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EVALUATION

Accompanying the document

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF REGIONS

on the interim evaluation of the EU4Health Programme 2021-2024

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Glossary

This glossary contains a list of relevant acronyms and their meanings, organised alphabetically for ease of reference.

AMR: Antimicrobial Resistance
ATC: Anatomical Therapeutic Chemical Classification System
ATMP: Advanced Therapy Medicinal Products
CBRN: Chemical, Biological, Radiological, and Nuclear Hazards
Commission: European Commission
Contracting Authority: Public procurement body
CORDA: Common Research Data Warehouse
DEP: Digital Europe Programme
DG ECFIN: Directorate-General for Economic and Financial Affairs
DG SANTE: Directorate-General for Health and Food Safety
Direct Management: Budget implementation by EC
DURABLE Network: Research Alliance against Epidemics
ECDC: European Centre for Disease Prevention and Control
ECHA: European Chemical Agency
EEA: European Economic Area
EEHRxF: European Electronic Health Record Exchange Format
eHAction: Joint Action supporting the eHealth Network
EHDS: European Health Data Space
eHDSI: eHealth Digital Service Infrastructure
EHRs: Electronic Health Records
EMA: European Medicines Agency
ePI: Electronic Product Information
Erasmus+: EU Education and Training Programme
ERDF: European Regional and Development Fund
ERNs: European Reference Networks
ESF+: European Social Fund Plus Programme
EU: European Union
EU FAB: Vaccine Manufacturing Contract
EU4Health Dashboard: Grants and Procurements Database
EUDAMED: European Database on Medical Devices
EUonQoL: European Quality of Life in Oncology
EURLs: European Reference Laboratories
EUSR: Second European Screening Report
EU-TOPIA: Improved Cancer Screening in Europe
EU-WISH: Wastewater Surveillance for Public Health
EWRS: Early Warning and Response System
GAPP: Good Practice Guidelines
GNI: Gross National Income

HaDEA: European Health and Digital Executive Agency
HDAB: Health Data Access Bodies
HERA: Health Emergency Preparedness Authority
HORIZON: Horizon Europe Research Programme
HBV: Hepatitis B Vaccine
HPV: Human Papillomaviruses
HSC: Health Security Committee
HTA: Health Technology Assessment
IHR: International Health Regulations
Indirect Management: Budget tasks by public bodies
IOM: International Organization for Migration
ISCTP: European Cancer Training Programme
IVDR: In Vitro Diagnostic Medical Devices Regulation
JACARDI: Cardiovascular and Diabetes Action
JA GHI: Global Health Strategy Action
JAMRAI2: Antimicrobial Resistance Action
JA PreventNCD: Preventing Non-communicable Diseases Action
JASeHN: eHealth Action
JA Xt-EHR: Electronic Health Record Systems Action
JRC: Joint Research Centre
KPI: Key Performance Indicator
LFS: Legal Financial Statements
MDR: Medical Devices Regulation
MFF: Multiannual Financial Framework
Mpox: Monkeypox Virus
NCD: Non-communicable Disease
NGO: Non-governmental Organization
OECD: Organisation for Economic Co-operation and Development
PPMEF: Performance Monitoring and Evaluation Framework
PYLL: Potential Years of Life Lost
RRF: Recovery and Resilience Facility
SDGs: Sustainable Development Goals
SGPP: Health Promotion and Disease Prevention Group
SoHO: Substances of Human Origin
Strands: EU4Health Programme Tool
UCPM: Union Civil Protection Mechanism
UNITED4Surveillance: Integrated Surveillance Capacity
WHO: World Health Organization

1. INTRODUCTION

The EU4Health Programme (referred to as 'the Programme') was created by Regulation (EU) 2021/522[1] ('the EU4Health Regulation'), adopted in March 2021[2], to improve human health throughout the EU and to ensure a high level of protection of human health in all EU policies and activities. The Programme is being implemented through annual work programmes prepared by the Commission, based on stakeholders' input and in consultation with Member State representatives in the EU4Health Steering Group. The Commission adopts the annual work programme following a positive opinion of Member States representatives in the Programme Committee. The Programme provides funding to address long-term health challenges in the EU. This Staff Working Document presents the results of the interim evaluation of the EU4Health Programme for the period 2021-2024.

1.1 Purpose and scope of the evaluation

The interim evaluation assesses the relevance of the Programme's objectives, the added value, effectiveness and efficiency of the funded actions, as well as the coherence within the Programme and with other relevant EU funding initiatives and policies. The interim evaluation provides insights for the ongoing EU4Health Programme implementation, sets the scene for the forthcoming final evaluation, and informs the Commission's reflections on a potential Programme successor during the next multiannual financial framework (MFF). The interim evaluation measures the Programme's progress until April 2024 in the 27 EU Member States and the six non-EU countries associated to the Programme[3]. It provides information on whether adjustments are considered necessary in line with Article 20 of the EU4Health Regulation. The interim evaluation followed a standard procedure without derogations (Annex I).

1.2 Methodological overview

The evaluation and its supporting study applied a mix of qualitative and quantitative methods to address the study questions under the five evaluation criteria, i.e. the effectiveness, efficiency, coherence, EU added value and relevance of EU4Health[4] (Annex II). The study questions and the evaluation criteria were addressed by using at least two different methodological tools or reflect results from more than one data source. The answers are provided in the evaluation matrix (Annex III).

To measure the Programme's progress at this interim stage, the evaluation collected data on the Programme's output and results, including data from both completed and ongoing actions. The evaluation draws on additional evidence provided by an external study[5] conducted between December 2023 and October 2024. The data collected at Programme and project level are complemented by case studies, evidence collected from stakeholders online and through interviews, as well as from a literature review. The data analysis includes comparisons against

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1 Regulation (EU) 2021/522 of the European Parliament and of the Council of 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).

2 As stipulated in Article 5(7) of Regulation (EU) 2021/522, activities supported by the EU4Health Programme are eligible as of 1 January 2021.

3 Bosnia and Herzegovina (since 1 January 2024), Iceland (since 1 January 2021), Moldova (since 1 January 2023), Montenegro (since 1 January 2024), Norway (since 1 January 2021) and Ukraine (since 1 January 2022).

4 Better regulation toolbox 2023, tool #47.

5 To be published together with this staff working document.

baseline and targets, cost-benefit to the extent possible, and customer journey mapping. An analysis of megatrends (such as demographic change, digitalisation etc.) was conducted to assess how they could impact interventions in health systems, including actions funded by the Programme.

The collection of **Programme data** was enabled by 52 indicators, which are described in the EU4Health Programme performance monitoring and evaluation framework (PPMEF)[6]. The indicators monitor inputs, outputs, results and impacts. Nine *key performance indicators* were designated for flagship health policies and serve to highlight the key achievements in the annual performance reporting[7].

The **action data** has been collected from grants, procurements and contribution agreements by the beneficiaries of EU funds, using action-level indicators developed by the Commission or the beneficiary[8] to monitor the effectiveness and efficiency of the actions funded. The quantitative action data are complemented by qualitative data from the *final reports* and, where relevant, from the *interim reports* and *selected deliverables*.

Contextual data were collected from indicators published by Eurostat including health status, health determinants, health services or health promotion, etc.

The **three case studies**, on *operating grants*, *joint actions* and *exceptional utility* provision, substantiate the analysis of the effectiveness, efficiency and coherence of the EU4Health Programme and take account of results from implemented actions.

The **stakeholders' consultations** used various quantitative and qualitative data collection tools and methods. These include seven exploratory interviews, an online call for evidence[9] and targeted surveys, 54 targeted interviews, and two focus group meetings. The call for evidence and targeted surveys elicited 30 and 258 contributions, respectively. The targeted interviews and the two focus group meetings provided further insights into the stakeholders' views.

A **literature review** was conducted on peer-reviewed and grey literature to complement the intervention logic and clarify the details of the implementation and data analysis.

1.3 Limitations and mitigation measures

The evaluation covers the implementation of the EU4Health Programme and its annual work programmes from 1 January 2021 to 30 April 2024. Consequently, few funded projects were completed and limited data on results and impacts was available. Some relevant data available after the cut-of date was included in the evaluation.

EU public health interventions often involve multiple components and stakeholders, making it difficult to isolate the effects of specific actions and to evaluate their impact accurately. The EU4Health investments complement the relatively larger and significant scale of the national health funding, which renders challenging to disentangle the EU4Health effects from those of the national funding. This applies, for example, to recruiting health workers, or improving

6 See Annex I of the Commission Staff Working Document EU4Health Programme Performance Monitoring and Evaluation Framework SWD(2024)223 final.
7 See Annex 2 of the SWD(2024)223 final.
8 All indicators are agreed by the Commission and incorporated in the contracts signed with the beneficiaries.
9 Call for evidence - EU4Health programme 2021-2027 – interim evaluation.

access to healthcare or cancer screening, where guidance from EU level[10] and funding provided through the EU4Health Programme go hand in hand with nationally led policy initiatives and investments.

Moreover, investments in health made by other EU funding programmes such as Horizon Europe, the Digital Europe Programme, the European Social Fund Plus (ESF+), the European Regional Development Fund (ERDF) or the Recovery and Resilience Facility (RRF) complement those made by EU4Health and may contribute to its objectives. The effects of these synergies are difficult to quantify at this stage of the implementation process. In addition, the results and impacts of the EU4Health actions are influenced by external factors.

Due to the long-term nature of health outcomes, it is difficult to measure change at the interim stage. Many health interventions have long-term goals and outcomes, which require extended periods of monitoring and evaluation. This can be resource-intensive and subject to various external influences over time.

All the Programme's output and results indicators have been operationalised and used for data collection except for the '*Age-standardised five-year net survival rate for paediatric cancer*'[11] impact indicator, for which the baseline, milestone and target are expected to be set in 2025 (Annex VI). The impact indicators corresponding to the other specific objectives and some of their relevant policy areas (e.g. mental health, health literacy, etc.) remain to be defined. In some cases, establishing a direct causal link between the EU4Health investments and the progress in a policy area is challenging. That is the case for some indicators, included in the Annex II of the EU4Health Regulation, which inform about actions such as vaccination or other similar policies that fall within the competence of the Member States.

In general, establishing a causal link between the inputs and outputs, results and impacts of an EU public health intervention is challenging due to the complex and multifaceted nature of such interventions, where multiple variables and external factors can influence the outcomes. Additionally, the diversity in healthcare systems and cultural contexts, and varying data quality across EU Member States, adds layers of complexity, making it difficult to attribute changes directly to specific interventions. Where possible, the causal link between EU4Health investments will be established for relevant policy areas following the review of the PPMEF and the definition of additional impact indicators.

The Programme data are becoming available progressively and was available in full (for the reference years 2021, 2022 and 2023) for 28 Programme indicators. Four indicators enabled data collection from two years, and ten others from one data point. Data will gradually become available for the remaining 10 indicators. The supporting study does not include or analyse the data that became available after the cut-off date of 30 April 2024, which is partly included in this evaluation report.

The interim evaluation mainly captures outputs and preliminary results at Programme level. A total of 204 actions have been completed (68 were grants entirely managed by the European Health and Digital Executive Agency (HaDEA), and 136 were procurements). By the cut-off date, 26 final reports from funded projects were available for analysis, of which 22 were funded by operating grants and 4 by direct grants. In addition, 7 periodic reports and 8 project

[10] Council Recommendation 2022/C 473/01 of 9 December 2022 on strengthening prevention through early detection: A new EU approach on cancer screening.

[11] See footnote 6.

deliverables were analysed. Except for the operating grants, the project reports are not a representative sample for the effectiveness and efficiency analysis, and the available results are indicative.

As regards procurement, 136 contracts had been finalised and were available for analysis by the cut-off date, of which 104 were executed by DG SANTE and 32 by HaDEA (25 of these were delegated by DG SANTE and 7 by HERA).

The effectiveness of the EU4Health Programme has been determined by analysing data from the PPMEF indicators, given that evidence on the outcomes of actions was limited.

The total budget allocated to one specific objective represents an estimate and is the sum of the budgets (or part it) of different actions that are implementing a particular objective. For example, if an action from the annual work programme implements *two or more specific objectives*, the activities and the total budget are not split per objective in the annual work programme. To allow quantification, the budget of that action is divided equally between the specific objectives that an action implements.

The quantification of benefits and costs relies on stakeholders' estimates. Some of those are derived from scientific and grey literature and may be based on several assumptions (Annex IV).

Stakeholders' views were collected through interviews and focus groups to ensure that different perspectives were represented. In some cases, as mentioned in the evaluation supporting study, the survey responses included multiple respondents from the same organisation. The response rates for the surveys were relatively low, limiting the diversity of perspectives, particularly from those who did not benefit from Programme funding.

The *EU4Health dashboard* data includes the following assumptions that are considered when analysing the data collected with the dashboard indicators[12]: (i) the budget of an action from the annual work programme that implements two or more specific objectives is divided equally between the objectives; (ii) the policy areas are not exclusive for a particular strand; and (iii) the specific objectives may be addressed by actions from different strands. Since the cut-off date (30 April 2024) routine quality checks of the dashboard data have revealed some inconsistencies that were corrected before they were included in the evaluation report. Thus, some discrepancies between the external supporting study and the evaluation report are possible.

The values for the Programme indicators' *baselines*, *milestones* and *targets* were set, except for one cancer indicator[13]. There is variation in the level of detail of the *baseline* data for the EU health policies implemented by EU4Health interventions, being based on publicly available information. In addition, the dates on which the baseline value is set differ between policies, e.g. the implementation of the cross-border threats to health regulation and others, which makes the analysis more complex.

It was challenging to define the Programme indicators, including their *baseline*, *milestone* and *target* values, because the Programme's objectives are deliberately broad to allow for the

[12] For example, number of actions per specific objective, budget per strand, budget per specific objective, number of and type of eligible beneficiaries per country, etc.

[13] Age-standardised five-year net survival rate for paediatric cancer.

financing of all relevant EU health policy priorities and related actions, including preparatory work during the 2021-2027 MFF.

There is *no impact assessment* for the EU4Health Programme, as has been proposed by the European Commission[14]. The existing impact assessment was carried out for a health component under the ESF+ for a much smaller programme with much less funding (EUR 449.4 million) and therefore has limitations as a point of reference[15]. To mitigate this, data were collected as far as available for the situation in 2020, or in the year for which data were available.

The evaluation *results and findings are robust and generally reliable.* The evidence-based approach of the evaluation employed a sound qualitative and quantitative methodology based on the best available evidence drawn from diverse sources.

[14] Proposal for a Regulation on the establishment of a Programme for the Union's action in the field of health –for the period 2021-2027 and repealing Regulation (EU) No 282/2014 ("EU4Health Programme") COM(2020)405 final.

[15] IMPACT ASSESSMENT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on the European Social Fund Plus (ESF+) SWD(2018)289 final.

2. WHAT WAS THE EXPECTED OUTCOME OF THE INTERVENTION?

2.1 Description of the intervention and its objectives

Context of the intervention

The European Health Union[16] was established in November 2020 to better protect the health of people in the EU, to equip the EU and its Member States so that they can better prevent and address future pandemics, and to improve the resilience of health systems in the EU. The European Health Union builds on the outcomes of decades of EU action in public health, including the EU health legislative framework[17] (**Figure 1**).

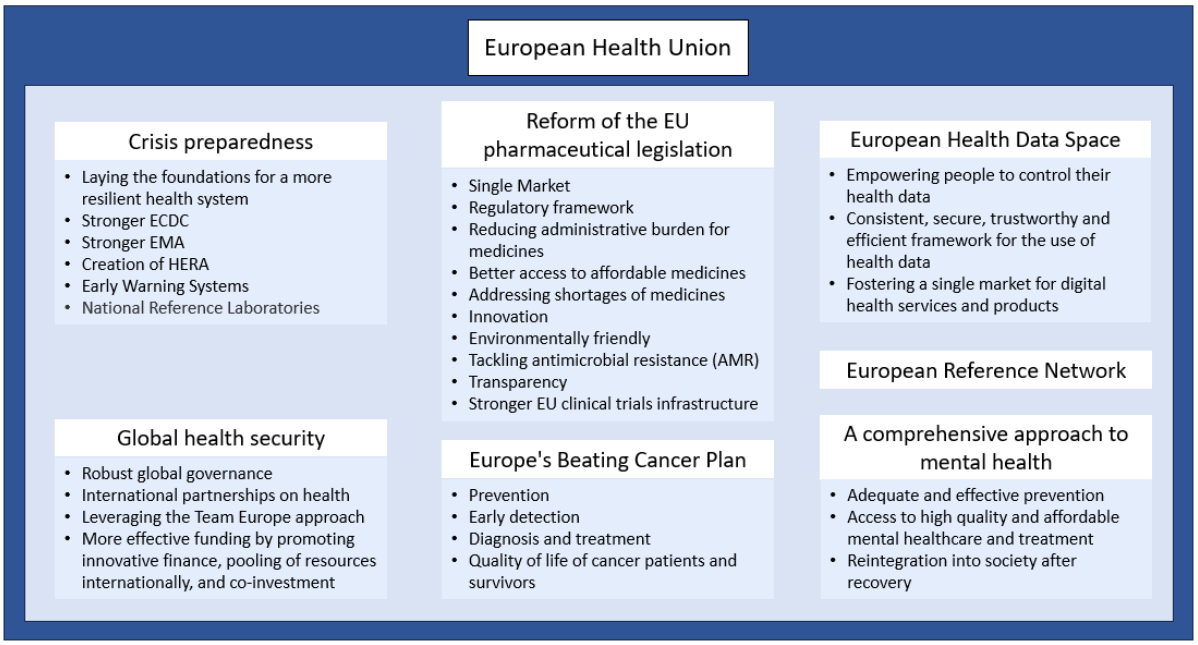


Figure 1 The European Health Union: priorities and legislation (a non-comprehensive illustration)

The EU4Health Programme is the main EU fund that underpins the development of a strong European Health Union[18]. EU4Health funds actions to build the European Health Union by implementing health priorities and policies such as: crisis preparedness and response, including to support the mission of HERA; Europe's Beating Cancer Plan[19]; the reform of EU pharmaceutical legislation or the comprehensive approach to mental health[20], as well as health technology assessments (HTA) and the European Health Data Space (EHDS) Regulation[21]. The

16 European Commission Communication on Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats COM(2020)724 final.

17 See Public Health, European Commission.

18 European Health Union initiatives supported by the Programme are outlined in the Political guidelines for the next European Commission 2019-2024, in the Mission letter to the Commissioner for Health and Food Safety, Political guidelines of the next European Commission 2024-2029, and the Mission letter to the Commissioner-designate for Health and Animal Welfare.

19 European Commission Communication on Europe's beating cancer plan COM(2021)44 final.

20 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on a comprehensive approach to mental health COM(2023) 298 final.

21 Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847, (OJ L, 2025/327, 5.3.2025).

EU4Health Programme also supports activities under the extended mandates of the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC). It also supports the new EU Global Health Strategy[22] and helps the Member States to reach the UN Sustainable Development Goals and targets[23]. In addition, EU4Health supports the development and evaluation of almost all EU health priorities and legislative acts.

Intervention logic architecture

The intervention logic (see Figure 2) reflects the complex interlinkages between the EU4Health Programme's intentionally broad specific objectives and those of the EU health policies and legislation that are building the European Health Union. The intervention logic is structured around 4 general objectives, 10 specific objectives, and 5 strands. The strands – *Crisis preparedness, Health promotion and disease prevention, Health systems and healthcare workforce*, *Digital* and *the* fight against *Cancer* – stem out from the annual work programme's structure. They aim to simplify and facilitate communication and reflect the approach to interact with Programme beneficiaries and stakeholders during programming and implementation. The Programme's intervention logic is further detailed in the PPMEF[24].

Problems and needs

In 2020, the European Union was faced with significant health-related challenges that required a coordinated and comprehensive response. Key areas of concern included:

- the COVID-19 pandemic and other cross-border threats to health, which highlighted the need for strong and proactive public health measures;
- preventing and managing infectious diseases, including combating antimicrobial resistance, which are a pressing concern that required attention and action;
- the burden of non-communicable diseases (NCDs) such as cancer, cardiovascular diseases, mental health and associated long-term care, which had a significant impact on health outcomes and required attention and action;
- cancer, a leading cause of death in the EU that required prioritised research, improved access to high-quality care, and more effective screening programmes;
- improving the management of rare diseases, including by developing high-impact prevention practices and strengthening the ERNs (European Reference Networks);
- addressing healthcare inequalities and unequal access to healthcare, which undermine health outcomes and required targeted efforts to address;
- addressing vaccine hesitancy and misinformation, which could undermine public health efforts and compromise the effectiveness of vaccination campaigns;
- improving health literacy, which is critical for empowering individuals to make informed decisions about their health;
- strengthening the healthcare workforce and healthcare systems, promoting digital transformation, and addressing health determinants;
- ensuring the interoperability of electronic health records, while protecting patient data and maintaining confidentiality, and addressing cybersecurity threats;

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22 EU GLOBAL HEALTH STRATEGY - Better Health for All in a Changing World.

23 In particular Sustainable Development Goal 3 'Ensuring healthy lives and promote well-being for all at all ages' and in particular but not exclusively Target 3.4, namely, to reduce premature mortality from non-communicable diseases by one third by 2030 through prevention and treatment and to promote mental health and well-being; UN resolution of 25 September 2015.

24 See footnote 66.

- addressing the varying levels of digital health literacy among healthcare professionals and patients, which could lead to unequal access to digital health services;
- the digital transition also raised questions about the role of artificial intelligence, the use of data analytics, and the need for a robust data governance framework in healthcare;
- improving access to quality, patient-centred, outcome-based healthcare and related care services, with the aim of achieving universal health coverage;
- ensuring access to medicines and medical devices, which were threatened by shortages and lack of affordability;
- addressing challenges related to the production and disposal of medicines and medical devices, and the regulation of substances of human origin;
- supporting the development, implementation, and enforcement of Union health legislation, and promoting the use of health impact assessments of other relevant EU policies;
- supporting global commitments and health initiatives, including by reinforcing the EU's support for action by international organisations, such as the World Health Organization (WHO).

A comprehensive and coordinated approach, involving Member States and health stakeholders, was needed to address these and other health challenges. The EU4Health Programme provides a crucial framework to address these challenges in the EU and promote a healthier European population and more resilient economy.

EU4Health intervention implements the European Health Union's priorities and related policies and legislation, addressing problems identified at the time of the EU4Health proposal preparation and until its adoption by the co-legislators.

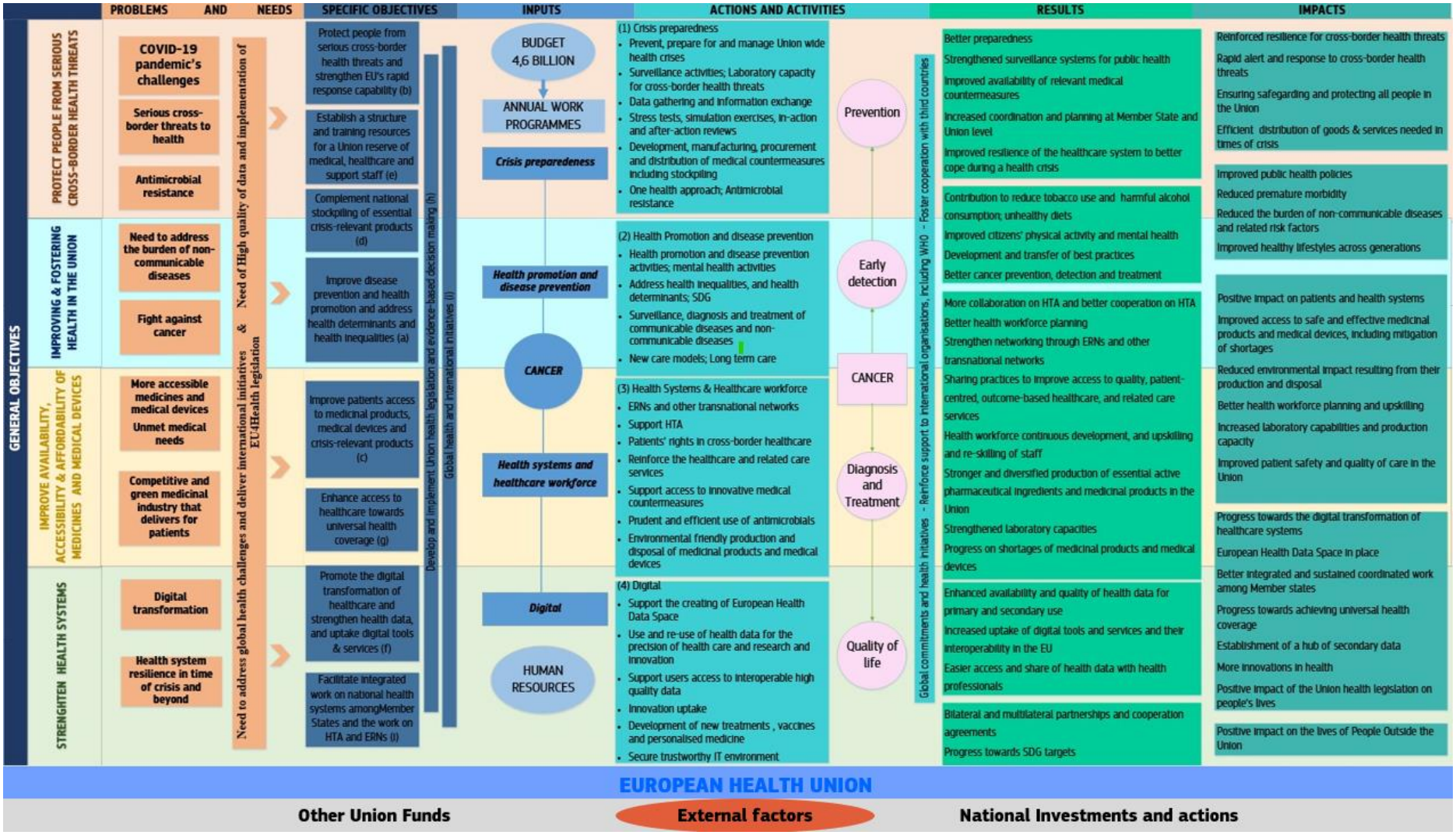


Figure 2 The EU4Health intervention logic

Programme objectives

The general and specific Programme objectives are broad, aligned with the priorities of the European Health Union[25], and closely interlinked with the objectives of the legislative and non-legislative EU health initiatives that the Programme supports financially. The 4 general objectives (*in italics, below*) are pursued through 10 specific objectives ((a) to (j))[26]:

General objective 1: Protecting people in the Union from serious cross-border threats to health

- Protect people from serious cross-border health threats and strengthen the EU's prevention, preparedness and rapid response capability (*b*)[27];
- Complement national stockpiling of essential crisis-relevant products at EU level *(d)*;
- Establish a structure and training resources for a Union reserve of medical, healthcare and support staff *(e)*;

General objective 2: Improving and fostering health in the Union

- Improve disease prevention and health promotion, including cancer, and address health determinants and health inequalities *(a)*;

General objective 3: Improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union

- Improve access to medicinal products, medical devices, and crisis-relevant products *(c)*;

General objective 4: Strengthening health systems

- Promote the digital transformation of healthcare and strengthen health data, and the uptake of digital tools and services *(f)*;
- Enhance access to healthcare towards achieving universal health coverage *(g)*;
- Facilitate integrated work on national health systems among Member States through Health Technology Assessment (HTA), European Reference Networks (ERNs) and other transnational networks *(i)*;

<u>Horizontal specific objectives</u>

- Support the development, implementation, enforcement and revision of Union health legislation as well as evidence-based decision-making *(h)*;
- Support global commitments and health initiatives *(j)*.

The implementation of measures to attain the specific objectives aims to ensure a high level of protection of human health in all EU policies and activities, keeping with the 'One Health'[28] approach, where applicable. The specific objectives are generally operationalised and progress

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25 European Commission Communication on Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats, COM(2020)724 final.

26 In order to simplify the illustration, the specific objectives are presented without the detailed areas of intervention mentioned in Article 4 of the EU4Health Regulation.

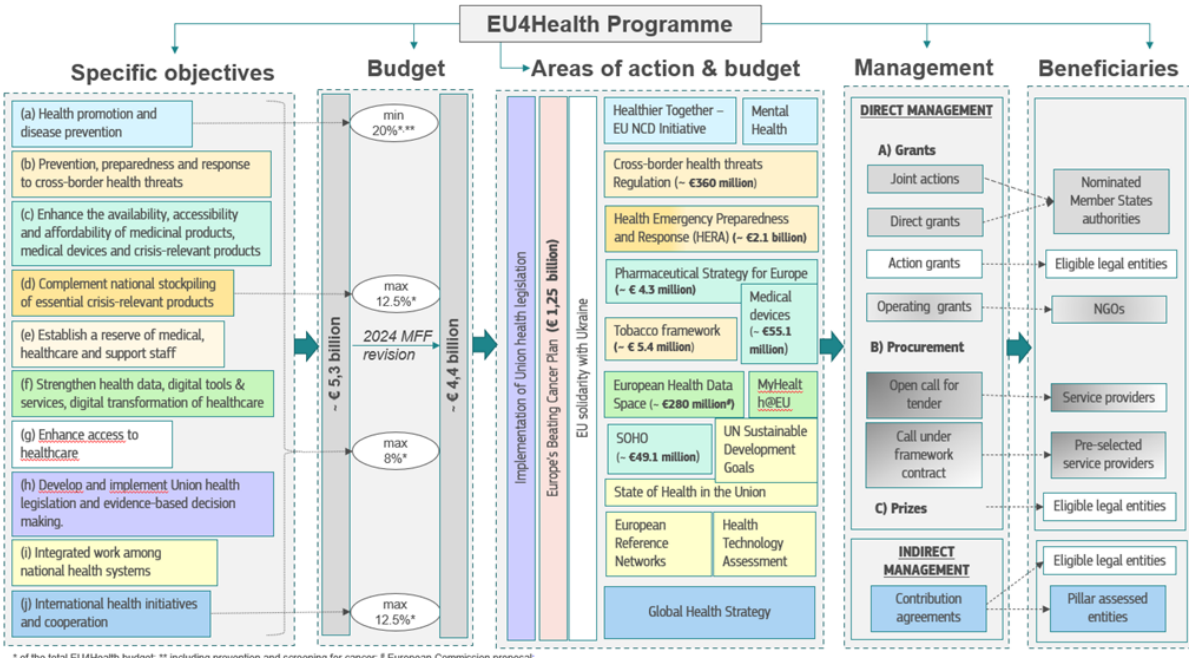
27 The letter indicates the correspondence with the specific objectives (a), (b), (c), (d), (e), (f), (g), (h), (i) or (j) from Article 3 of theEU4Health Regulation.

28 One Health is defined as an integrated, unifying approach that aims to sustainably balance and optimise the health of people, animals, and ecosystems. You can find more information on the Commission webpage.

towards the targets is measured by using Programme output and results indicators. Impact indicators remain to be defined. The specific objectives include specific policy areas that are not covered by the Programme indicators, and these are measured using the action-level indicators defined and included in the funding agreement by the contracting authority and/or the beneficiary in agreement with the contracting authority (*see Programme Performance Monitoring and Evaluation Framework – PPMEF initial assessment in Section 3*).

Inputs

The EU4Health inputs consist of the Programme's budget, the annual work programmes, their budget, and the human resources necessary for programming and implementation. According to the EU4Health Regulation, at least **20% of the Programme budget** must be reserved for health promotion and disease prevention. The Programme should invest no more than 12.5% of its budget in procurement to complement national stockpiling of essential crisis-relevant products and no more than 12.5% in supporting global commitments and international health initiatives and spend a maximum of 8% on administrative expenses[29]. The initial Programme budget of EUR 5.8 billion was reduced to **EUR 4.6 billion**[30] by the revision of the 2021-2027 MFF that redeployed funds across the EU budget, including from EU4Health[31]. The redeployed funds were allocated, among other things, to meet Ukraine's immediate needs, to support Ukraine's recovery and its European path, and to address the needs related to migration pressures, strengthen global partnerships and respond to emergencies.



29 Article 5(4) of the EU4Health Regulation (OJ L 107, 26.3.2021).

30 The initial EU4Health budget was EUR 5.775 billion. The multiannual financial framework revisions reduced it by EUR 1 billion. Furthermore, there were net decreases for compensation of agency reinforcements of EUR 253 million and net increases of around EUR 40 million, leading to an overall budget amounting to EUR 4.562 billion.

31 Council Regulation (EU, Euratom) 2024/765 of 29 February 2024 amending Regulation (EU, Euratom) 2020/2093 laying down the multiannual financial framework for the years 2021 to 2027 (OJ L, 2024/765, 29.2.2024).

Figure 3 The links between the EU4Health Programme and the European Health Union: management and beneficiaries (Source: 2023 Programme performance statement for 2024 draft budget)

In addition to the above legal obligation, other **budget pre-allocations** (Figure 3) need to be considered and are included in the legal financial statements[32] that accompanied the legislative proposals. For example, those linked to the creation of HERA[33] (EUR 2.176 billion for 2022-2027), Regulation (EU) 2022/2371[34] (EUR 360.5 million), the European Health Data Space Regulation[35] (EUR 280 million), or the Medical Devices[36] and In Vitro Diagnostic Medical Devices Regulations[37] (EUR 55 million), etc. Some pre-allocations are included in relevant non-legislative EU health initiatives, for example, Europe's Beating Cancer Plan (EUR 1.25 billion)[38].

The EU4Health Programme budget is implemented through **annual work programmes**[39], adopted by the Commission following a positive opinion of the Member States in the EU4Health Programme Committee and building on relevant stakeholders' views. The annual EU4Health programming process is based on the Commission's analysis of the gap between the current state of implementation and the desired one, as prescribed by the Programme's specific objectives. The Programme's priorities and strategic orientations are defined based on stakeholders' input and in consultation with the Member States to ensure the implementation of the EU's health policy objectives.

The '**strands'** of the Programme cover one or more specific objectives: *Strand 1 – Crisis preparedness*[40]*, Strand 2 – Health promotion and disease prevention*[41]*, Strand 3 – Health systems and healthcare workforce*[42], *Strand 4 – Digital*[43]*,* and the fight against *Cancer (Cross-*

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32 The legal financial statements (LFS) accompanying the legislative proposals include the estimated financial impact of the proposal on appropriations. The LFS therefore pre-allocates a certain budget to the future initiative. To successfully implement the adopted initiative the EU is expected to invest those funds effective and efficiently.

33 LFS of the Proposal for a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level COM(2021) 577 final.

34 LFS of the Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU COM(2020)727 final.

35 LFS of the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space COM(2022)197 final.

36 Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 COM/2012/0542 final.

37 LFS of the Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices COM(2012)541 final.

38 See footnote 19.

39 The annual financing decision, constituting the annual work programme for the implementation of the EU4Health programme for a particular year, is set out in Annex I of the Commission implementing decision. The European Commission adopts implementing decisions pursuant to Article 17(2) of the EU4Health Regulation on the 'Implementation of the Programme'.

