), and a need to reduce stigma and discrimination related to HIV and AIDS.

stakeholders[132] also reported that health and social inequalities represent a key health need in the EU as there are health differences across regions and socio-economic groups. There were also a few identified needs under objective 3 (health systems).[133]

The Programme has largely been relevant to these key health needs in the EU. More than three quarters of PC respondents said that the Programme correctly identified the health and healthcare needs and problems at the time of its development, to at least a moderate extent (52 responses, 77%). Similarly, a large majority of survey respondents said that all four of the Programme's specific objectives were relevant in relation to EU health needs at the time of the Programme's development. PC respondents and interviewees[134] believed that all four of the Programme's specific objectives were very relevant in relation to EU health needs. In the PC, objective 1 was rated as the most relevant to EU health needs (46 responses, 69%). Objective 1 was also deemed relevant by most survey respondents (29 out of 32 or 91%). In the survey, objective 3 was seen as the most relevant out of the four priorities, with almost all respondents considering it was relevant to at least a moderate extent (31 out of 32, 97%).

There were some factors about the Programme which enabled the Programme to address the most important health needs. In interviews, some government policy makers (at the regional, national, and EU level) reported that the Programme was aligned with national-level priorities potentially due to the involvement of participating countries in designing parts of Programme. In the focus group on procurement mechanisms, a government and policy maker reported that each unit in their organisation contributed to defining the Health Programmes, ensuring that health needs are covered throughout the Programme because all policy units are involved.

***The Programme has for the most part remained relevant to changes in health needs over time*.** In the survey, respondents were asked about the extent to which the Programme's specific objectives had remained relevant over time. More than two thirds (20 responses, 67%) said that objective 2 had become more relevant over time, mainly due to new and emerging cross-border health threats during the time of the Programme[135] and the severity of communicable diseases. This was a higher proportion than for the other three specific objectives (between 12 and 13 responses, or between 39% and 42%). One specific change in health needs was that in 2015, the

[132] Including an academic / research stakeholder, a governmental public health organisation, and an organisation representing patients and services users

[133] Including a lack of training in certain procedures or conditions or about health inequalities (academic / research stakeholder; healthcare professionals' organisation) and a lack of capacity to monitor and/or respond to serious cross-border health threats (academic / research stakeholder; governmental public health organisation).

[134] Including some governmental policy makers and governmental public health organisations, a few stakeholders from organisations representing patients and services users, an academic / research stakeholder, a stakeholder from a healthcare professionals' organisation, and a stakeholder from an organisation representing healthcare service providers

[135] A note in the survey indicated to respondents that Covid-19 was not in the scope of this study. However, respondents did mention Covid-19 as a factor explaining why this specific objective became more relevant over time. Other factors mentioned by respondents included cross-border movement/migrations, globalisation and environmental threats.

EU was impacted by increased migration; some governmental public health organisations felt this need was addressed, however some stakeholders[136] reported that refugee and migrant health was not a topic adequately addressed by the Programme. Another major health challenge during the period of the Programme was the Covid-19 pandemic, and for the most part stakeholders[137] felt this need was well-addressed. However, in the focus groups on Project Grants, a governmental public health organisation reported it would have been beneficial if the Programme had more leeway to act on unanticipated priorities through contingency funding.

There were some limiting factors to the relevance of the Programme overall. Overall, a few stakeholders[138] indicated that the objectives of the Programme were not always as aligned to key health needs as they could have been. A few governmental public health organisations reported that healthcare needs were not addressed because of factors to do with participating countries, for example the countries were not involved enough, or experienced financial difficulties which hindered their ability to participate in activities. Another somewhat commonly reported limitation to the relevance of the Programme was insufficient funding.[139] Most stakeholders consulted in the focus group on Project Grants considered that the thematic priorities of the Programme were too broad.

There were a few notable topics or needs which the Programme did not adequately address. In the PC, a large proportion of respondents said that some relevant problems or needs were not identified by the Programme at the time of its development (30 responses, 45%). Some consulted stakeholders[140] did not feel the Programme adequately addressed needs related to health inequalities. For example, a few stakeholders from an organisation representing patients and service users also reported the work on access to healthcare and health inequalities has not been done comprehensively, particularly around patient empowerment. A few stakeholders[141] also reported the Programme did not adequately address mental health or wellbeing. PC respondents said that although the Programme acknowledged the high prevalence of mental health problems, they felt that the issue was not extensively included as a key thematic priority in and of itself. They added that the Programme could have been a key tool in integrating a psychosocial approach to mental wellbeing, considering and linking to the social and environmental factors that undeniably play a role in community positive mental health. Some stakeholders also

[136] An interviewed academic stakeholder and participants in the focus group on Project Grants.
[137] Academic / research stakeholders; stakeholder from an organisation representing patients and services users; NGO.
[138] including a few governmental public health organisations, a few NGOs, and a few healthcare professionals' organisations.
[139] Reported by an NGO and a stakeholder from a healthcare professionals' organisation.
[140] OPC respondents; interviewed governmental public health organisation; A few stakeholders from an organisation representing patients and services users; academic / research stakeholders.
[141] an interviewed academic / research stakeholder and participants in the focus group on Project Grants

reported the Programme did not adequately address environmental issues[142], including interplays between the climate and health, as key health needs in the EU.

There was clear alignment between funded actions and the specific thematic priorities set out by the Programme. In the survey and interviews[143], a large majority of respondents said that the Programme's funded actions were aligned with the Programme's four specific objectives. In particular, 85% of respondents to the survey said actions were aligned to a large or moderate extent with objective 1. However, a national governmental policy maker reported that some objectives of Programme were implemented or used more than others. For example, actions related to health security (objective 2) were not used often. Two EU-level policy makers reported that the objectives and thematic priorities were very broad and wide-reaching, therefore it was not possible to address them all with the same level of intensity or funding.

The funded actions were also aligned with the Commission's wider priorities. In the survey, a large majority of respondents said that the Programme's thematic priorities were relevant to the Commission's wider priorities to a large (36%) or moderate extent (30%). More than 30% of respondents said the Programme's thematic priorities were relevant to a large extent to the following two Commission's wider priorities: "Promoting our European Way of Life" and "Europe 2020 strategy for smart, sustainable and inclusive growth". Notably, there were large rates of "I don't know" responses to this question (between 10-33% of respondents varying by Commission priority), illustrating how those involved with Programme may not have been aware of the Commission's wider priorities.

The Programme has largely been relevant to citizens' needs. In the survey, almost 90% of respondents believed that the Programme's thematic priorities were relevant in light of citizens' perceptions of key health issues in the EU, to at least a moderate extent (28 responses, 89%). Similarly, almost 90% of respondents believed that the Programme responded to citizens' health needs, to at least a moderate extent (27 responses, 86%). However, a national public authority involved in the Programme implementation said that these were not relevant at all due to a mismatch of health priorities between the Programme and the national context, citing that, in their country, the waiting list to receive medical services was a greater problem and that this was not resolved by the Programme thematic priorities. Two EU-level NGOs who benefited from the Programme noted that the funding opportunities for childhood cancer were valuable but insufficient to address the magnitude of the issues in this disease area.

There has been some variation in the engagement of citizens with the Programme. Some interviewees reported there were differences in the engagement of citizens in the Programme. A few stakeholders reported that there were differences across the Member States in the participation and effectiveness of work relating to migrants (academic / research stakeholder).

[142] academic / research stakeholder and a governmental public health organisation.

[143] an academic / research stakeholder, a few governmental policy makers and governmental public health organisations, a stakeholder from an organisation representing patients and services users.