40 Includes mainly actions implementing the Programme specific objectives (a,) (b), (c), and (j).

41 Includes mainly actions implementing the Programme specific objective (a).

42 Includes mainly actions implementing the Programme specific objectives (c), (e), (g), and (i).

43 Includes mainly actions implementing the Programme specific objective (f).

cutting strand)[44]. The strands are complemented by *cross-cutting actions* to improve evidence-based legislation[45] and global health[46].

The Programme is implemented mainly in direct management (90.2% of the total budget) by the Commission or the executive agency and uses various **forms of EU funding**[47] for **grants**[48], **procurements**[49] and **prizes**. International organisations pre-selected following 'pillar assessment'[50] by the Commission, implement the Programme in indirect management (9.8% of the total budget) **through contribution agreements and co-delegations**. For grants the **co-financing rate** is up to 60%, or up to 80% in cases of *exceptional utility*, and 100% in the case of direct grants. Though EU4Health supports innovation, so far it has not funded actions via precommercial procurement[51] or public procurement of innovative solutions[52].

DG SANTE and HERA, also referred as the **parent DGs**, are responsible for the annual programming of their respective budgets. HaDEA implements part of the annual work programme as delegated by the parent DGs. A limited number of procurements and all the contribution agreements are launched and monitored by the parent DGs.

The link between problems and needs, actions and activities, results and impacts

Actions funded by EU4Health implement the European Health Union's priorities and contribute to the objectives of the EU Global Health Strategy, addressing problems that were identified at the time of the EU4Health proposal preparation and until its adoption by the co-legislators.

Protecting people from serious cross-border health threats

Cross-border threats to health arise from pathogens such as viruses (e.g. pandemic influenza A(H1N1) pdm09, Ebola, Zika, SARS-CoV-2 or Mpox) that can emerge at any time or may be of a continuous nature such as antimicrobial resistance (AMR). In recent years, AMR has emerged as a major global health threat, with the potential to undermine the effectiveness of modern medicine. The overuse and misuse of antibiotics have led to the development and transmission of resistant bacteria in healthcare and intensive care units, which are also resistant to new antibiotics, making infections harder to treat and threatening patients' lives. These threats are a pressing issue that needs to be addressed at EU level because they pose a serious

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44 Includes mainly actions implementing the Programme specific objectives (a), (c), (f), (g), (h), (i) and (j).

45 Includes mainly actions implementing the programme specific objective (h).

46 Includes mainly actions implementing the programme specific objective (j).

47 Reimbursement of eligible costs actually incurred and unit costs; see Article 125 of the Financial Regulation (EU, Euratom) 2024/2509 (recast).

48 Action grants and operating grants are awarded following competitive calls for proposals. The action grants may be awarded without competition to support the collaborative work of Member State authorities (joint actions) or to set up Europe-wide structures (e.g. European reference laboratories) or national bodies (e.g. data access bodies).

49 Such as, competitive open procedure, restricted procedure, negotiated procedure;, or joint procurement; see Articles 167 and 168 of the Financial Regulation (EU, Euratom) 2024/2509 (recast).

50 The *ex-ante* pillar assessment checks if entities to be entrusted by the Commission with budget implementation tasks under indirect management demonstrate a level of protection of the EU's financial interests equivalent to that existing when the Commission implements the budget itself.

51 Precommercial procurement concerns the research and development (R&D) phase before commercialisation. For details, see Communication from the Commission on Pre-commercial Procurement: driving innovation to ensure sustainable high-quality public services in Europe, COM(2007) 799 final.

52 Public Procurement of Innovative solutions.

hazard to Europe and globally, with the potential to significantly impact public health and disrupt societies and economies.

To address cross-border threats to health and achieve better preparedness, the EU4Health Programme finances actions that help provide a clearer understanding of the risks and challenges posed by cross-border threats, increase the availability of medical countermeasures, increase coordination and planning at Member State and EU level, strengthen the resilience of health systems, and support a global health strategy.

Supporting the development of surveillance activities, data gathering and information exchange will help improve our knowledge, understanding and rapid detection of risks and challenges. The financing of IT platforms, communication modules, laboratory capacity and surveillance systems in the EU and the rest of the world will also provide timely information for prevention and early response.

By investing in the late-stage development, manufacturing, procurement and distribution of medical countermeasures we can ensure that the necessary tools are in place to respond effectively to these threats. The EU4Health Programme finances actions to improve the ever-warm capacity for the production of essential medicines, put procurement processes in place and ensure supply chains for essential crisis-relevant products, as well as actions that support the national stockpiling of such products. The actions should incentivise the industrial development of new antimicrobials and alternative treatments to replace existing ones, resulting in a reserve of treatments against microbes that have developed multiple resistance. Prevention will also be improved by reducing antimicrobial consumption, together with improved infection prevention and control practices in hospitals and long-term care facilities, as well as improved surveillance and monitoring of antimicrobial resistance combined with enhanced global cooperation to track its spread.

By facilitating and supporting collaboration and the exchange of best practices between Member States, the EU4Health Programme contributes to a better alignment of existing and new national plans, including on AMR. EU4Health includes actions that finance the creation of an EU prevention, preparedness and response plan, which complements the national plans in a coherent manner. Regular stress tests, simulation exercises and reviews with the Member States provide Member States with the necessary knowledge to keep updated effective prevention, preparedness and response plans.

Building up capacities to prepare, prevent and manage health crises will make health systems more resilient. Financing the training of trainers on preparedness and the response to serious cross-border health threats and AMR will help to disseminate knowledge within Member States and improve the capacities of national healthcare services and the skills of the healthcare workforce. The EU4Health Programme supports the development of plans and procedures to coordinate hospitals' responses to health crises by combining these measures a more robust framework for addressing health threats is being created.

By supporting international health initiatives and enhancing cooperation with the WHO, the EU4Health Programme is helping to build global resilience and strengthen international partners' capacity to prevent, withstand and effectively respond to health crises. Fostering collaboration with EU candidate countries on medical countermeasures, promoting the exchange of knowledge and best practices, and strengthening the prevention, preparedness and response capacities for all threats (chemical, biological and radio-nuclear) in Ukraine and

neighbouring countries, are expected to improve their health systems' preparedness and response capacity.

The success of these actions depends on national implementation, which is influenced by national policies and the national budget available. The successful implementation of these measures is expected to result in better prevention, a rapid alert system and a more effective response to cross-border threats. This can be observed through the efficient distribution of goods and services needed in times of crisis. By taking proactive and coordinated action at EU and national level, healthcare systems become more robust and resilient, and better equipped to address the challenges posed by cross-border threats to health. The availability of alternative treatments should lead to improved patient outcomes and reduced morbidity and mortality associated with AMR. A reduction in the spread of antimicrobial-resistant microorganisms, together with better treatment, will reduce the economic burdens associated with AMR, including the costs of medical care and loss of productivity. The EU's efforts to address cross-border threats to health, including AMR as a major public health concern, are helping to improve global health security. Thus, the Programme will contribute to the effective protection of people from serious cross-border threats to health.

Improving and fostering health in the EU

Non-communicable diseases, including cancer, diabetes and cardiovascular and neurological diseases, which reduce life expectancy and quality of life, account for around 80% of the disease burden in the EU. Up to 80%[53] of cases of premature heart disease, strokes and diabetes are preventable by reducing major risk factors such as tobacco use, harmful alcohol consumption, unhealthy diets, physical inactivity, air pollution and exposure to carcinogenic agents and radiation.

Improving and fostering health in the EU requires a holistic and comprehensive approach. Investment in *health promotion and disease prevention* are crucial for creating a healthier and more productive society and economy. This not only improves the quality of life of people and communities, but also reduces healthcare costs, increases productivity and addresses health inequities.

For example, in 2020, 2.7 million people in the EU were diagnosed with cancer, and another 1.3 million people lost their lives to it. The EU accounted for a tenth of the world's population, but a quarter of the world's cancer cases. To respond to this issue, the comprehensive Europe's Beating Cancer Plan, which aims to tackle the entire disease pathway, was adopted in February 2021.

As the mental health of many people deteriorated during the COVID-19 pandemic, major actions were taken at EU level under the EU4Health Programme to address mental health diseases and their burden on societies and economies. The EU continues to pursue a comprehensive, prevention-oriented approach to mental health.

The EU funds the *development and transfer of best practices on prevention* that EU Member States can implement through their policies and programmes to promote healthy behaviours and provide access to healthy food and physical activity. Financial support is necessary to adapt the legislation that encourages behavioural changes and addresses health inequalities and health determinants. Actions under the EU4Health Programme that aim to develop communication

[53] World Health Organization (WHO) Noncommunicable diseases.

strategies, identify barriers and facilitators, raise awareness, train health professionals, and exchange of best practices, should allow Member States to improve various prevention activities such as cancer screening, vaccination campaigns, and many more.

EU4Health finances actions that facilitate data sharing and collaboration between Member States through the development of health information systems, including the development of health information frameworks that help track NCDs and monitor their impact. These actions should lead to a better understanding of these diseases including related mortality, morbidity and the prevalence of risk factors. Such improved understanding would make it possible to design and support the development of new diagnostic tools and technologies to improve the accuracy and timeliness of diagnosis. By strengthening surveillance and diagnosis, the trends and patterns in NCDs can be identified, which will help support Member States to make informed decisions about resource allocation. Providing financial support for screening and early detection methodologies and diagnostic tools such as genetic profiling would complement early detection measures, in particular for cancer, and help implement the Council Recommendation on cancer screening.

EU4Health funding supports the sharing of best practice and the creation of networks of expertise that focus on innovative treatment, care models development and solutions to addressing the challenges of long-term care. Direct support to patient groups and vulnerable groups will make it possible to identify and better address their specific needs in care and treatment. The creation of inequalities registers can help Member States to map disparities in treatment and care and thus focus their action on closing these gaps. For cancer patients, access to high-quality information and data are expected to be facilitated through digital tools and online platforms, improving also patient-clinician relationships. This leads to better communication and more personalised care.

The actions funded will provide national health authorities and care facilities with tools and knowledge that they can implement to improve their public health policies to better tackle non-communicable diseases, with a particular focus on cancer. If Member States put in place initiatives and funding for implementation, this will lead to long-term results such as reduced premature mortality, improved cancer survival rates, improved quality of life, and a reduction in the burden of NCDs and related risk factors. This approach is expected to improve health outcomes, reduce healthcare costs, increase productivity and reduce health inequalities. By working together, the EU and its Member States can create a healthier and more resilient population, in line with the EU's goals of improving health promotion, preventing disease and reducing health inequalities. This strand will thus help the Member States to reach the UN SDGs and targets[54], and the relevant WHO global NCD targets for 2025[55].

Improve the availability, accessibility and affordability of medicinal products and medical devices

It is challenging to ensure that patients across the EU have access to essential healthcare resources, including medicinal products and medical devices, due to high costs, disparities in access, and regulatory complexities.

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54 UN resolution of 25 September 2015. In particular, Sustainable Development Goal 3 Ensuring healthy lives and promote well-being for all at all ages and its Target 3.4, namely, to reduce premature mortality from non-communicable diseases by one third by 2030 through prevention and treatment and promote mental health and well-being.

55 Set of nine voluntary global NCD targets for 2025, World Health Organization 2022.

To achieve this objective, the EU4Health Programme provides funding for actions aiming to promote the development and availability of generic and biosimilar medicines; improve the regulatory framework for pharmaceuticals, including through capacity building in the competent authorities for medicines in the Member States; support health technology assessments (HTAs); and increase laboratory and production capacities for medicines, medical devices and health crisis medical countermeasures. A robust and harmonised regulatory framework for pharmaceuticals and medical devices will facilitate the development, authorisation and marketing of medicinal products and medical devices that are safe and effective. Such a framework will also incentivise industry to invest in the EU market and thus ensure the availability of these products. Accessibility, availability and affordability of medical products in Member States depends on national pricing and reimbursement policies. EU4Health provides financial support for the implementation of the HTA Regulation[56], for example for the training and capacity building of national assessors and for the training of patients' experts. The expected output includes improved coordination and collaboration between Member States and experts through the consolidation of knowledge and experience on joint HTA work.

Supporting the development of generic and biosimilar medicines is expected to increase their availability and to have a long-term positive impact on access to affordable medicines, reducing healthcare costs and improving access to treatment for patients. Disparities in access to healthcare across the EU will be reduced, ensuring that all patients have equal access to essential healthcare resources.

The development of laboratory and production capacities for medicines, medical devices and crisis countermeasures will improve the EU's ability to respond to public health emergencies.

Strengthen health systems

The EU's health systems face significant challenges, including fragmented and underdeveloped systems, limited capacity for health research and innovation, healthcare inequalities, insufficient adaptation to digital developments as well as inadequate planning for and skill gaps in the health workforce. To address these challenges, the EU4Health Programme aims to strengthen Europe's health systems by improving access to healthcare with a special focus on healthcare for vulnerable groups. It will also tackle these challenges by promoting the digital transformation of healthcare and by improving training and planning for the healthcare workforce.

To achieve this objective, EU4Health supports the development of EU legislation on health issues, as well as capacity building and networking efforts to enhance collaboration between national, regional and local authorities, facilitate more effective healthcare planning and delivery and improve access to healthcare. EU funding would also strengthen collaboration between Member States to: address common health challenges; facilitate the development of guidelines and health services across borders; spur research, development and the use of innovative solutions in healthcare; support the exchange of knowledge and good practices to help health systems become more efficient, resilient and sustainable.

To improve access to healthcare for vulnerable populations, including Roma, migrants, refugees (including people displaced from Ukraine) and people with a disability, EU4Health

[56] 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).

finances actions to improve health literacy and health promotion, particularly in rural and remote areas. To tackle rare diseases, the Programme finances the creation and integration of European networks for rare diseases, bringing together specialised healthcare providers and experts to improve diagnosis and the coordination of care. This includes the development and implementation of standardised care pathways and guidelines, as well as the provision of training and capacity-building programmes for healthcare professionals. By reducing healthcare inequalities, the Programme will help implement the European Pillar of Social Rights and help reduce poverty and social exclusion.

Moreover, the EU4Health Programme provides funding and support for the development of digital building blocks like the European Health Data Space (EHDS), the electronic health records (EHRs) system, and data analytics capabilities. Supporting the development of telemedicine and telemonitoring can improve access to health services for populations in medical deserts, reduce the costs of long-term care and healthcare services, and support longer independent living. The Programme is expected to drive increased national investment in the digital transformation and a skilled healthcare workforce, fuelling innovation in health and improving health outcomes, and allowing healthcare providers to use interoperable digital health tools and services across the EU. Ultimately, the EU's efforts to promote the digital transformation of healthcare will have a significant impact on the healthcare sector, leading to the development of sustainable digital healthcare systems, improved health outcomes, higher quality care for patients, and a continued boost in efficiency and productivity.

The EU provides funding and support for the development of skills in the healthcare workforce that are necessary for the digital transformation of health systems, and innovative solutions for quality healthcare services. The Programme also aims to enhance the resilience and sustainability of the healthcare workforce, addressing issues related to working conditions and workers' mental health. The expected results of these efforts include improved capacities in Member States to plan, recruit and train a skilled and flexible healthcare workforce.

The actions funded by EU4Health provide Member States with building blocks and tools that they can use to improve their national health systems. To do this, Member States must make the necessary human and financial resources available. Ultimately, the expected impacts include: improved access to healthcare; reduced health inequities; improved health and well-being for people in the EU, with the costs of healthcare contained; the enhanced economic competitiveness and productivity of the EU's healthcare sector; increased cooperation and collaboration between Member States on health policy and healthcare delivery; improved resilience of health systems and preparedness for future health challenges; a lasting impact on health systems across the EU.

2.1.5 Expected achievements at the time of the evaluation

By April 2024, it was expected that the **Programme's governance and the programming and implementation processes** would be well established in the parent DGs and HaDEA, and that the parent DGs and HaDEA would be delivering annual work programmes on time, making amendments as necessary, and implementing the Programme and executing the budget according to the responsibility of each contracting authority[57].

In terms of ***crisis preparedness***, most of the actions were planned to focus on a rapid response to the COVID-19 pandemic, the preparatory actions to implement Regulation (EU) 2022/2371

[57] DG SANTE, HERA or HaDEA.

on serious cross-border threats to health[58] (as well the provisions of its predecessor[59]), to address the consequences of the pandemic, and increase the preparedness of Member States and the EU in case of a new pandemic. The EU must be ready to ensure the development, manufacturing, procurement and equitable distribution of key medical countermeasures in line with the mission and work plans of HERA[60]. The Programme's milestones[61] provide that 27 Member States were expected to report an **increased level of preparedness and response planning**[62] and 18 Member States were to have improved their preparedness and response planning for medical countermeasures by 2023[i]. By mid- or end- 2024, it was expected that 20 actions would contribute to the fight against communicable diseases[ii], 26 Member States and associated countries would be participating in more than one EU action to improve prevention, preparedness and response planning for serious cross-border threats to health[iii], and that 3 Member States and associated countries would have improved their procurement procedures for medical countermeasures during a health crisis[iv]. At least one Member State and or associated country should have increased its laboratory and diagnostic capacity for cross-border health threats, contributing to the mission of HERA[v].

By mid-2024, it was expected that the Programme would have financed five actions aimed at **complementing national stockpiling of essential crisis-relevant products**, and that five Member States or associated countries would be participating in the joint action on stockpiling[vi].

It was also envisaged that the Programme would finance, in synergy with other EU funds, actions putting in place a **structure and training resources for a reserve of medical, healthcare and support staff** allocated voluntarily by Member States for mobilisation in the event of a health crisis. By mid-2024, training actions on preparedness and response to cross-border health threats, targeting healthcare staff and public health staff[63], and on medical countermeasures[vii], were to reach 955 participants, and the participants' satisfaction rate in HERA training programmes[viii] was to reach 85%.

On the '**One Health**' approach, new investments were expected to contribute to the late-stage development and uptake of new medical countermeasures, as well as to support actions implementing the Council Recommendation on stepping up EU action to combat antimicrobial resistance[64] in the areas of human health, animal health and the environment. It was projected that the One Health surveillance programmes would have been successfully implemented[ix] in 23 countries by mid-2024. In addition, the antimicrobial consumption for systemic use of

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58 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 (OJ L 314, 6.12.2022).

59 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.

60 European Commission Communication on Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union, COM(2021)576 final.

In most cases they are set in 2024 and in few cases in a preceding (e.g. 2023) or subsequent year (e.g. 2026). expected data at the time of evaluation stems from the Programme indicators' milestones set usually in 2024; see PPMEF also for more details.

62 The Roman numbers e.g. 'i' indicate an endnote that is found at the end of this document. To improve readability, repetitive references to the programme indicators are presented in the 'endnote' section of this document.

63 Regulation 2022/2371, Article 11, Train the trainers.

64 Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach, (OJ C 220, 22.6.2023).

anatomical therapeutic chemical (ATC) group J01[x] was expected to decrease by almost 2 measurement units.

By the time of the evaluation, it was expected that the annual work programmes would include actions supporting ***health promotion and disease prevention***, as outlined by the *Healthier together* EU NCD initiative,[65] and help the Member States and associated countries to reach the UN Sustainable Developmental Goals. By mid- or end-2024, at least five actions were to be financed on reducing avoidable mortality in the area of NCDs and associated risk factors[xi]. Ten Member States were expected to implement and roll out at the national level EU-funded projects on 'best' and 'promising' practices in health promotion, disease prevention and health inequalities. In addition, at least one action was to be funded on addressing the prevalence of the harmful use of alcohol[xii] and four on addressing environmental risk factors for health[xiii]. By the same deadline, six Member States should have reached 95% coverage for both the first and second dose of the measles vaccine for eligible individuals, one Member State was expected to reach 75% coverage for the seasonal influenza vaccine in older age groups, and it was anticipated that two Member States would reach at least 90% coverage for the human papillomaviruses (HPV) full vaccination course (last dose) in eligible girls.

The progress expected under the ***health systems and healthcare workforce*** strand is proportional to the amount of EU funding and greatly relies on the Member States' responsibilities enshrined in the EU Treaty[66].

As a general reference on expected outcomes from investing in health systems, a societal multiplier for spending on healthcare and related public health measures of slightly more than three can be assumed. This is based on an analysis of megatrends in historically reported population health outcomes, of findings from the literature on the role of healthcare investments in improved population health status and using standard methods to monetise health outcomes. Moreover, a recent systematic review[67] of the expected return on investment for various categories of health-related policy interventions indicated a median return on investment of 14.3 across reported studies[68] for public health interventions, underscoring the importance of investing in prevention.

The Programme's actions help strengthen national health systems and the health workforce by improving their resilience and resource efficiency. Actions were expected to support the implementation of the HTA Regulation, and the Directive on patients' rights in cross-border healthcare, including as regards the ERNs[69].

By mid-2024, the number of healthcare units involved in ERNs[xiv] was expected to reach 1 619 and the number of patients referred to ERNs whose cases are reviewed by the members of ERNs to reach 1.5 million.

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65 Healthier Together EU Non-Communicable Diseases Initiative.

66 Article 168 (7) of the Treaty on the Functioning of the European Union.

67 Masters R, Anwar E, Collins B, et al., Return on investment of public health interventions: a systematic review, J Epidemiol Community Health 2017;71:827-834.

68 Various caveats apply when comparing studies reporting return-on-Investment outcomes, stemming notably from differences in calculation methods, timeframe inconsistencies, cost and benefit definitions. The methodological quality (and comparability) of studies considered for this systematic review was explicitly addressed.

69 Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.

The Programme was expected to improve the *availability, accessibility and affordability of medicinal products, medical devices and crisis-relevant products.* It was expected to support the implementation of the pharmaceutical strategy for Europe[70]; the EU regulatory frameworks on pharmaceuticals[71], medical devices[72] and substances of human origin[73], and the measures proposed in the Communication on addressing medicine shortages in the EU[74]. By mid- or end 2024, the number of single marketing authorisations of specific medicines valid across the European Union should have increased to 96[xv], and the number of certificates for medical devices to be placed on the EU market were expected to increase by a factor of 18[xvi]. The number of certificates for in vitro diagnostic medical devices intended for the EU market was expected to increase by a factor of 32[xvii]. The level of monitoring and reporting on relevant shortages of human and veterinary medicines was expected to reach maturity, and the level of shortages was expected to remain at 110 reported medicines shortages.[xviii]. In addition, at least three actions were expected to contribute to increasing the security and continuity of global supply chains and to address the EU's dependence on imports from third countries to produce essential active pharmaceutical ingredients and medicinal products[xix]. It was expected that four new producers, and producers with enhanced capacity to increase the security and continuity of supply of medical countermeasures, raw materials and components in the EU, including 'ever-warm capacities', would be identified[xx]. Four times more audits were to be conducted in the EU and in third countries, including the EU candidate countries, to ensure that good manufacturing practices and good clinical practices were in place (EU control on compliance with these EU minimum standards)[xxi]. Lastly, three Member States were expected to participate in actions to support innovation, uptake and access to the market of medical countermeasures at EU and global level[xxii].

Improvements were expected on *enhancing access to healthcare with the aim of achieving universal health coverage*. By mid-2024, at least three actions were to be financed on producing guidance on improving access to healthcare services.

The ***digital*** strand was expected to support the actions to prepare the implementation of the European Health Data Space Regulation[75], which aims to advance the digital transformation of health systems and the creation of a European Health Data Space. By mid-2024, it was projected that the number of actions included under EU4Health work programmes (grants and procurements) to support the digital transformation of healthcare systems and the implementation of the EHDS should reach 28. In addition, the number of Member States connected to MyHealth@EU and/or to the cross-border infrastructure for secondary uses

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70 Communication from the Commission to the European Parliament, the Council, The European Economic and Social Committee and the Committee of the Regions, Pharmaceutical Strategy for Europe, COM(2020)761 final.

71 A pharmaceutical strategy for Europe.

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

73 Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L, 2024/1938, 17.7.2024).

74 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Addressing medicine shortages in the EU, COM(2023) 672 final.

75 Proposal for a regulation of the European Parliament and of the Council on the European Health Data Space COM(2022)197 final.

should more than double, and five times more health data access bodies should be set up by the Member States and associated countries.

Several Programme indicators monitor the progress expected under the ***cancer*** strand (a cross-cutting topic). The number of Member States that have achieved a defined coverage of cancer screening among the population was expected to be six for breast cancer and five for cervical cancer, and to remain stable at nine countries for colorectal cancer. The percentage of the population covered by cancer registries reporting information on cervical, breast, colorectal and paediatric cancer at the diagnosis stage was projected to be 60% for each type of cancer.

On *horizontal actions*, it was expected that at least two impact assessments, supporting reports and staff working documents on EU health policies supported by the Programme[xxiii] would be published. The Programme was expected to finance 14 published studies supporting the evaluation, monitoring the implementation, and assessing the functioning of legislative and non-legislative policies[xxiv].

The Programme contributes to international health initiatives and cooperation supporting the implementation of the EU Global Health Strategy, global efforts on pandemic preparedness and the implementation of international health legislation. By 2024, it was expected that there would be 19 actions supporting global commitments and health initiatives concluded with global partners[xxv], that EU and the WHO would collaborate in 9 areas[xxvi] , and that the EU and relevant global partners and EU Member States would coordinate actions in 4 areas[xxvii]. The expected achievements at the time of the interim evaluation as well as the targets for the *ex-post* evaluation, including the situation at the time of the evaluation, are presented in Annex VII.

2.2 Point(s) of comparison for the EU4Health intervention

The ***reference point of comparison*** for the EU4Health intervention is the **2020 situation**, which existed in the EU and its Member States between the onset of the pandemic early in 2020 and June 2021, when the Programme began to be implemented. The baseline for 33 Programme indicators is set at 2020, and for 25 indicators the baseline value is zero. In some cases, the reference is the situation **before 2020** (for 5 indicators) or **after 2021** (for 14 indicators), depending on the data available or the time when implementation of the specific policy intervention began[76]. The *reference point of comparison* for some policy areas and their Programme indicators, for example for vaccination coverage for seasonal influenza, was set before March 2020 because the data were not available during the baseline period. The baseline for some indicators was also set before 2020 because of the lack of available data[77].

The *reference point of comparison* for some policy areas and their Programme indicators was set after March 2021 because the legal base (e.g. the Regulation on serious cross-border threats to health, the HTA Regulation) dates from several years after the EU4Health intervention had started, or because the data were not available during the baseline period, for example in the case of vaccination coverage for human papillomaviruses (HPV) and data on the age-standardised five-year net survival rate for paediatric cancer (to the extent available)[78].

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76 See Annex IV of this document.
77 Annex I of the PPMEF.
78 Annex I of the PPMEF.

The baselines, milestones and targets for the Programme indicators have been defined as far as possible at this stage. The details for all the other indicators are provided in Annex VII.

The ***main point of comparison*** for assessing the progress of the EU4Health intervention at interim stage is the **expected situation in 2024** (milestone). The milestone for 44 indicators is set as 2024; for 2 indicators it is set before 2024, and after 2024 for 6 indicators, according to the availability of data or the stage of implementation of the policy.

The ***main point of comparison*** for the final evaluation of the EU4Health intervention is the **expected situation in 2027** (target), or in some cases 2030 or 2031 for actions that will be launched under the last annual work programme in 2027.

The above points of comparison are described qualitatively in Annex VIII based on information from the explanatory memorandum of the proposal for an EU4Health Regulation[79], the relevant recitals of the EU4Health Regulation[80], the mid-term[81] and *ex post* evaluation[82] of the third Health Programme[83], in relevant reports and evaluations of the various EU health policies, and other relevant literature.

No impact assessment was made for the proposed EU4Health Programme.

79 Proposal for a regulation of the European Parliament and of the Council on the establishment of a Programme for the Union's action in the field of health –for the period 2021-2027 and repealing Regulation (EU) No 282/2014 ("EU4Health Programme") COM/2020/405 final.

80 See footnote 1.

81 European Commission: Directorate-General for Health and Food Safety, *Mid-term evaluation of the third Health Programme (2014 – 2020) – Final report*, Publications Office, 2017, https://data.europa.eu/doi/10.2875/359384.

82 Commission Staff Working Document Evaluation: Final Evaluation of the Third Health Programme 2014-2020 (SWD(2023)370 final).

83 The third Health Programme for the years 2014-2020 was established by Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC (OJ L 86, 21.3.2014).

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

3.1 Current state of play

The **EU4Health programming** process is operating as expected and four annual work programmes and five amendments were adopted by the Commission by the cut-off date. There is a well-established process to consult stakeholders and four consultations, and four events have been organised for that purpose. The Member States were initially consulted about the programming for 2021 in an ad hoc expert group and, after the adoption of the EU4Health Regulation, in 14 meetings of the EU4Health Steering Group. The Member States provided their opinion in the Programme Committee, which met on 6 occasions. The Commission made amendments to the EU4Health Programme through written procedures.

At the time of the interim evaluation, the expected achievements consist mainly of outputs (e.g. the number of actions addressing the fight against communicable diseases, the number of actions contributing to the reduction of avoidable mortality in the area of non-communicable diseases and risk factors, etc.). As expected, only a limited number of projects (162) delivered results by April 2024, as many of them are still in their early stages. A total of 26 grant final reports and 136 procurements were validated by the contracting authority and were then suitable for analysis (e.g. number of Member States and associated countries with improved procurement procedures for medical countermeasures during a health crisis, percentage of the population covered by cancer registries reporting information on cervical, breast, colorectal and paediatric cancer stage at diagnosis). The impacts are expected to be measurable at a later stage, after relevant and significant results have been delivered.

At the interim stage (by April 2024), the Programme is performing as expected and has made substantial financial contributions to the EU's horizontal priorities such as the digital transition (EUR 349.6 million), gender equality (EUR 178.1 million) and green budgeting (EUR 314 million). The parent DGs have programmed about EUR 2.63 billion of expenditure and the contracting authority has signed 726 contracts and committed about EUR 1.39 billion, which represents more than half (53%) of the programmed budget and covers each specific objective (Figure 4; see also Annex VIII).

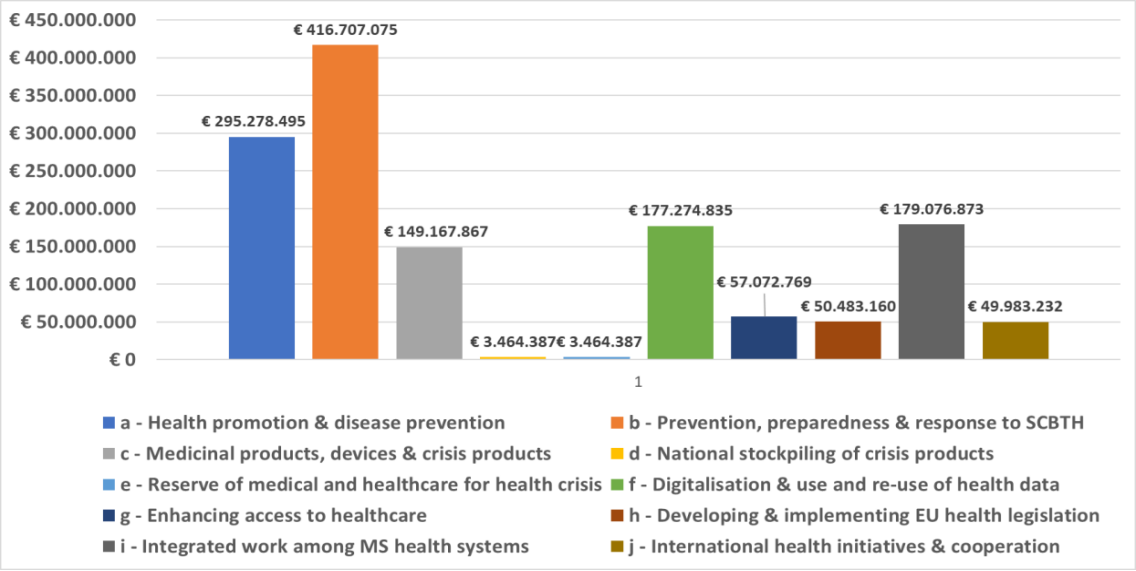


Figure 4 Total EU4Health commitments under each specific objective

The commitments shown above include grants, procurement, contribution agreements and prizes.

The absorption of EU4Health funding per Member States and their legal entities shows that 15 Member States and associated countries (see Figure 5) have benefited to a total of EUR 916 million, each receiving more than EUR 20 million. The remaining 16 Member States and associated countries received EUR 163 million, of which 6 have received about EUR 15 million and 10 have received about EUR 10 million or less. One country associated to the Programme has not managed to access any EU4Health funds (Figure 5). Designated national focal points will intensify the promotion of the EU4Health Programme and, where relevant, in the dissemination of its results and the information available on its impact in the Member States and associated countries.

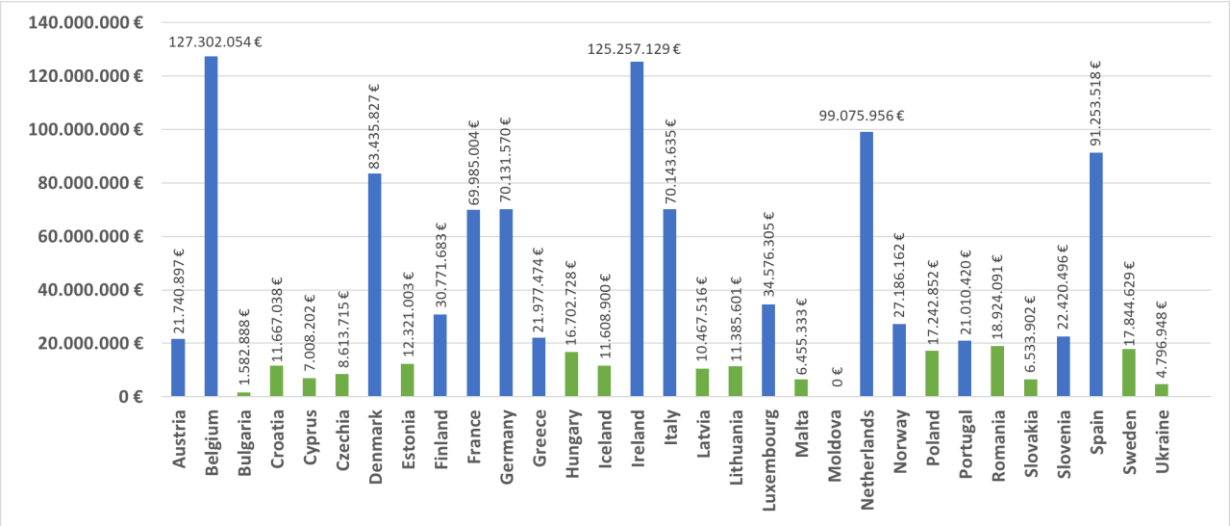


Figure 5 Total EU4Health commitments per Member State and Associated non-EU country

The grants beneficiaries from 22 countries[84] are mainly national or regional authorities nominated by their home country to participate in joint actions or to receive other direct grants. The other grant beneficiaries are public health organisations (such as healthcare units, research organisations, NGOs, etc.).