An NGO reported that Balkan countries are facing severe funding problems and are struggling with more basic services, and different countries have different needs and interests. Further, a stakeholder from an organisation representing patients and services users reported there has not been much investment in disseminating the Programme, which has limited citizen engagement. Interestingly, a stakeholder from an organisation representing patients and services users reported that in many cases citizens may be engaged in actions of the Programme but not know there is a Programme behind it.

Effectiveness

Consulted stakeholders reported that overall, the Programme contributed to a more comprehensive and uniform approach to health issues across the EU. Most targeted survey respondents (20 respondents, 63%) and PC respondents (37 responses, 55%) believed that measures implemented by Member States were aligned with the specific objectives and thematic priorities of the Programme, at least to a moderate extent. Similarly, most survey respondents believed that national programmes and actions reflected evidence and evidence-based approaches developed through Programme funding (23 respondents said this was true to at least a moderate extent, 72%).

However, some limitations exist mostly due to national differences in terms of organisation of health systems and national priorities. Some stakeholders who contributed to the PC noted limitations to the alignment of measures implemented by Member States with the specific objectives and thematic priorities of the Programme, mostly because national health systems are complex and sometimes fragmented infrastructures and national priorities do not always reflect Programme priorities.

Overall, consulted stakeholders reported that the knowledge produced by the Programme was used in policymaking and the Programme contributed to improvements in health and healthcare in the EU and at Member State level. For instance, several interviewed national policymakers reported that actions funded under the Programme, including Joint Actions and other funded projects, influenced national strategies, helped establish national plans and create national legislation. Moreover, 79% of survey respondents believed that the Programme actions led to new knowledge and evidence which were used in the development of policy and decision-making at least to a moderate extent.

Overall, most survey respondents believed that **the Programme actions led to general improvements in health and healthcare in the EU and at Member State level** (23 respondents said this was true to at least a moderate extent, 73%). Respondents said that the Programme contributed to improvements mainly in the following areas: vaccination in the EU and at Member State level (19 respondents said this was true to at least a moderate extent, 60%), AMR prevention in the EU and at Member State level (18, 57%), and the creation of a well-functioning HTA system in Europe (18, 57%).

Most consulted stakeholders believed that **the Programme contributed to some extent to the EU's influence on health and healthcare standards, policies and practices at international level**. Overall, public authorities surveyed as part of this study believed that the results of Programme (e.g., establishment of Joint Actions and European Reference Networks, evaluations and studies, establishment of EU-wide data systems) were used at an international level, and that the EU's coordination with international bodies in the field of health had been strengthened in Programme priority areas (18 respondents said these two statements were true to at least a moderate extent, 90%).

Not many consulted stakeholders were familiar with the exceptional utility criteria, but those who were felt it increased participation from some countries. In the survey, a majority of public authorities said they did not know whether their Member State applied for funding under the exceptional utility criteria (14 respondents, 70%). In the focus group on Joint Actions, an academic / research organisation stakeholder reported that in two Joint Actions they worked on, they used the exceptional utility criteria as they had several low Gross National Income (GNI) countries involved, so more budget could go to low GNI countries. Nevertheless, some stakeholders felt the criteria increased participation from low-GNI countries[144]. Some public authorities reported factors which contributed to their country's participation, including securing co-financing, followed by the administrative capacity to manage actions in the Member State and language skills.[145]

However, there may have been some limitations to the benefits of the exceptional utility criteria. In the survey, only six academic/research organisations and NGOs (50% of survey respondents) said that the scope of the exceptional utility criteria reduced the differences in costs and benefits between countries. Similarly, more than half of surveyed respondents said they did not know whether simplification measures related to the exceptional utility criteria had reduced administrative costs (17 responses, 53%). Those who did provide an answer tended to say that these measures did not reduce administrative costs, or only to a small extent. A number of factors determined stakeholders' decision not to apply for funding under the exceptional utility criteria including that the criteria is not always easy to use[146]; the lack of administrative capacity

[144] "Low-GDP" and "high-GDP" are used here to refer to countries which did and did not meet the exceptional utility criteria, respectively.

[145] Further, in interviews, some EU-level government policy makers felt that there were more partners participating low-GDP countries due to added benefits from the exceptional utility criteria. A stakeholder from HADEA mentioned information sessions run by the Agency as particularly useful for alerting potential beneficiaries to actions. Further, in the focus group on joint actions, a governmental public health organisation reported that the criteria were sensible and effective for partners who worked heavily on the action. In the same focus group, a stakeholder from a Governmental public health organisation reported that the criteria made it much easier for partners to participate as a 40% contribution is prohibitive to some partners, so the 20% level makes it more accessible.

[146] Reported by an academic / research organisation stakeholder in the focus group on Joint Actions

to manage actions in the Member State; administrative burden (once a project is up and running); complexity of the application process.[147]

Some consulted stakeholders believed that Programme results have been published to a good extent. Some interviewed stakeholders and participants in the focus group on Joint Actions confirmed that Programme results and outputs were published on the HaDEA dedicated database. Moreover, different stakeholders from academic institutions and national policymakers reported that scientific publications linked to Programme actions were published in scientific journals. Stakeholders noted that barriers to accessing results of funded actions include that many deliverables were delayed due to the Covid-19 crisis, as well as a lack of clarity regarding where publications can be found.

Publications resulting from the Programme are available to wider stakeholders and the public to a moderate extent. Most survey respondents said they had access to publications resulting from the Programme's actions/outcomes/results at least to a moderate extent (23 respondents, 73%). Some interviewed stakeholders and participants in the focus group on Joint Actions indicated that dissemination activities were effective in reaching the scientific community and the wider public.

However, improvements to the dissemination of results are needed. Several consulted stakeholders reported limitations to access to publications and dissemination activities, including a lack of contact between researchers and the private sector; weak engagement with health services and healthcare professional; and lack of a systematic way to monitor the extent to which Programme beneficiaries disseminate findings after a project.

Data emerging from the consultation activities shows that stakeholders have used outputs and results from Programme activities. Some results used by stakeholders included outputs from the EUnetHTA which supported legislation; results of CHRODIS and CHRODIS + which generated screening guidelines; outputs of the RARHA Joint Action and the Oramma projects; the Health at a Glance publications, chronic disease reports and reports on pharmaceuticals.

Moreover, ***Programme results have been reported as impactful by different stakeholders***, for instance by raising awareness among patients and healthcare providers in the field of digital health, tackling scepticism and helping realise a European Health Data Space; proving to ministries of health the effectiveness of undertaken interventions and creating an impact on citizens at the local and regional level.

Evidence reported by stakeholders suggests that ***some of the previous recommendations of the Programme have been addressed***. This includes strengthening and building links between the Programme and wider Commission & EU policy agenda to maximise impact. There is evidence

[147] Three public authorities responding to survey and a stakeholder from an NGO in the focus group on project grants

that there is room to improve systems for monitoring programme implementation, and thus other recommendations are likely yet to be implemented.

Some consulted stakeholders felt the effects of the Programme were sustainable. In the survey, six respondents (19%) thought that the results of the Programme were very sustainable. Similarly, some interviewees and focus group participants felt the actions were sustainable. Some elements or aspects of the Programme itself seemed to help ensure projects would be sustainable following their conclusion. For example, according to a governmental public health organisation, adding the compulsory work package 4 on sustainability[148] was a key success factor of Programme. Stakeholders from an international organisation felt that when funds were more structured, sustainability was more assured[149]. Another key to ensuring sustainability seemed to be the relationships and connections built through an action.[150] Some results have been sustainable because of the actions of participating countries.[151]

Some consulted stakeholders mentioned specific topics which were seen as having particularly high sustainability. Survey respondents highlighted the following specific fields as having achieved most sustainability: Health Technology Assessments (8 responses, 25%), vaccination policies (5, 16%) and antimicrobial resistance (4, 13%). According to an NGO and an EU-level government policymaker, the Programme increased knowledge and skills in crisis preparedness for professionals in the health sector and NGOs, and evidence generated on this topic will be used beyond the Programme. There were also certain funded actions which seemed to be especially sustainable, including many Joint Actions.[152] A few stakeholders also highlighted sustainability within the European Reference Networks, and finally, the SCIROCCO[153] project has created sustainable outputs.

However, there were some reported challenges to sustainability.

[148] work package introduced as part of all funded actions to ensure demonstration of sustainability after funding period ends

[149] Further, a stakeholder from DG SANTE highlighted that implementation of best practices are a positive way of ensuring sustainability as it is moving from an older to a newer system. Related to best practices, in the focus group on joint actions, an academic/research organisation stakeholder discussed how the transfer of good practices to other regions across Europe needs to be supported by guidelines which in turn support knowledge from expert beneficiaries. Overall, a stakeholder from a governmental public health organisation reported that there was increased planning around sustainability from Member States and the Commission regarding the Programme.

[150] Reported by academic/research stakeholders and a governmental public health organisation

[151] An EU-level government policy maker felt that the Programme allowed Member States to see whether actions are suitable and if they are, they can apply for other funding, and indeed an interviewed academic/research stakeholder stated that many projects received more funding to continue beyond the Programme. In the focus group on joint actions, an academic/research organisation stakeholder highlighted policy dialogues as a useful approach to make actions more sustainable, commenting on good buy-in from policymakers in member states. As a specific example of Member States creating sustainability, an EU-level government policy maker mentioned that Member States drafted and introduced their national cancer strategies following Programme.

[152] EUnetHTA, AMR Joint Actions, Joint Action on alcohol, Shipsend JA, CHRODIS and CHRODIS+, JA Healthy Gateways, and a joint action involving promotion of policy dialogues for media advertising beverages and food for children.

[153] Scaling Integrated Care in Context

For purposes of this study, we consider sustainability to mean the extent to which the results of funded actions are likely to last once funding from the Programme has ceased. Most respondents thought the results of the Programme were somewhat sustainable (21 responses, 66%). Further, two stakeholders[154] reported that results from Programme were not always integrated into policy. It seems that some threats to sustainability were regarding issues with sustained funding including due to a lack of permanent funding in the EU budget.[155] There may also be barriers related to political will or interest to continue with work; some survey respondents stated that results might not be used nor capitalised on fully by Member States due to a lack of interest and involvement from national authorities which leads to results of funded actions remaining at a local level. Some stakeholders[156] also mentioned that the design of the programme or actions did not lend themselves to increasing sustainability: in the survey, an EU public authority involved in the Programme design explained that results were mostly too limited in scale and/or ambition to be sustainable, and that sustainability was not "*in the DNA of the Programme or the participants*".

Efficiency

The Programme was largely viewed as cost-effective, with high quantities of work achieved with a low budget. Generally, stakeholders interviewed across all groups, actions, and funding mechanisms felt that the Programme was relatively cost-effective, with many highlighting the quantity and quality of work achieved with a small budget. Respondents to the stakeholder survey considered some costs associated with the Programme to be reasonable and kept to a minimum necessary to achieve expected results. Deemed to be most reasonable (to a moderate extent) by those who provided an answer were management costs for funding (10 respondents, 50%) and Programme operational costs (design and implementation) (8 respondents, 40%). Several stakeholders reported achieving more than they expected to with the funding they received, and those who had worked on Joint Actions particularly stressed the cost-effectiveness of their work.[157] In the survey, internal factors which positively influenced the Programme's results were identified as collaboration between Member States and development of guidance to assist funding applicants (22 responses each, 69%), followed by facilitation/coordination of the Programme by DG SANTE/CHAFEA (20 responses, 63%). External factors that positively influenced the Programme's results were identified as science and technological progress in the area of health and healthcare (25 responses, 79%), followed by solutions developed at national

[154] A stakeholder from an organisation representing patients and services users in interview and a governmental public health organisation in the focus group on project grants

[155] A stakeholder from DG SANTE.

[156] EU public authority involved in the Programme design, EU-level government policymaker, NGO, government public health organisation, Healthcare Professionals' Association.

[157] Including a stakeholder from a governmental public health organisation and a government official/policymaker

level, or by private or non-for-profit actors (19 responses, 60%) and changes in citizens' opinions or perspectives on health systems (13 responses, 41%).

While there were some deviations from the originally planned resources, this was expected and not seen as an issue. Some stakeholders reported deviating from planned resource budgets due to personal costs, partners leaving the project, the Covid-19 pandemic, lack of Member State capacity, or changing priorities over the course of the action. However, due to the high number of partners involved in some actions and the duration of projects, it was generally expected that changes would be made to budgets. Several stakeholders (particularly those involved in Project Grants and Joint Actions) were grateful that the budget could be changed without having to request an amendment from HaDEA; budgets were permitted to be transferred between allowed institutions at a certain percentage because of Covid-19. The flexibility of the management of the budget in the Programme was thus identified as a key success in cost efficiency.

There were some factors of the Programme which meant that costs may not have been proportional to all benefits. A large proportion of respondents said some types of costs were either not reasonable or only to a small extent: administrative costs for applicants and CHAFEA (8 responses, 40%), and monitoring and reporting costs for Member States and the Commission (5 responses, 25%). Factors influencing any disparities between Programme funded action costs and the expected results were to do with additional costs associated with Programme preparation, coordination, administration, and delivery, followed by additional costs for personnel, and, to a lesser extent, by additional costs for materials.

According to survey respondents, external factors which had a negative influence on the results of the Programme included changes in prevalence and severity of communicable diseases, and the demographic context affecting health and sustainability of health systems (9 responses each, 29%), followed by new and emerging cross-border health threats during the time of the Programme (6 responses, 19%).[2] Stakeholders in interviews and focus groups stressed the need for tasks to be commensurate with the budget if costs are to be outweighed by benefits. Stakeholders who had utilised Project Grants highlighted that projects focused on scaling up findings, exchange, and promotion of best practices needed to receive more support that is proportional to the expected benefits. Stakeholders in the focus group on Operating Grants also underlined that appropriate budgets attract good candidates.

***Evolving and established procedures of the programme impacted its efficiency*.** The number of partners involved in an action was identified by stakeholders as a factor which sometimes negatively influenced the efficiency with which achievements were attained.[158] Another factor in

[158] A government official/policy maker in the focus group for Procurement Mechanisms mentioned that there were too many partners in the HTA Joint Action and suggested that the maximum number of partners should be indicated by the European Commission in the eligibility criteria. This sentiment was echoed by a stakeholder from the government officials and policymakers' group, who reported difficulty in coordinating a number of

observed disparities between costs and benefits was co-funding, for example a stakeholder from an international organisation reported that 40% co-funding within a Direct Grant Agreement from international organisations is 'unbearable' and may negatively impact future collaborations.[159] Several stakeholders also mentioned that timing of projects and funding caps could negatively impact the efficiency with which achievements are attained, for example the projects had short durations and insufficient accountability mechanisms.[160] More emphasis on planning for sustainability before an action begins and sustainability mechanisms when an action ends was perceived as a way to marry costs with benefits. Available financial and human resources was identified as a defining factor in efficiency of achievements.