[84] Austria, Bulgaria, Croatia, Cyprus, Czechia, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Malta, Netherlands, Norway, Slovenia, Spain, Sweden and Ukraine.

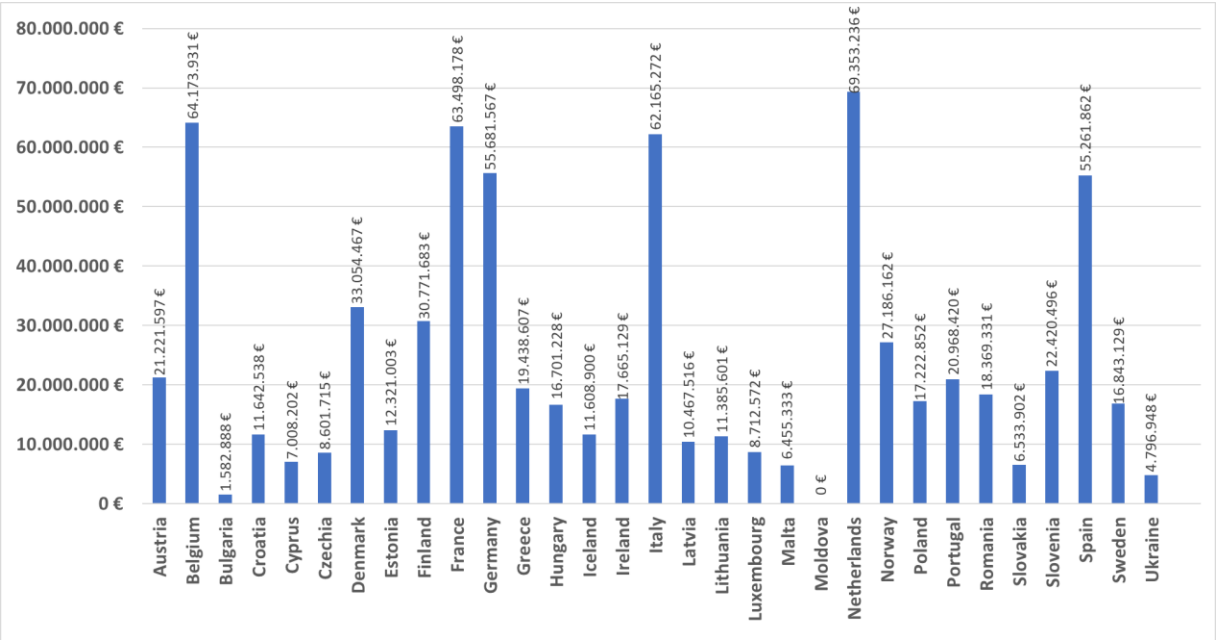


Figure 6 Total EU4Health commitments through grants per Member States

HaDEA has managed the largest budget share of procurement of services (Figure 7), which were made under the crisis preparedness strand. This includes HERA's flagship initiatives such as EU FAB (the framework contract for the reservation of capacities and a priority right for manufacturing of vaccines), which aims to ensure ever-warm facilities for vaccine production. The crisis preparedness envelope also includes funding for the development of IT tools for early warning, modelling, simulation and forecasting, as well as to develop and put in place infrastructures for the governance of the health data space in Luxembourg.

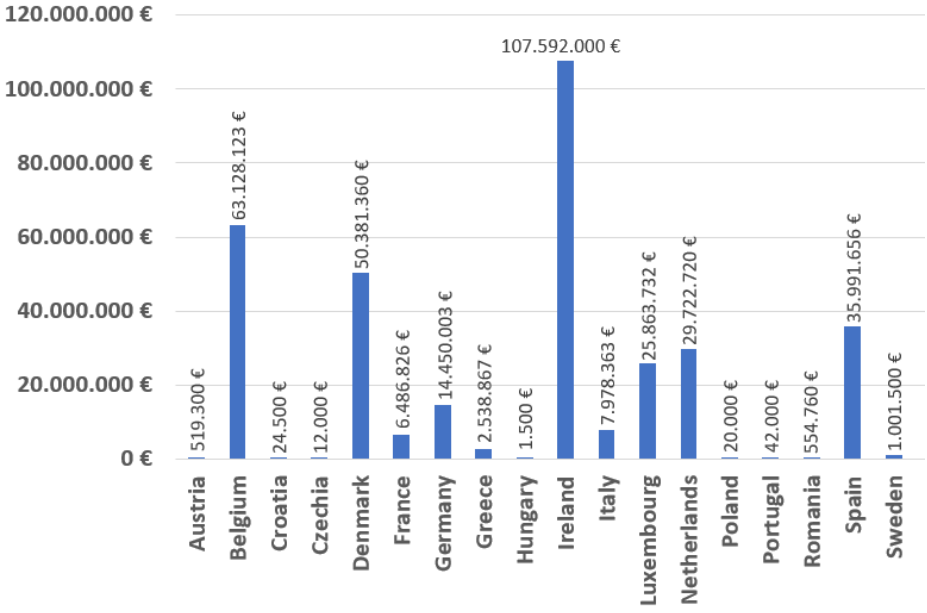


Figure 7 Total EU4Health commitments through procurements with legal entities from Member States

Although EU4Health supports innovation, so far it has not funded any actions via precommercial procurement[85] and public procurement of innovative solutions.

The evaluation supporting study found that projects to support the strengthening of preparedness and response capacities in the field of medical countermeasures are typically awarded almost EUR 20 million each through procurement. Projects that support other EU health priorities, such as implementing the Regulation on serious cross-border threats to health or the EU pharmaceutical framework, or which are aimed at health promotion and disease prevention, or the health digital transition, are typically granted around EUR 2.5 million in funding.

The breakdown of financing per strand (Figure 8) shows that crisis preparedness has received close to half of the EU4Health funding so far: 47.7% (EUR 623 million) has been committed to actions in this strand. This is followed by 17.2% (EUR 239 million) for health systems and 15.8% (EUR 220 million) for cancer. For health promotion and disease prevention, the current share is 11.2% (EUR 154.4 million). The digital strand has received 9% (EUR 125 million) of funding, and 2.3% (EUR 31.4 million) has been committed to other actions.

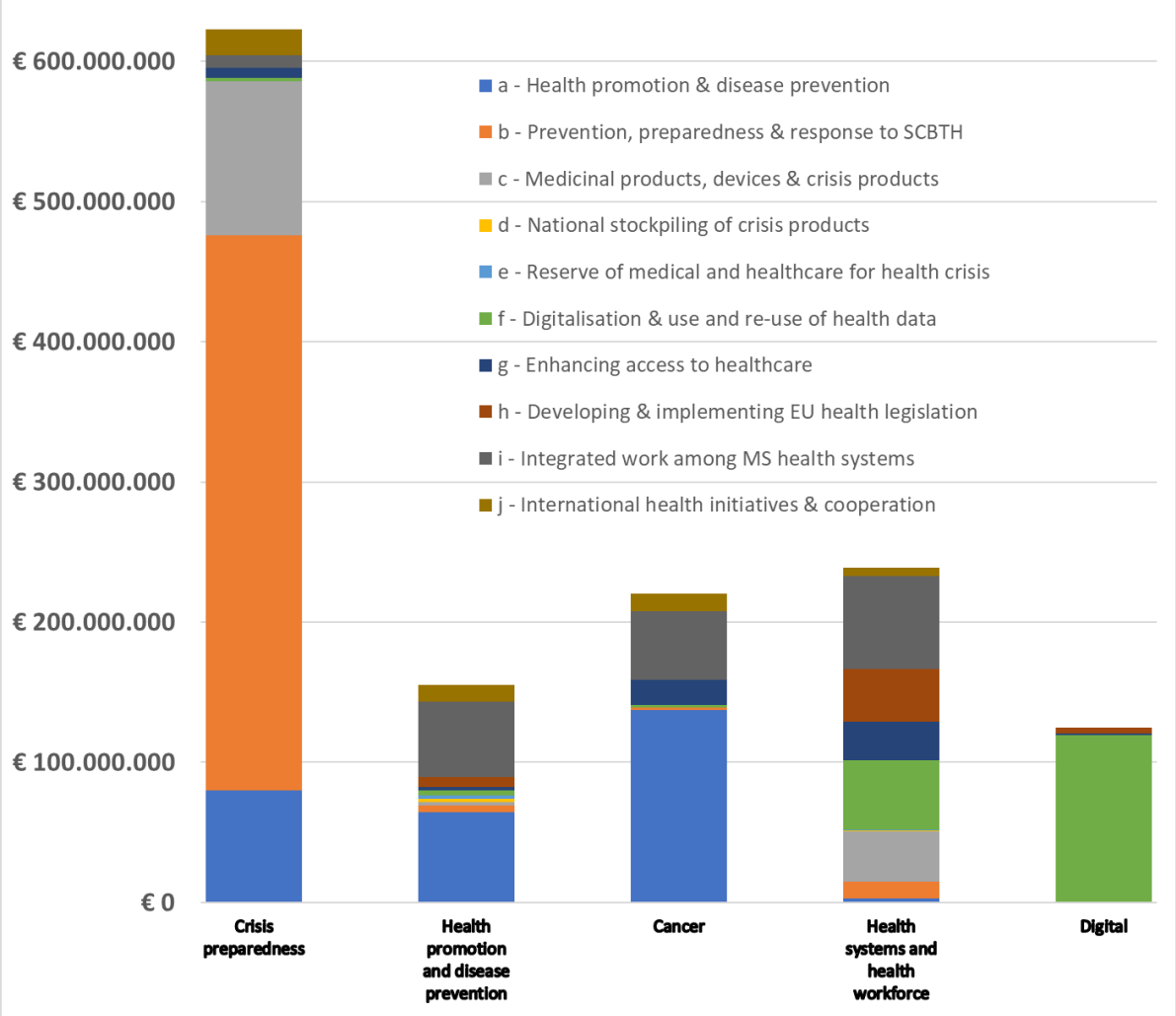


Figure 8 Total commitments by strand and specific objectives

[85] See footnote 51, page 13.

There are a total of 1 274 participants in EU4Health projects. The total EU contribution they receive is slightly above EUR 1.39 billion. The main beneficiaries, both in terms of the EU contribution received and the number of project participations, are public entities, such as national health agencies, institutes and laboratories, national ministries, university hospitals and research organisations (see Figure 9)[86].

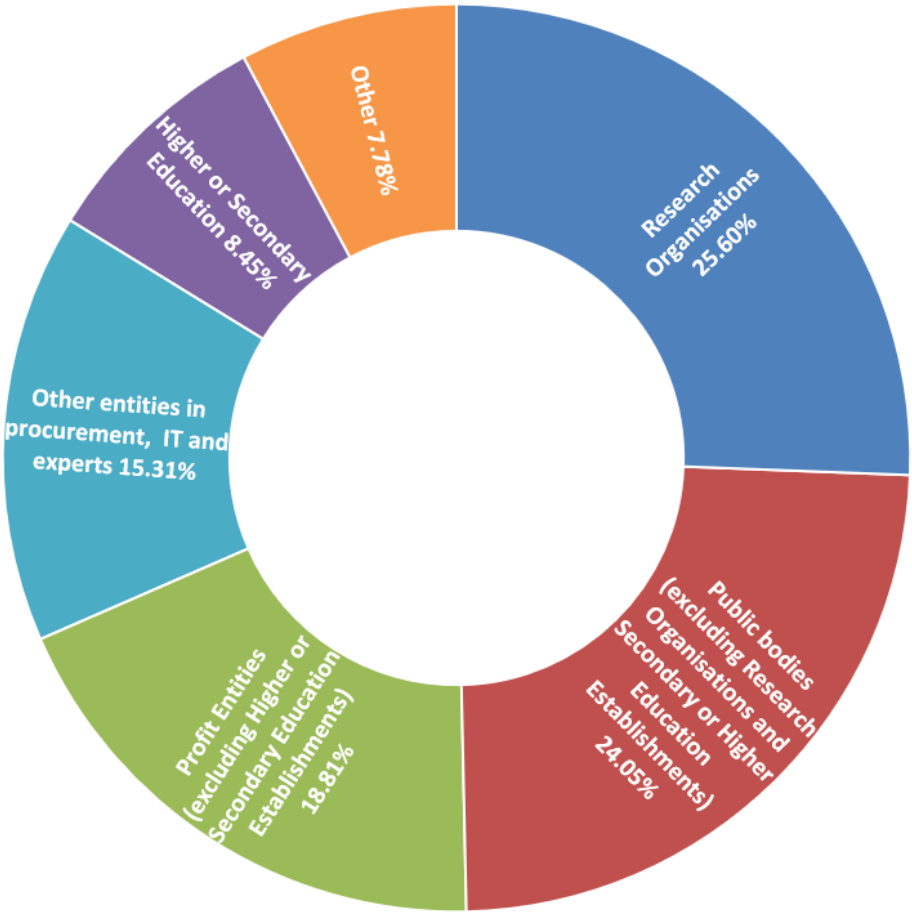


Figure 9 The main types of EU4Health beneficiaries and % of absorbed budget

For grants, 303 agreements had been signed by the cut-off date, with 1 162 participants, for a total budget of EUR 741.84 million. The main grantees are the public bodies of national authorities, research organisations and higher education establishments.

For procurement, 391 contracts were signed with 104 service providers, committing a total budget of around EUR 420.44 million. The main service providers are private entities in Belgium (service providers in 141 contracts), followed by Luxembourg (104 contracts), Italy (21 contracts), Spain (16 contracts), Greece (14 contracts) and the Netherlands (13 contracts) as main countries. In terms of the Member States that received the most financing, Ireland is in the lead, with over EUR 107 million, followed by Belgium (EUR 63.1 million), Denmark

86 Other entities, e.g. experts or IT specialists, private entities benefiting from EU4Health funds (procurement contracts that were concluded outside the eSubmission system and requiring Participant Identification Code).

(EUR 50 million), Spain (EUR 36 million), the Netherlands (EUR 29.72 million), and Luxembourg (EUR 25.86 million) (see Figure 7 for the full list of countries).

The *cumulative financial implementation* by April 2024 amounted to EUR 2 215 million[87] in commitments and EUR 658.2 million in payments[88], representing 50.52% and 15.01% of the total programmed amount, respectively.

Overview of the investments by strand with breakdown per specific objective

Strand 1: Crisis preparedness

By April 2024, the contracting authorities had committed EUR 623 million and signed 103 financing agreements that contribute to the *crisis preparedness* strand. EUR 395.69 million have been allocated to specific objective (b) on crisis preparedness and response, EUR 110.41 million to specific objective (c) on improving access to medicinal and medical products, EUR 79.45 million to specific objective (a) on health promotion and disease prevention, and EUR 18.86 million contribute to specific objective (j) on global commitments and health initiatives. There are no programmed actions yet contributing to specific objective (e) on a reserve of medical and healthcare staff.

A total of 70.2% of the budget of the crisis preparedness strand has been committed to actions supporting medical countermeasures and intelligence gathering[89] and the remaining 29.8% will finance actions implementing the Regulation on serious cross-border threats to health (e.g. setting up European reference laboratories, support for early warning and response capacities, the EU immunisation agenda) including countermeasures against antimicrobial resistance[90]. These commitments also support the first actions establishing a structure and training resources for a reserve of medical, healthcare and support staff.

On medical countermeasures, several actions were funded by the Commission between 2021 and 2024. For example, EUR 100 million were allocated to HERA Invest, which supports investments in innovative European companies developing diagnostics, therapeutics and vaccines against priority cross-border health threats such as pathogens with high pandemic potential, AMR, and chemical, biological, radiological and nuclear (CBRN) hazards. Moreover, the Commission reacted very rapidly to the Mpox outbreak in Africa, mobilising EUR 20 million for the purchase of 215 000 doses of Mpox vaccines to be donated to the Africa Centres for Disease Control and Prevention (Africa CDC). In addition, since 2022, the EU FAB network – a network of ever-warm production capacities for vaccine manufacturing in the EU/EEA – has maintained its operations through regular funding from the EU4Health Programme, with four facilities participating.

In 2024, direct grants were signed for 23 countries to close national gaps in surveillance systems, to digitalise surveillance systems and to build capacity for surveillance, such as personal data protection and data quality assurance. These grants will support Member States in improving their surveillance systems in line with and building on the outcomes of the joint

87 C1 credits - L1 commitments included.

88 Payments as a percentage of the total programmed amount for EU4Health for the period 2021-2027 (C1 Credits). Potential decommitments have not been taken into account.

89 See Footnote 60.

90 Council recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach, 2023/C 220/01.

action UNITED4Surveillance[91]. This is an EU4Health joint action with 40 partners from across Europe promoting and supporting the development of digitalised, integrated surveillance systems. Further support for surveillance was ensured through the joint action EU-WISH[92], which aims to help the 26 Member States participating to develop, expand and consolidate national monitoring of wastewater for reasons of public health. In 2024, the Commission started to designate certain laboratories as European reference laboratories (EURLs) for public health that will further strengthen the EU's preparedness for and response to serious cross-border threats. The EURLs bring together scientific expertise from across the European Union, to improve preparedness, rapid detection and response. EURLs will support national public health laboratories by ensuring data comparability and capacity strengthening on laboratory methods at EU level. The first six EURLs were designated in March 2024, and three more in November 2024. All EURLs receive direct grants from the EU4Health Programme to fund their work. Furthermore, the DURABLE[93] network was established by HERA to respond to the threat of any biological agent. It does this by leveraging the broad expertise in the network to work across scientific disciplines and different pathogens, with a special focus on developing medical countermeasures and novel detection methods for cross-border health threats. In addition, in 2022 agreements for direct grants were signed with 21 Member States to create enhanced whole genome sequencing and RT-PCR[94] infrastructures and to ensure their sustainable use and integration into routine surveillance and outbreak investigation activities. HERA launched a similar project with the Africa Pathogen Genomics Initiative to support the member states of the African Union in building local data analytics capacities for rapid outbreak response, to scale up sequencing-based surveillance and to strengthen the network capacity to ensure the detection of new SARS-CoV-2 variants and systematically implement AMR surveillance.

Under the EU4Health Programme, EUR 50 million have been committed for a joint action on antimicrobial resistance (JAMRAI-2[95]). This new joint action, which started in early 2024, brings together the authorities of all the EU Member States, Iceland, Norway and Ukraine in carrying out a range of policies and measures to tackle AMR, applying a One Health approach. The Commission also supports the development of innovative diagnostic solutions for AMR. Furthermore, through the contribution agreement signed between HERA and the WHO, funding was provided for activities to develop new medical countermeasures against AMR and for the Global Antibiotic Research & Development Partnership[96], which accelerates the development and provision of treatments for drug-resistant infections. Based on the agreement, funding will also be provided to SECURE[97] – an action to set up a public health consortium dedicated to accelerating access to newly registered and generic essential antibiotics and to support countries in addressing drug-resistant bacterial infections. Funding has also been provided for a new vaccine against tuberculosis and for anti-tuberculosis medicines for children in the EU.

91 Joint Action UNITED4Surveillance.
92 Joint Action EU-WISH.
93 DURABLE Research Network against Epidemics.
94 Reverse transcription–polymerase chain reaction.
95 Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections EUJAMRAI2
96 Global Antibiotic Research & Development Partnership.
97 SECURE.

In 2023, around EUR 2 million were mobilised by HERA for training activities and tabletop exercises on preparedness and response related to medical countermeasures, with particular attention paid to public procurement strategies and the procurement instruments available.

A contribution agreement was signed with the International Nuclear Energy Agency (IAEA) in 2024 to create the capacity to use the sterile insect technique as a tool to eliminate the *Aedes aegypti* mosquito in one Member State and, potentially, in other EU countries if detected.

A contribution agreement with the World Health Organization was signed in April 2024 to enhance public health and crisis-response capacities in Ukraine and neighbouring countries, focusing on CBRN hazards.

A contribution agreement with the ECDC was signed in late 2024 to upgrade and develop its early warning and response system. The aim is to increase the effectiveness of how all threat events are managed, including preparedness, alerting, situational awareness, risk assessment and crisis-response coordination.

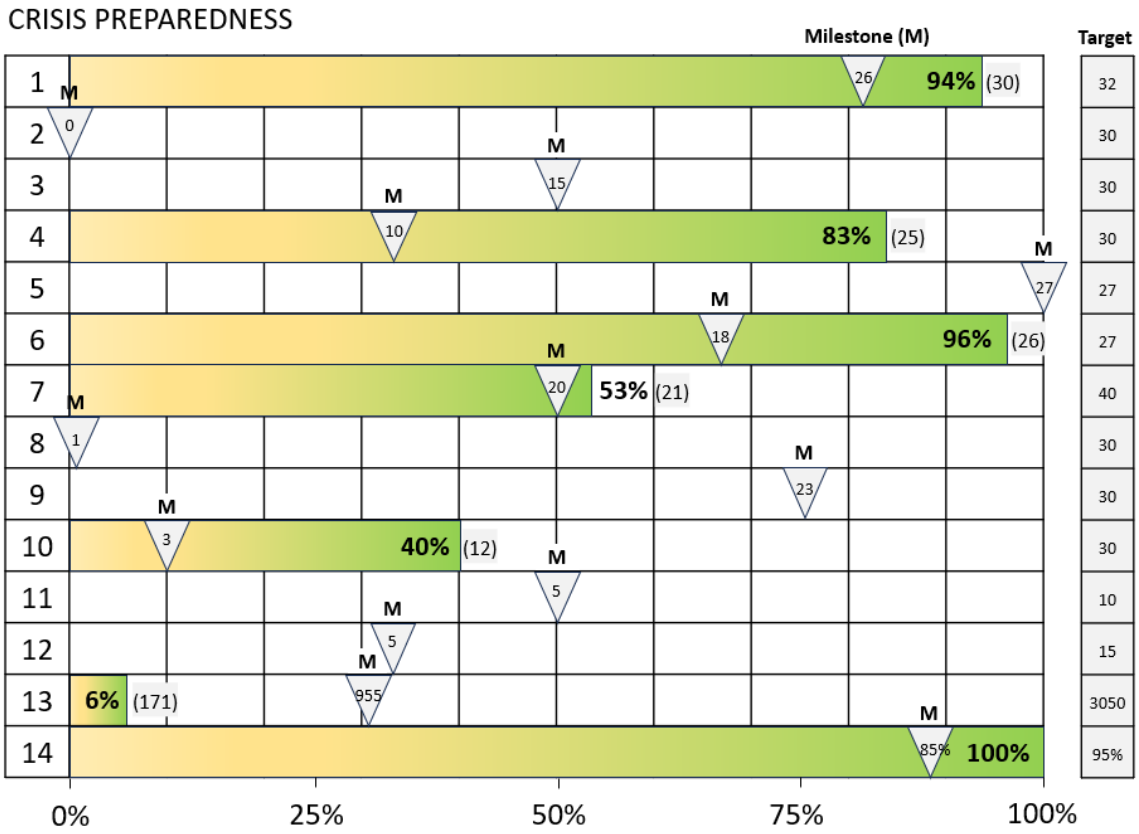


Figure 10 Progress on the 2024 milestones and 2027 targets for crisis preparedness

Legend: **0** Baseline; M 10 Milestone; 25 Target; (30) Current value; **Indicators:** 1 - Member States with preparedness and response planning for cross-border health threats – (sub-indicator 1.1); 2 - Member States participating in the prevention, preparedness and response planning joint action – (sub-indicator 1.2); 3 - Member States with improved integrated surveillance systems – (sub-indicator 1.3); 4 - New capacity-building activities (EU, Member States) for improved integrated surveillance systems (sub-indicator 1.4); 5 - Number of Member States with improved preparedness and response planning (sub-indicator 6.1); 6 - Member States with improved preparedness and response planning on medical countermeasures (sub-indicator 6.2); 7 - Actions addressing the fight against communicable diseases (indicator 22); 8 - Countries with increased laboratory and diagnostic capacity for cross-border health threats (HERA); 9 - Countries where One Health surveillance programmes were successfully implemented; 10 - Countries with improved procurement procedures for medical countermeasures during a health crisis; 11 - Actions complementing national stockpiling of essential crisis-relevant products; 12 - Member States participating in

stockpiling activities; 13 - Healthcare and public health staff (Article 11 of Regulation (EU) 2022/2371 on serious cross-border threats to health); 14 - Stakeholders' satisfaction rate in HERA training programmes. Data are not available for the lines 2, 3, 5, 8, 9, 11, and 12.

The World Health Organization receives several grants from the EU4Health Programme. One action focuses on the implementation of the new regional roadmap on antimicrobial resistance and associated infections in EU Member States and EU4Health associated countries. Other actions support the work of the WHO in the field of health preparedness and vaccination.

By the cut-off date, 30 Member States had participated in more than one EU action aimed at improving prevention, preparedness and response planning for serious cross-border threats to health, and 25 new capacity-building activities for an improved and integrated epidemiological surveillance system and 21 actions on the fight against communicable diseases had been launched. By the same date, 26 Member States had improved their preparedness and response planning with regard to medical countermeasures. One country successfully implemented a One Health surveillance programme, and 12 Member States and associated countries had improved their procurement procedures for medical countermeasures during a health crisis. A total of 171 healthcare and public health staff (Article 11 of Regulation (EU) 2022/2371 on serious cross-border threats to health) had been trained and 96% of the trainees were satisfied with their training[xxviii].

Strand 2: Health promotion and disease prevention

A total of EUR 155.4 million was committed to 108 *health promotion and disease prevention* actions, which does not include cancer investments. EUR 64.74 million of the budget implements specific objective (b) on crisis preparedness and response. The strand receives a contribution of EUR 53.81 million from actions implementing specific objective (i) on integrated work on national health systems, EUR 12.25 million from actions supporting specific objective (j) on global commitments and health initiatives, and smaller amounts from all the other specific objectives[98].

37.1% of the strand's budget was committed to the prevention of cardiovascular disease and diabetes. The other policy areas covered are mental health support to Ukrainians (16.9%), operating grants (14.9%), mental health in the EU (7.8%), prevention of mental health disorders (4.3%), prevention of risk factors (6.2%), HIV and AIDS (4.3%), prevention of NCDs (2.6%), tobacco-related actions (2.4%) chronic respiratory diseases (1.9%) and other related actions (1.6%).

In 2024, 24 direct grants supporting the work of the ERNs were signed, for a total value of 77.4 EUR million and covering their work for a period of four years. The Commission has provided continuous funding to the ERNs since their launch in 2017.

98 The budget of the operating grants has been distributed equally across all the specific objectives, given that these types of grants usually cover a broad spectrum of activities.

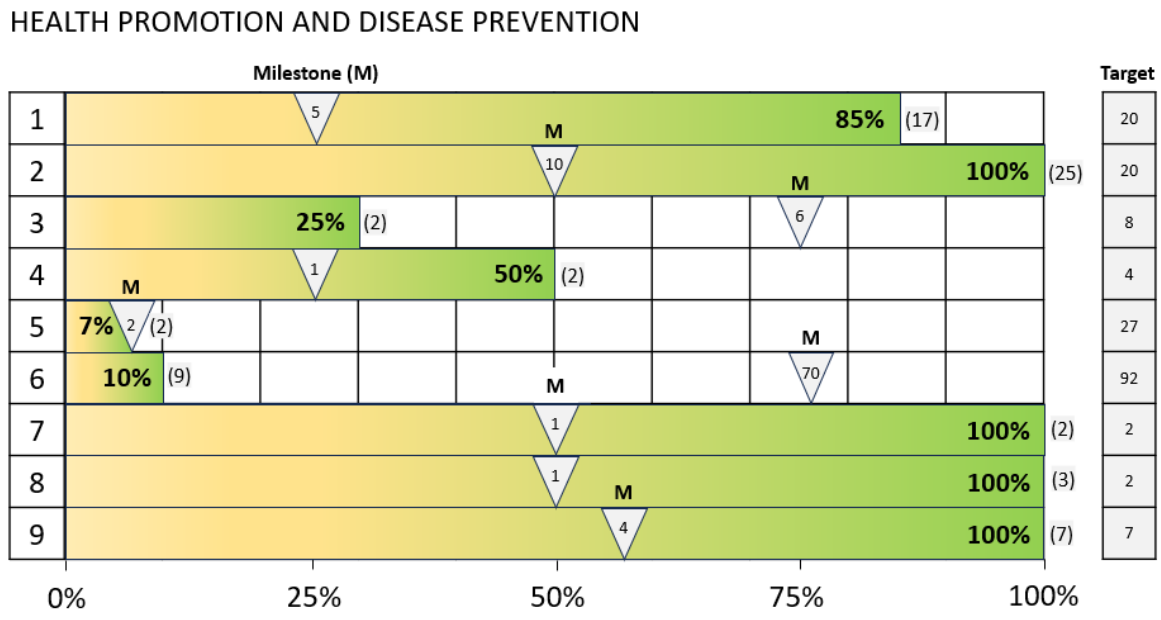


Figure 11 Progress on the 2024 milestones and 2027 targets for health promotion and disease prevention.

Legend: **0** Baseline; M 10 Milestone; 25 Target; (30) Current value; **Indicators:** 1 - Number of actions contributing to the reduction of avoidable mortality in the area of non-communicable diseases and risk factors; 2 - Number of Member States implementing best practices regarding health promotion, disease prevention and addressing health inequalities; 3 - Vaccination coverage for measles(indicator 7.1); 4 - Vaccination coverage for seasonal influenza – (indicator 7.2); 5 - Vaccination coverage for human papillomaviruses (HPV) – (indicator 7.3); 6 - Number of actions addressing the prevalence of major chronic diseases per Member State, by disease, gender, and age – (indicator 12); 7 - Number of actions addressing the age prevalence of tobacco use, if possible, differentiated by gender – (indicator 13); 8 - Number of actions addressing the prevalence of harmful use of alcohol, if possible, differentiated by gender and age – (indicator 14); 9 - Number of actions addressing environmental risk factors for health – (indicator 23).

A total of 17 actions contributing to the reduction of avoidable mortality in the area of non-communicable diseases and other risk factors have been launched so far. 25 Member States are implementing best practices in health promotion, disease prevention and addressing health inequalities. Two Member States have reached the vaccination target for measles, two for seasonal influenza, and two for human papillomaviruses. A total of nine actions have been launched to address the prevalence of major chronic diseases in Member States, by disease, gender and age. Two actions have been launched to address the prevalence of tobacco use by different age groups and differentiated, if possible, by gender. Three actions address the prevalence of the harmful use of alcohol, differentiated, if possible, by gender and age and seven actions addressing environmental risk factors for health have also been launched.

Strand 3: Health systems and healthcare workforce

EUR 239 million in funding has been committed for 288 actions under the *health systems and healthcare workforce* strand. EUR 66.66 million of that total mainly implement specific objective (i) on integrated work on national health systems, and EUR 49.74 million are aimed at implementing specific objective (f) on digital transformation. EUR 37.23 million have been allocated to specific objective (h) on support for the development and implementation of legislation, EUR 35.75 million to specific objective (c) on improving access to medicinal and medical products, EUR 27.5 million to specific objective (g) on access to healthcare, and EUR 12 million to specific objective (b) on crisis preparedness and response. Some of the actions

under this strand contribute a total of EUR 5 million to specific objective (j) on global commitments and health initiatives.

A total of 42.2% of the investments have been allocated to ERNs and 25% on health systems resilience and the healthcare workforce, followed by the pharmaceutical strategy and the implementation of related legislation (11.7%), implementation of the Medical Devices Regulation (9.1%), substances of human origin (5.9%), HTA (2.1%), global health (2%), improving the access of Ukrainian refugees to healthcare (2%), and the rest to 'other' actions. In 2023, 'State of Health in the EU'[99] country health profiles were drafted for all EU Member States, Iceland, and Norway to support better policymaking on health.

In 2023, 68 medicines[100] received a centralised marketing authorisation from the Commission, which is valid across the EU. In 2022, 103 medicines were authorised and in 2021, 89 medicines were authorised. Notified bodies under the Medical Devices Regulation (MDR) issued 5 599 certificates by 2023 and 702 certificates were issued by notified bodies under the In Vitro Diagnostic Medical Devices Regulation (IVDR). There were shortages of 54 medicinal products in the Member States, as reported through the single point of contact network (SPOC), a small increase from 52 in 2022. Two actions were launched that aimed to increase the security and continuity of global supply chains and address dependence on imports from third countries for the production of essential active pharmaceutical ingredients and medicinal products in the EU[101]. Four production facilities with enhanced capacities in increasing security and continuity of supply for medical countermeasures, raw materials, and components at EU level were also supported. A total of 28 audits were carried out in the EU and in third countries to ensure good manufacturing practices and good clinical practices. Three actions were carried out to produce guidance on improving access to healthcare services. 1 619 healthcare units were involved in ERNs and 2.24 million patients were diagnosed and treated by the members of the ERNs.

99 State of Health in the EU.

100 This is orphan authorisations, advanced therapy medicinal products, medicinal products for paediatric use, vaccines.

101 2021 work programme actions HS-g-18.2.1 with a budget of EUR 2.15 million and CP-g-01.1.1 with a budget of EUR 10 million.

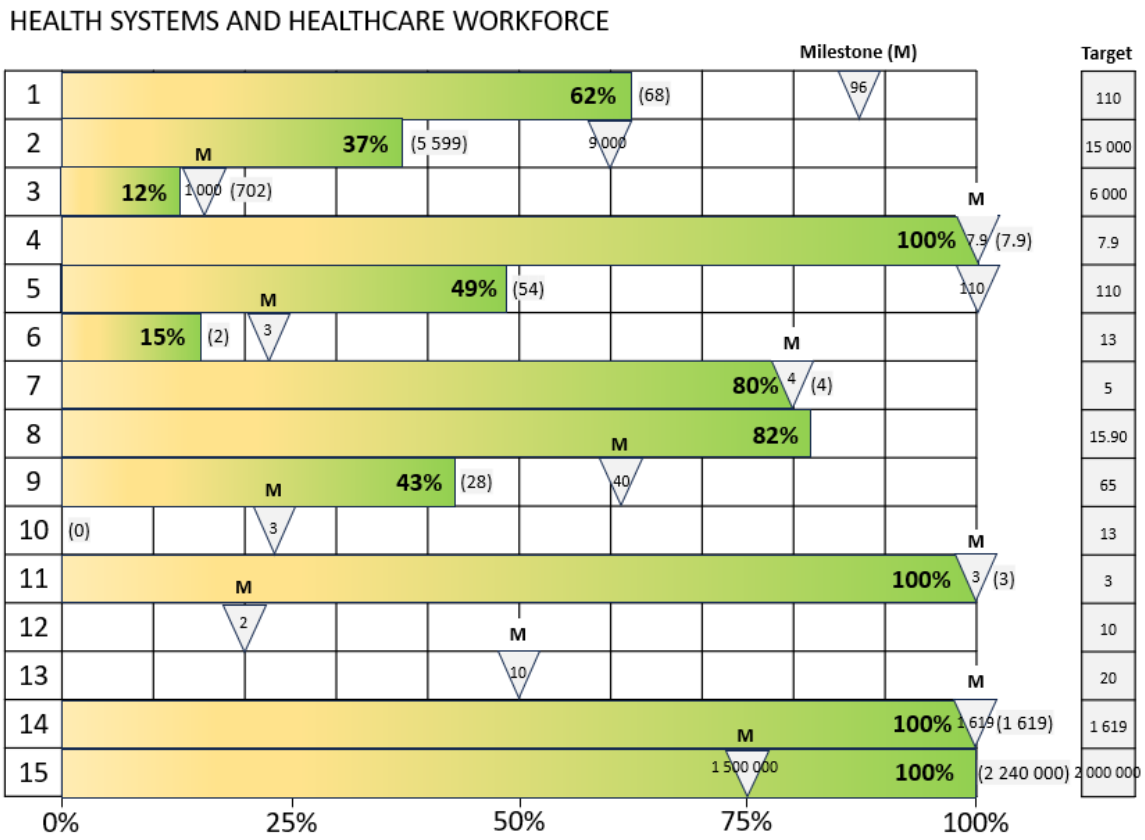


Figure 12 **Progress on the 2024 milestones and 2027 targets for health systems and healthcare workforce**.