There were few stakeholders who reported that programme objectives were unmet or partially unmet. Further, programme credits were distributed efficiently between the four thematic priorities. A majority of stakeholders consulted in interviews and focus groups felt that there was an efficient distribution of Programme credits among the four thematic priorities and several stakeholders mentioned priorities being in line more widely with EU objectives. For example, those who had received Operating Grants largely agreed that they were in line with Programme objectives, and stakeholders in the Procurement Contracts focus group also felt that the funding was aligned with EU objectives.

Most stakeholders considered funding allocation to be critical to achieve expected results. Stakeholders from the Operating Grants focus group felt that funding allowed them to plan and deliver on projects with (financial) security. Those in governmental public health organisations also emphasised how invaluable funding was to achieving results: one stakeholder reported that funds would not have been directed to the identified priorities without Programme, and another stakeholder from the same group highlighted that funding was critical for enabling low-GNI countries to achieve results with other Member States. A stakeholder from a healthcare professionals' association also highlighted how external stakeholders would not have been engaged in innovations in healthcare systems in the same way without the funding.

***There were some differences in costs between countries, caused by several factors*.** Some academic/research organisations and NGOs believed there were differences in costs between countries. Some respondents believed these differences were caused by differing staff expenses, which impacted achievable goals and work performance. Some stakeholders also identified cost

entities working on a Joint Action. If one partner does not submit cost, then it cannot be funded by the Commission.

[159] Further, a stakeholder from an NGO who utilised a Project Grant also felt that the standard co-funding requirement (40%) is too high and the application process for the 80% co-funding is difficult, particularly for smaller organisations. A stakeholder from the same focus group in an academic/research organisation also discussed the difficulty of co-funding in ERNs (but acknowledged this as a point which has been addressed in EU4HEALTH). Similarly, a stakeholder from a governmental public health organisation stressed that 20% commitment to their own funding was challenging for NGOs and may prevent them from contributing despite the value they add to projects.

[160] reported by a stakeholder from a government public health organisation

differences which could be linked to the Programme.[161] Survey results suggested a larger perceived difference in benefits gained through the Programme; stakeholders believed that tasks and the level of involvement of Member States in projects/actions dictated to what degree countries benefited from the Programme. The exceptional utility criteria were perceived by half of respondents as a factor which reduced differences in costs and benefits. Other factors affecting differences were identified in the survey as: organisational capacity to deliver funded actions (8 responses, 67%), administrative burden of applying for and receiving funding (7 responses, 59%), and countries' public health capacity to apply for and manage funding (6 responses, 50%). Stakeholders interviewed identified geographical location as another factor which caused differences in benefits between participating countries.[162]

***While some respondents did not know much about the simplification measures, those who did generally felt they contributed to the efficiency of the Programme*.** 32% of respondents in the survey did not know whether the simplification measures contributed to the efficiency of the Programme, and those who did answer were divided. Ways in which simplification measures *were* deemed to be efficient were in the introduction of electronic tools for the submission of proposals, management of grants and e-reporting and monitoring (subject to the system functioning efficiently), the introduction of a negotiation process for Joint Actions, and the ability for beneficiaries to transfer resources between different cost categories without the need for an amendment. Stakeholders consulted[163] generally felt that simplification measures had reduced administrative costs and improved efficiency of the Programme, for example by reducing paperwork and improving operational running of Joint Actions.[164]

Many stakeholders felt that there was further scope to reduce costs. Most proposed changes were related to application processes.[165] Further simplification of administrative processes was a common improvement suggested by stakeholders. One stakeholder from a healthcare service provider/ organisation representing them praised the reduction in paperwork, but felt that

[161] A stakeholder from a governmental public health organisation felt that the divergence in daily payment amounts from participating countries in Joint Actions should be reconsidered. One stakeholder from a healthcare service provider/ organisation representing them highlighted that payments to those working on projects were adjusted to countries' levels, meaning different people were paid different amounts.

[162] Stakeholders in focus groups on Joint Actions and Operating Grants particularly felt that Western European countries were still overrepresented in the Programme, and a stakeholder in the focus group on Project Grants felt that this was due to the difficulty faced by low GNI countries in meeting co-funding rates. A stakeholder from a governmental public health organisation highlighted that countries with low GDP struggled to see the same benefits of Joint Actions due to not having the resources and capacity to participate. However, one stakeholder from the government officials/policy makers group highlighted that even with more funding, some countries still would not have had the resources or capacity to participate effectively in the Programme.

[163] Including in the Project Grants focus group and the Operating Grants focus group.

[164] Reported by a stakeholder from research/academic organisation

[165] One government/policy maker stated that more flexibility was still needed in Project Grant funding for Joint Actions. The stakeholder worked on a Joint Action on vaccination where the Ministry of Health were nominated as the competent authority to work with a university, but they were not able to justify the affiliated entity aspect of the university. Another stakeholder from a healthcare professionals' association felt that applications for ERNs should not be annual, but every 5-10 years to reduce administrative burden.

locating documents was difficult, especially when trying to find out why a project was declined. Another stakeholder from a healthcare professionals' association highlighted that, prior to the pandemic, some financial officers required face-to-face meetings whereas others allowed e-meetings; this affected the financing as travel expenses were difficult to cover.

Monitoring costs were largely seen as reasonable and cost-effective. A majority of respondents who were involved in the management and administration of an action from the Programme said that the monitoring costs were reasonable and kept to the minimum necessary in order to achieve the expected results, at least to a moderate extent (11 responses, 55%). According to some respondents, the key factors enabling efficiency were the relevance of indicators (10 responses, 50%) and the level of clarity of the indicators (9 responses, 45%).

However, there were a few challenges with the monitoring processes. While some stakeholders noticed improvements in the monitoring process, many still felt it could be simplified (particularly stakeholders from healthcare professionals' associations and NGOs). A stakeholder belonging to the governmental policymakers group mentioned that experts they worked alongside struggled with the budgeting table due to uncertainty and level of detail required. Increased dissemination of project information was seen to make the Programme more efficient as a whole. Communication within project teams was also highlighted as key to having an efficient monitoring process.[166] Some stakeholders suggested different, more efficient methods of monitoring the Programme.[167]

Reporting systems were seen as reasonably-priced and beneficial. In the survey, respondents involved in the management and administration of an action reported benefits of the reporting system, including allowing the tracking of progress on actions against their original plan (11 responses, 55%), increasing visibility of the Programme and its actions (6 responses, 30%) and allowing Programme participants to manage budgets effectively (5 responses, 25%). Eight respondents (40%) said that the costs of the reporting system were reasonable and kept to the minimum necessary to achieve expected results, at least to a moderate extent. Interviews with stakeholders revealed perceived benefits of the reporting system.[168]

[166] reported by stakeholder from an academic/research organisation

[167] Several government and policy makers in the Procurement Mechanism focus group highlighted the difficulty of measuring/monitoring impact of funding as there is no specific framework for measuring results of activities and quantifying progress is challenging. One stakeholder from the group suggested that operational units should put emphasis on what is the best that can be achieved with the available budget at the beginning as a better way of monitoring. Another stakeholder (from an NGO) suggested monitoring progress through 'looking at how actions affect communities – assessing to what extent is everyone at the table'. One government official/policy maker stakeholder reported that there is a need for a dedicated data collection system to perform monitoring activities per objective and per priorities, as there is currently a missing link between individual projects and specific objectives and thematic priorities.