Legend: **0** Baseline; Milestone; Target; (30) Current value; Indicators: 1 - Access to centrally authorised medicinal products, for example the number of existing and new orphan authorisations, advanced therapy medicinal products (ATMPs), medicinal products for paediatric use or vaccines, for unmet needs- (indicator 2); 2 - Number of certificates issued by notified bodies under the Medical Device Regulation(MDR); W3 - The number of certificates issued by notified bodies under the In Vitro Diagnostic Medical Devices (IVDR).; HS&HW4 - EU Laboratory capacity index (EULabCap)– (indicator 8); 5 - Number of shortages of medicinal products in the Member States as reported through the single point of contact network – (indicator 15); 6 - Number of actions aimed at increasing the security and continuity of the global supply chains and addressing dependence on imports from third countries for the production of essential active pharmaceutical ingredients and medicinal products in the Union - (indicator 16); 7 - Number of production facilities with enhanced capacities in increasing security and continuity of supply for medical countermeasures, raw materials, and components at EU level; 8 - Antimicrobial consumption for systemic use ATC (group J01) – (indicator 18); 9 - Number of audits conducted in the EU and in third countries to ensure good manufacturing practices and good clinical practices (Union control) - (indicator 17); 10 - Number of Member States participating in actions aimed at supporting innovation, uptake and access to market of medical countermeasures supported at EU and global level for better preparedness and response; 11 - Number of actions producing guidance for improving access to healthcare services; 12 - Number of measures taken by Member States to improve access to healthcare services; 13 - Number of Health Technology Assessment (HTA) reports jointly carried out - (indicator 20); 14 - Number of healthcare units involved in ERNs– (indicator 19.1); 15 - Number of patients diagnosed and treated by the members of the European Reference Networks (ERNs)-– (Indicator 19.2); Data are not available for lines 10, 12 and 13.

Strand 4: Digital

The investment of EUR 124.96 million in 108 actions under the *digital* strand is mainly supporting the specific objectives on digital transformation (f), on support for legislation development and implementation (h), and on access to healthcare (g). The investments are balanced between the primary and the secondary use of data. 45.6% of the total budget is being invested in MyHealth@EU, an action on the primary use of health data. An additional EU 3.8 million has been invested in a joint action[102]. The actions on secondary use of data support setting up services by health data access bodies representing 33% of the strands' budget, and

[102] Extended EHR@EU Data Space for Primary Use (Xt-Ehr).

8.6% was additionally allocated to developing HealthData@EU. The actions on primary data therefore receive 58.4% of the funding and those on the secondary use of data receive 41.6%. In addition, 22 European countries (including 20 Member States) have received funding to improve their digital health systems and access to health data.

37 actions contribute to the digital transformation of healthcare systems and the implementation of the EHDS. A total of 15 Member States are participating in the EHDS and 6 Member States have set up or are in the process of setting up a health data access body.

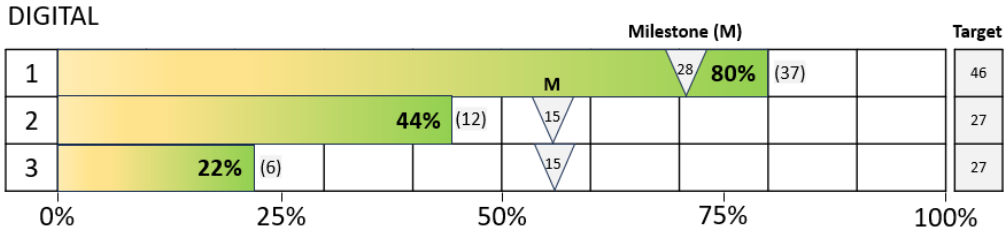


Figure 13 Progress on the 2024 milestones and the 2027 targets for digital.

Legend: 0-Baseline; M 10 **Milestone;** 25 **Target; (30); Actual value; Indicators**: 1 - Number of actions contributing to the digital transformation of healthcare systems and the implementation of the European Health Data Space (EHDS); 2 - Number of Member States participating in the European Health Data Space (EHDS); 3 - Progress on setting up health data access bodies in the EU.

Cross-cutting strand: Cancer

62 actions with a total budget of EUR 220 million are included under the ***cancer*** strand, which supports the implementation of the Cancer Plan and contributes mainly to the specific objectives on health promotion and disease prevention (a), integrated work on national health systems (i), on access to healthcare (g), and on global commitments and health initiatives (j).

Almost half (49.3%) of the allocated budget under the cancer strand supports prevention actions against cancer including HPV and tobacco and alcohol-related cancers, followed by screening actions including those on breast, colorectal, cervical, gastric, prostate, liver and lung cancer (25% of the budget), treatment (including radiation) (13.9%), quality of life (6.8%), inequalities (4.6%), and other actions (0.4%).

Several of the Cancer Plan flagship actions that are supported by the EU4Health Programme have been launched. The European Commission Knowledge Centre on Cancer was the first flagship to be launched in June 2021, fostering the scientific and technological alignment of all the Commission's initiatives on cancer. The European Cancer Inequalities Registry was created in February 2022, with a first set of cancer country profiles published in February 2023, and the first cross-cutting report on inequalities in cancer prevention and screening in February 2024.

Data are not yet available to assess the age-standardised five-year net survival rate for paediatric cancer. Five Member States have reached the planned screening coverage of 70% of the population for breast and cervical cancer. Seven Member States have reached the screening coverage of at least 45% for colorectal cancer and 75% of the population is covered by cancer registries reporting information on cervical, breast, colorectal and paediatric cancer stage at diagnosis. A total of 25 Member States have reported information on cervical, breast, colorectal and paediatric cancer stage at diagnosis.

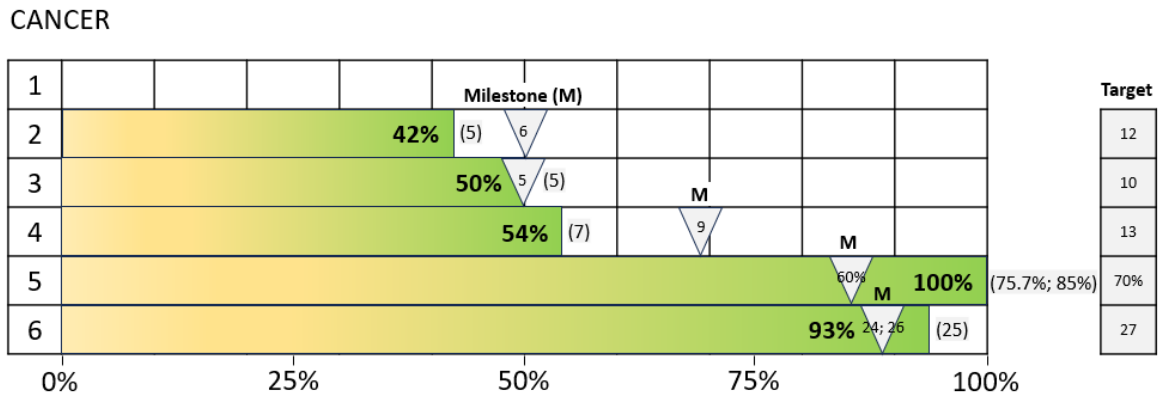


Figure 14 Progress on the 2024 milestones and 2027 targets for cancer.

Legend: 0 Baseline; M 10 **Milestone;** 25 **Target; (30) Current value; Indicators**: 1 - Age-standardised five-year net survival rate for paediatric cancer (to the extent available); 2 - Screening coverage for breast cancer screening programmes; 3 - Screening coverage cervical cancer screening programmes; 4 - Screening coverage for colorectal cancer screening programmes; 5 - Percentage of population covered by Cancer Registries reporting information on cervical, breast, colorectal and paediatric cancer stage at diagnosis – (indicator 11); 6 - Number of Member States reporting information on cervical, breast, colorectal and paediatric cancer stage at diagnosis. Data are not available for line 1.

Cross-cutting topic: Global Health

The EU4Health Programme's specific objective to support global commitments and health initiatives remains very relevant. In this regard, the Programme supports actions that benefit health in Europe and beyond. Since the launch of the 2021-2027 EU4Health Programme, the Commission has further committed to prioritise global health across all relevant EU budget financing programmes, including EU4Health[103]. The EU Global Health Strategy, adopted in November 2022, is the external dimension of the Health Union and the main policy framework that guides EU health principles and actions at the global level. A one-year study to design and test a monitoring framework for the implementation of the EU Global Health Strategy is being carried out with EUR 616 120 of funding. The study aims to develop and evaluate an effective monitoring framework to assess the progress and outcomes of the implementation of the strategy.

EU4Health's support to the EU Global Health Strategy amounts to EUR 61.5 million, of which around EUR 50 million has been committed to actions such as strengthening preparedness and response at a global level to cross-border threats to health, including, for instance, by supporting the Africa Pathogen Genomics Initiative. HERA is also collaborating with the WHO to increase intelligence gathering and laboratory capacities in Africa, as well as to support a rapid response to outbreaks of diseases with high pandemic potential, such as Mpox, Marburg and Ebola.

In total, 23 actions and contribution agreements to support global commitments and health initiatives have been concluded with global partners such as the WHO, the Red Cross, the OECD and the IOM. The EU and the WHO collaborate in four thematic areas[104] and coordination between the EU, global partners and EU Member States is ongoing in three areas.

103 EU GLOBAL HEALTH STRATEGY - Better Health for All in a Changing World, page 26.

104 The thematic areas are health systems, crisis preparedness, cancer and health promotion.

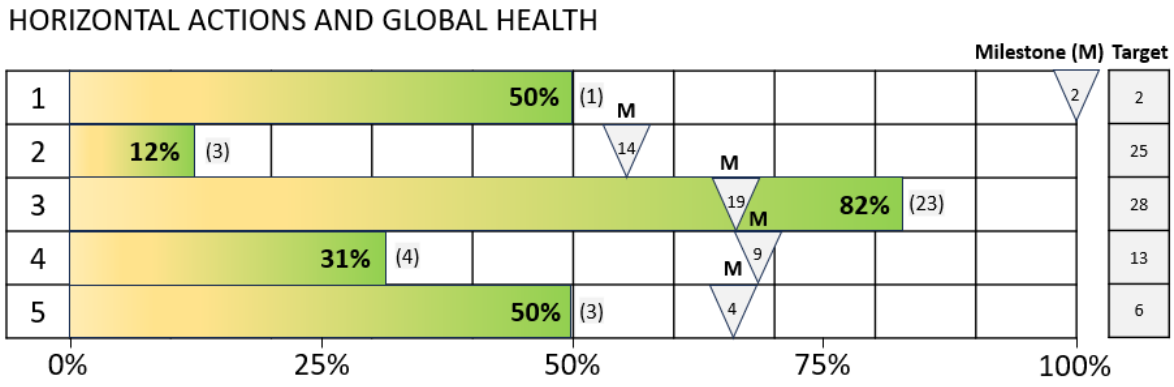


Figure 15 Progress on the 2024 milestones and 2027 targets for global health

Legend: 0 Baseline; M 10 Milestone; 25 Target; (30) Current value; Indicators: 1 - Number of impact assessments of Union policies; 2 - Number of studies supporting the evaluations of legislative and non-legislative health Union policies; 3 - Number of actions and contribution agreements supporting global commitments and health initiatives concluded with global partners; 4 - Number of areas where EU and WHO collaborate; 5 - Areas of coordination between EU and relevant global partners and EU Member States;

Support for the development and evaluation of legislation

The Programme has supported one published impact assessment and supporting report and Staff Working Document on EU health policies and has funded three studies supporting evaluations of legislative and non-legislative EU health policies.

Synergies and complementarities with other EU funding programmes

Several EU funding programmes support health priorities. Horizon Europe is a key EU programme advancing research and innovation with a strong focus on health through its Cluster 1 initiatives. It addresses integrated approaches to disease prevention and health promotion, and fosters synergies with public health policies across Europe. The Programme exhibits adaptability, funding research in areas like infectious diseases, preparedness and response for health crisis, mental health, AMR, cancer and other NCDs, promoting the digital health transition, and enhancing global cooperation on health. Partnerships within Horizon Europe, such as the European Partnership on Transforming Health and Care Systems, the European Partnership on Rare Diseases and the Joint Undertaking for Global Health (EDCTP 3), as well as the EU Cancer Mission and Global Health initiatives, are meeting their objectives effectively, further strengthening Europe's health innovation ecosystem.

The Digital Europe Programme (DEP) aims to upskill individuals in advanced digital skills, including in health, and supports platforms for digital skills information. Moreover, the DEP plays a key role in implementing the EHDS, facilitating improved access to health data and greater interoperability across the EU.

The RRF is a central component of the NextGenerationEU plan, with EUR 42 billion dedicated to reforms and investments in the healthcare sector, including improving primary healthcare, transitioning to outpatient care, and deploying digital health solutions.

The European Social Fund+, the European Regional Development Fund (ERDF), and the Just Transition Fund plan for investments in eHealth, health infrastructure and improving access to healthcare for vulnerable groups. In addition, the Pact for Skills supports partnerships focusing on the health workforce and the Erasmus+ BeWell initiative pilots innovative curricula for digital and green skills in health.

Synergies and complementarities with Member States' national funds

EU Member States make significant investments in health at the national level to improve the overall well-being of their populations, and their objectives at national level often concur with those at EU level. These investments totalled EUR 1.59 trillion in 2021 and EUR 1.65 trillion in 2022[105] and encompass a broad range of initiatives aimed at transforming healthcare delivery and ensuring health systems are robust and adaptable. A key focus is on modernising healthcare infrastructure, which includes upgrading hospital facilities, improving medical equipment, and incorporating advanced technologies to enhance diagnostic and treatment capabilities.

Furthermore, with the growing importance of digital solutions, many countries are investing in digital health technologies. This includes the development of EHRs, telemedicine platforms and health data analytics, which are designed to enhance patient care, facilitate efficient healthcare delivery, and enable the cross-border exchange of health data within the EU.

Addressing demographic challenges, such as ageing populations and the rise of chronic illnesses, is another priority. Investments often target preventive care, health promotion and disease prevention, and management strategies that include chronic disease management programmes and initiatives to foster healthy lifestyles.

Unexpected or unintended changes

Interview feedback from EU4Health beneficiaries has indicated that the large budget of some actions combined with the high co-funding requirement for beneficiaries (40% or 20% in case of exceptional utility) has posed absorption challenges for the authorities of some Member States and for some NGOs. This problem was confirmed by health experts from the national authorities from some Member States, who said it was due to difficulties in aligning the EU4Health budget cycle with those of the Member States[106].

External factors

The **Russian war of aggression against Ukraine** has triggered the prioritisations of actions to address the (health) consequences of the war. The swift deployment of actions under EU4Health to support Ukraine during the ongoing crisis was intended to improve access to healthcare for refugees and people displaced from Ukraine, as well as to reduce the burden of mental health issues for this group. Moreover, the interventions aimed to reinforce the prevention, preparedness and response capacities for all threats (chemical, biological and radio-nuclear) in Ukraine and neighbouring countries as well as to increase the vaccination coverage of children and adults.

The **COVID-19 pandemic** exposed critical vulnerabilities in pandemic preparedness systems across Europe, underscoring the need for robust mechanisms to prevent, detect and respond to

105 Eurostat, Health care expenditure by function [hlth_sha11_hc].

106 Laurence Ballieux, Silke Baumann and Guy Dargent: EU JOINT ACTIONS 2.0: A BOOSTER FOR HEALTH IN THE EU? Eurohealth – Vol.29 | No.3 | 2023.

public health emergencies. Lessons learnt from the pandemic highlighted the importance of ensuring supply chain resilience, investing in innovative medical products, bolstering intelligence-gathering capacities, and investing in cross-border cooperation and data sharing to mitigate future crises effectively. Beyond COVID-19, recent outbreaks of diseases such as Marburg and Ebola in Africa further demonstrate the devastating impact of emerging infectious diseases with epidemic potential, and the need for Europe to be vigilant and prepared. Furthermore, the growing impacts of climate change have intensified the urgency of health crisis preparedness. Climate-related events such as heatwaves, floods and the spread of vector-borne diseases pose new and complex challenges to public health systems. Addressing these threats requires a comprehensive and forward-looking approach to pandemic preparedness.

Programme performance monitoring and evaluation framework (PPMEF) – initial assessment

The PPMEF and its indicators served well the annual performance assessment and the Programme interim evaluation analysis. The annual Programme performance analyses for 2021, 2022 and 2023[107] indicate that the number of Programme indicators is rather high, and it will be necessary to cover each of the 10 specific objectives and their policy areas. To fully operationalise the specific objectives, the existing action-level indicators will be used to monitor achievements in policy areas that are not covered by the Programme indicators, such as patient safety, mental health and others.

The available Programme indicators generally make it possible to operationalise the broad objectives and are measurable against the quantitative milestones and targets. The milestones and targets are set in line with the ambition and targets of the EU's health priorities (e.g. the Council Recommendation on AMR[108]) and legal acts (e.g. Regulation (EU) 2022/2371 on serious cross-border threats to health), where those exist. The output indicators referring to 'number of actions' have been very useful in assessing the programming process; however, to assess the Programme's performance for the final evaluation, they need to better reflect the outcomes and the results of the actions. Based on the lessons learnt, a revised PPMEF will focus on indicators that better link output, results and impacts for each specific objective. This will make it possible to measure progress on milestones and targets. The review will also leverage the information on health systems collected in the context of the European Semester and country profiles[109] for the purpose of evaluating EU4Health.

The nine key performance indicators need to be revised given that for two of them data are not available.

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108 Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach 2023/C 220/01, (OJ C 220, 22.6.2023).

109 Country Health Profiles - European Commission

4. **Evaluation findings** (analytical part)

As expected at the time of the interim evaluation, limited data on results and no data on impacts was available, which is an unavoidable drawback. However, the findings show that the approach to data collection is reliable, and that the evaluation methodology used, albeit improvable, is a good basis to deliver the final evaluation. The final evaluation should be delivered by the Commission no later than the end of 2031[110], when evidence from most EU4Health actions (i.e. deliverables and final reports) will be validated by the contracting authority and available for analysis. The data collection made possible by the revised PPMEF indicators will ensure that data are available in good time for the final evaluation.

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

4.1.1. Programming and implementation progress

EU4Health intervention is a policy-driven EU funding programme that successfully provides financial support to implement the priorities of the European Health Union, the underlying legislation and related preparatory work. It complements Member States' actions in the field of health. The progress that EU4Health has made in reaching the health policy objectives of the Programme itself and, more widely, of the EU is consistent with the expectations at the interim stage as regards outputs and results. A limited number of actions have been completed, many actions have only recently begun, and their results are becoming progressively available.

The architecture of the EU4Health Regulation is sound overall. The comprehensive specific objectives are coherent and allow the financing of measures to implement EU health policy priorities, including the existing EU health legislation for the period 2021-2027, and the new health priorities provided in Commission's mandate.

EU4Health's programming and governance processes are effective, as illustrated by the delivery of the 2021 and 2022 annual work programmes in less than a year, considering that the regular programming cycle is usually around one year for one work programme. The annual work programmes for 2023 and 2024 were adopted in the year before implementation began (n-1). The actions funded under the work programmes for 2021, 2022 and 2023 are coherent with the objectives they are meant to implement, as confirmed by the findings of the evaluation supporting study. Thus, the Programme's governance is agile, although the consultative step with the Member States in the EU4Health Steering Group, in advance of and in addition to the Programme Committee, is administratively somewhat burdensome. The EU4Health Steering Group is convened three to four times a year. The European Parliament is informed about the stakeholder consultation proceedings prior to the last Steering Group before approval of the work programme. In practice these consultation steps are complemented by the consultation of dedicated Commission expert groups on health policies, including the HERA Board, which provide useful technical expertise. These technical consultations of expert groups provide useful support in specific areas where the relevant expertise is lacking within the EU4Health Steering Group.

The annual programming and implementation process for a programme of the magnitude of EU4Health is resource intensive. Lessons learnt from four EU4Health programming cycles and the EU's Horizon research and innovation programme indicate that

[110] Article 20 of EU4Health Regulation.

setting priorities for a period longer than one year may better inform the Member States and other stakeholders on the longer-term perspective.

HaDEA is instrumental to the implementation of the Programme and annual work programmes. The implementation processes, which were adapted very rapidly to the severalfold increase in the budget of EU4Health as compared to the previous EU health programmes, are very effective and efficient. Implementation of the 2021, 2022 and 2023 work programmes was delegated to HaDEA, which launched all the actions as planned. A total of 726 financing agreements were signed with 1 274 legal entities such as ministries of health, national, regional and other public authorities, healthcare and health research organisations, non-profit organisations and private entities.

The level of commitments is as expected and has reached more than half (53%) of the programmed budget. The payment execution is about 15% of the committed budget and is expected to steadily increase because of an earlier launch in the year 'n'[111] of the joint actions and other direct grants with Member States authorities, starting with the 2025 annual work programmes. **A concerted effort from the nominated national authorities is required to shorten the preparatory phase, which is currently about a year**. In addition, the launch of procurements could be brought forward, although increased human resources may be needed to do this. The **potential simplification of procurement processes and better use of framework contracts could also contribute to a faster execution of payments**. After initial efforts to draft and sign framework contracts, using them for specific procurement is a simpler process, with fewer steps to be followed.

Under **direct management**, the larger budget of some actions in combination with a high co-funding requirement for beneficiaries posed some absorption challenges for the authorities of some Member States and for some NGOs. The Commission explored with the Member States in the EU4Health Steering Group and in the Council Working Party on Public Health possible mitigating measures to address current absorption challenges.

NGOs have benefited from both operating grants and action grants. During 2021-2024, 27 NGOs received operating grants, totalling EUR 23.2 million, and 255 NGOs received action grants and participated in 55 projects, with total funding of EUR 41.2 million[112]. Grants covered the following policy areas: strengthening health systems, diabetes, substances of human origin, the health workforce, digital skills, medical devices, health technology assessments, rare diseases, tobacco control, thalassaemia and other haemoglobin disorders, alcohol, respiratory diseases, palliative care, biomedical research, public health, health promotion and disease prevention, cancer, mental health, HIV/AIDS, cardiovascular diseases and tuberculosis, and also provided support to patients' organisations.

In the short term, **dedicated national info days and awareness-raising events in national or EU-level political settings may improve awareness in the Member States, with positive effects expected on political ownership and participation.** The Commission has already launched the joint action NFP4Health[113] that aims to financially support and strengthen the network of national focal points and offers applicants and beneficiaries information and guidance on the EU4Health Programme and its calls. The preparations to continue this joint action are underway and the Commission is closely following the process to ensure that

111 The year for which the annual programme is adopted.
112 EU Funding & Tenders Portal.
113 Joint Action on Increasing Capacity building of National Focal Points.

additional and tailored support is given to all categories of applicants. The joint action will maintain and increase the capacities of the NFPs to deliver tailored support to potential applicants who can implement EU4Health's objectives. In the long term, a possible reassessment of the co-funding requirements may be considered.

The findings of the interim evaluation supporting study underscore that **the joint actions are instrumental in facilitating collaborations to address shared European health challenges**. They are effective in involving a diverse range of organisations, promoting cooperation between Member States. The scale of funding provided by joint actions means that 499 organisations have been involved in joint actions, with nearly 40% of them participating in several joint actions. Joint actions align with EU4Health's objectives and contribute to significant health outcomes. **Their effectiveness and sustainability could be enhanced by, among other things, a reassessment of the co-funding requirements and proposal evaluation criteria.**

The exceptional utility criteria make it possible to provide up to 80% EU co-funding and are instrumental in attracting lower-GNI Member States. The findings of the case study indicate that **the exceptional utility criteria continue to be relevant in providing increased financial support for actions involving lower-GNI countries.** However, the criteria are insufficient to fully address the difficulties that some countries face because their required contribution (20% of the total eligible costs) still poses an obstacle to their participation in joint actions. Despite these limitations, the exceptional utility criteria have positively impacted lower-GNI countries' participation in joint actions and encouraged their involvement in more projects compared to the previous third Health programme. In addition, lower-GNI countries increasingly taking on coordinating roles and leading work packages, showing their increased capacity. The grants to ERNs and other networks (e.g. crisis preparedness EURLs) may cover up to 100% of the eligible costs[114] and many stakeholders have indicated that such an approach could be extended to more areas with proven EU added value.

The administrative burden is often associated with an application for funding (e.g. complexity of the budget template) and the implementation of an EU4Health project (e.g. the large number of required deliverables). HaDEA has already simplified the budget template to reduce some of the administrative burden, and Member States now have the possibility to include several competent authorities as beneficiaries in direct grant.

Under the **indirect management** of the budget, **the contribution agreements signed with international organisations (e.g. the WHO or OECD) allow the EU to reach out effectively at global level**. The contribution agreements provide a flexible way to deliver actions in the EU's neighbourhood, such as in Ukraine, e.g. by the International Federation of Red Cross and Red Crescent Societies and help to mitigate the health consequences of the Russian war of aggression against Ukraine.

The annual work programmes are coherent and foster synergies with other relevant EU funding programmes, including Pillar 5 of the Single Market Programme (SMP) on the food chain, Horizon Europe, the DEP, ESF+ and others, due to an effective approach to programming and implementation that eliminates potential overlaps.

For example, AMR is a key priority addressed under both EU4Health and Pillar 5 of the Single Market Programme. Each programme has contributed in a distinct yet complementary way.

[114] Article 8(4) of Regulation (EU) 2021/522.

For example, SMP Pillar 5 implements veterinary surveillance programmes like the coordinated control plan for AMR Monitoring, which tracks antimicrobial usage and resistance in farmed animals. This effort directly contributes to reducing AMR in the food chain. EU4Health complements these efforts by developing cross-border health data tools, promoting prudent antimicrobial use in clinical settings, and bolstering preparedness for AMR-related health threats.

In addition, while both programmes engage in awareness-raising campaigns, their target audiences differ: EU4Health addresses healthcare professionals and policymakers, whereas SMP Pillar 5 focuses on veterinarians and agricultural stakeholders. This well-defined division of responsibilities ensures that the two programmes not only complement each other but also avoid duplication of efforts, thus maximising the impact of EU-funded interventions.

Survey data from the supporting study reveals varying levels of agreement among stakeholders on these synergies, with many respondents indicating limited knowledge, potentially because they represent an organisation that is not eligible for a particular funding instrument. However, when omitting the responses from these stakeholders, 70% of survey respondents perceived a strong alignment between EU4Health and Horizon Europe, particularly among research institutions (78%). Similar trends were observed with the DEP, where 61% of respondents saw a significant coherence with EU4Health, though only 33% of NGOs agreed.

Horizon Europe is frequently referenced in EU4Health work programmes, with 21 actions linked to it. These **EU4Health actions build on the results of Horizon Europe or follow recommendations from entities supported Horizon Europe**[115]. They align with Horizon Europe's objectives or involve national health authorities and/or healthcare services that are also members of European partnerships funded by Horizon Europe. In addition, the EU Cancer Mission spent EUR 90 million on research focusing on cancer screening methods and technology and early detection of heritable cancers, thus complementing the Cancer Plan's work contributing to the EU4Health specific objective (a), the European Partnership on Transforming Health and Care Systems, with a budget of over EUR 305 million, contributes to EU4Health's specific objectives on health promotion and disease prevention (a), on digital transformation (f), on access to healthcare (g) and on integrated work on national health systems (i). Mental health and AMR are another example of areas where the results of research and innovation projects funded by Horizon Europe can contribute to the design of public health actions. At the same time, the needs or research gaps identified during implementation of EU4Health actions can be addressed by research supported by Horizon Europe interventions.

Moreover, the DEP contributes to the EU4Health specific objective on digital transformation (f) by supporting the EHDS, among others, with specific actions totalling EUR 18 million under the 2024 work programme aimed at expanding the adoption of the EHR exchange format, and deploying solutions that make it easier for patients to access their health data and that develop AI in health through health data access bodies. Additionally, the DEP contributes to the EHDS with the development and deployment of infrastructures and initiatives for the reuse of cancer images, genomic data and data from intensive care units.

The **redeployed EUR 1 billion** had no impact on the programming for 2021, 2022, 2023 and 2024 annual work programmes. **However, the significant budget reduction of the EU4Health Programme has an impact from the 2025 programming onwards. Nevertheless, it is important to ensure sufficient support to both ongoing as well as new**

[115] For example, the European Innovation Council or the European Research Council.

initiatives and commitments of the Commission. The resources for certain priorities will have to be adjusted and the implementation focus on prioritised initiatives expected to deliver significant impact. This will require balancing the reduced financial capacity with the legal obligation of the EU4Health Regulation to reserve at least 20% for supporting health promotion and disease prevention.

4.1.2. Achievements in implementing policies and legislation

Strand 1: Crisis preparedness

The EU4Health Programme has demonstrated particular efficiency and effectiveness in launching actions aimed at achieving the Programme's objectives on crisis preparedness – already during the COVID-19 pandemic. In addition, the rapid allocation of funds for capacity building on pandemic preparedness and Mpox vaccine procurement and distribution helped to limiting the spread of the disease. Similarly, longer-term actions were put in place to increase the EU's preparedness capacities, including through the development of intelligence-gathering tools and ever-warm facilities for vaccine production (EU FAB).

The crisis preparedness actions were amongst the first to be launched soon after the adoption of the 2021 annual work programme. They have featured in every annual work programme and have the highest overall programmed budget (EUR 623 million).

The main factor influencing the efficiency of the actions under this strand was the high level of collaboration through partnerships with national health authorities, international organisations and research institutions. This cooperation has been crucial in leveraging expertise and resources. The Programme's ability to respond quickly to emerging health threats has been crucial to mitigating their impact. The use of evidence-based decision-making to design the actions and set their budgets has ensured that resources have been allocated effectively and efficiently.

The crisis preparedness programming has been very effective, and the Programme's outputs have exceeded expectations with 25 new capacity-building activities to improve integrated surveillance systems launched and committed, instead of the 10 planned by 2024. This reflects the urgency of properly addressing the COVID-19 pandemic and its consequences, being better prepared for potential future health crises, and of fulfilling the legal obligations stemming from Regulation (EU) 2022/2371. A total of 21 actions on the fight against communicable diseases have been launched, one more than the 20 initially planned.

Entities from 30 Member States and associated countries have participated in more than one EU action aimed at improving prevention, preparedness and response planning for serious cross-border threats to health, showing a high level of engagement and adherence to the programmed actions. This shows that crisis preparedness is an important priority not only at EU level but also for the Member States, especially when we compare the number of countries participating (30) with the 2024 milestone target of 26 (see Figure 16 below). In particular, it is very promising that 26 Member States have improved their preparedness and response planning with regard to medical countermeasures, compared to the 18 planned, which illustrates the importance of a unified European approach that fosters collaboration. 12 Member States and associated countries have improved their procurement procedures for health crisis medical countermeasures, which is 4 times more than the expected number (3). Furthermore, for crisis preparedness, stakeholders attributed the significant progress, and enhanced training in preparedness, predominantly to the large budget increase under EU4Health, expressing a very high satisfaction rate (96%) for HERA training programmes (see Figure 16 below). If

funding had not been increased, Member States would likely have continued working on crisis preparedness predominantly at national level, resulting in less coordinated and potentially less effective outcomes. This underscores the important role that the EU4Health budget plays in boosting the collective capacity of the Member States to address health crises in a unified manner.

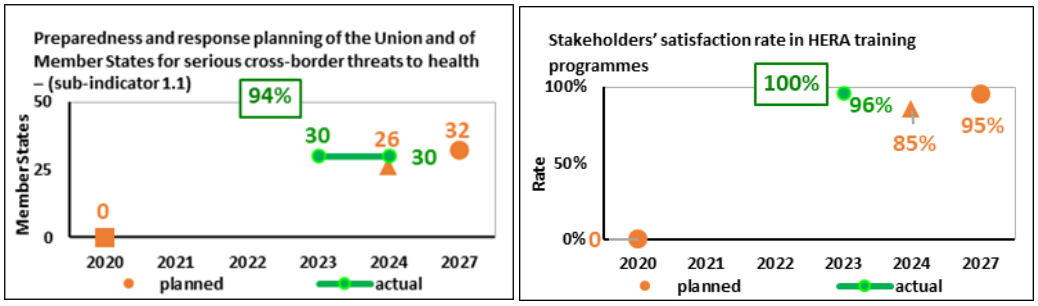


Figure 16 Selected crisis preparedness and response indicators – see Annex VII for a full list of the PPMEF crisis preparedness indicators monitored. (Legend: ■ baseline; ▲ milestone; ● target; ● actual). * Percentage indicates progress on the 2027 targets.

EU4Health's increased budget and its focus on crisis preparedness accelerated the progress on related policy areas that were also supported by the third Health programme, which had similar objectives on crisis prevention, preparedness and response, including provision for countermeasures. Stakeholders indicate that EU4Health plays a vital role in crisis preparedness and response. National authorities have benefited significantly from the collaborative efforts fostered by the Programme and, subsequently, EU4Health has helped to strengthen public health systems. It has also fostered the work of international organisations by financing their efforts to support vulnerable groups during health crises and implement community-based health interventions. Consequently, people in the EU have fully benefited from the actions of the EU4Health Programme.

The actions launched under the crisis preparedness strand also help countries to comply with the International Health Regulations[116] (IHR) by strengthening their capacities to address cross-border health threats, for example through the EU-WISH and UNITED4Surveillance joint actions.

As key elements responding to the Commission's policy priorities, the EU4Health Programme has funded advanced research and development on new vaccines, and reinforced prevention and response through the acquisition of vaccines and by facilitating their distribution across the EU. EUR 205.97 million have already been allocated to on these issues.