[168] Such as: the portal, which made reporting more efficient (according to a government official/policy maker); Compass and SYGMA reporting systems, which enabled beneficiaries to report back to the Commission with less administrative burden and to track projects from start to end (according to a government/policy maker); and

However, there were some limitations of the reporting system identified. 65% of respondents felt that the reporting system could be improved by 'simplifying the reporting procedure' (through reducing administrative burden, time and effort required). In line with survey findings, a few stakeholders consulted in focus groups and interviews indicated that reporting systems could be more effectively implemented in the Programme. Suggested improvements were related to reducing administrative burden on applicants; stakeholders in the Project Grants focus group highlighted the need to reduce the level of detail required for financial reports, and two stakeholders from NGO and organisations representing patients and service users groups mentioned the administrative burden of submitting Operating Grant reports specifically. For smaller organisations without technical capacity and knowledge, the administration involved in Operating Grant reports was discouraging according to a stakeholder from organisations representing patients and services users. The stakeholder from an NGO also felt that submitting a few smaller Operating Grant reports throughout the year as opposed to one big report annually may be more efficient.

EU added value

***The Programme achieved more added value than what Member States could have achieved acting individually*.** Most respondents to the PC[169] considered that Programme provided added value beyond what could have been achieved by Member States acting alone. The additional value of having an EU health programme was also validated by stakeholders who attended the focus group on Joint Actions. Stakeholders representing governmental public health organisations mentioned that the Programme enabled partners to contact other EU organisations and use that support to have a greater impact at national level. Furthermore, these stakeholders considered that it was beneficial to have actions at regional, national and EU level depending on the level of devolution within a country.

Coherence

***The activities carried out under Programme were aligned with the thematic priorities of the Programme*.** The majority of survey respondents mentioned that there were consistent and coherent funding decisions across specific objectives during the Programme period. Very few respondents to the survey said that funding decisions were not at all coherent with the specific objectives. For example, just 2 respondents to the survey (7%) said this was the case for objective 2,[170] and another 2 respondents for objective 3.[171] There were very few stakeholders reporting inconsistencies between actions, or gaps, duplications or contradictions, which lead to inefficiencies) (2 respondents to the survey, 4%).

the role of FPA and SGA in reducing administrative burden for applicants and the European Commission (according to a government/policy maker).

[169] Almost four in ten respondents to the OPC said the Programme provided high added-value (26 responses, 39%) and an additional third said that it provided moderate added-value (23 responses, 34%).

[170] Objective 2: Protect Union citizens from serious cross border health threats" (2 respondents

[171] Objective 3: Contribute to innovative, efficient, and sustainable health systems

Reasons given by stakeholders for a inconsistencies, gaps, duplications or contradictions within the Programme detailed that these were mainly due to: issues linked with the relationships between different actors/beneficiaries; programme management and communication with core stakeholders; and the lack of national political uptake or capitalisation of findings arising from the Programme funding actions.

The Programme complemented and created synergies with other EU Programmes. A majority of PC respondents believed that the Programme complemented and/or created synergies with other EU programmes or with wider EU policies, to at least a moderate extent (37 out of 67, responses, 55%). These respondents explained that the Programme was coherent with contributions of the European Structural and Investment Funds (ESIF), the Horizon 2020 Programme and the European Social Fund. They added that complementarities between the Programme and these other EU policies made it possible to investigate some topics (e.g. chronic diseases, non-communicable diseases, rare diseases) in-depth.

The Programme was coherent with other EU policies in the field of health. Several stakeholders representing government and policymakers, academic and research organisations and governmental public health organisations agreed that the Programme was aligned and coherent with other EU policies in the field of health. Furthermore, some stakeholders representing government and policymakers and governmental public health organisations highlighted the alignment with other EU funded actions and policies such as Horizon 2020, and the Farm to Fork Strategy.

However, some respondents felt the Programme was not as coherent with other EU programmes. Some PC respondents (13 out of 67, 19%) said the Programme was not coherent with other EU programmes or with wider EU policies, with one NGO noting very few synergies for instance between the Programme and the Horizon 2020 programme for R&D and a public authority explaining that programmes were not interlinked with no joint funding possible. This public authority added that priorities as well as grants and tenders from other EU Programmes were often not known to delegates of the Programme. Furthermore, some stakeholders representing government and policymakers, and organisations that represent patients and service users mentioned that coherence and synergies between the Programme and Horizon 2020 could have been improved.[172] Furthermore, looking at the relation between the Programme and EU financial instruments, some stakeholders representing government and policy makers and organisations representing patient and service users were asked if the health programme

[172] They reported that synergies between Joint Actions and Horizon were difficult to unlock because the latter programme is more research oriented. Further, there could have been more coherence between the funded actions and the research programme (Horizon 2020). The stakeholder did not see any methods to motivate/promote synergies with the actions funded under the programme to feed into others. She pointed that some recipients of these programme acknowledge these synergies and made the best use of them. But in her view, there was not a consistent effort to connect projects and/or programmes.

encouraged cooperation with the European Structural and Investment Funds (ESIF) and other EU financial instruments. Stakeholders agreed there was a room for further cooperation between the Programme and the ERDF, the European Social Fund Plus (ESF) and ESIF.

Funded actions within the Programme contributed to, and were aligned with, wider EU policies. This was confirmed by some stakeholders representing NGOs, international organisations and organisations representing patients and service users. For example, one stakeholder representing NGOs highlighted that there was alignment between the Programme and other EU funding mechanisms in relation to migrant health. Furthermore, a government policy maker that attended the focus group on Procurement Contracts mentioned that the work of the Programme in the migration crisis was linked to the wider EU policy on the migration crisis. This work therefore contributed to achieving a specific objective of the Programme as well as a wider EU priority.

The Programme was aligned with national priorities. In the PC, a majority of public authorities said that the Programme was aligned with and addressed national health priorities during the Programme period to at least a moderate extent (14 out of 20 responses, 70%). Additionally, half of respondents to the PC believed that the Programme complemented and/or created synergies with national initiatives and/or programmes, to at least a moderate extent (33 out of 67 responses, 49%). Several stakeholders[173] agreed that the Programme priorities and objectives were aligned with Member State initiatives in the field of health. Among the national initiatives that were aligned with the Programme, stakeholders mentioned actions on tobacco use and alcohol abuse by young people, obesity, and the prevention of frailty. Similarly, three out of five stakeholders that attended the focus group on Joint Actions indicated that the Programme's interventions were complementary to other EU or Member State initiatives in the field of health. However, a few other respondents to the PC (13 responses, 19%) said the Programme was not coherent with national initiatives and/or programmes.

5 FEEDBACK ON THE CONSULTATION PROCESS

During the consultation period, a few stakeholders noted that they were unable to participate in the interviews and focus groups due to competing priorities including responding to the effects of the Covid-19 pandemic and the conflict in Ukraine. Lastly, due to technical issues on the last day of the PC, one stakeholder was initially unable to submit their response to the survey and PC, however this was addressed by extending the deadline for these consultation activities.

[173] Stakeholders from the following groups mentioned this: stakeholders representing government policy makers, governmental public health organisations, NGOs, academic and research organisations, and organisations representing patients and service users

6 USE OF THE INFORMATION GATHERED

All of the information gathered as part of the stakeholder consultations was firstly converted into useable units of analysis. For example, interview audio recordings were used to write notes for each interview to summarise key points and quotes. A summary of key findings per evaluation question was written for each focus group. Summary tables and graphs were created per question for the PC, and stakeholder survey and open-text responses were collated into a file.

Then, these data sources were analysed to identify patterns and trends across stakeholder groups. These data sources were used to examine each evaluation question alongside the desk research conducted for this study, and to reach the conclusions and recommendations contained in the final study.

ANNEX VI. THEMATIC PRIORITIES OF THE 3RD HEALTH PROGRAMME

1. Promote health, prevent diseases and foster supportive environments for healthy lifestyles
1.1. Risk factors such as use of tobacco and passive smoking, harmful use of alcohol, unhealthy dietary habits and physical inactivity
1.2. Drugs-related health damage, including information and prevention
1.3. HIV/AIDS, tuberculosis and hepatitis
1.4. Chronic diseases including cancer, age-related diseases and neurodegenerative diseases
1.5. Tobacco legislation
1.6. Health information and knowledge system to contribute to evidence-based decision-making

2. **Protect Union citizens from serious cross-border health threats**
2.1. Additional capacities of scientific expertise for risk assessment
2.2. Capacity-building against health threats in Member States, including, where appropriate, cooperation with neighbouring countries
2.3. Implementation of Union legislation on communicable diseases and other health threats, including those caused by biological and chemical incidents, environment and climate change
2.4 Health information and knowledge system to contribute to evidence-based decision-making

3. **Contribute to innovative, efficient and sustainable health systems**
3.1. Health Technology Assessment
3.2. Innovation and e-health
3.3. Health workforce forecasting and planning
3.4. Setting up a mechanism for pooling expertise at Union level
3.5. European Innovation Partnership on Active and Healthy Ageing
3.6. Implementation of Union legislation in the field of medical devices, medicinal products and cross border healthcare
3.7. Health information and knowledge system including support to the Scientific Committees set up in accordance with Commission Decision 2008/721/EC

4. **Facilitate access to better and safer healthcare for Union citizens**
4.1. European Reference Networks
4.2. Rare diseases
4.3. Patient safety and quality of healthcare
4.4. Measures to prevent antimicrobial resistance and control healthcare-associated infections
4.5. Implementation of Union legislation in the fields of tissues and cells, blood, organs
4.6. Health information and knowledge system to contribute to evidence-based decision-making

ANNEX VII. KEY MONITORING INDICATORS OF THE 3RD HEALTH PROGRAMME

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	2021	2022	Target
Men										
2012	Milestones									2020
61,0										
	Actual Progress									Final
	61,1	62,4	63,6	63,5	63,7	64,2	63,5			
Women										
2012	Milestones									2020
61,7										
	Actual Progress									Final
	61,4	63,3	64,4	64,3	64,2	65,1	64,5			

Are we on track	Moderate progress
Indicator type	Input
Unit of measurement	Healthy years
Cut-Off Date	31/05/2021
Data source	Eurostat. Data for 2017 will be made available by Eurostat in May 2019, and for year 2018 in May 2020, and so on.
Narrative	Baseline: Men 2012: 61.0%, Women 2012: 61.7%
Methodology	
Link MFF 14-20 / MFF 21/27	
Other methodological comments	The above indicator is taken directly from the 3rd Health Programme Regulation. The 2 indicators below are an operationalization. Note: 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.
Full metadata available at this adress	
Justification of the trend	General positive trends for the 2 indicators (men and women) even if there has been stabilisation or slight decrease for women over the period 2016-2018 (to be confirmed by future revisions of these data)

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	2021	2022	Target
Fat										
2012	Milestones									2020
12	16	18	20	22	24	25	28			28
	Actual Progress									Final
	21	21	21	22	24	24	24			
Cancer										
2012	Milestones									2020
				10			28			28
	Actual Progress									Final
	0	0	0	10	10	6	6			

Are we on track	On track
Indicator type	
Unit of measurement	Member States having a national initiative on reduction of saturated fat & MS in which the European accreditation scheme for breast cancer services is implemented - establishment of the scheme.
Cut-Off Date	
Data source	
Narrative	
Methodology	
Link MFF 14-20 / MFF 21/27	
Other methodological comments	(relevant for Cancer sub-indicators): In 2019, Guideline developers and/or national authorities from six EU Member States 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).
Full metadata available at this adress	
Justification of the trend	

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	2021	2022	Target
2013	Milestones									2020
0	0	4	18	20	22	24	28			28
	Actual Progress									Final
	0	16	16	16	22	22	22			

Are we on track	Moderate progress
Indicator type	
Unit of measurement	Member States
Cut-Off Date	
Data source	
Narrative	
Methodology	
Link MFF 14-20 / MFF 21/27	
Other methodological comments	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 took place in 2020.
Full metadata available at this adress	
Justification of the trend	

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	2021	2022	Target
Advice produced, in particular the number of Health Technology Assessments (HTA) produced per year										
2012	Milestones									2020
2	11	6	12	18	22	29	50			50
	Actual Progress									Final
	6	9	0	4	22	27	41			
Number of Member States using the tools and mechanisms identified in order to contribute to effective results in their health systems										
2012	Milestones									2020
		5	9	8	10	12	18			18
	Actual Progress									Final
		5	10	9	22	23	23			

Are we on track	On track
Indicator type	Output
Unit of measurement	For second sub indicator: Number of Member States HTA bodies reporting uptake of joint HTA reports produced by EUnetHTA.
Cut-Off Date	01/02/2021
Data source	EUnetHTA JA3 (2017-2021).
Narrative	
Methodology	Annually
Link MFF 14-20 / MFF 21/27	
Other methodological comments	Relevant for the first sub indicator: In 2020, EUnetHTA Joint Action 3 carried out 40 joint reports This is an increase from the previous years, especially in the difficult context of the COVID-19 pandemic. In addition to 18 joint assessments and early dialogues (that are well-established joint HTA activities), EUnetHTA adapted to the COVID-19 crisis by introducing two new type of joint reports: rapid collaborative reviews of SARS-CoV-2 diagnostic methods (2 reports) and rolling and rapid collaborative reviews of potential treatments for COVID-19 (21

	reports).Relevant for the second indicator: The uptake of joint HTA reports by MS depends on the needs of national HTA bodies (i.e. was affected by the COVID-19 crisis) and the market strategy of health technology developers (e.g. usually a health technology is not introduced simultaneously in all MS)
Full metadata available at this adress	www.eunethta.eu
Justification of the trend	

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	2021	2022	Target
	Milestones									2020
	0	0	10	24	24	24	30	24	27	30
	Actual Progress									Final
	0	0	23	24	24	24	24			

Are we on track	On track
Indicator type	
Unit of measurement	
Cut-Off Date	
Data source	
Narrative	
Methodology	
Link MFF 14-20 / MFF 21/27	
Other methodological comments	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 where 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. Recent discussions in the Board of Member States and in the Coordinators group show that 3 more networks could be expected by the end of the Programme.
Full metadata available at this adress	
Justification of the trend	

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

BaseLine	2014	2015	2016	2017	2018	2019	2020	2021	2022	Target
	Milestones									2020
	0	0	120	936	1136	1342	1450	1180	1780	1450

	Actual Progress									Final
	0	0	936	956	956	953	1185			

Are we on track	On track
Indicator type	
Unit of measurement	
Cut-Off Date	
Data source	
Narrative	
Methodology	
Link MFF 14-20 / MFF 21/27	
Other methodological comments	The difference with regard to 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 be explained by external factors linked with the ERNs' infrastructure and work procedures – first, Member States took much longer to endorse Affiliated Partners (which only joined during 2021) and secondly new members can only be accepted after a long assessment process (which is coming to an end in 2021).
Full metadata available at this address	
Justification of the trend	

Indicator 3: number of Member States using the tools developed

BaseLine	2014	2015	2016	2017	2018	2019	2020	2021	2022	Target
	Milestones									2020
0	0	0	0	18	20	24	28			28
	Actual Progress									Final
	0	0	0	25	25	25	28			

Are we on track	On track
Indicator type	
Unit of measurement	
Cut-Off Date	
Data source	
Narrative	
Methodology	
Link MFF 14-20 / MFF 21/27	
Other methodological comments	27 MS+Norway (following BREXIT)
Full metadata available at this address	
Justification of the trend	

ANNEX VIII. *EXAMPLES OF FUNDED ACTIONS IMPLEMENTED UNDER THE THIRD HEALTH PROGRAMME 2014-2020*

This section non-exhaustively presents examples of actions funded by the Programme under the 4 specific objectives or addressing cross-cutting issues.