The provision of medical countermeasures has been supported with EUR 20.3 million in funding and nine grants to Member States with a total value of EUR 19.6 million, which contributed to setting up coordinated surveillance systems under the One Health approach, an important element in the added value of the Programme.

The Programme has also supported the fight against AMR, a growing global health threat, with funding of EUR 55.5 million. This has prompted 30 Member States and associated countries

116 International Health Regulations.

to participate in the joint action on antimicrobial resistance and healthcare-associated infections[117].

Horizon Europe stands out as the Programme most closely aligned with EU4Health, particularly in the Health Cluster of its Pillar II, which focuses on improving and protecting health, mitigating risks, and strengthening health systems. These goals closely align with EU4Health's objectives. For example, Horizon Europe promotes international cooperation on infectious diseases and public health emergencies, which aligns with EU4Health's specific objectives on crisis preparedness and response (b) and on global commitments and health initiatives (j).

Horizon Europe is frequently referenced in EU4Health work programmes, with 21 actions linked to it. These linked actions build on the results of the Horizon programmes or follow recommendations from its bodies. They align with Horizon Europe's objectives or involve national health authorities and/or healthcare services that are also members of European partnerships funded by Horizon Europe. Three actions in the crisis preparedness strand[118] concern, access to medical countermeasures, including critical medicines, the development of novel antivirals and the European Hub for vaccine development, respectively. In total, they are funded by EU4Health with an amount of EUR 154.2 million.

In 2024, a series of workshops and exchange visits were organised in several Member States to assess training needs. They serve as the basis on which the general EU health security preparedness training programme is being developed.

Since December 2022, there have been 17 events to train healthcare staff on preparedness and the response to cross-border health threats, with the inclusion of all EU Member States and EEA countries. A total of 530 people participated in these training courses, of whom 79 participated in one of the four pilot training courses.

'One Health' surveillance programmes were successfully implemented in one country[119] and the total consumption (by community and hospital sectors) of antibacterials for systemic use was reduced to 19.40[120], which was within expectations. Data for the remaining Programme indicators on prevention and response to cross-border health threats is progressively becoming available. Actions under the crisis preparedness strand contribute to Sustainable Development Goal 3, building on the results of the third Health programme. For example, in 2020, 22 Member States integrated coherent approaches into their preparedness plans, as shown by the assessment of the reports on national preparedness plans transmitted to the Commission[121].

The number of actions complementing national stockpiling of essential crisis-relevant products is lower than expected at this stage, one action[122] implemented, compared to five being the 2024 milestone. This is partly due to the fact that the number and nature of actions depend on the

117 EU-JAMRAI2.

118 CP-p-24-15 Support to speed up the development of access to and/or uptake of medical countermeasures including critical medicines (HERA), CP-g-24-105 Call for proposals to support the development of novel antivirals (HERA), CP-g-24-10 Call for proposals on the European Hub for vaccine development (HERA).

119 The Netherlands.

120 The indicator measures the total consumption (community and hospital sectors) of antibacterials for systemic use (ATC group J01) expressed as 'defined daily dose – DDD per 1 000 inhabitants per day'.

121 Ex-post evaluation of the third Health Programme (see page 25).

122 Joint action CHESSMEN Coordination and Harmonisation of the Existing Systems against Shortages of Medicines – European Network involves 25 Member States. This one joint action was launched instead of launching several direct grants with each interested Member State separately.

priorities identified each year for the annual work programme during the programming phased and agreed between the Commission and Member States.

The co-financing structure of EU4Health encourages the efficient use of funds. As regards administrative costs, while recognising the potential to further improve further efficiency, it should be noted that administrative costs have not significantly hindered the achievement of the Programme's objectives under this strand.

Strand 2: Health promotion and disease prevention

The implementation of actions targeting the specific objectives of the health promotion and disease prevention strand is ongoing and the results at the interim stage are better than expected. The actions of this strand support very effectively the delivery of the 'Healthier together' – EU NCD Initiative as demonstrated, for example, by JA PreventNCD[123] and JACARDI[124]. Moreover, the legal obligation to allocate a minimum of 20% of the total budget to these actions has already been fulfilled[125].

The number of implemented actions contributing to reducing avoidable mortality from NCDs is 17, more than three times what was expected (5), and the number of actions addressing environmental risk factors for health is 7, above the planned 4 in 2024. The increased number of actions illustrates the importance of addressing environmental risk factors for health and contributing to the priorities of the Green Deal. In addition, the fact that the Member States have significantly increased their participation (more than double the 10 planned for 2024) in actions that transfer best and promising practices to reduce the burden of non-communicable diseases indicates the need to address this issue[126]. Investments in cardiovascular disease, respiratory diseases and diabetes were given priority. Initial actions have been rolled out, implementing effectively the 'Healthier together' – EU NCD initiative and the Programme's specific objective on health promotion and disease prevention. The roll-out of mental health actions is in line with the Commission's political commitments. The EU's investments in mental health[127] have been increased considerably, including to support people suffering due to the Russian war of aggression against Ukraine. This covers activities to prevent and manage mental health problems, target depression or provide training and capacity building to support a 'mental health across policies' approach. Despite these efforts, stakeholders consider that mental health should be given higher priority in EU4Health, even if it is addressed in a complementary and synergistic manner by other EU funding programmes.

EU4Health's actions on vaccination are consistent with the international vaccination agenda, complement the actions of Member States and support the delivery of national vaccination programmes. Only two countries have reached 95% coverage for both the first and second dose of the measles vaccine for eligible individuals, which is below the 2024 milestone of 6 countries. The 2024 milestone for influenza coverage was achieved by 2021 and remains stable. The 2024 milestone for HPV vaccination was met in 2023. The national vaccination coverage

123 https://preventncd.eu.

124 Joint Action on CARdiovascular diseases and Diabetes.

125 Article 5 of the EU4Health Regulation provides that a minimum of 20% of the total EU4Health budget shall be reserved for health promotion and disease prevention actions.

126 Programme Performance Statement 2024.

127 The total amount is EUR 29 million, which amongst others, was committed to the International Federation of the Red Cross to address the relevant health consequences of the Russian war of aggression against Ukraine.

depends on several factors (not all directly linked to EU funding[128]), but continued use by Member States of funding opportunities from the EU's budget could reduce health inequalities and health inequities linked to access to and availability of vaccination, increase the uptake of HPV and HBV vaccination in a cancer prevention perspective, and improve the monitoring of rates of coverage.

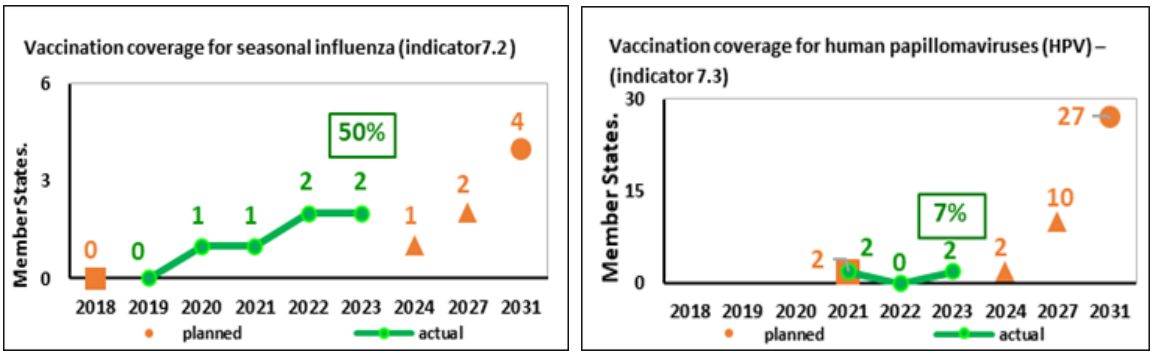


Figure 17 Selected vaccination coverage indicators – see Annex VII for a full list of PPMEF vaccination indicators monitored. (Legend: ■ baseline; ▲ milestone; ● target; ● actual). * The percentage indicates the progress on the 2031 targets.

There are 9 actions addressing the prevalence of major chronic diseases per Member State, by disease, gender, and age (instead of 70 as planned), which indicates the need to reassess and adjust the milestone and target, which were set at an overly ambitious level. The number of actions launched by the cut-off date that address the prevalence by age of tobacco use and differentiated, if possible, by gender, is two, while three actions address the prevalence of the harmful use of alcohol and differentiated, if possible, by gender – both types of action have surpassed their 2024 milestone of one action. The number of actions depends also on the prioritisations made during the programming process, which involves Member States and builds on input from stakeholders.

EU4Health actions on non-communicable diseases build on actions and employ mechanisms that were already proven to be effective in the third Health programme, such as the identification and transfer of best practices. This was done through the EU-Compass for Action on Mental Health and Well-being, which is a web-based mechanism to collect and exchange best practices and analyse information on policies and stakeholder activities on mental health. Another joint action supported the exchange and implementation of best practices in the field of mental health with a particular focus on suicide prevention and the reform of mental health services[129]. In addition, the joint action on tobacco control (JATC2) facilitates the exchange of good practices between Member States to improve the implementation of the Tobacco Products Directive and the Tobacco Advertising Directive. The functioning of the European Reference Networks (ERNs), which clearly has a high level of EU added value, is another example[130]. It is, therefore, expected that the actions on non-communicable diseases will have positive effects. Involving Member States in the programming of the EU4Health actions ensures they are consistent with actions taken by Member States at national level, which has been confirmed by stakeholders.

128 COUNCIL RECOMMENDATION of 21 June 2024 on vaccine-preventable cancers.
129 ImpleMENTAL.
130 Staff Working Document on Ex-Post Evaluation of third Health Programme, SWD(2023) 369 final.

The Programme's coherence with other EU funding programmes such as Horizon Europe is ensured through consultation with the relevant Commission departments on the annual work programmes, and the organisation of joint stakeholder events to present projects in specific thematic areas (e.g. mental health).

Five actions (with EUR 91.36 million in funding)[131] that support the *Health promotion and disease prevention* strand are creating synergies with Horizon Europe. Three of these actions implement the 'Healthier together' initiative, one is on prevention of mental health problems in the area of NCDs and the last is on the health determinants of cancer and other NCDs[132].

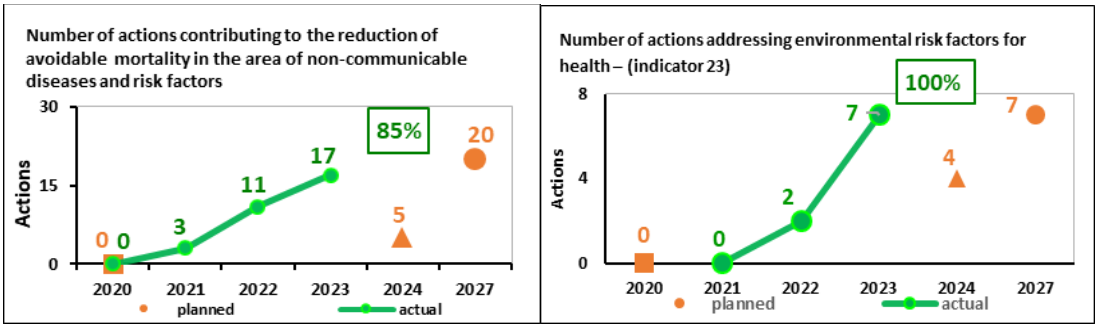


Figure 18 Selected health promotion and disease prevention indicators – see Annex VII for a full list of PPMEF Health promotion and disease prevention indicators monitored**.** (Legend: ■ baseline; ▲ milestone; ● target;● actual); * The percentage indicates the progress towards 2027 targets.

Strand 3: Health systems and healthcare workforce

Actions under the *Health systems and healthcare workforce* strand have been successfully launched. These actions aim to strengthen health systems (e.g. by supporting Member States in their policies on the healthcare workforce and on access to healthcare or improving expertise on reforming health systems); support the functioning of the ERNs; and contribute to the design and implementation of EU health legislation in areas like medical devices and in vitro diagnostic medical devices, pharmaceutical legislation and HTA.

Health systems and healthcare workforce is the strand with the highest number of actions and the second lowest average budget per action and is thus very resource intensive[133].

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131 DP-g-23-31-01 Direct grants to Member States' authorities: 'Healthier Together' EU NCD initiative– chronic respiratory diseases (CRDs), DP-g-23-32-01 Direct grants to Member States' authorities: 'Healthier Together' EU NCD initiative – Mental health, DP-g-23-33-01 Direct grants to Member States' authorities: 'Healthier Together' EU NCD initiative – Dementia and other neurological disorders, DP-g-23-32-02 Call for proposals on the prevention of NCDs in the area of mental health including actions supporting vulnerable population groups, such as migrants, refugees, Roma people and displaced people from Ukraine.

132 For more information on the relationship between EU4Health and Horizon Europe, see 4.1.1 Crisis preparedness.

133 Crisis preparedness – 103 actions programmed, average budget per action EUR 6 048 341; Health promotion and disease prevention – 108 actions programmed, average budget per action EUR 1 439 252; Health systems and healthcare workforce – 288 actions programmed, average budget per action EUR 830 107; Digital – 108 actions programmed, average budget per action EUR 1 157 035: Cancer – 62 actions programmed, average budget per action EUR 3 549 437: Other activities – 65 actions programmed, average budget per action EUR 484 167.

The actions launched under this strand have already helped improve knowledge at national level in the field of health and will support the implementation of the MDR and IVDR (EUR 19.8 million). They facilitate access to innovative treatment for patients, including for people with rare diseases (via the ERNs). Awareness-raising activities financed by the Programme have played a part in helping more than 500 000 cross-border patients per year benefit from the provisions of the Directive on cross-border healthcare[134]. Several actions financed by the Programme are expected to enhance the quality of medicinal products and improve the availability of medical devices and in vitro medical devices. Lastly, they will help to strengthen health systems for the benefit of people in the EU and will lead to costs savings thanks to advancements in HTA.

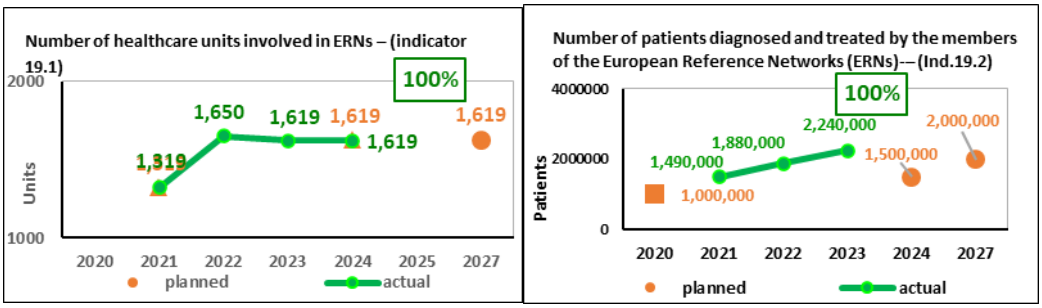


Figure 19 Selected ERNs' indicators – see Annex VII for a full list of PPMEF ERNs' indicators monitored (Legend: ■ baseline; ▲ milestone; ● target;● actual). The percentage indicates the progress on the 2027 targets.

EU4Health has committed funding of EUR 100.5 million for the functioning of the **ERNs** and their activities to exchange information and expertise. The Programme indicators show that, as expected, 1 619 healthcare units were involved in the ERNs by mid-2024, and that 2.24 million patients had been diagnosed and treated by members of the ERNs, which is 50% more than the 2024 milestone. This result reflects the recommendation in the third Health programme to focus on areas with high EU added value, such as rare diseases.

The EU4Health Programme also helped to prepare the ground for the successful implementation of the **Health Technology Assessment (HTA) Regulation**. The Commission is mandated by the HTA Regulation to create and maintain an IT environment for cooperation on HTA at EU level. EU4Health is funding this IT environment and the governance groups in this area (EUR 11.35 million programmed, of which EUR 5 million has been committed)[135]. A dedicated EU4Health action aims to prepare patients and train clinical experts so they can participate in joint clinical assessments and joint scientific consultations.

134 Cross-border Healthcare in 2022: Recent data on Member States' implementation of Directive 2011/24/EU.

135 According to the HTA Regulation, the European Commission acts as the HTA Secretariat and serves a complex governance system. It provides administrative, technical and IT support to the HTA Coordination Group and its four subgroups, which are chaired by the Member States. In addition, the Commission manages the HTA Stakeholders Network and ensures the implementation of the HTA (legal) framework as stipulated in the HTA Regulation.

The Programme also contributes to the implementation of **legislation on substances of human origin** (SoHO)[136]. These directives will be replaced by a new Regulation[137] which will enter into force in 2027. One action made it possible to prepare a tailored plan to authorise and improve access to SoHO innovations, while new technical guidelines have been developed to help professionals in over 5 000 establishments to ensure the safety and quality of tissues, cells, blood and organs. Using EU4Health funds, the Commission is developing a new digital platform to support the authorities in all 27 Member States to perform the different oversight tasks. Underlying digital public service(s) will be designed with interoperability in mind, to ensure smooth interconnection and exchange of data with relevant national systems such as those managing electronic health records or other registries and databases. EU4Health actions have also allowed different SoHO sectors to improve the continuity of supply, including for organs and plasma-derived medicines.

The Programme contributes to the implementation of the **pharmaceutical strategy for Europe** and related legislation and has supported the preparation of proposals for a new directive and a new regulation to reform EU pharmaceutical legislation. The Programme indicators recorded that 103 medicines received an EU-wide authorisation in 2022. This number fell to 68 in 2023. This indicator reflects rather the capacity of the pharmaceutical industry to deliver, which is very little influenced by EU4Health actions. The level of relevant shortages of human and veterinary medicines has remained under control. EU4Health contributes to the creation of a regulatory-approved electronic version of medicinal product information (ePI). This opens up new possibilities for patients and healthcare professionals to access and use vital, up-to-date information about their medicines, when and where needed.

EU4Health supports the implementation of legislation on **medical devices (MDR) and in vitro diagnostic medical devices (IVDR)** and related tools. For instance, the Programme supports the ongoing IT development of the European Database on Medical Devices (EUDAMED), its helpdesk and information centre (a repository of all EUDAMED technical documentation) and an independent audit verifying the systems' functionality. New EUDAMED modules for voluntary use have been developed, building on investment from the third Health programme. Another action funded by EU4Health, which is also a continuation from the previous health programme, supports the Commission and national experts in appointing and reassessing notified bodies. This action led to the designation of 50 notified bodies under the MDR and 12 notified bodies under the IVDR. Other EU4Health actions in this field include the establishment and funding of EU reference laboratories, a joint action on market surveillance in this field and an initiative to support the development of orphan devices. The culmination of all the actions supporting the implementation of the MDR and IVDR lead to significant increases in the number of certificates issued for medical devices and in vitro diagnostic medical devices: 5 599 certificates were issued for medical devices (almost three times more than in 2022), and 702 certificates for in vitro diagnostic medical devices (more than double the number in 2022).

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136 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); 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).

137 Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L, 2024/1938, 17.7.2024).

The digitalisation of **health systems** requires safe, ethical and trustworthy solutions. Using digital health systems to their full extent means that healthcare workers must be trained in specific (digital) skills. EU4Health funding is addressing this skills gap and will help digital health to play a stronger role in supporting the work of health professionals and facilitating the transformation of healthcare models to the benefit of patients. EUR 37.3 million has been programmed for actions addressing the **healthcare workforce**. Among other things, EU4Health funding contributes to improving databases and to developing effective tools and methods used by the Member States to carry out health workforce planning.

The Programme continues to fund the 'State of Health in the EU' cycle that contributes to health policymaking in the Member States. EUR 17 million has been programmed to co-fund two joint actions on the transfer of best practices in primary care and on forecasting and planning the needs of the health workforce. These actions improve cooperation between the Member States and help to strengthen health systems.

In line with expectations for 2024, EU4Health funded three actions producing guidance on improving access to healthcare services. These actions contribute to SDG 3.8[138].

Two actions are helping to address dependence on imports from outside the EU of essential active pharmaceutical ingredients and medicinal products. 28 audits were conducted in the EU and in third countries, including candidate countries, to ensure good manufacturing practices and good clinical practices (EU control on minimum standards). Lastly, Member States are participating in actions to support innovation, uptake and access to the market of medical countermeasures at EU and global levels.

It was expected that in 2024, there will be 110 shortages of medicinal products in the Member States reported through the single point of contact network. This value measured in 2024 was 69. Although this value also depends on the level of reporting by companies, this suggests EU and national policies have become more effective to prevent critical shortages.

Strand 4: Digital

The *digital* strand supported actions to prepare the implementation of Regulation (EU) 2025/327, which aims to advance the digital transformation of health systems and improve the accessibility, coverage and interoperability of health data.

The actions financed by the Programme are focused on improving health data and digital tools and services, on supporting digital transformation, and increasing the interoperability of health data (a total of EUR 163 million has been programmed in the 2021, 2022, 2023 and 2024 work programmes)[139]. Several actions support the development of cross-border digital health infrastructures (MyHealth@EU and HealthData@EU) to facilitate patient care for any EU citizen travelling in Europe while giving the treating medical professionals access to relevant medical data.

A total of 37 actions were launched by the end of 2023 (surpassing the target of 28 actions by mid-2024) to support the digital transformation of healthcare systems and the implementation of the EHDS, indicating an efficient programming process (see Figure 20). Two other

138 SDG Target 3.8 Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

139 EU4Health – Performance.

indicators were on track to be achieved in 2024, with 13 Member States participating in the EHDS by mid-2024, and 15 in total by late-2024 (the target for mid-2024 was 15), and with 21 health data access bodies set up or in the process of being set up (the target for mid-2024 was 15). 22 European countries, including 20 Member States, have received support to digitalise their health systems and to increase the geographic coverage and interoperability of systems and/or improve patient access to their own health data. In addition, 44 key projects were launched in late 2023 and early 2024 to implement MyHealth@EU and to set up health data access bodies that will pave the way for the EHDS. These projects build on the actions launched under the third Health programme, such as the joint actions on the primary and secondary uses of health data (e.g. TEHDAS and eHAction).

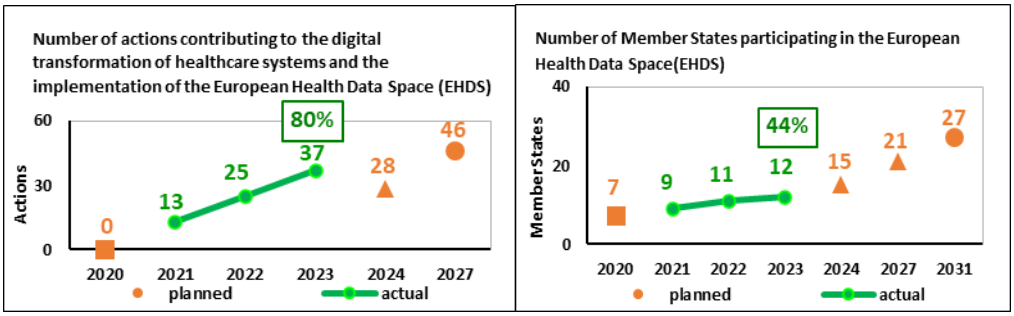


Figure 20 Selected digital transformation indicators – see Annex VII for a full list of PPMEF Digital transformation indicators monitored. (Legend: ■ baseline; ▲ milestone; ● target;● actual); * The percentage indicates the progress on the 2027 and 2031 targets.

The actions funded by EU4Health that contribute to the EHDS are complemented by initiatives under the DEP, which aims to drive innovation in data space technologies, such as actions to harmonise exchanges of health data[140]. They are further complemented by Horizon Europe actions, e.g. on the data quality and utility label for the EHDS[141], or by Member State actions supported by the RRF.

This evaluation finds that there is clear complementarity between EU4Health, Horizon Europe and the DEP on health research, and health data use, and digital transformation, respectively.

For example, the specific objective from the DEP on the use of digital technologies refers to health as one of the areas of public interest for digital transformation, which requires the continuation and expansion of digital service infrastructures. However, DEP does not provide direct grants for Member States authorities as EU4Health does, which are fundamental for the deployment of cross-border infrastructures such as MyHealth@EU. This point emphasises the complementarity between these two programmes.

In addition to the DEP, feedback from stakeholders reveals that digital actions funded through EU4Health are being followed up with new actions, funded at times through different initiatives. The RRF focuses on economic recovery post-COVID, including action to

140 Examples from the 2023-2024 Digital Europe work programme include: Federated European Infrastructure for Intensive Care Units' Data to provide a harmonised approach to accessing acute care-related data and to link it with other health data sources, which are interoperable with the EHDS (EUR 5.1 million); Supporting patients' access to their health data in the context of healthcare services for citizens across the EU (EUR 10 million); and Demonstrating the in-service use of the European Electronic Health Record Exchange Format (EEHRxF) in healthcare settings (EUR 4 million).

141 https://quantumproject.eu/.

strengthen the resilience of health systems. RRF expenditure on resilience in 2023 amounted to EUR 84.1 billion, of which around 49% can be linked to healthcare[142]. In particular, the RRF's focus on digital health, access to healthcare, strengthening public health capacities and improving prevention, show coherence with the objectives of EU4Health. The RRF has dedicated EUR 14.5 billion to the digitalisation of healthcare systems. One example from the RRF is the EUR 300 million plan by Portugal to invest in the digital transition of its national health service. A mid-term evaluation case study has found that the coherence between the digital health measures in the RRF, the EU4Health Programme and the 2030 Digital Compass depends on the country concerned. Given the substantial amounts of money being spent by the RRF on healthcare resilience, it is worthwhile to improve the existing synergies and complementarities between it and EU4Health funds to strengthen health systems.

Another example of a complementary source of funding is InvestEU[143], which supports projects in the health sector. The links between EU4Health actions and the investments under several InvestEU projects could be strengthened. Investments in digital infrastructure and digital technologies offer opportunities for complementarity with EU4Health and would set the path towards a more competitive EU health sector. In this area, 10 out of 29 InvestEU operations show some link with healthcare. The possibility to support large-scale health projects and innovations through InvestEU seems to be underutilised.

Cross-cutting strand: Cancer

The fight against cancer is driven by Europe's Beating Cancer Plan and funded through EU4Health (EUR 531 million programmed by April 2024) and other EU funding programmes. Horizon Europe and the EU Cancer Mission have already invested EUR 1.8 billion in the fight against cancer. This mission complements the objectives of EU4Health, helping achieve a comprehensive approach to cancer prevention, diagnosis, treatment and care across the EU.

The actions on cancer funded by EU4Health support better cancer prevention and treatment by reducing exposure to and raising awareness of relevant risk factors; ensuring access to high-quality healthcare and related care services; improving vaccination coverage rates for vaccine-preventable diseases; increasing screening coverage for certain cancers, and through a comprehensive information system on cancer.

Three years into the Programme, many initiatives have already been launched and are expected to have a tangible impact on the lives of people in the Europe. The European Commission Knowledge Centre on Cancer has been established and is sharing reliable, independent and up-to-date information on topics related to cancer. It aims to foster the scientific and technological alignment of all Commission activities on cancer, particularly between the Europe's Beating Cancer Plan and the EU Cancer Mission. An upgraded European Cancer Information System makes it possible to monitor and forecast the burden of cancer in Europe (EUR 14.5 million), alongside the European Cancer Inequalities Registry (EUR 6.6 million), which provides insights on disparities in rates of cancer, and on prevention and care. The European Cancer Imaging Initiative improves personalised medicine by making an EU 'atlas' of anonymised cancer-related images accessible. Another notable example is the collaboration between EU4Health, Euratom and the EU Cancer Mission through the SAMIRA Action Plan, an

[142] Report from the European Commission to the European Parliament and the Council on the implementation of the Recovery and Resilience Facility: Moving forward. Brussels, 25.9.2023 COM(2023)545 final/2.

[143] InvestEU offers loans, guarantees or equity investments as a complement to other public and private investments. With EUR 100 million, HERA Invest contributes to the InvestEU programme.

initiative supporting safe, reliable and effective use of radiological and nuclear technology in healthcare[144].

Because early detection through screening offers the best chance of treating cancer and increases treatment options, the European Guidelines and Quality Assurance Schemes for cancer screening, diagnosis and care are being rolled out. This initiative is aligned with and aims to support the implementation of the 2022 Council Recommendation on cancer screening[145].

Several cancer screening projects launched under the EU Cancer Mission financed by Horizon Europe are helping to implement the 2020 Cancer Recommendation on cancer screening[146] with an investment of about EUR 51 million.

Major initiatives to train the healthcare workforce, personalise cancer care and improve cross-border cooperation have been launched. The EU network linking recognised National Comprehensive Cancer Centres (EUR 94 million) and new networks of expertise (EUR 44 million) tap into the whole European oncology community to address specific, challenging cancer conditions. In a complementary manner, the EU Cancer Mission Comprehensive Cancer Infrastructures (EUR 9.9 million) project helps Member States and associated countries to enhance research capacities through a capacity building programme[147].

Six Programme indicators[148] are being used to assess the progress of actions on cancer. 25 Member States, one more than expected (the milestone target was 24) are reporting information on cervical, breast and colorectal cancer on the percentage of population covered by Cancer Registries. 25 Member States are reporting information on paediatric cancer at the stage of diagnosis, very close to reaching the 2024 milestone of 26 countries.

Cancer screening is one of the pillars of the Cancer Plan, to which EUR 60 million have been committed from the EU4Health budget. Several EU4Health-funded projects contribute to cancer prevention efforts with the goal of reducing the incidence of cancer and improving overall public health.

The data from population-based cancer registries are the basis for the estimation of the cancer burden and its trends over time and are crucial for the planning and evaluation of cancer control programmes. During the Programme implementation, the proportion of the population covered by cancer registries reporting information on cervical, breast, colorectal and paediatric cancer

144 SAMIRA: Strategic Agenda for Medical Ionising Radiation Applications.

145 Council Recommendation of 9 December 2022 on strengthening prevention through early detection: A new EU approach on cancer screening replacing Council Recommendation 2003/878/EC 2022/C 473/01 (OJ C 473, 13.12.2022).

146 Pancaid, Home - PANCAID (pancaid-project.eu) Lucia Home | LUCIA (technion.ac.il) Dioptra Home DIOPTRA - DIOPTRA project (dioptra-project.eu) Sanguine SANGUINE - Early Diagnostics of Haematological Malignancies (Blood Cancer) | Cancer care (sanguine-project.eu) Mammoscreen The MammoScreen Project.

147 CCI4EU fights against cancer, Horizon Europe.

148 See the end notes on cancer indicators.

stage at diagnosis will be assessed during the implementation of EU4Health. The values for 2024 are already above the 2024 milestone at the time of reporting[149, 150, 151].

When the Cancer Plan was adopted in 2021, 22 EU Member States, Iceland and Norway had a national cancer plan in place. After the adoption of the Cancer Plan, four more countries developed national cancer plans and ten updated their existing plans. In addition, by December 2023 three countries were updating their plans. The majority of cancer plans were found to be well aligned with the Cancer Plan and covering its four pillars, which demonstrates the added value of an EU-wide programme. All the countries with national plans have addressed prevention by including initiatives to tackle lifestyle habits that are related to cancer risk factors. For early detection, in most countries, national cancer screening programmes for breast, colorectal and cervical cancer are in place, with a few exceptions, where opportunistic[152] or private screening programmes are available. Additionally, two Member States have set up screening programmes for lung cancer, while six other Member States are running or planning to run pilot programmes, following the 2022 update of the Council Recommendation on cancer screening which proposed the extension of organised screening programmes to include lung, prostate and gastric cancer. All the national cancer plans outline a wide range of initiatives to improve the quality of diagnosis and treatment, such as strengthening patient involvement in decision-making, boosting personalised treatments and providing continuous training for healthcare professionals. To improve the quality of life of cancer patients and survivors, several national plans include actions on financial support for cancer patients and carers, psychological support for patients and relatives, and the introduction of legislation on the 'right to be forgotten' to ensure easier access to financial services, such as insurances. Most national plans also touch upon the Cancer Plan's cross-cutting themes of research and innovation, inequalities and paediatric cancers. Several countries have financed cancer research; however, funding varies depending on the size of the country and the availability of suitable infrastructure and personnel. While paediatric cancers are a priority area in some national plans, this often falls under the umbrella of other priority areas on care or quality of life.

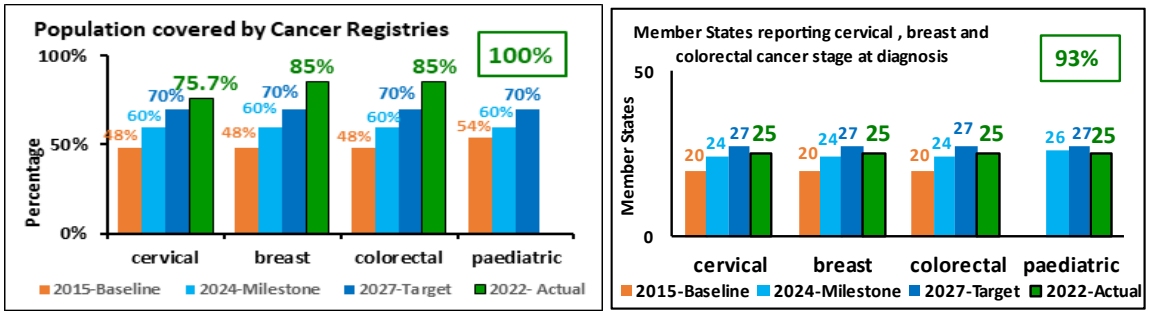


Figure 21 Selected cancer indicators – see Annex VII for a full list of PPMEF cancer indicators monitored. The percentage indicates the progress on the 2027 targets.

149 L Villani, M T Riccardi, A Barbara, T Sabetta, M C Nurchis, A Sabetta, A Solipaca, W Ricciardi, A shared battle against cancer: overcoming screening uptake differences within European countries, *European Journal of Public Health*, Volume 30, Issue Supplement_5, September 2020, ckaa166.1132, https://doi.org/10.1093/eurpub/ckaa166.1132.

150 Cardoso, R. et al. (2021). Colorectal cancer incidence, mortality, and stage distribution in European countries in the colorectal cancer screening era: an international population-based study. The Lancet. Oncology. https://doi.org/10.1016/S1470-2045(21)00199-6.

151 Cardoso, R., Hoffmeister, M., & Brenner, H. (2023). Breast cancer screening programmes and self-reported mammography use in European countries. International Journal of Cancer, 152, 2512 - 2527.

152 Screening that occurs outside of a structured, population-based screening programme.

Overall, the actions on cancer are being successfully implemented and are contributing towards the ambitious goal of 'beating cancer'. These actions complement and expand on the initiatives launched under the third Health programme. As an example, the activities of the European Network of Cancer Registries, coordinated by the Commission, provided a harmonised European dataset used for different purposes under the third Health Programme[153]. This concept has been further developed in the Cancer Plan through the European Cancer Information System and the European Cancer Inequalities Registry. Similarly, the Joint Action Innovative Partnership for Action Against Cancer[154], also under the third Health programme, aimed to develop innovative approaches to cancer control. The Cancer Plan is taking this forward, prioritising research and innovation as a cross-cutting theme in all its flagship initiatives. The final evaluation of the third Health programme pointed out the lack of cancer actions aimed at children and young people. The Cancer Plan has a section, and a flagship action dedicated to childhood cancer. In 2021, the Commission launched the 'Helping Children with Cancer Initiative' to ensure that children have access to rapid and optimal detection, diagnosis, treatment and care. As part of these initiatives the EU Network of Youth Cancer Survivors has been launched, and it is collaborating-with the EU Cancer Mission. Furthermore, a new section on paediatric cancers was added to the European Cancer Information System and renewed funding for the PaedCan ERN is ensured.

Coherence between EU4Health and Horizon Europe is most prominent in the case of cancer actions[155]. This stems from the close alignment of Horizon Europe's EU Cancer Mission with EU4Health's cancer strand, which is ensured by the joint governance of the EU Cancer Mission and the Cancer Plan.

Of the 21 actions in EU4Health annual work programmes that reference Horizon Europe, 12 focus on cancer[156]. Their budget amounts to EUR 262.6 million. Some EU4Health actions are building upon the results of projects funded by Horizon Europe[157]. A visual representation of the cancer-related actions and their interconnection, along with a cancer projects dashboard, have been developed by the Knowledge Centre on Cancer[158].

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

4.2.1. Main beneficiaries and relevant gains

The Programme finances actions with EU added value under the pillars of the European Health Union that reach **all Europeans.** 54% of stakeholders report that EU4Health delivers to a large or very large extent results that go beyond what could reasonably be expected from the Member States acting independently[159]. This view is particularly strong among national authorities and

153 Staff Working Document on Ex-Post Evaluation of third Health Programme (europa.eu).
154 iPAAC Home.
155 For more information on the coherence between EU4Health and Horizon Europe, see 4.1.3 Crisis preparedness.
156 See Annex VIII.
157 For example, action CR-p-23-43 builds on outcomes from Horizon Europe projects like 'European Quality of Life in Oncology' (EUonQoL) and 'HORIZON-MISS-2023-CANCER-01-04', aiming to improve the quality of life for childhood cancer patients and their families.
158 https://knowledge4policy.ec.europa.eu/visualisation/cancer-projects-tool_en .
159 Targeted surveys in the context of the study supporting EU4Health interim evaluation.

EU-level non-profit organisations, who value the Programme's role in addressing health inequalities and supporting smaller Member States.

The Programme is expected to have significant economic impacts as **healthier populations** contribute to higher productivity and reduced healthcare costs. Societally, the Programme directly contributes to improving public health and the quality of life for people in the Europe, by addressing critical health issues such as cancer, mental health, chronic diseases and communicable diseases, ensuring that all the participating countries have access to the best practices and innovations in healthcare. Continuous funding of ERNs since 2017, including the considerable budget increase received from EU4Health, made it possible to treat and diagnose 2.24 million patients with rare diseases in 2023. A total of 1 619 members of the ERNs were able to continue to develop their expertise and strengthen links with other healthcare providers in the EU. Thus, the ERNs improve the life of patients with rare diseases and add to the capacity of healthcare providers.

The Programme is helping **participating countries and their authorities** to navigate an era of complex, overlapping and interlinked crises. It provides significant added value by improving the coordination and implementation of health-related legislation across Member States, thereby strengthening the collective response to health challenges. Its role is crucial for achieving a cohesive approach to health emergencies, chronic disease management and improvements in public health. This is particularly evident in how the Programme supports the dissemination and adoption of best practices across borders. EU4Health funds collaborative projects that enhance the capabilities of people in the *healthcare workforce*, which is vital for countries that need to improve their delivery of health services. Additionally, the Programme supports the integration of digital health technologies, benefiting health systems by improving efficiency and patient outcomes. By financing and fostering *HTA cooperation*, EU4Health can increase the probability that new medical treatments and innovations will reach all Member States, not just those with the most resources. The EU4Health Programme helps to improve health equity and universal healthcare access across the EU.

The EU and its Member States stand to benefit from investments in health including through EU4Health. Pooling resources at the EU level can lead to *economies of scale* in (joint) procurement (for vaccines, medical equipment, etc.), research and health initiatives, making them more cost-effective than if each Member State acted independently. The EU's collective voice and resources enable it to play a significant role in global health matters. Research highlights that the EU's approach to health impact assessments and its 'health in all policies' approach offer a more integrated and comprehensive strategy compared to individual national efforts, which often face limitations in resources and scope[160]. While some critiques point to weaknesses in strategic planning, they also recognise the broader ambition and scale of EU health programmes, suggesting that the EU's initiatives achieve impacts beyond the reach of national actions alone[161]. The evaluation supporting study found that the Programme's benefits are especially pronounced for smaller Member States, which often face challenges in

[160] Hübel, M., & Hedin, A. (2003). Developing health impact assessment in the European Union. *Bulletin of the World Health Organization*, 81 6, 463-4. https://doi.org/10.1590/S0042-96862003000600020.; Koivusalo, M. (2010). The state of Health in All policies (HiAP) in the European Union: potential and pitfalls. *Journal of Epidemiology & Community Health*, 64, 500 - 503. https://doi.org/10.1136/jech.2009.102020.; Salay, R., & Lincoln, P. (2008). Health impact assessments in the European Union. *The Lancet*, 372, 860-861. https://doi.org/10.1016/S0140-6736(08)61337-9.

[161] Watson, R. (2009). European auditors question the value of EU-funded public health programmes. *BMJ: British Medical Journal*, 339. https://doi.org/10.1136/BMJ.B2819.

addressing rare diseases due to limited resources and, in their health systems, due to limited capacity and small market size. Prior studies highlight these issues, indicating that smaller countries often struggle with healthcare reforms and resource limitations[162] and receive a disproportionately low share of EU healthcare research funds[163].

Additionally, the Programme's collaborative framework empowers **NGOs** and other organisations to operate on a larger scale, thereby increasing their impact and, through the procurement of health-related services, stimulating **private sector entities** to provide and maintain specialised jobs. The evaluation supporting study found that NGOs also play a critical role in this narrative. They report that without EU4Health, they would struggle to sustain their initiatives due to limited national funding. The Programme enables significant knowledge exchange between NGOs and the Commission, fostering a more cohesive and informed approach to health challenges. The cessation of EU4Health could result in a loss of these valuable exchanges.

Added value of EU-wide cooperation

Stakeholders consistently emphasise that EU4Health's most evident contribution is in **facilitating collaboration between Member States**[164]. This collective effort enables countries to share knowledge, exchange information, and build connections that would be much harder to establish individually. For example, one interviewee highlighted how EU4Health enabled the adoption and implementation of a mental health strategy from another Member State, underscoring the importance of sharing best practices. Such exchanges foster innovation and prevent duplication of efforts, ensuring a more efficient use of resources across the EU. Without such a collaborative approach, many of these innovations might have taken much longer to develop or would have required far more resources, leading to inefficiencies. The provision of European evidence-based guidelines and quality schemes that ensure essential levels of quality care and can be deployed and adapted at national level, maximises the use of resources and facilitates equity in access to quality care. Joint actions of Member States coordinated at EU level help to reduce disparities in the availability and affordability of healthcare, especially for rare diseases or cancer, and to address vulnerable groups. The growing emergence of medical deserts underscores the need to prioritise support to reduce disparities in health outcomes and the levels of unmet needs within and across Member States, remote regions and partner countries to ensure territorial cohesion.

Cross-border regional cooperation on healthcare improves knowledge sharing, management, and patient treatment and strengthens the preparedness of both regional and national authorities for crisis management. Several EU border regions played a vital role during the COVID-19 crisis by providing intensive care places and treatment to relieve over-burdened hospitals across the border or by sending healthcare professionals and essential medical equipment to other regions in need. The significant added value of health investments in facilitating collaboration and **fostering the alignment of priorities across Member States** is confirmed by the literature. Studies on *cross-border healthcare* collaboration reveal that such initiatives are more effective in regions with established cooperation, and which have received significant

[162] Azzopardi-Muscat, N., Funk, T., Buttigieg, S., Grech, K., & Brand, H. (2016). Policy challenges and reforms in small EU member state health systems: a narrative literature review. *European journal of public health*, 26 6, 916-922. https://doi.org/10.1093/eurpub/ckw091.

[163] Kaló, Z., Akker, L., Vokó, Z., Csanádi, M., & Pitter, J. (2019). Is there a fair allocation of healthcare research funds by the European Union. *PLoS ONE*, 14. https://doi.org/10.1371/journal.pone.0207046.

[164] Targeted surveys in the context of the study supporting EU4Health interim evaluation.

support from EU funding. For example, a comprehensive study on cross-border cooperation found that EU-funded projects in healthcare lead to improved knowledge sharing, management and patient treatment, demonstrating both economic and social benefits[165]. Similarly, a review of cross-border health activities in various EU regions identified that these projects, which span education, training and disaster control, have considerable potential for development and offer substantial improvements in healthcare delivery[166]. The importance of these collaborations was particularly evident during the COVID-19 pandemic, which highlighted how cross-border efforts can enhance access to healthcare and create synergies between regional capacities.

EU4Health funding ensures the creation of interoperable systems at EU level via setting up and maintaining the data standards and federated structure of the EHDS. These are necessary for EU-wide access to health datasets by both public services and industry. Access to large and diverse datasets will assist in the developments of policies and innovation, provide developers of AI-based devices with solutions and AI algorithm datasets sufficiently large for more accurate and inclusive applications in healthcare, and help public services in finding better healthcare solutions.

The evaluation supporting study revealed that the Programme also creates a **level playing field across** Member States, as the negative externalities for certain countries are much smaller. This is also evident from the different responses from Member States on whether they can continue all or at least some EU-funded initiatives and actions by themselves at national level. Some Member States indicate that national funding alone is insufficient, and initiatives would discontinue. Others indicate that all national initiatives would still exist but perhaps at a smaller scale or slower pace. This might be explained by differences in the dependence of Member States on EU4Health funding.

The percentage effect or multiplier of EU cross-country cooperation in cohesion policy and research and innovation varies based on the area and type of cooperation. However, multipliers generally range from **1.3**[167] **to 5.0**[168], depending on the specific context and sector. These values highlight the significant economic impact of EU-wide initiatives, which benefit from pooling resources, reducing barriers and fostering greater integration among Member States.

Added value of healthcare expenditure

Based on an analysis of megatrends in historically reported population health outcomes and findings from the literature on the role of healthcare investments in improved population health status, a societal multiplier for spending on healthcare and related public health measures of slightly above 3 can be assumed (see Annex II). This result is derived from monetising the

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165 Bobek, J., Schmidt, A., Röhrling, I., Seethaler, J., Feichter, A., Habimana, K., Piso, B., Bachner, F., Miteniece, E., Groot, W., & Pavlova, M. (2018). Study on Cross-Border Cooperation: Capitalising on existing initiatives for cooperation in cross-border regions Final report. https://doi.org/10.2875/825256.

166 Brand, H., Hollederer, A., Wolf, U., & Brand, A. (2008). Cross-border health activities in the Euregios: good practice for better health. *Health policy*, 86 2-3, 245-54. https://doi.org/10.1016/J.HEALTHPOL.2007.10.015.

167 Christou, T., Garcia Rodriguez, A., Heidelk, T., Lazarou, N., Monfort, P. and Salotti, S., A RHOMOLO assessment of 2014-2027 cohesion policy, European Commission, Seville, 2024, JRC136790.

168 COMMISSION STAFF WORKING DOCUMENT EVALUATION Accompanying the document REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL Ex-post evaluation of Horizon 2020, the EU Framework Programme for Research and Innovation, SWD(2024) 29 final.

estimated number of life years saved through healthcare investments. As such, it sets a general benchmark for the expected return on investment in the healthcare domain.

The EU 'health response' in Ukraine and neighbouring countries

The EU4Health Programme addressed the health consequences of the Russian war of aggression against Ukraine through four projects[169] supporting persons displaced from Ukraine. It also supports, with a budget of EUR 23.19 million, the work of the International Federation of Red Cross and Red Crescent to improve mental health and psychosocial support for displaced people coming from Ukraine. In 2023, 600 000 displaced people from Ukraine received psychological first aid and mental health services in 22 Member States and three non-EU countries.

[169] MESUR – Mental Health Support for Ukraine Refugees, U-RISE – Ukraine's displaced people in the EU: Reach out, Implement, Scale-up and Evaluate interventions promoting mental wellbeing, Well-U – Promoting the mental health and psychosocial wellbeing of refugee children and their caregivers through lay professionals amidst Ukraine's displacement crisis, and Peace of Mind and Strength of Heart.

4.2.2. The added value by Programme strand

Strand 1: Crisis preparedness

The stakeholders consulted for the supporting study[170] broadly agree that many of EU4Health's objectives are best met through coordinated action at the EU level. Survey results indicate significant support for this view, particularly for objectives related to protecting people from cross-border health threats – general objective (b) – with 66% of respondents agreeing to a large or very large extent that EU-level action is needed. This perspective is echoed in interviews, where stakeholders highlighted the fact that certain results, especially those involving cross-border challenges and crisis preparedness, could not be achieved as effectively by Member States acting alone. For instance, the fight against medicine shortages benefits from EU-level coordination and funding that would be difficult to replicate nationally.

EU4Health has played a pivotal role in strengthening the EU's preparedness for health crises such as COVID-19 and Mpox. This has been achieved by fostering collaboration, promoting advanced research and development on medical countermeasures and related technologies, and reinforcing early warning response systems and surveillance, thus also supporting the mandate of HERA. The Programme has enhanced the EU's capacity to respond effectively to emerging threats. The Programme has also helped to ensure that the EU has sufficient stocks of essential medical supplies to respond to crises.

By pooling resources and efforts across Member States, for example, by establishing European reference laboratories and early warning and response capacities, or developing the EU immunisation agenda, the EU significantly increases its capacity to respond to public health crises, improve population health outcomes, and strengthen political cohesion and social resilience. The EU4Health funds have mobilised 23 Member States to work together on creating and scaling up a coordinated surveillance system under the One Health approach for cross-border pathogens.

From a political perspective, the EU4Health Programme reflects a collective effort to tackle shared challenges, such as cross-border epidemics and pandemics, which no single country can fully address alone. Additionally, joint EU health actions reduce fragmentation within the EU and foster trust between Member States.

In terms of social added value, the EU4Health Programme allows for a proactive approach that safeguards public health across Member States by strengthening early warning and surveillance systems for the early detection and assessment of threats, ensuring timely access to essential medical countermeasures, such as vaccines, therapeutics and diagnostics. For people living in the EU, this translates to increased protection from emerging health threats, reducing the social disruption caused by crises like COVID-19.

Actions under the crisis preparedness strand demonstrate additionality by helping countries comply with the International Health Regulations[171] by strengthening their capacities to address cross-border health threats. Projects such as EU-Wastewater Integrated Surveillance for Public Health (EU-WISH[172]) and UNITED4Surveillance directly contribute to these aims,

170 Targeted surveys in the context of the study supporting the EU4Health interim evaluation.
171 International Health Regulations.
172 EU-WISH and UNITED4Surveillance on EU – Wastewater Integrated Surveillance for Public Health.

enhancing EU-wide prevention of and preparedness for health crises and ensuring that the EU can respond to health emergencies more effectively.

The stakeholders interviewed as part of the supporting study[173] acknowledged the additionality of the Programme since they had observed significant progress in creating bigger reserves of vaccines and better training on preparedness. In their view, this was predominantly due to the large budget increase under EU4Health. This underscores the importance of EU4Health in increasing the collective capacity of Member States to address health crises in a unified manner. It is also to be noted that further emphasis on crisis preparedness was a natural consequence of the COVID-19 pandemic, which was further substantiated by the creation of HERA.

It is highly unlikely that the EU could have achieved the same level of preparedness for health crises without the EU4Health Programme. The Programme's ability to coordinate efforts across Member States, leverage economies of scale, and promote innovation has been essential in strengthening the EU's resilience.

Limiting the EU4Health Programme would have significant negative consequences on the EU's ability to respond to health crises. This would likely lead to a fragmentation of efforts, less innovation, and a weakened capacity to prevent, detect and respond to emerging threats.

In summary, the EU4Health Programme has played a vital role in enhancing the EU's preparedness for health crises. Its continued operation is essential for ensuring the EU's resilience and protecting the health of its population.

Strand 2: Health promotion and disease prevention

The EU4Health Programme demonstrates significant EU added value by strengthening collaboration between Member States and by facilitating targeted interventions in the field of health promotion and disease prevention. By supporting exchanges of best practices, EU4Health enables Member States to tackle common health challenges more effectively than they could alone. 21 Member States have taken steps to implement elements of the Belgian mental health reform and Austrian initiative on suicide prevention[174], multiple Member States have engaged to enhance mental health systems and reduce stigma[175], and several Member States and other stakeholders have decided to implement training and capacity building activities for the support of a mental health across policies approach.

By providing targeted funding, fostering collaboration and promoting the exchange of best practices through platforms like the Commission's Best Practice Portal[176], and the Health Promotion and Disease Prevention Knowledge Gateway[177], the EU4Health Programme empowers Member States to strengthen their national health systems, and improve health outcomes across Europe, demonstrating a clear added value that goes beyond what individual countries could achieve. Shifting the investments from EU4Health to individual Member States' national budgets would likely result in fragmentation and reduced coordination.

Strand 3: Health systems and healthcare workforce

173 Targeted surveys in the context of the study supporting EU4Health interim evaluation.
174 Joint Action ImpleMENTAL.
175 European Alliance Against Depression-Best action.
176 Best Practice Portal.
177 Health Promotion and Disease Prevention Knowledge Gateway.

Support for the ERNs is exemplary in demonstrating the EU added value of EU4Health. The Programme makes it possible to share scarce knowledge which would not otherwise be available, especially in Member States where the number of patients with rare diseases is not big enough to allow the health service to build up the necessary expertise. ERNs give patients an opportunity to access diagnosis and treatment services without the added burden of having to travel to other countries.

EU4Health funded the joint action CIRCE-JA, which focuses on transferring best practices in primary healthcare between Member States, demonstrates how EU-level collaboration leverages shared experiences and builds capacity to improve the quality of healthcare[178]. Individual Member States, in the absence of such collaborative efforts, might resort to isolated approaches and less efficient implementation[179].

Similar benefits, mainly for the Member States that do not have the necessary capacity themselves, stem from the EU HTA legislation. EU4Health has contributed to the preparations to implement the HTA Regulation by financing several actions in this field, which enhance the pooling of expertise and resources and provide added value to Member States' HTA activities.

EU4Health funds the continuous professional development of health professionals, with a focus on digital skills in the areas of oncology, AMR, gynaecology and hospital care as well as more transversal and advanced digital skills in healthcare. This helps professionals from different countries to improve their professional skills in a coherent manner. EU4Health supports the successful implementation of the MDR and IVDR as well as the legislation on pharmaceuticals, and their contribution to the Single Market. It funds initiatives that increase the availability of safe and effective medicines, ensuring that Member States can benefit from more efficient clinical trial frameworks and improved public health outcomes.

Without the Programme, the health challenges and related investments would rest with the Member States, and implementation would have been slower and uneven across the EU.

Strand 4: Digital

The EU4Health Programme plays a critical role in developing and facilitating interoperability and aligning Member States' digital health priorities with broader EU and international objectives such as on developing comprehensive, interoperable and secure EHR systems, aligned with the objectives of the EHDS[180].

Interoperability is at the core of the EHDS and the work in the area of digital health at EU level. Through joint work between Member States, EU4Health also supports the deployment of key cross-border digital health infrastructures (such as MyHealth@EU or HealthData@EU) and capabilities for the reuse of health data that might otherwise remain out of reach for individual Member States. These efforts align with the Interoperable Europe Act, notably by promoting the uptake of shared interoperability solutions. EU4Health serves as a catalyst for digital innovation within healthcare systems, particularly benefiting smaller Member States. The Programme drives the adoption of digital tools that are interoperable, such as services for the exchange of e-prescriptions and other categories of electronic health records in cross-border

178 Borghini, A., Scotellaro, M., Baldini, L., Cosi, R., Carriazo, A., Elarre, V., Guerrero, V., Carini, E., & Mantoan, D. (2023). Sustainability of organisational models implementation in primary care: the CIRCE-JA approach. *The European Journal of Public Health*, 33. https://doi.org/10.1093/eurpub/ckad160.1381.

179 Targeted surveys in the context of the study supporting EU4Health interim evaluation.

180 XT-EHR. (n.d.). *Home*.

settings, ensuring that these advancements are implemented more swiftly and effectively across the EU.

Stakeholders also noted that without EU4Health, these digital transitions would likely progress much more slowly or might not occur at all in some Member States, highlighting the Programme's critical role in modernising healthcare systems across the EU. Similarly, feedback from a stakeholder in one Member State highlighted EU4Health's role as a catalyst for advancing digital health initiatives. Without EU4Health support, the development of the EHDS in that country would have been significantly slower and less efficient. They noted that while the EHDS would have been established eventually, the accelerated progress and greater efficiency provided by EU4Health funding were crucial for achieving timely advancements in digital health.

Cross-cutting strand: Cancer

The coordinated joint actions on cancer under EU4Health are facilitating the roll-out of cancer screening programmes and standardising screening protocols and treatment guidelines across Member States. These initiatives not only improve immediate health outcomes but also establish a framework for future collaborative health initiatives under the Programme. They are also pooling specific medical capacity to provide high quality standards. This makes it possible to draw on complementary knowledge and skills in a highly interdisciplinary field to advance knowledge and improve treatment.

The European Cancer Inequalities Registry covers all Member States, as well as Iceland and Norway, and helps to identify challenges and specific areas of action to guide investment and interventions at EU, national and regional levels. The European Guidelines and Quality Assurance Scheme for Breast Cancer funded by the Programme support better quality and person-centred care in breast cancer services across Europe and can be rolled out in Member States. The inter-speciality training curriculum developed and rolled out with EU4Health support in 105 cancer centres across 21 Member States and 4 associated countries will ensure the sustainability of the Inter-Speciality Cancer Training programme in these countries[181]. In this context two new modules have been introduced, focusing on paediatric oncology and the specific needs of displaced people with cancer, with a special focus on Ukraine.

The adoption of the Cancer Plan and the support pledged by EU4Health gave an impulse to 17 more countries to develop national plans, the majority of which are aligned with the Cancer Plan's structure, reflecting EU-wide added value. In all plans, prevention efforts have addressed lifestyle-related cancer risks. Most countries have screening programmes for breast, colorectal and cervical cancer, with some offering screening for lung cancer, spurred by the 2022 update of the Council Recommendation. Plans emphasise the improvement of diagnosis and treatment quality through patient involvement, personalised treatments, and training of healthcare professionals. To enhance quality of life, actions include financial and psychological support, and 'right to be forgotten' legislation. Cross-cutting themes such as research, inequalities and paediatric cancers are prevalent, though research initiatives vary by the size of the country and its resources. Paediatric cancer is often integrated with other priorities.

[181] INTERACT-EUROPE 100.

4.3 Is the intervention still relevant?

4.2.3. The relevance of the EU's health intervention

Across the board, the overall health of the EU population, measured as the rate of Potential Life Years Lost (i.e. life years lost before the age of 70, or PYLL) per 100 000 residents, improved between 2011 and 2021. However, the variance across Member States increased, with some low-performing countries not showing an improvement over time. Assuming all Member States would perform as well as Sweden (which has the lowest rate of PYLL) would yield a reduction of almost 6 million PYLL per year (monetised to a value of almost EUR 530 billion).

Preventable[182] and treatable[183] mortality make up the bulk of PYLL, with mental health (as part of preventable mortality) as well as cancer and cardiovascular diseases confirmed as the leading causes of premature death.

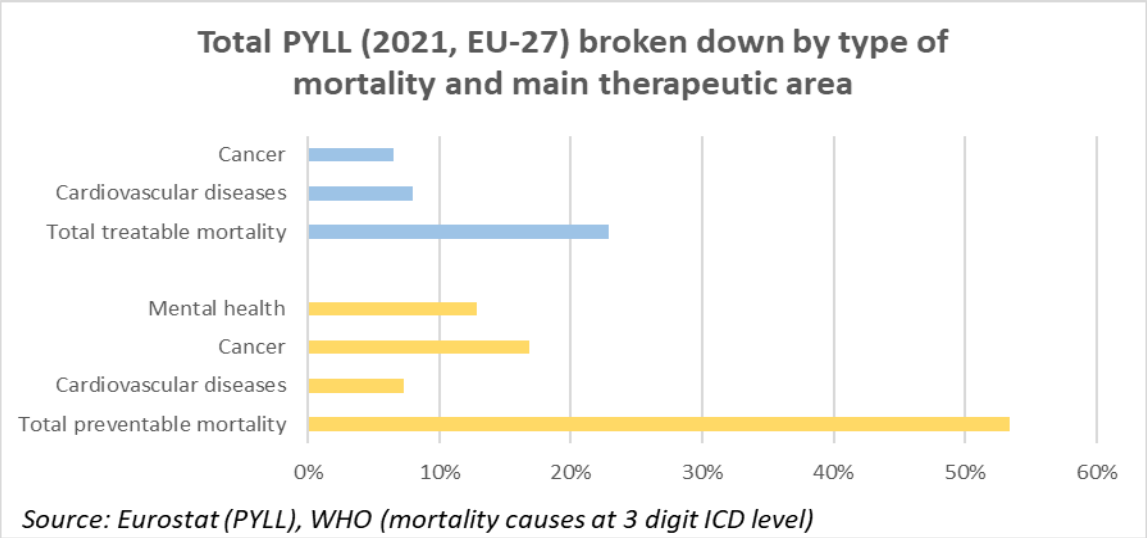


Figure 22 Total potential years of life lost by type of mortality and main therapeutic area

4.2.4. The relevance of the specific objectives and EU4Health actions

The findings of the evaluation supporting study indicate that **all of the general and specific objectives of the EU4Health Programme were highly relevant**, reflecting accurately and comprehensively the health needs and challenges at the time the Programme was drawn up. The specific objectives were well aligned with the EU's strategic public health priorities for the period 2019-2024, which include improving the supply of affordable medicines, ensuring the effective implementation of the new regulatory framework on medical devices, and prioritising eHealth[184].

Given that all the 2020 health challenges persisted during the implementation of the Programme, the study's findings, and further analysis, also revealed that, during 2021-2024,

[182] Deaths which could have been avoided by public health interventions focusing on wider determinants of public health, such as behaviour and lifestyle factors, socio-economic status and environmental factors.

[183] Deaths which could have been avoided by more effective and timely healthcare.

[184] European Commission (2019), Mission letter from Ursula von der Leyen, President of the European Commission, to the Commissioner for Health and Food Safety.

EU4Health was very relevant to European Health Union priorities such as cross-border health threats, the Cancer Plan, Healthier together, HTA, the EHDS, the pharmaceutical strategy for Europe; and generally relevant to all the other initiatives managed by the parent DGs. The objectives of EU4Health and the initiatives just mentioned are closely aligned, and their implementation is supported by EU4Health's budget.

The Programme's continued relevance is underscored by stakeholders' high opinion of its relevance over the implementation period: at least two thirds of survey respondents reported that each general objective was relevant to either 'a very large' or 'a large' extent, while at least half of the respondents felt the same way about each specific objective. These findings were confirmed in the targeted interviews. The actions funded in the 2021-2024 annual work programmes were considered highly relevant for implementing all the general and specific objectives, as confirmed by a mapping exercise and stakeholders' agreement in the consultation.

Strand 1: Crisis preparedness

The Programme has successfully launched a wide range of initiatives to support the specific objectives on crisis preparedness and response (b), and on a reserve of medical and healthcare staff (e)185. This includes the substantial efforts to improve preparedness and response capabilities as regards cross-border health threats, which strengthen the EU's ability to manage and respond to health crises effectively. Funding has supported various Member States to enhance their surveillance and intelligence-gathering capabilities, strengthen European reference laboratories, and boost the development of early warning and response systems. The Programme's efforts in pandemic preparedness have led to significant progress in improving research and development, innovation and manufacturing infrastructure for medical countermeasures. For instance, the establishment of the EU FAB network, which rapidly activates vaccine production in the event of a crisis, is a significant achievement. Additionally, the Programme has made advances in addressing AMR, conducting comprehensive assessments and feasibility studies to determine critical needs in Member States. International collaboration has also been strengthened, particularly with the WHO, to enhance global pandemic preparedness.

The EU4Health Programme also supports the integration of the European Chemical Agency and the European Environment Agency into the network of EU agencies and bodies that will perform a rapid risk assessment in case of a serious cross-border threat to health.

Stakeholders indicate that EU4Health plays a vital role in crisis preparedness and response, as it offers flexibility and anticipatory capabilities essential for addressing health threats. National authorities have benefited significantly from the collaborative efforts fostered by the Programme. These collaborations have enabled Member States to work together to address common health threats, developing and implementing tools that enhance the safety and quality of health activities. Moreover, the Programme has helped strengthen public health systems, particularly in their ability to respond to cross-border health threats.

International organisations have also seen benefits, particularly in their efforts to support vulnerable groups during health crises. The Programme has empowered these organisations to

[185] b) Protect people from serious cross-border health threats and strengthen the EU's rapid response capacity, d) Complement national stockpiling essential crisis-relevant products, e) establish a structure and training resources for a Union reserve of medical, healthcare and support staff.

implement community-based health interventions, contributing to the overall resilience and capacity of public health systems in the EU.

Stakeholder feedback shows that nearly half (48%) of the respondents believe that EU4Health has contributed to a (very) large extent to protecting people from cross-border health threats (general objective b). They also broadly consider that many of EU4Health's objectives are best met through coordinated action at the EU level, with 66% of respondents agreeing to a large or very large extent that EU-level action is needed. This finding is echoed in interviews, where stakeholders highlighted that the Programme's results, especially those involving cross-border challenges and crisis preparedness, could not be achieved as effectively by Member States acting alone.

The EU needs to continue to invest in crisis preparedness to protect its population from emerging and future threats. The recent outbreak of Mpox in Africa serves as a stark reminder of the unpredictable nature of infectious diseases. The swift mobilisation of EU4Health funds made it possible to rapidly procure and deliver 215 000 vaccine doses to the affected countries in Africa[186].

By maintaining a robust crisis preparedness framework and adequate EU funding, the EU can ensure that it is better equipped to respond to such outbreaks, mitigating their impact on public health and the economy.

By sustaining funding for crisis preparedness, the EU can support the development of new treatments, enhance surveillance and detection capabilities, and bolster the resilience of its healthcare systems. This proactive approach will not only save lives but also reduce the economic burden of responding to a crisis. Consequently, prioritisation and continued funding of crisis preparedness is necessary and essential to ensure the health, security, and prosperity of Europeans.

Strand 2: Health promotion and disease prevention

The health promotion and disease prevention strand has remained highly relevant throughout the implementation period, as demonstrated by strong stakeholder support. Survey responses indicate that 'improving and fostering health' is perceived as the most relevant general objective, with 82% of respondents affirming its importance to a very large extent. Specific objectives such as 'Health promotion and disease prevention' were particularly well aligned with current needs, with 83% of respondents recognising its relevance. The Programme has addressed pressing health issues effectively, including disease prevention and health promotion, as well as health inequalities, which were given high priority by stakeholders. Actions such as the multidisciplinary training and exchange programme on mental health (EU PROMENS) support the capacity building of health and other professionals such as teachers and social workers, in a comprehensive, prevention-oriented approach to mental health. To support EU tobacco control policy, the Programme has funded a series of studies on combined health-warning strategies across countries and on packaging and labelling strategies.

Despite the strong alignment, stakeholders also highlighted some areas requiring further attention, such as protection of vulnerable groups, further promotion of mental health, NCDs,

[186] First delivery of mpox vaccine doses from the Commission arrive today in the Democratic Republic of Congo.

healthy lifestyles, and addressing socio-economic inequalities, indicating the ongoing relevance of these issues and the need to invest more in them.

Despite all efforts, 80% of the overall burden of disease in Europe[187] is due to NCDs such as cardiovascular diseases, cancer and respiratory diseases, which are all exacerbated by factors such as unhealthy lifestyles and environmental pollution. This trend persists and NCDs place a significant burden on health systems[188]. There is still a need for sufficient investment in health promotion and disease prevention measures, which are essential for building resilient health systems and improving the overall health of the European population. This need will increase with an ageing population, increasing health inequalities and growing demand for mental health support.

Strand 3: Health systems and healthcare workforce

Specific objectives under the strand *Health systems and health workforce* have been relevant throughout the whole period covered by the interim evaluation and are highly likely to remain so in the future. The COVID-19 pandemic only exacerbated difficulties with access to medicines, medical devices and crisis-relevant products. To ensure its proper implementation and effectiveness, the EU health legislation on HTA, medical and in vitro diagnostic medical devices, and medicinal products requires continuous support. Many patients in the EU have struggled with difficulties in accessing healthcare for many years. Problems like shortages of health professionals or their uneven geographical distribution remain. Cooperation between Member States to exchange best practices on reforming health systems needs to continue and EU4Health is instrumental for this. The ERNs proved to be effective in ensuring that patients suffering from rare diseases could access the right diagnosis and treatment. In the future, all patients should continue to benefit from such services. The launch of the European Rare Diseases Research Alliance (ERDERA) under Horizon Europe, which is creating 'national mirror groups' to enhance national activities in the field of rare diseases, should further strengthen these efforts.

Actions supported by the EU4Health Programme are aligned with the challenges in reforming health systems at national level. Such challenges have been raised in the country-specific recommendations issued under the European Semester process[189]. Over the period 2019-2024 the recommendations touched upon a range of issues, including the need to improve the resilience of health systems (with all Member States receiving such a recommendation under the 2020 European Semester), enhance healthcare access and equity, boost healthcare financing and sustainability, address shortages in the health workforce, and improve health infrastructure and technology.

Workforce shortages are set to further increase, both for nurses and physicians. An analysis, using Eurostat data on the number and age composition of the nursing workforce in the EU, as well as time trends for nursing graduates, has been developed to assess how the currently reported workforce shortages are likely to evolve. The analysis assumed an active career for nurses between the ages of 23 and 67. The projected supply of nurses would increase by around 5% up to 2040. This should be compared to the likely change in the demand for healthcare. For example, the population aged 85 or older in the EU is expected to grow by more than 50% over the same period. This suggests a further intensification of recent trends (between 2014 and

187 Health at a Glance: Europe 2022.
188 European Commission, Shifting health challenges, accessed in October 2024.
189 The European Semester.