These actions were selected through a large consultation of DG SANTE services in charge of health policy and by triangulation with stakeholders surveyed.

1. Actions under *Specific objective 1: promote health, prevent diseases, and foster supportive environments for healthy lifestyles:*

(i) 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. Stakeholders can also submit a practice for evaluation.

As of 2020, more than 12 best practices selected by the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases are implemented across 75% of the EU Member States, in areas such as integrated care; mental health and the fight against depression; nutrition and physical activity; prevention of alcohol abuse or chronic disease prevention and management. A joint action with EU Member States was launched on the exchange and implementation of best practices in the field mental health, in particular best practices regarding suicide prevention and the reform of mental health services.

(ii) The Health Programme has developed the EU-Compass for Action on **mental health** and wellbeing which is a web-based mechanism used to collect exchange of best practices and analyse information on policy and stakeholder activities in mental health.

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).

In 2020, the SGPP launched two joint actions with member state involvement, notably on mental health and on nutrition.

(iii) On **dementia**, and in particular post-diagnostic support, crisis and care coordination, quality of residential care and dementia friendly communities, best practices already selected have been piloted under second Joint Action with Member States competent authorities.

(iv) Actions to promote health and to prevent diseases also included the launching of a joint action with EU Member States[174] on the exchange of best practices for the implementation of the Tobacco Products Directive (2014/40/EU)[175] and e-cigarette regulation.

(v) Set up of an EU-wide tobacco tracking and tracing system to combat illicit tobacco products trafficking.

(vi) Second joint action on tobacco control (JATC2) was launched in order to facilitate the exchange of good practices between the Member States, therefore, aiming to improve the implementation of the Tobacco Products Directive (2014/40/EU)[176] as well as implementing and delegated acts relating to e-cigarette regulation

(vii) In 2020 the Joint Action on Tobacco control (JATC) produced key deliverables fostering an harmonised implementation of the Tobacco products' directive across the EU: it mapped the implementation's state of play across the EU; it conducted a needs assessment identifying the areas of support for national competent authorities; it assessed the laboratory testing capacity of national regulators; it looked at emerging trends and new challenges, such as the electronic cigarettes; it reviewed the system of enhanced reporting of additives; and it developed guidelines both on the technical and legal dimensions for improving data sharing and exchange from the EU-CEG across the Member States. The Health Programme also supported the **EU tobacco tracking and tracing system**, in cooperation with WHO and is implementing the development of a set of automatic alerts, exploiting the massive amount of traceability data so as to identify fraud patterns, suspicious behaviours and spot possible fraudsters[177].
These actions were followed in 2021 by the launching with EU Member States[178] of a joint action (JATC2) on the exchange of best practices for the implementation of the Tobacco Products Directive (2014/40/EU)[179] and e-cigarette regulation.
Amongst others, JATC2 aims to ensure greater consistency in the application of the Tobacco Products Directive to ensure a fair internal market for tobacco and related products, especially regarding market surveillance and enforcement. In that direction, it will identify and assess the existing legal framework regarding tobacco advertising and advertising of emerging products.

(viii) Actions in the field of nutrition delivered important outputs and tools, justifying the need for public health decision makers to invest in prevention rather than cure. A review of the available evidence for cost-effective prevention interventions has identified the food reformulation as the 'best value for money' action to improve nutrition patterns. The Programme also supported the development of a database of nutritional information on processed food and drink products on the market in 16 Member States.

[174] 'EU countries' includes all countries participating in the Third Health Programme.
[175] EUR-Lex - 32014L0040 - EN - EUR-Lex (europa.eu).
[176] EUR-Lex - 32014L0040 - EN - EUR-Lex (europa.eu)
[177] The current COVID-19 related restrictions are impacting progress in this work: the contractor cannot access the data room located in the Commission premises
[178] 'EU countries' includes all countries participating in the Third Health Programme.
[179] EUR-Lex - 32014L0040 - EN - EUR-Lex (europa.eu).

(ix) On **cancer**, the European Quality Assurance scheme has been developed in harmonised, evidence based and flexible way to grant equal and quality-benchmarked treatment to patients.
The activities of the European Network of Cancer Registries coordinated by the JRC delivers important results providing a 'data-brokering' service to ensure integrity of a single European dataset for different purposes. 128 Cancer Registries from 29 European countries are regularly providing data to JRC with more than 25 900 000 records so far in the database

(x) Following an extensive consultation with Member States in the Steering group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases, antimicrobial resistance (AMR), cancer, and access and availability of medical products, followed by prevention of non-communicable diseases (NCDs) were identified as a priority area for population-level health interventions and best practices in September 2020 at the formal meeting. After the priority assigned to prevention of NCDs, the next three priorities relate to risk factors on tobacco, environmental determinants of health (notably pollution) and obesity. For these four risk factors, a Best Practice call was published at the end of 2020 in the Best Practice Portal. In addition, a Best Practice call on Primary Care was opened

(xi) 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.

(xii) A **prize** for non-governmental organisations has been organised annually by the Health Programme for encouraging those organisations that made a significant contribution in the field of public health

2. Actions under specific objective 2 *Specific objective 2: protect Union citizens from serious cross-border health threats:*

(i) Health security and Covid-19
Although the overall EU response to COVID-19 is not in the scope of this evaluation, it should be noted that the Commission steered running actions in the area of health security to contribute to the fight against the pandemic. Key examples are: the Joint Action Healthy gateways supports the coordination among EU Member States 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 (SHARP)[180] which collaborated with the European Centre for Disease Prevention and Control (ECDC) EVD-LabNet (Emerging Viral Diseases-Expert Laboratory Network) in ensuring quality control and capacity building for precise diagnostics at an early phase of the pandemic and demonstrated the importance of using laboratory networks as a preparedness and response tool.

[180] The JA SHARP supports coordination among EU reference laboratories to prevent, detect and respond to biological outbreaks, chemical contamination and environmental and unknown threats to human health

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).

(ii) During the Ebola and Zika outbreaks, part of the funds of the programme were used to support interventions to limit the spread of these threats by strengthening Member States preparedness and response in particular through the actions of the Health Security Committee (entry screening, medical evacuations, prevention of transmission in transport and hospital settings). The budget in 2014-2016 for strengthening EU response to health threats amounted to EUR 11 million.

(iii) 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). The Joint Action also contributed to combating the outbreaks of ZIKA and Ebola.

(iv) Four projects funded in 2021 targeting the increase vaccination uptake. Three of them were focused on increasing access to vaccination for disadvantaged, isolated, difficult-to-reach groups and newly arrived migrants (taking into account a life-course approach). The fourth project ActToVAx4Nam (Increased Access To Vaccination for Newly Arrived Migrants), targets exclusively newly arrived migrants – in first-line, transit and destination countries – and aims to make access to vaccination equitable and guaranteed.