2020 the number of practising nurses increased by around 15% whereas the number of people aged 85 or older increased by 20%). Under current trends, the difficulty in supplying the workforce to meet the increase in demand for healthcare is expected to be further exacerbated in the coming decades. EU4Health is financing a number of targeted actions to help address challenges in the health workforce: the joint action HEROES to improve forecasting and planning for the health workforce in Member States; a project in collaboration with WHO Europe to improve the recruitment and retention of nurses; and several collaborative projects to develop new training programmes to upskill the health workforce, with particular attention to digital skills. Some Member States have the possibility to use ESF+ funds for health workforce training in regional or national settings. These Member States can benefit from the new training programmes developed by EU4Health-funded projects; they could consider rolling out such programmes regionally or nationally with the use of their ESF+ funds.

Strand 4: Digital

EU4Health has contributed to developing the capacity to maintain and operate cross-border infrastructures at EU level by financing, among other things, the central services for MyHealth@EU and HealthData@EU, as well as to building capacity in Member State public authorities though dedicated actions.

In total, 81% of survey respondents perceived that specific objective on 'strengthening health data, digital tools and services, and the digital transformation of healthcare' were relevant to a large extent (35%) or to a very large extent (46%); this was perceived to be the third most relevant of all the specific objectives. Survey respondents also perceived that some current health needs relating to this specific objective were either missing from current health objectives or required further attention.

The COVID-19 pandemic accelerated the adoption of digital health technologies, such as telemedicine, EHR systems[190] and digital contact tracing, showing that continued investment in digital health infrastructure was able to support efficient data sharing, improve patient care, and ensure rapid responses to health threats. These innovations are now an integral part of healthcare delivery in many parts of Europe.

The financial contribution of the EU4Health Programme is fundamental for the EHDS[191]. Therefore, there is a strong alignment between the EHDS and EU4Health's general objective (d) of 'Strengthening health systems', as well as specific objective (f) on digital transformation.

However, despite significant progress, there are still important gaps in the Member States in the adoption and integration of digital health technologies in health systems.

Cross-cutting strand: Cancer

The overall relevance of the fight against cancer is borne out by the survey results since respondents that deemed that each specific objective was relevant 'to a very large extent' or to 'a large extent', including the cancer strand covered by the general and specific objectives on health promotion and disease prevention. A total of 66 EU4Health actions contribute towards

190 World Health Organization (WHO) (2022) COVID-19 and the use of digital health tools: opportunity amid crisis that could transform health care delivery Eurohealth, Vol.28, No.1, 2022.

191 European Commission (2022) COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL A European Health Data Space: harnessing the power of health data for people, patients and innovation, COM(2022) 196 final and the EU4Health Regulation.

the objectives of the Cancer Plan objectives and 9 out of the 10 flagship initiatives supporting the Cancer Plan will be fully or partially funded by the Programme.

The EU4Health actions supporting the Cancer Plan have greatly contributed to tackling cancer-related challenges in Europe since its creation. However, recent societal megatrends such as 'shifting health challenges'[192] have the potential to significantly impact the occurrence and awareness of cancer in Europe. Obesity rates continue to rise, contributing to a significant cancer burden. Work-related and environmental carcinogen exposure remains a concern. Socio-economic disparities exacerbate inequalities in cancer care between European regions, highlighting the need for comprehensive policy responses. The number of cancer cases is projected to increase to an additional 504 000 diagnoses by 2040. The European population is ageing, and this trend is set to continue. By 2040, the 65+ age group is estimated to increase by 29%. Given that the risk of cancer is higher in this age group, the European cancer burden is expected to increase by about 31% in terms of new cancer cases and 35% of cancer deaths[193]. A continued investment in tackling cancer will be essential in the future.

Through the 2022 Council Recommendation on cancer screening, Member States have emphasised the ongoing importance of taking action in this area at EU level with the support of EU funding. The Council Recommendation calls on Member States to both ensure the full implementation of cancer screening programmes for breast, colorectal and cervical cancer, as well as to prepare for the stepwise roll-out of screening programmes for lung, prostate and gastric cancer.

Therefore, major improvements still need to be achieved made in lifestyle habits (healthy diets, regular physical activity) and in addressing other major risk factors, with relevant disparities persisting across between Member States and among between different socio-economic categories. Moreover, early-onset cancer morbidity has continued to increase worldwide in recent years with notable variances in mortality and disability-adjusted life years (DALYs) between areas, countries, sex and cancer types. This is highlighting the need to further encourage a healthy lifestyle which can reduce the rate of early-onset cancer disease burden. These findings show that the concerning trends in the prevalence of harmful lifestyle habits continue to require action at EU level, while the technology and policy developments contribute to achieving the objectives of the Cancer Plan[194].

Cross-cutting topic: Global Health

The investment made to support the EU Global Health Strategy remains below the maximum 12.5% ceiling that is reserved for supporting global commitments and health initiatives. There are two main actions under this strand. The first is ongoing support amounting to EUR 4.7 million for the 2-year joint action seeking to strengthen the EU's leadership in global health by improving the coordination of actions and the exchange of knowledge between Member States and EU institutions, as well as with civil society and non-EU stakeholders. It also aims to improve coordination and advance on the implementation of the strategy[195]. The second is an ongoing study (with a total budget of EUR 0.6 million) on designing and testing a monitoring framework for the implementation of the EU Global Health Strategy.

192 European Commission, Shifting health challenges, accessed in October 2024.
193 European Commission – Joint Research Centre (2023). Cancer in 2040: Estimates for an ageing Europe.
194 Zhao et al. (2023). Global trends in incidence, death, burden and risk factors of early-onset cancer from 1990 to 2019.
195 European Joint Action to maximise the impact of the EU Global Health Strategy (JA GHI).

The investments made under other strands (e.g. crisis preparedness or health promotion and disease prevention) are expected to have spillover effects and to contribute as well to global health through the impact they may have on global health challenges.

4.2.5. EU4Health's continued relevance in the context of the European Health Union

In addition to the health needs identified in 2020, some important additional needs have arisen during the EU4Health implementation period, mainly as direct consequences of the COVID-19 pandemic. These include: accelerating the introduction of digital health measures; an increase in vaccine hesitancy and the related spread of misinformation and disinformation; the increase in mental health issues, including as a result of the Russian war of aggression against Ukraine; long COVID; the increased pressure on health services caused by chronic health issues, and increased pressure on healthcare workers. The Russian war of aggression on Ukraine and the related health consequences for people fleeing Ukraine brought new challenges.

EU4Health fits well with initiatives that are part of the European Health Union[196]. The link between EU4Health and the European Health Union was again underlined in June 2024 when the European Council called on the Commission to keep health as a priority[197]. The evaluation supporting study found that all four European Health Union objectives, as stated in the EU's communication 'The European Health Union: acting together for people's health[198] are backed by the EU4Health Programme and its specific objectives.

In summary, the analysis set out in the evaluation supporting study revealed that EU4Health was very relevant to the priorities of the European Health Union as well as to existing European Health Union initiatives.

196 European Commission website. What is the European Health Union. https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en.

197 European Council (2024). European Health Union: Council calls on Commission to keep health as a priority. https://www.consilium.europa.eu/en/press/press-releases/2024/06/21/european-health-union-council-calls-on-commission-to-keep-health-as-a-priority/.

198 European Commission (2024). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - The European Health Union: acting together for people's health. https://commission.europa.eu/document/download/98c6e4dc-0fc3-4ec6-8ec2-bfcdcb2f018a_en?filename=policy_com-2024-206_en.pdf.

5. WHAT ARE THE CONCLUSIONS AND LESSONS LEARNT?

The EU4Health Programme, launched in the wake of the COVID-19 pandemic, has proven to be a vital element in the European Union's efforts to improve public health and strengthen healthcare systems across its Member States, building the European Health Union. For the first time, a programme of this magnitude has been dedicated exclusively to health, marking a significant milestone in European health policy. This initiative has enabled the EU to address critical issues on a large scale, issues that would not typically receive front-line attention, such as screening programmes and antimicrobial resistance. This represents a quantum leap not only in terms of the scope of health initiatives but also in the capacity of Member States to respond more effectively to these challenges. This unprecedented focus on health has fostered collaboration and innovation across the EU, ensuring that vital areas of public health receive the attention and resources they deserve. As the interim evaluation reveals, the Programme has made valuable progress in several key areas while also highlighting opportunities for further improvements to maximise its long-term impact including addressing administrative inefficiencies and disparities in funding allocation across the EU Member States.

Conclusions

The programming processes

The architecture of the EU4Health Regulation is overall sound, and the intervention remains very relevant, as shown in the analysis in the previous chapters and in the replies received during the consultation of stakeholders. All of the Programme's general and specific objectives are highly relevant, accurately and comprehensively reflecting the EU's health needs and challenges.

The comprehensive specific objectives of the Programme are highly relevant and coherent and make it possible to fund the EU's current (2021-2027) EU health policy priorities, including the existing EU health legislation. It should be noted that the health challenges that arose in 2020 due to the COVID-19 pandemic persisted throughout the Programme's implementation. The findings of the study reveal that during the period 2021-2024, the EU4Health Programme has proven to be highly relevant for achieving the priorities of the European Health Union, including: health crisis prevention, preparedness and response, the implementation of Regulation (EU) 2022/2371 on serious cross-border threats to health[199], Europe's Beating Cancer Plan[200], the 'Healthier together' initiative[201], the Health Technology Assessment Regulation[202], the European Health Data Space Regulation[203], and the pharmaceutical strategy for Europe[204]. The EU4Health Programme is vital for achieving the objectives of these important initiatives and provides the budgetary foundation for their successful implementation. Stakeholders expressed a high level of appreciation of the Programme's crucial role during the implementation period, which highlights the **relevance of the**

199 Regulation (EU) 2022/2371, OJ L 314, 6.12.2022, p. 26.
200 European Commission Communication on Europe's beating cancer plan COM(2021)44 final.
201 Healthier Together EU Non-Communicable Diseases Initiative.
202 Regulation (EU) 2021/2282 (OJ L 458, 22.12.2021).
203 Regulation (EU) 2025/327 (OJ L, 2025/327, 5.3.2025).
204 A pharmaceutical strategy for Europe.

EU4Health Programme for the effective and efficient implementation of important EU health initiatives.

EU4Health's governance and programming processes have been successfully established and have proved effective in the timely adoption of four annual work programmes and necessary amendments.

The EU4Health Programme governance was set up promptly, which allowed the programming process to unfold swiftly and efficiently. The EU4Health programming process has been a critical enabler in aligning the Programme's activities with its overarching objectives. Coordination between DG SANTE, HERA and HaDEA as well as the active participation of Member States in steering committees and Programme development processes, have ensured that actions address urgent public health needs and align with broader EU strategies including the European Health Union. The process to consult stakeholders is well established, and four consultations and four stakeholder events have been organised for this purpose. Member States were first consulted in an ad hoc expert group for the 2021 programming exercise, and after on the adoption of the EU4Health Regulation in the EU4Health Steering Group. Member States continued to provide their opinion on the Programme and it annual work programmes in the Programme Committee. The annual work programmes have been effective in translating EU4Health's broad objectives into concrete actions, with a clear allocation of resources to priority areas such as crisis preparedness, digital health and disease prevention. The first work programme, for 2021, was adopted about three months after the adoption of the EU4Health Regulation. The programming processes were run in parallel for the 2021 and 2022 work programmes, which were adopted in around ten months. The 2023 and 2024 programming cycles did not encounter any problems, and the work programmes were adopted on time. The written amendments process was effective.

The programmed actions are designed to provide significant EU added value through capacity building, strategic planning, the promotion and upscaling of innovation, and the translation of research results into practice.

The Programme's actions aim to address the following aspects, among others: cross-border threats to health, health challenges such as antimicrobial resistance, the burden of non-communicable diseases (notably the fight against cancer) and unmet healthcare needs.

The EU4Health Programme launched actions worth EUR 623 million on *crisis preparedness and health security*, improving the EU's ability to better prevent, prepare for and respond to health emergencies and to ensure access to medical countermeasures. Examples include activities on vaccine development and procurement, European reference laboratories, the enhancement of surveillance and intelligence-gathering capabilities, as well as early warning and response systems. These actions are crucial to counteracting future cross-border threats to health in the EU.

The Programme has made considerable investments to directly support *health promotion and disease prevention* (EUR 155.4 million), particularly on non-communicable diseases including cancer, mental ill health, cardiovascular diseases, diabetes, respiratory diseases, and the promotion of healthier lifestyles, which are expected to have positive impacts on the long-term health of people in the EU. Actions under other strands also include health promotion and disease prevention activities. Together with the direct support in this area of intervention, EU4Health has programmed an investment of EUR 536.7 million in this area, which meets the 20% legal commitment made by the EU4Health Regulation.

EU4Health has invested EUR 239 million in actions *to strengthen the national health systems,* for example with the CIRCE Joint Action which transfers best practices in primary healthcare between the Member States, by increasing funding for the ERNs to EUR 100.5 million, and by actions to increase the resilience of the healthcare workforce, which build on the outcomes of previous health programmes. The ERNs have facilitated and enhanced collaboration between healthcare providers and they continue to provide useful advice on the most appropriate diagnoses and best treatments available to rare diseases patients. Furthermore, the Programme has improved the preparedness of the healthcare workforce through targeted training and capacity-building initiatives, ensuring that Member States are better equipped to manage surges in demand for healthcare.

The *digital transformation of healthcare systems* across the EU has advanced through the preparatory work for and the development of the EHDS infrastructure, supported by EUR 124.96 million in funding from EU4Health. The EHDS infrastructure makes it possible to exchange health data across borders and improves access to quality healthcare. People in the EU have easier access to their health records and can receive continuous care when travelling between EU countries. The Member States are better connected, paving the way for a more integrated and efficient healthcare infrastructure across the EU. The Programme's focus on the secondary use of health data for research and policymaking aims to make the EU a global leader in medical research and healthcare innovation. Relevant actions from other strands include digital transformation activities, which also contribute to the EU's cross-cutting priorities.

The *investments supporting the implementation of Europe's Beating Cancer Plan* (EUR 220 million in total) include funding for key actions that aimed to reduce cancer risk factors, increase the coverage of vaccination and screening, and enhance cancer registries by improving data collection for effective early detection and treatment strategies. Progress has been made in several other areas, including on the European Commission Knowledge Centre on Cancer and the European cancer inequalities registry, as well as the EU Network linking recognised National Comprehensive Cancer Centres and new Networks of Expertise. The latter supports the European oncology community on specific, challenging types of cancer that benefit from cross-border cooperation.

EU4Health support to the *EU Global Health Strategy* amounted to EUR 61.5 million, of which around 50 million has been committed to actions such as strengthening preparedness and response to cross-border health threats at global level. An ongoing study aims to develop an effective monitoring framework to assess the progress and outcomes of the global strategy's implementation. The EU4Health support to Member States and associated countries strengthens the EU's leadership in global health by improving the coordination of actions between these countries and the EU institutions. The global commitments and health initiatives agreed with global partners such as the WHO and the Red Cross have addressed, amongst other things, the health consequences of the Russian war of aggression against Ukraine and the needs of refugees.

The Programme contributed to the EU's cross-cutting priorities such as the digital transition (EUR 349.6 million), gender equality (EUR 178.1 million) and green budgeting (EUR 314 million) through the funds committed to relevant EU4Health actions.

The implementation processes, forms of funding, and EU4Health beneficiaries

The implementation processes are effective and have been adapted in good time to the manifold increase in the budget as a result of the creation of the Health and Digital Executive Agency (HaDEA). The executive agency is essential to the Programme and the implementation of its annual work programmes.

All actions programmed for 2021, 2022 and 2023 and delegated to HaDEA by the parent DGs have been successfully launched, and the implementation of those actions programmed for 2024 has started. A total of 726 financing agreements have been signed with 1 274 legal entities such as ministries of health, national, regional and other public authorities, healthcare and health research organisations, non-profit organisations and private entities. Most of these funds were disbursed through grants and procurements. Contributions to global health priorities were financed through contribution agreements with international organisations. By April 2024, around EUR 2.63 billion of the total EU4Health budget had been programmed and EUR 1.39 billion had been committed.

The overall distribution of EU4Health funding per Member State and their legal entities is uneven, as is the distribution of grants and procurement contracts across the EU.

A total of EUR 916.3 million in funding has been absorbed by 15 Member States and associated countries with longer experience in accessing EU funds, and EUR 163.2 million by the 16 other countries[205]. Most of the beneficiaries from 21 Member States[206] are grantees (EUR 346 million) that are national or regional authorities nominated by their home country to participate in joint actions or other direct grants. Other public health organisations such as healthcare units, research organisations or NGOs, etc. have accessed EUR 279.7 million in funding through competitive processes. 94 legal entities from 18 Member States[207] benefited from funding through procurement amounting to EUR 346.3 million. The largest procurements of services were made under the crisis preparedness strand and included, for instance, support for ever-warm facilities for vaccine production (EU FAB) and support to develop IT for early warning, modelling, simulation and forecasting. Most of the procurement funds were absorbed by six Member States[208], each receiving at least EUR 22 million. The *crisis preparedness strand* has committed close to half (44.7%) of EU4Health's funding so far, i.e. EUR 623 million. This is followed by 17.2% (EUR 239 million) for the *health systems strand*, and 15.8% (EUR 220 million) for the *cross-cutting cancer topic*. For the *health promotion and disease prevention strand*, the current share is 11.2% (EUR 154.4 million). Finally, the *digital strand* has received 9% (EUR 125 million) of the funding, and 2.8% (EUR 31.4 million) has been committed to other actions.

Grants, procurements and contribution agreements have been instrumental in operationalising the Programme's objectives and translating them into action.

Grants and the procurement of goods and services have enabled targeted actions to take place under all work programme strands. The joint actions and other direct grants to Member States bring together national authorities, thus facilitating and enhancing collaboration, capacity

205 See Figure 5.

206 Austria, Bulgaria, Croatia, Cyprus, Czechia, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Malta, Netherlands, Norway, Slovenia, Spain, Sweden and Ukraine.

207 Austria, Belgium, Croatia, Czechia, Denmark, France, Germany, Greece, Hungary, Ireland, Italy, Luxembourg, Netherlands, Poland, Portugal, Romania, Spain and Sweden.

208 Belgium, Denmark, Ireland, the Netherlands, Luxembourg and Spain.

building and the transfer of knowledge. The procurement of goods and services engages private sector providers mainly from the Member States and, in a few cases, from outside the EU. Contribution agreements with international organisations have enabled initiatives beyond the EU's borders as well, such as addressing the health consequences of the Russian war of aggression against Ukraine or supporting crisis preparedness actions that address emerging cross-border health threats at the place of origin (such as Africa, in the case of Mpox, Marburg and Ebola).

Joint actions provide crucial funding to national authorities, including from lower-GNI countries, through the 'exceptional utility' criteria. **They enable collaboration that addresses common European health challenges** and implements effective solutions at the national level.

In joint actions, funds are awarded directly to legal entities nominated by the Member States' and associated countries' ministries of health, which has enabled 499 organisations to collaborate between European countries, with 40% of all organisations participating in more than one joint action. There is a good spread of European regions in joint actions, however, organisations from countries in the eastern part of the EU could benefit further. The *exceptional utility criteria* have demonstrated their relevance as a funding mechanism in the EU4Health Programme, providing increased financial support (up to 80% EU contribution) for actions involving at least 14 Member States (of which at least 4 are lower-GNI countries[209]), or where 30% of the action's budget is directed to such countries.

The main beneficiaries, in terms of both the EU contribution received and in the number of project participations, are public entities, such as ministries of health, national health agencies, institutes, laboratories, universities, hospitals and research organisations. In total, 1 274 beneficiaries from the Member States and associated countries are participating in EU4Health projects, which receive a total EU contribution of around EUR 1.39 billion. This allows these countries and their public institutions to work, within their areas of competence, on improving their national health systems and public health and preparedness policies.

Administrative burdens remain a significant challenge, particularly for smaller Member States and NGOs. These include complex application and reporting requirements, which may discourage participation. Improving the transparency and efficiency of procurement management processes, for example through improved digital tools, could reduce delays and increase stakeholder satisfaction.

Initial results and achievements

The Programme's performance is as expected at interim stage when only a limited number of actions have been completed and delivered results. The impacts of these results are expected to increasingly unfold in the years to come and will be analysed in the final evaluation.

As expected at this stage of implementation, a limited number of projects have delivered results, which have been analysed for this evaluation. The analysis includes 26 grant final reports (of which 22 were operating grants) and 136 contracts for procurement validated by the contracting authority.

[209] Article 8(3) of the EU4Health Regulation.

The latest annual performance analysis indicates that overall, the Programme is on track to achieve its objectives. The key 2024 milestones were reached for 13[210] indicators. The actions measured by 10 indicators have already reached their 2027 targets.

The progress of the *nine key performance indicators* is illustrative. The 2027 target was already overachieved for ERNs, by the Member States implementing best practices on health promotion and disease prevention. 10% more patients than planned have benefited from the ERNs' services and 25 Member States (instead of the 20 expected) have implemented best practices. Almost all Member States and associated countries (30 in total) have received support to improve their preparedness and response planning for serious cross-border threats to health. The 2024 milestone is close to being met with four production facilities in place to increase the security and continuity of supply for medical countermeasures and raw materials at EU level. The milestone is on track to be met for the number of Member States participating in the EHDS, for the number of audits conducted in the EU and in third countries to ensure good manufacturing practices and good clinical practices, for the training of healthcare and public health staff, and for studies supporting evaluations of legislative and non-legislative EU health policies.

The 2024 milestones, for example, have been reached and even exceeded under different strands. All the planned actions on the fight against communicable diseases have been programmed. As a result, all the expected Member States plus four additional ones[211] were able to develop their preparedness and response plans for cross-border threats to health. Moreover, 25 new capacity-building actions to improve integrated surveillance systems were supported, instead of the 10 actions expected. A total of 21 actions on the fight against communicable diseases were launched instead of the 20 planned. Entities from 30 Member States and associated countries have participated in more than one EU action aimed at improving prevention, preparedness and response planning for serious cross-border threats to health. 26 Member States have improved their preparedness and response planning with regard to medical countermeasures, compared to the 18 envisaged. 12 Member States and associated countries have improved their procurement procedures for health crisis medical countermeasures. On health promotion and disease prevention, 17 actions were launched, contributing to the reduction of avoidable mortality from non-communicable diseases and risk factors, and exceeding the planned 5 actions. The number of Member States with vaccination coverage for seasonal influenza and for HPV has also reached its 2024 milestone.

As implementation of the Programme advances, several key indicators have made significant progress towards their 2027 targets in key areas such as crisis preparedness and response, health promotion and disease prevention, cancer, and addressing the needs of patients with rare diseases through the ERNs.

As data available in 2024 for milestone values show, there are indicators that require further attention to be sure that their values will achieve expected levels in the future. These are the number of shortages of medicinal products in the Member States reported through the single point of contact and the number of actions complimenting national stockpiling of essential crisis-relevant products. In case of these indicators, there are many external factors (e.g. national policies, including funding, or shortages' monitoring systems at the national level) that

210 Out of 52 indicators.

211 The 2024 milestone was 26 Member States.

are beyond the control of the Commission, that influence their values. This should be accounted for when the Programme's overall performance is assessed.

The Programme's performance at interim stage is reflected in the *most relevant policy achievements,* which are:

- 600 000 people displaced from Ukraine received psychological first aid and mental health services in 22 Member States and three non-EU countries (Iceland, Norway and Ukraine);
- over 215 000 doses of the Mpox vaccine were purchased and donated by the Commission to the Africa Centres for Disease Control and Prevention (Africa CDC);
- 6 economic operators have reserved manufacturing capacities for vaccines to be fully produced within the EU in case of an emergency through EU FAB;
- 26 countries (24 EU Member States, plus Norway and Ukraine) participate in the joint action EU-WISH, aimed at strengthening their capacity to prevent, prepare for and respond rapidly to serious cross-border health threats through wastewater surveillance;
- 1 619 healthcare providers are now part of the ERNs, an increase of approximately 40% compared to 2021;
- 2 240 000 patients with rare diseases received advice on the most appropriate diagnosis and the best treatment available for their disease;
- 22 European countries (20 EU Member States, plus Iceland and Norway) received support for the digitalisation of their health system and to increase its geographic coverage and interoperability, and/or to improve patients' access to their own health data;
- 44 key projects were selected for the implementation of MyHealth@EU and to set up health data access bodies that will pave the way for the EHDS;
- EUR 104 million was made available to support innovation in and access to medical countermeasures, including pull incentives to ensure access to antibiotics;
- 20 breast cancer services in nine Member States have piloted the European guidelines and quality assurance scheme for breast cancer, an action linked to the 2022 Council Recommendation on cancer screening[212];
- by January 2024, 23 Member States had started implementing a surveillance system under the One Health approach for cross-border pathogens that threaten the EU.

EU FAB has played a crucial role in establishing a network of vaccine manufacturers capable of responding rapidly to public health emergencies. Additionally, EU4Health funding has made a significant contribution to improving outbreak detection capabilities, as demonstrated by HERA's data collection and capacity to respond during events such as the Mpox outbreak. Furthermore, the investment in tackling AMR and fostering international collaboration underscores the EU's dedication to global health initiatives and preparedness.

[212] Council Recommendation of 9 December 2022 on strengthening prevention through early detection: A new EU approach on cancer screening replacing Council Recommendation 2003/878/EC 2022/C 473/01 (OJ C 473, 13.12.2022).

EU4Health has successfully created synergies with Horizon Europe and the Digital Europe Programme and contributed to the Green Deal objectives by financing actions that support health promotion, disease prevention and the environmental risk factors to health.

The programme performance monitoring and evaluation framework (PPMEF)

The EU4Health PPMEF served well the annual performance assessments and the Programme's interim evaluation analysis.

The annual Programme performance analyses for 2021, 2022 and 2023 have found that the Programme indicators cover each of the 10 specific objectives and most of their policy areas. The output and results indicators were useful in monitoring the programming process and annual performance. The Programme indicators, in general, make it possible to operationalise the broad objectives, which are measurable against the quantitative milestones and targets set according to the ambition and the figures defined by the EU's health priorities (e.g. Council Recommendation on AMR[213]) and legal acts (e.g. Regulation (EU) 2022/2371), where those exist. The Programme indicators aim to provide relevant data to make it possible to follow the progress in performance each year and during the entire MFF. **However, in many cases, such as with proxy indicators, the causal link between inputs and results is difficult to analyse and confirm.**

The impact of the EUR 1 billion redeployment

The EUR 1 billion redeployment had no impact on the programming for 2021, 2022, 2023 and 2024 annual work programme. However, this significant budget reduction of the EU4Health Programme has an impact from the 2025 programming onwards. Nevertheless, it is important to ensure sufficient support to both ongoing as well as new initiatives and commitments, including those with international bodies, while supporting the policy priorities in the area of public health for the Commission's 2024-2029 mandate. Since 2021, EUR 2.6 billion have been programmed under work programmes for 2021, 2022, 2023 and 2024. With several commitments already made in recent years to support the implementation of both legislative obligations and ongoing flagship initiatives, the remaining funding available is more limited than planned and needs careful consideration if it is to support new health priorities.

The health challenges that the EU4Health Programme was designed to address will be increasingly relevant in the years to come. Digitalisation, the increased risk of outbreaks and epidemics or pandemics due to global environmental and climate change, growing antimicrobial resistance, and increased longevity (which, in the absence of continued support, is associated with an increased prevalence of non-communicable diseases) will require EU-level action and commensurate resources. Action on these issues will entail, for example: , the continued building of a One Health approach; upscaling innovation across health policies; the digital transition; the mitigation of workforce shortages; stepping up the prevention of non-communicable diseases; and enabling healthy ageing through a comprehensive approach to health promotion and disease prevention across one's lifetime (including cardiovascular diseases and the continued fight against cancer).

[213] Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach 2023/C 220/01 (OJ C 220, 22.6.2023).

Lessons learnt

The evidence collected and analysed during this interim Programme evaluation makes it possible to extract concrete lessons learnt and distil lessons from certain aspects to further refine how the Programme is carried out.

Programming and implementation

In the programming phase, **setting strategic and thematic priorities for periods longer than one year** would enable stakeholders to make long-term plans. Moreover, where appropriate, in some specific areas such as health systems and the healthcare workforce, the strategic grouping of actions within specific instruments may be beneficial. This could offer greater flexibility in accommodating the Programme's actions to changing policy needs.

The growing impacts of climate change have intensified the urgency of health crisis preparedness. Climate change-related events such as heatwaves, floods, and the spread of vector-borne diseases pose new and complex challenges to public health systems.

Forms of funding

Fostering political ownership and engagement within Member States in joint actions can help these initiatives to realise their full potential and, ultimately, improve health outcomes across the EU.

It is challenging to set out the roles and responsibilities (e.g. coordinator or affiliated entities) of participants in consortia. The EU4Health Programme provides a robust set of tools to assist in this task, which could be further improved through closer collaboration and **alignment of priorities at both EU and national/regional levels**. The EU4Health Programme complements the efforts of Member States by providing essential tools and resources to support national health actions as well as collaboration between Member States and associated countries. The success of health actions at national level requires the active engagement of Member State authorities, who play a key role in implementing impactful initiatives.

In addition, **innovative funding mechanisms** and schemes should be explored to maximise the impact of the Programme, considering the existing legal frameworks and challenges. This is particularly important for fostering innovation in the development of medicines and prototypes for medical devices, highlighting some categories which are often affected by market failures due to a lack of commercial viability (e.g. communicable diseases and CBRN hazards). Leveraging stronger and larger **public-private partnerships**, blended financing models, and incentive-based funding strategies, among other mechanisms, could bridge critical gaps in development, manufacturing, and market access for new medical countermeasures that target both communicable and non-communicable diseases.

Simplification and reduction of administrative burden

Improving administrative efficiency by simplifying complex procurement procedures, introducing flexible tendering, reducing reporting burdens and streamlining grant application processes could significantly ease the workload for beneficiaries, especially smaller Member States and organisations.

Simplifying administrative requirements for funding applications and streamlining monitoring and reporting processes could improve efficiency and encourage a broader range of

organisations to apply to participate grants or participate in projects. Simplified templates, fewer required documents, simplified reporting deliverables, simplified cost reporting, the use of actual costs (for travel) or simplified cost models like those in Horizon Europe and recording staff activity via timesheets are specific examples of how the administrative burden could be reduced. Expanding the use of framework contracts could make procurement processes more cost-effective and reduce the administrative workload for beneficiaries and Programme managers alike. The burden of proving that an affiliated entity is connected to the national competent authority could be shifted to the stage when the affiliated entity is nominated rather than during the application stage. Additional improvements could include the provision of clearer and more concise financial guidelines as well as further consolidation of the information available on the EU Funding & Tenders Portal[214], where applicants submit their calls.

The possibility to adjust, when justified, and provide for more flexibility in the co-funding rates, including full coverage of eligible costs, could be considered. With the exception of the ERNs[215], most of the actions in the Programme have only partially covered their eligible costs (60% to 80%).

Standardising procedures and aligning administrative requirements across different EU funding programmes, such as Horizon Europe, could reduce duplication of administrative actions and streamline operations, particularly in areas like audit certificates, where different rules increase the complexity of implementation. Also, this would improve coherence between different initiatives.

The identified measures to reduce the administrative burden in the EU4Health Programme can enhance the effectiveness and efficiency of its implementation, while actively contributing to the Commission's priority of greater simplification across all policies.

Promoting innovation upscale

Looking ahead, **there are further opportunities to unlock the potential of innovation in health**, in particular by mobilising additional funds for the deployment of health innovation in healthcare systems and clinical practice, including innovative organisational models and technological solutions. This is especially the case for **investments in digital tools**, given their potentially huge positive impact on people's health, the economy, and the competitiveness of the European healthcare sector. Additionally, fostering innovation is crucial for medical countermeasures that strengthen preparedness and the capacity to respond to existing and emerging health threats.

By investing more in the deployment and upscaling of innovative solutions in healthcare in Europe, the EU4Health Programme will continue to play a vital role in achieving the Commission's objective of positioning the EU as a global innovation and technology leader, and in boosting the competitiveness of the European health sector.

214 EU Funding & Tenders Portal.

215 The direct grants to the WHO may also be financed up to 100% of the eligible costs. However, after the pillar assessment of the WHO, the OECD and other international organisations was completed, the Programme financed them via contribution agreements (indirect management).

The methodology for the final evaluation

To optimise the performance monitoring and evaluation methodology in light of the upcoming final evaluation, **the Commission will carry out a comprehensive assessment of the programme performance monitoring and evaluation framework. An update on this is expected by the end of 2025**. Based on the lessons learnt, a revised PPMEF will focus on better links between the output, result and impact indicators for each specific objective. This will make it possible to better measure progress towards milestones and targets and to assess the ultimate impact of EU4Health's investments. The review will also consider information collected in the context of drafting the country profiles and attempt to define a methodology to link and quantify the contribution of relevant EU4Health actions to addressing health (system) challenges at Member State level.

Synergies and complementarities

EU4Health has harnessed synergies with Horizon Europe and the Digital Europe Programme, showcasing the value of collaboration. By systematically seeking these synergies, the impact of the Programme will be further enhanced across its different components. By expanding partnerships with other funding mechanisms, such as InvestEU, the Technical Support Instrument, the European Regional Development Fund, and the European Social Fund Plus, there will be opportunities to further amplify the Programme's impact. Strengthening these complementarities will support a more integrated approach to addressing health challenges, while also optimising investments that enhance the EU's global competitiveness in key sectors like pharmaceuticals, medical devices and digitalisation.

ANNEX I: PROCEDURAL INFORMATION

1. LEAD DG, DECIDE PLANNING/CWP REFERENCES

This evaluation was carried out by DG SANTE as an initiative published in Decide with the reference number PLAN/2023/1633. The call for evidence was published in December 2023 (https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14055-EU4Health-programme-2021-2027-interim-evaluation_en).

2. DEROGATIONS GRANTED AND JUSTIFICATION

N/A

3. ORGANISATION AND TIMING

An interservice steering group (ISG) was established in September 2023. It included representatives of the following DGs: AGRI, BUDG, CLIMA, CNECT, COMP, DEFIS, DGT, DIGIT, ECFIN, EEAS, EMPL, ENER, ENV, ESTAT, GROW, HERA, HOME, INTPA, JRC, JUST, Legal Service, MOVE, NEAR, REFORM, RTD, SG and TAXUD.
The ISG was consulted in writing on the main deliverables of the supporting study: in February 2024 on the inception report, in May 2024 on the interim report and in October on the draft final report. One ISG meeting took place on 11 October 2024 on the draft Staff Working Document.
The call for evidence was published in December 2023 (https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14055-EU4Health-programme-2021-2027-interim-evaluation_en).
A study supporting the evaluation started in December 2023 and was completed by October 2024.

4. CONSULTATION OF THE REGULATORY SCRUTINY BOARD

The evaluation was selected for scrutiny by the Regulatory Scrutiny Board (the Board). The upstream meeting with the Regulatory Scrutiny Board took place on 22 April 2024. The Board received the draft of the evaluation Staff Working Document on 17 October 2024. The hearing took place on 13 November 2024. The Board issued a negative opinion on 15 November 2024.