(v) In December 2019, the Health Programme launched a feasibility study for the development of a common EU vaccination card**.** The proposed templates resulting from this study are tested in a sample of 10 000 citizens per country across 10 Member States, this pilot testing covering a potential population of more than 200 million citizens. In 2020, the **Joint Action on Vaccination** focused specifically on vaccine hesitancy and uptake, identified by the WHO in 2019 as one of ten top health threats to global health and included in the Commission's roadmap on strengthening cooperation against vaccine preventable diseases.

Four projects were launched in 2021 on improving vaccination access and uptake. The IMMUNION project (Improving IMMunisation cooperation in the European UNION) focuses on increasing vaccine uptake and contributing to the 2018 Council Recommendation on vaccination while also adding value to EU and national initiatives - particularly the Coalition for Vaccination.

(vi) 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 AMR and healthcare associated infections (HCAI).

3. Actions under specific objective 3: *support public health capacity-building and contribute to innovative, efficient and sustainable health systems:*

(i) State of Health in the EU - (1) Country Health Profiles 2019 and (2) Health at a Glance 2020: Europe
On 28 November 2019, the European Commission published 30 *Country Health Profiles* delivered as part of the *State of Health in the EU* cycle. The accompanying 'Companion Report' (a Commission Staff Working Document) and factsheet flagged five key challenges faced by 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 and to the key priorities of the 2019-2024 Commission as set out in the mission letter to Commissioner Kyriakides. Several of these actions were supported by the 3rd Health Programme (see below sections on health and innovation, vaccination and access to medicines).

In November 2020, the European Commission and the OECD published *Health at a Glance: Europe 2020*, which the first comparative study on how European countries have experienced and responded to the COVID-19 pandemic.

(ii) Setting up of the **EU Health Policy Platform (HPP),** a **collaborative online tool** that makes it easy for European Commission services, health-related interest groups and stakeholders to communicate with each other.

(iii) *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 digital 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, innovation and policy making. European Health Data Space will lead to better health outcomes for patients and public, reduced costs, increased efficiency, more resilient health systems, new treatments and better policy-making. The Joint Action TEHDAS (The European Health Data Space) was launched, with 25 participating countries, to facilitate the establishment of a European Health Data Space, by developing principles for the cross-border secondary use of health data.

(iv) 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 Member States.

The Scientific Committee on health, environmental and emerging risks (SCHEER) is providing the Commission with risk assessment and scientific advice on medical devices (like hip implants, breast implants, phthalates used in medical devices…).

(vv) 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.

i(vi) Establishment of an Organ Database, which has helped 34 000 transplants only in 2017.

(vii) A service contract was concluded in 2021 for the provision of joint Health Technology Assessment (HTA) work supporting the continuation of EU cooperation on HTA. The scope of this tender is to address the existing methodological issues in order to foster joint work on HTA, while also supporting EU cooperation on HTA beyond the end of the Joint Action EUnetHTA. Therefore, this service provides relevant input for a potential new legal framework on HTA. In particular, the tender shall lead to the further development of HTA methodology applicable to both Joint Clinical Assessments and Joint Scientific Consultations, a task of high significance in areas where divergent opinions persist. Furthermore, the HTA tender shall continue and advance work undertaken under the Joint Action EUnetHTA, through the coordination of the above-mentioned joint activities, the interaction with stakeholders' representatives (i.e. patients, health professionals and industry), academia and relevant EU/international organisations and initiatives on HTA.

(viii) European Innovation Partnership on Active and Healthy Ageing: based on several projects and one joint action which focus on the topics of frailty, one overall European Framework for Frailty Prevention has been developed as well as practical tools e.g. to screen older adults for (pre)frailty and innovative care paths.

(ix) The programme supported work on health information: EUR 13.2 million spent in 2014-2016 for the collection and analysis of health information, data and indicators in cooperation with the Organisation for Economic Cooperation and Development (OECD), the World Health Organization (WHO) and the Observatory on Health Systems and Policies, as well as ESTAT and Joint Research Centre (JRC), contributing to the development of country specific and cross-country knowledge to inform policies at national and EU level, through such actions as the State of Health in the EU cycle.

(x) The BRIDGE health project has coordinated, improved, and advanced some of the most influential EU health indicator development networks since its 2015 inception, creating synergies between the efforts of several earlier projects on health information.

These expert networks have been developing and maintaining indicators in the domains of population health and health systems, health examination surveys, and population injury, and developed methods to produce health indicators more cost-effectively in various areas using disease registries and administrative health data collection systems. Various options to improve the sustainability of producing indicators to underpin health policy and research in the EU have been developed, and a blueprint for a more sustainable organisation of these activities is being finalised.

4. Actions under specific objective 4 ***facilitate access to better and safer healthcare for Union citizens:***

(i) 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.

The first ERNs are up and running since March 2017. Over the five subsequent years, as the ERNs reach full capacity, thousands of EU patients suffering from a rare or complex condition have benefited from specialised treatments.

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

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

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

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

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

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

(iii) The Commission carried out in 2021 an evaluation on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.

(iv) A study supporting the impact assessment of the revision 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 and of their implementing acts was launched. The duration of the contract is nine months, and the scope of the study is to support the European Commission in preparing an impact assessment supporting the Revision of the Union legislation on blood, tissues and cells.
The specific objectives are to:

- Provide a description of the baseline. Moreover, to summarise the key elements of the evaluation and complement the problem definition by gathering and analysing evidence on borderline technologies/therapies and the impact and lessons learned from the COVID-19 pandemic.
- Measure the likely economic, social and environmental impacts of each of the options. A preliminary identification of the key impacts is in section 1.6. of the study.
- Analyse the effectiveness, efficiency and coherence of policy options in order to achieve the objectives of the revision.

5. Actions addressing cross-cutting issues – health inequalities, legislation, SDGs

(i) The Joint Action on Health Equity Europe (JAHEE), funded under the 3rd Health Programme 2014-2020 has been an important opportunity for Member States to work jointly to address health inequalities and achieve greater equity in health outcomes across all groups in society, in all participating countries and in Europe at large. The general objective of this initiative is to improve health and well-being of European citizens across all groups in society. It also has a specific focus on both vulnerable groups and migrants.

(ii) The programme also provided the resources for implementing the EU's political commitments and legal obligations in health (e.g. implementation of the tobacco or health threats legislation, the EU regulatory framework for medicinal products and medical devices, for substance of human origin, and cross-border health care). It also supports the Member States implementation of this legislation through the development of common tools, such as networks, IT platforms, guidance and sharing of best practices. The development and maintenance of these tools (e.g. EUDAMED database, Euripid database) is essential in order to ensure the smooth operation of the Internal Market in these sectors.

(iii) A joint action was launched in 2021 on Increasing the capacity of National Focal Points to provide guidance, information and assistance to national applicants on the EU4Health programme and other EU funding instruments, and another joint action addressing the Differences in national implementation of the General Data Protection Regulation (GDPR) in the health sector-Development of a code of conduct for data processing.

(vi) The Programme contributes to the EU work towards the WHO's nine voluntary targets on non-communicable disease and the UN Sustainable Development Goals 3-Ensure healthy lives and promote well-being for all at all ages, DG SANTE works through the Steering Group on Health Promotion, Disease Prevention and Management

of Non-Communicable Diseases (SGPP). Examples of such support included funding for operating grants to NGOs. Specific grant agreements were signed with 15 NGOs in 2020.

Four direct grant agreements were also concluded with international organisations, as follows:

- Three direct grant agreements were signed with the OECD, on best practices implementation; on patient reported outcomes and on pharmaceutical products' accessibility.
- One direct grant agreement was signed with the Council of Europe to support the European Pharmacopeia work.