5. CHANGES MADE TO THE STAFF WORKING DOCUMENT TO ADDRESS COMMENTS MADE BY THE REGULATORY SCRUTINY BOARD

In response to the Board's recommendations, the Staff Working Document was redrafted before the interservice consultation was launched.

- **Intervention logic and causal links**

The intervention logic was redrafted, further described and simplified.

- **Operationalisation of specific objectives**

The redrafted text clearly shows how concrete actions funded by the Programme are linked to its specific objectives so as to make them operational.

– **Programme Performance Monitoring and Evaluation Framework (PPMEF)**

The values of the PPMEF indicators that were already described in the Staff Working Document were updated. Information about additional indicators measured was added. The Staff Working Document provides information on the planned revision of the PPMEF.

– **Points of comparison**

In the Staff Working Document, the section on points of comparison was shortened. Graphs illustrating the baseline, expected achievements and situation at the interim evaluation cut-off date (30 April 2024) were added. Annex VII provides more information on points of comparison.

– **EU4Health additionality**

The additionality of EU4Health has been further developed to include aspects like the Programme's social and economic benefits and its ability to support the EU and its Member States when cooperating to respond to common challenges.

– **Limitations of the interim evaluation**

The Staff Working Document clarifies the limitations of the EU4Health interim evaluation. It points out that the Programme is still being implemented and that it is therefore possible to properly evaluate the Programme's efficiency and effectiveness.

– **Return on investment**

The return on investment is not used for the analysis because its estimates in the Staff Working Document are not specific for EU4Health.

– **Overview of the costs and benefits of the Programme**

Annex IV, which provides an overview of the Programme's costs and benefits, was amended to present the most comprehensive information possible at the interim evaluation stage.

– **Conclusions and lesson learnt**

The relevant parts of the Staff Working Document were revised to ensure that the conclusions and lessons learnt from the EU4Health interim evaluation are supported by the analysis.

ANNEX II. METHODOLOGY AND ANALYTICAL MODELS USED

The EU4Health interim evaluation covers the implementation of the EU4Health Programme and its annual work programmes from January 2021 until April 2024 across the 27 Member States and 5 non-EU countries. The evaluation was carried out by the relevant units in the Commission, supported by an external study which took place between December 2023 and October 2024.

To measure the Programme's progress at the interim stage, the Commission collected output and results data from the Programme, and action results data from completed and ongoing actions. To complement this data, a supporting study contractor carried out a literature review, collected evidence from stakeholders via online surveys and interviews, organised focus groups and conducted case studies. The contractor also analysed data from the call for evidence that was launched by the Commission. Its data analysis included comparison against the baseline and targets; cost-benefit analysis (as far as possible); and consumer journey mapping. A megatrends analysis (complementing the contractor's work) was carried out by another external contractor in order to assess how these megatrends could impact interventions in health systems, including actions funded by the Programme.

Throughout the evaluation and its supporting study, the Commission and the supporting study contractor applied a mix of qualitative and quantitative methods to address the study questions under five evaluation criteria (effectiveness, efficiency, coherence, EU added value and relevance). All the study questions and the evaluation criteria were either addressed using at least two different methodological tools or reflect results from at least two different data sources.

Limitations and mitigating measures

The Commission encountered certain limitations during the evaluation process. For instance, the evaluation covers the implementation of the EU4Health Programme and its annual work programmes from 25 July 2021 until the cut-off date of 30 April 2024. Consequently, only limited data were available on results and impacts. In some cases, the analysis includes relevant data after the cut-off date and all Programme indicators are used for data collection. However, in other cases (e.g. the *'Age-standardised five-year net survival rate for paediatric cancer'*) it is expected that the baseline, milestone and target will only be defined by early 2025. The Programme data become available progressively. 29 Programme indicators were fully available at the time of the study. 2 data points were available for 3 indicators and 1 data point was available for another 10 indicators. Data will gradually become available for the remaining 10 indicators (see Annex I).

At this point, the Commission has data mainly on outputs and preliminary results at the Programme level. By 30 April 2024, 57.2% of the Programme's budget (EUR 4.6 billion) was programmed; and 53% of the programmed budget was committed in 726 grant agreements, procurement contracts or under indirect management. However, only 204 (68 grants and 136 procurements) of the 726 actions had been concluded by April 2024.

41 grant reports accepted by the contracting authority were available for analysis. This included 26 final reports (22 concerned operating grants and 4 concerned direct grants), 7 periodic

reports and 8 project deliverables. Except for the operating grants, the reports were not a representative sample for the analysis and the available results could only be indicative.

136 procurement contracts were finalised by the interim evaluation cut-off date (30 April 2024). 104 contracts were executed by DG SANTE and 32 by HaDEA. 25 of the contracts executed by HaDEA implemented actions for which DG SANTE is responsible and 7 implemented actions for which HERA is responsible.

There were also certain limitations on actions that targeted *two or more specific objectives.* If an action from the annual work programme implements two or more specific objectives, the activities or the total budget are not split per objective in the annual work programme. Consequently, the total budget allocated to one specific objective is an estimation. For the purposes of data collection, the *EU4Health Dashboard* uses the following assumptions when analysing the data with the dashboard indicators: the budget of an action from the annual work programme that implements two or more specific objectives is split equally between the objectives; the policy areas are not exclusive for a particular strand; and the specific objectives may be addressed by actions from different strands.

Baseline, *milestone* and *target* values were set for the Programme indicators (except for one cancer indicator). The level of detail of the *baseline* data for the EU's health policies implemented by EU4Health intervention varies because it is based on publicly available information. In addition, the dates on which the baseline value is set vary between policies (e.g. between the implementation of the Regulation on serious cross-border threats to health, on the one hand, and other policies, on the other hand) and this makes the analysis more complex. The definition of the Programme indicators (including their *baselines*, *milestones* and *targets* values) was challenging because the Programme objectives are deliberately broad in order to allow the financing of all relevant EU health policy priorities and related actions (including related preparatory work during the 2021-2027 MFF).

No impact assessment exists for the Commission's proposal for the Regulation establishing the EU4Health Programme. The existing impact assessment for a health component under the ESF+ was developed for a programme of much smaller scope and funding (EUR 449.4 million), as compared to EU4Health budget of EUR 5.8 billion, and is of limited value as a point of reference. To mitigate this, data were collected as far as available for the situation in 2020 (or for the latest time before that for which data were available).

Establishing a direct causal link between the EU4Health investment and the progress made in a policy area is challenging in some cases. That is the case for some indicators (as described in the PPMEF and in Annex II to the EU4Health Regulation), which provide information on measures such as vaccination and other similar policies that fall within the competence of the Member States.

In addition to these limitations, the supporting study contractor highlighted further restraints that it had during their study, including potential inaccuracy in linking specific projects to specific objectives. They nevertheless acknowledged that these discrepancies were limited and had only a minimal impact on the study findings.

Limited quantitative data were available during the interim stage of the EU4Health Programme (specifically on project administration and implementation costs). The quantification of benefits and costs was therefore constrained, and the supporting study contractor relied on

estimates derived from scientific and grey literature, as well as on several assumptions. These assumptions are explicitly stated but they may reduce the reliability of the conclusions drawn by the supporting study team.

The supporting study contractor also noted that the response rates for the surveys were relatively low (particularly from those members of the survey sample who did not benefit from the Programme funding) and that this limited the diversity of perspectives. The supporting study contractor tried to address this by, for example, sending multiple reminders and taking alternative contact approaches. This helped increase participation and broaden the diversity of input. Stakeholders' views were also collected through interviews and focus groups to further enhance the representation of perspectives.

In some cases, survey responses included multiple respondents from the same organisation. The supporting study team employed flexible data analysis techniques to ensure that all relevant insights were captured without introducing bias. This included consolidating multiple responses from the same organisation.

The supporting study contractor also raised concerns about some indicators (particularly those related to results and impacts), which they believed could be influenced by external factors, including both the fact that national health funding is larger than EU4Health's and the long-term nature of health outcomes.

Despite these limitations, the Commission believes the *evaluation results and findings are robust and generally reliable.* The supporting study contractor took various steps to mitigate the limitations they encountered and addressed the objectives of the study through various quantitative and qualitative data-collection tools and methods. These included desk research, targeted surveys, targeted interviews, focus group meetings and case studies. The evaluation's evidence-based approach applied sound qualitative and quantitative methodology to the best available evidence drawn from diverse sources.

Detailed description of the evaluation process

Throughout the evaluation process, the supporting study contractor and the Commission relied on a wide range of data collected from various sources. *Programme data* were collected taking into account the 52 indicators described in the PPMEF. The indicators monitor inputs, outputs, results and impacts. 9 *key performance indicators* are related to flagship health policies and reflect key achievements in the annual performance reporting.

Action data were collected by the EU4Health beneficiaries using action-level indicators developed by the Commission or the beneficiary (and agreed by the Commission) with a view to monitoring the effectiveness and efficiency of the funded actions (grants, procurements and contribution agreements). The action data are complemented by data from the *final reports* and, where relevant, from the *interim reports* and *selected deliverables*.

Contextual data were collected from indicators published by Eurostat (e.g. health status, health determinants, health services and health promotion). The initial phase of the supporting study contractor's study involved extensive desk research that integrated both quantitative and qualitative data from various reputable sources. The primary sources included peer-reviewed literature accessed through databases such as Google Scholar; grey literature from international organisations (e.g. the WHO and the OECD); reports from EU institutions and agencies; and

interim and final reports from grants provided by DG SANTE. The study also used data from the EU4Health Dashboard, which provided detailed information on funded actions. The data from the EU4Health Dashboard were analysed to assess the distribution of funding across various dimensions (including the managing DG, funding instruments, stakeholder groups and specific objectives). The supporting study contractor analysed data from the PPMEF, which includes data collected by DG SANTE, HERA, HaDEA, the Joint Research Centre, the ECDC and Eurostat. The aim of the *literature review* was to complement the intervention logic and clarify the details of the implementation and this analysis.

After conducting the desk research, the supporting study contractor consulted stakeholders, applying various quantitative and qualitative data-collection tools and methods. Those included 7 exploratory interviews, the call for evidence and online targeted surveys; 54 targeted interviews; and 2 focus group meetings. The stakeholder consultation was a key component of the methodology, which involved a broad range of groups. These groups included intergovernmental organisations, EU institutions, national authorities, non-governmental organisations, research bodies, businesses, social partners and citizens. A comprehensive list of 308 stakeholders was compiled using public information and additional research. This ensured that all relevant sectors were represented.

The following consultation activities were conducted:

- Feedback was gathered through the Commission's 'Have Your Say' portal during the *call for evidence* period. 30 responses were received. This feedback helped shape the survey and interview questions by providing initial insights into the Programme's impact. The Commission conducted the call for evidence and the supporting study contractor carried out data analysis. The Commission considered that, for the interim evaluation of the Programme, the call for evidence as the possibility for public feedback was sufficient. The call for evidence was expected to provide general feedback on the Programme's relevance. The aim of the interim evaluation was to assess the progress made to date and, where relevant, the need to adjust the Programme. DG SANTE considered, on the basis of Better Regulation Tool #52[216], that targeted consultation of the potential beneficiary groups (i.e. Member States' authorities, NGOs and academia) was a sufficient means to achieve that aim. For the final evaluation, the Commission will conduct a public consultation. The EU4Health Programme is a matter of public interest, but many of the programmed actions have only just started and others are still at the planning stage. The Programme's effects will only come to the public indirectly and with a time-lag.

- The contractor conducted 2 *surveys*. One targeted the successful applicants (grant beneficiaries) of the EU4Health Programme. The other focused on unsuccessful applicants. The aim of the surveys was to capture different perspectives on the Programme's effectiveness, efficiency and overall impact. The surveys were conducted using EUSurvey, with a response rate of 8% for beneficiaries and 4% for unsuccessful applicants.

- 7 scoping *interviews* were conducted at the beginning of the study to refine the study's focus. 54 targeted interviews were then conducted with 75 individuals from various stakeholder groups, thus ensuring a balanced representation across regions and sectors. These interviews provided deeper insights and validated the findings from the desk research and surveys.

[216] Better Regulation Tool #52.

- 2 *focus groups* were held towards the end of the data-collection period, focusing on specific funding instruments (operating grants and joint actions). These discussions helped address gaps in the findings and test hypotheses.

The supporting study contractor also carried out case studies for each of the three following topics: operating grants (OGs), joint actions (JAs) and the exceptional utility criterion (EUC). The role of the case studies was to investigate the functioning of OGs, JAs and the EUC in the EU4Health Programme. The contractor together with the Commission defined the list of questions to be answered by each study.

The case studies built on preliminary findings from the overall study, desk research, survey and interviews. The two above-mentioned focus groups were also used as part of these case studies. The findings of these consultations were analysed and complemented with additional data collection activities that were specific to the case studies and consisted of desk research and in-depth interviews (with a small number of stakeholders that used OGs or that participated in JAs or other actions benefiting from the EUC). These stakeholders were selected by the contractor together with the Commission. Desk research included analysis of funding call documents (including application forms and funding agreements), project monitoring reports, peer-reviewed articles, EU regulations and EU4Health Dashboard data.

In the study, the supporting study contractor used data triangulation to enhance the reliability and validity of the findings. The supporting study team drew on various data sources (including the Programme indicators as per PPMEF, EU4Health Dashboard, stakeholder surveys, interviews, focus groups, and peer-reviewed and grey literature) in order to cross-verify information and identify patterns or inconsistencies.

The *megatrends analysis* supporting this evaluation suggests that healthcare and related public health policies directly account for 20% of the observed extra potential years of life lost (PYLL) in the modelling exercise (some 56 million PYLL). For example, factors such as improved sanitation and nutrition have played an important role in mortality reductions observed since the nineteenth century.

A value of EUR 90 000 per life year can be assumed (by estimating EUR 3.5 million for the statistical value of life [217] and by factoring in the EU median age of 44 and conditional life expectancy at age 44. Multiplying this value by the assumed avoided loss of 56 million PYLL through healthcare and related public health policies produces a monetised outcome of approximately EUR 5 trillion annually.

Total expenditure on healthcare in the EU-27 amounted to some EUR 1.6 trillion in 2021 [xxix]. The societal multiplier for spending on healthcare and related public health measures was therefore slightly greater than 3. This is in line with findings (for instance by Reeves et al. 2013[218]) that there is a 'fiscal multiplier' (measuring the contribution of public spending on

[217] Better Regulation tool #57. For example, the OECD has done a study to explain the variation in the estimates of value of statistical life (VSL) according to the characteristics of risk (type and size of risk, baseline risks, latency, etc.) and socio-economic characteristics (age, income, gender, health status, etc.). Their meta-analysis suggests a VSL of around EUR 3.5 million.

[218] See Does investment in the health sector promote or inhibit economic growth? | Globalization and Health | Full Text (biomedcentral.com).

healthcare to GDP growth) of 4.3 for health (95% CI: 2.5 to 6.1). The study also found that the multiplier for total government spending was 1.61 (95% CI: 1.37 to 1.86).

This multiplier effect varies across specific subdomains of healthcare and public health (as evidenced by a review conducted by the contractor of the study supporting the interim evaluation – Annex X). It can therefore be argued that healthcare and public health investments may be marginally declining because payers will prioritise high value investments (such as maternal and infant care).

ANNEX III. EVALUATION MATRIX AND, WHERE RELEVANT, DETAILS ON ANSWERS TO THE EVALUATION QUESTIONS (BY CRITERION)

Table III.1 Evaluation matrix – Effectiveness

Evaluation questions	Sub-questions (where needed)	Judgement criteria	Indicators	Data sources	Reference in the report
EQ5: To what extent and in which way has the EU4Health Programme been effective?		The EU4Health Programme contributes towards achieving its GOs	Summative results from other effectiveness evaluation questions.	See the other effectiveness evaluation questions	Section 4.1.1 (To what extent was EU4Health effective)
EQ6: How successful has the EU4Health Programme been in achieving (or progressing towards) its SOs? To what extent were the expected changes resulting from the EU action delivered?	EQ6.1: What have the quantitative and qualitative outputs and results of the intervention been (by area, sector, etc)? Were they as expected when introducing the intervention? If not, why not?	Outputs and results of the Programme are quantifiable for the defined indicators Additional qualitative information on outputs, results and impacts of the Programme are available to complement the quantifiable information or to substitute for data gaps	Specification of output and result indicators in the PPMEF Statistics on the Programme indicators as defined in the PPMEF for each of the related SO Statistics on key metrics of the Programme, notably: Number of actions per strand	Desk research: PPMEF EU4Health Dashboard Statistics and data of the stakeholder consultations in relation to the EU4Health Annual Work Programme Annual Work Programmes Case studies	Section 4.1.1 (Achieving objectives and measuring impact)

		The results of the Programme are in line with the expectations	Number of financed projects per action, and per strand Number of actions per policy area Number of financed projects per action and per policy area Number of actions per SOs Number of financed projects per SOs Number of beneficiaries per eligible countries, per strand, per policy area and per SO. Stakeholder perception on the progress of the Programme to date Stakeholder expectations on delivery under the Programme to date Financial allocation by strand and SO	Consultation activities: Call for Evidence Targeted surveys Interviews	

	EQ6.2: How do the outputs, results (and impacts) achieved so far as measured by the PPMEF compare to the milestones and targets defined by the Programme?	Outputs, results (and impacts) for the different indicators of the Programme correspond to the milestones and targets as defined in the PPMEF	Statistics on the milestones and targets defined for the individual indicators as presented in the PPMEF (including impact indicators) Statistics on the outputs and results (and impacts) to date (see sub-question above)	Desk research: PPMEF (Programme Performance Measuring and Evaluation Framework EU4Health Dashboard	Section 4.1.1 (Achieving objectives and measuring impact)
	EQ6.3: What success and hindering factors have affected progress towards the SOs and how are they linked to the EU intervention?	There have been internal factors that benefitted the progress towards the SOs There have been external factors that benefitted the progress towards the SOs There have been internal factors that hindered the progress towards the SOs There have been external factors that hindered the progress towards the SOs	Stakeholder perception on success and hindering factors Evidence from studies and reports on related initiatives and policies that mention relevant factors for the EU4Health Programme	Desk research: Studies and reports on the factors contributing to or hindering the progress of the EU4Health Programme, including sources from related policies and initiatives Case studies Consultation activities: Targeted surveys Interviews Focus groups Case studies	Section 4.1.1 (Success and hindering factors)

	EQ6.5: If the SOs have not been achieved as expected at the interim stage, can they and the targets still be achieved in time? If not, what is needed to do that?	The targets can be achieved in time The SOs can be achieved in time	Annual Work Programmes Stakeholder perception on the achievability of the targets and objectives	Desk research: Annual Work Programmes Consultation activities: Interviews Focus groups Case studies	Section 4.1.1 (Success and hindering factors)
EQ7: Are there any unexpected or unintended effects that have occurred, and which drove or hindered progress towards the SOs? What can explain these effects?		There have been unexpected or unintended positive effects There have been unexpected or unintended negative effects Additional qualitative information on unexpected or unintended effects	Stakeholder perspectives on unintended or unexpected positive or negative effects Evidence from the annual implementation report about unintended or unexpected effects Evidence from studies and reports on related initiatives and policies that mention potential interlinkages with the EU4Health Programme	Desk research: Annual Implementation Reports (if available) Studies and reports on the effects of the EU4Health Programme, including sources from related policies and initiatives Input from the coherence analysis Case studies Consultation activities: Call for Evidence Targeted surveys Interviews	Section 4.1.1 (Success and hindering factors)

Table III.2 Evaluation matrix – Efficiency

Evaluation questions	Sub-questions (where needed)	Judgement criteria	Indicators	Data sources	Reference in the report
EQ8: To what extent is the EU4Health Programme cost effective?	EQ8.1: What are the costs of implementing the actions of the Programme?	Identification of different types of costs, such as application costs, implementation costs, reporting costs, possible other costs Assessment of the size of the costs per type per actions or group of actions and procurement type (grant, joint actions, exceptional utility)	Costs for applicants Costs for others involved in implementing the actions Costs for reporting for beneficiaries	Desk research: Data on costs for application and reporting processes under similar EU programmes, (e.g. ESF+, Horizon Europe, Digital Europe, rescEU, and the Innovation Fund) Eurostat data on labour costs EU4Health Dashboard Budget allocations (breakdown) and resources (human and capital) used for the management of the Programme Case studies Consultation activities: Call for Evidence	Section 4.1.2 (Cost-effectiveness of the EU4Health Programme)

				Targeted surveys Interviews Focus groups Case studies	
	EQ8.2: What are the benefits of the Programme?	The EU4Health Programme achieves the following type of benefits, e.g.: diseases prevented; avoided health care treatments; avoided operational health care costs, sharing of best practices, enhancing knowledge and skills, improved populations health outcomes for treating diseases through enhanced access and affordability The approximate size of these benefits in terms of numbers	Data on outputs and outcomes (indicators explored under effectiveness) Quantification of benefits where possible[219] Qualitative information on the benefits for contextualisation and where a quantification does not appear feasible.	Findings from the effectiveness analysis Desk research: Studies and evidence on the monetisation of help impacts	Section 4.1.2 (Costs and benefits of EU4Health)

[219] Please note that in line with the PPMEF, benefits of the Programme could mostly be measures through its impact indicators. However, at this interim stage of the Programme implementation, not all impacts have yet materialised and limited data on these impacts are available.

		If possible: the monetised value of these benefits			
	EQ8.3: How do the costs and benefits of the Programme compare?	A qualitative assessment of the benefits and costs of the programme leads to the conclusion that the benefits outweigh the costs (The monetised benefits of the Programme outweigh its costs) (The monetised benefits of the Programme are below costs, but there also non-monetised benefits)	Data on costs of actions in the Programme explored through the case studies, including additional costs for actors involved not covered by Programme actions (from above) Data on outputs, results and impacts from (a sample of) the Programme actions, converted into benefits (from above)	Findings from EQ8.1 and EQ8.2 Case studies	Section 4.1.2 (Costs and benefits of EU4Health)
EQ9: What are the costs and benefits for different actors involved?	EQ9.1: How are costs and (monetised and non-monetised) benefits distributed over the actors involved, such as: governments, health care services, patients, informal carers, production companies (pharmaceutical and medical devices)?	The identified costs and benefits (monetised and non-monetised) are shown by type of actor The balance is shown by type of actor	Data on costs of actions in the Programme (from above) Data on outputs, results and impacts from the Programme actions (covered by the case studies), converted into benefits (from above)	Findings from the cost-effectiveness analysis. Case studies Consultation activities: Call for Evidence Targeted surveys Focus groups	Section 4.1.2 (Costs and benefits of EU4Health)

EQ10: To what extent are the administrative costs of the EU4Health Programme justified, given the changes/effects it has achieved?	EQ10.1: How do administrative costs of EU4Health compare to other, comparable interventions with similar objectives and similar outcomes?	The administrative costs of the Programme appear justified in light of its achievements and compared to comparable interventions.	Data on administrative costs for applicants and beneficiaries for EU4Health and comparable interventions Data on outputs/ results/ impacts, including those of comparable interventions	Desk research: Information on costs and outputs and results of comparable interventions Case studies Consultation activities: Targeted surveys Focus groups Case studies Findings from the cost-effectiveness analysis	Section 4.1.2 (Costs and benefits of EU4Health)
EQ11: Which factors influenced the efficiency with which the observed achievements were attained and to what extent are these factors linked to the EU4Health Programme?	EQ11.1: Have any inefficiencies been identified? What are the reasons for inefficiencies identified?	Inefficiencies can be reduced	Evidence from the analysis of costs Stakeholder perception on inefficiencies and their causes Evidence on inefficiencies due to overlaps or contradictions with national interventions, policies and priorities	Consultation activities: Interviews Focus groups Case studies Findings from the cost-effectiveness analysis Findings from the coherence analysis	Section 4.1.2 (Inefficiencies and simplification)

	EQ11.2: Is there scope for simplification to make the programme more efficient?	Simplifications are achievable	Evidence from the analysis of costs Evidence on inefficiencies Stakeholder perception on opportunities for simplification	Consultation activities: Interviews Focus groups Case studies Findings from the cost-effectiveness analysis	Section 4.1.2 (Inefficiencies and simplification)

Table III.3 Evaluation matrix – Coherence

Evaluation questions	Sub-questions (where needed)	Judgement criteria	Indicators	Data sources	Reference in the report
EQ12: To what extent is the EU4Health Programme internally coherent?	EQ12.1: To what extent are the various elements (objectives, priorities, actions, etc.) of the EU4Health Programme coherent with one another?	The different elements of the EU4Health Programme are coherent with each other	Stakeholder perception on the coherence of the elements of the Programme Evidence from the desk research on the internal coherence of the Programme	Desk research: Annual Reports Annual work programmes Regulation 2021/522 Consultation activities: Call for Evidence Targeted surveys Interviews	Section 4.1.3 (Internal conference of EU4Health)

	EQ12.2: To what extent have the various elements (objectives, priorities, strands, actions, etc.) of the EU4Health Programme generated synergies and complementarities and/or compensated possible trade-offs among them?	The different elements of the Programme have created synergies and/or complementarities The Programme is able to compensate for potential trade-offs among its elements internally	Examples from stakeholders highlighting synergies, complementarities, or the internal compensation of trade-offs Evidence from desk research highlighting synergies, complementarities, or the internal compensation of trade-offs	Desk research: Annual Reports Annual work programmes Regulation 2021/522 Consultation activities: Call for Evidence Targeted surveys Interviews Case studies	Section 4.1.3 (Internal conference of EU4Health)
EQ13: To what extent is the EU4Health Programme externally coherent?	EQ13.1: To what extent is the EU4Health Programme coherent with other EU and national financing instruments that have similar objectives?	The Programme is coherent with other EU interventions The Programme is coherent with other national interventions	Stakeholder perception on the coherence of the Programme with other EU and national interventions Examples of synergies, complementarities, or inconsistencies between the Programme and other interventions	Desk research: EU policies in health and other relevant fields (e.g., ESF+, UCPM/rescEU, Digital Europe and Connecting Europe Facility, European Regional and Development Fund, Horizon Europe, TSI) Consultation activities: Call for Evidence	Section 4.1.3 (External conference of EU4Health)

				Targeted surveys Interviews Case studies	
	EQ13.2: To what extent is the EU4Health Programme coherent with current wider EU policies and priorities?[220]	The Programme is coherent with wider EU policies The Programme is coherent with wider EU priorities	Stakeholder perception on the coherence of the Programme with other policies and priorities Examples of synergies, complementarities, and inconsistencies between the Programme and other policies and priorities	Desk research: EU policies in health, environment, digital transformation, development, and other relevant fields Consultation activities: Call for Evidence Targeted surveys Interviews Case studies	Section 4.1.3 (External conference of EU4Health)
	EQ13.3: 'How did the SOs of the EU4Health Programme correspond to wider EU policy	The SOs of the Programme have been coherent with wider EU policy goals and priorities	Stakeholder perception on the past coherence of the SOs with other policies and priorities	Desk research: EU policies in health, environment, digital transformation,	Section 4.1.3 (Coherence with wider EU policies and priorities)

[220] This encompasses policies including InvestEU, SMP, RRF, Erasmus+, and the Emergency Support Instrument, and the six Commission priorities for 2019 to 2024: European Green Deal, a Europe fit for the digital age, an economy that works for people, a stronger Europe in the world, promoting our European way of life, and a new push for European democracy.

	goals and priorities in the past years?		Examples of synergies, complementarities, and inconsistencies between the SOs and other policies and priorities	development, and other relevant fields Consultation activities: Call for Evidence Targeted surveys Interviews Case studies	
	EQ13.4: To what extent is the EU4Health Programme coherent with international obligations, including the SDGs	The Programme is coherent with international obligations	Evidence on relevant international obligations Stakeholder perception on the coherence of the Programme with international obligations Evidence on synergies, complementarities, or contradictions between the EU4Health Programme and its provisions and international obligations	Desk research: WHO, UN, OECD priorities. relevant policy documents and treaties Consultation activities: Interviews	Section 4.1.3 (Coherence with international obligations)

Table III.4 Evaluation matrix – EU added value

Evaluation questions	Sub-questions (where needed)	Judgement criteria	Indicators	Data sources	Reference in the report
EQ14: What is the additional value resulting from the programme, compared to what could reasonably have been expected from MS acting at national and/or regional levels?	EQ14.1: Could the identified outputs/results/impacts have been achieved without the EU4Health Programme?	The identified outputs, results, and impacts could not have been achieved without the EU4Health Programme	The outputs, results and impacts of the Programme Stakeholder perception on the possibility to achieve the same without EU intervention Evidence on the added value of the Programme from (academic) research	Desk research: (Academic) studies and grey literature on the benefits of the EU4Health Programme and its ability to add value Consultation activities: Targeted surveys Interviews Findings from the effectiveness analysis	Section 4.2.1 (Added value compared to Member States action)
	EQ14.2: Is it still valid to assume that the objectives of the EU4Health Programme can best be met by action at EU level?	The objectives of the EU4Health Programme can still be best met by EU action	Evidence from the previous analysis of the past and current relevance and external coherence of the Programme Stakeholder perception on the continued added value of the EU4Health Programme	Consultation activities: Targeted surveys Interviews Findings from the relevance analysis Findings from the external coherence analysis	Section 4.2.2 (Necessity of EU action for achieving objectives)

	EQ14.3: What would be the most likely consequences of stopping or withdrawing the EU4Health Programme?	The objectives of the EU4Health Programme cannot be met without EU action The objectives of the EU4Health Programme can still be (partially) met by action from other actors (i.e. IGOs)	Stakeholder perception on potential implications of the withdrawal or stop of the EU4Health Programme Evidence from (academic) research on aspects that can only be delivered at EU-level but not at national level	Desk research: (Academic) studies and grey literature on the benefits of the EU4Health Programme and its ability to add value Consultation activities: Targeted surveys Interviews	Section 4.2.2 (Necessity of EU action for achieving objectives)

Table III.5 Evaluation matrix – Relevance

Evaluation questions	Sub-questions (where needed)	Judgement criteria	Indicators	Data sources	Reference in the report
EQ1: To what extent did the scope and SOs of the EU4Health Programme remain relevant over the implementation period?	EQ1.1: To what extent did the scope defined by the GOs of the EU4Health Programme remain relevant over the implementation period?	The scope defined by the four GOs of the Programme remained relevant over the implementation period Jointly, the four GOss capture the most important needs in relation to health The four general objectives are aligned	Stakeholder perception on the relevance of the four GOs and their exhaustiveness Evidence from desk research on potential gaps Findings from the coherence analysis on the consistency of the GOs	Desk research: Annual Work Programmes Statistics and data gathered from the stakeholder consultations in relation to the EU4Health Annual Work Programme	Section 4.3.2 (Relevance of the GOs and SOs to health needs over the implementation period)

		with the general (health-related) principles of the EU	with the (health-related) principles of the EU	Annual Strategic Foresight Reports Studies and reports financed through the EU4Health Programme procurement[221] Findings from the external coherence analysis Consultation activities: Call for Evidence Targeted surveys Interviews	
	EQ1.2: To what extent did the SOs of the EU4Health Programme remain relevant over the implementation period?	The ten SOs of the Programme remained relevant over the implementation period There are no major need gaps created by the definition of the ten SOs There are no SOs where related calls received very low numbers of	Stakeholder perception on the relevance of the ten SOs and their exhaustiveness Evidence from desk research on potential gaps Number of applications by call	Desk research: Annual Work Programmes Annual implementation reports (pending availability) Statistics and data gathered from the stakeholder consultations	Section 4.3.2 (Relevance of the GOs and SOs to health needs over the implementation period)

221 https://hadea.ec.europa.eu/programmes/EU4Health/studies_en.

		applications because the calls and the related SOs were deemed less relevant	Views of stakeholders on the continued relevance of the objectives	in relation to the EU4Health Annual Work Programme Annual Strategic Foresight Reports Input from the external coherence on SO/ call specific overlaps Consultation activities: Call for Evidence Targeted surveys Interviews	
EQ2: How well do the SOs of the Programme correspond to the current needs within the EU?		The SOs of the Programme correspond to the current needs withing the EU The SOs are likely to correspond to the main needs in the foreseeable future	Stakeholder perception on the annual work programmes until 2024 in relation to these addressing the needs identified by stakeholders Stakeholder perception on the most important needs in the near future Evidence on relevant recent and potential trends and developments	Desk research: Annual Work Programmes until 2024 Annual Strategic Foresight Reports Studies and reports on current and likely trends, developments, and challenges in the health sector in the EU and globally	Section 4.3.3 (Continued relevance of EU4Health)

				Input from the coherence analysis Consultation activities: Call for Evidence Targeted surveys Interviews	
EQ3: To what extent were the actions included in the 2021, 2022, 2023, and 2024 annual work programmes covered by the programme SOs and were relevant to those objectives?	EQ3.1: To which extent did the actions included in the 2021, 2022, 2023, and 2024 annual work programmes implement the EU4Health Programme's general / SOs?	All actions in each annual work programme can be attributed to at least one of the 10 SOs	Number and share of actions that can be attributed to a SO from the work programmes (by year), by SO Number and share of actions that cannot be attributed to any of the SOs, for each work programme	Desk research: Annual Work Programmes Annual implementation reports Data from the PPMEF and the EU4Health Dashboard	Section 4.3.2 (Alignment of actions in the AWPs over the implementation period to the GOs and SOs)
	EQ3.2: To which extent did the actions included in the 2021, 2022, 2023, and 2024 annual work programmes implement the list of possible eligible actions in Annex I of the EU4Health Regulation?	A majority of actions included in each annual work programme can be subsumed under the non-exclusive list of eligible actions in Annex I of the EU4Health Regulation Actions that cannot be subsumed under Annex I actions can be attributed	Number and share of actions from the work programmes (by year) that can be attributed to each of the actions listed in Annex I Number and share of actions (matching Annex I as well as those not matching Annex I) from	Desk research: Annual Work Programmes Annual implementation reports (pending availability)	

		to at least one of the SOs directly.	the work programmes (by year) that can be directly attributed to each SO	Data from the PPMEF and the EU4Health Dashboards	
EQ4: To which extent were the actions included in the 2021, 2022, 2023, and 2024 annual work programmes relevant to achieving the objectives set out in existing legislative and non-legislative EU health initiatives?		Taken together, actions included in each annual work programme contribute to achieving EU's objectives set out in existing legislative and non-legislative EU health initiatives	Evidence from desk research of links between EU4Health actions and relevant health initiatives Number and share of EU4Health actions that cannot be linked to any other initiatives, for each work programme List of relevant initiatives that are not reflected in the actions of the Programme, for each work programme Stakeholders' view on the relevance and contribution of actions to other health initiatives	Desk research: Annual Work Programmes Annual implementation reports (pending availability) Statistics and data gathered from the stakeholder consultations in relation to the EU4Health Annual Work Programme Input from the coherence analysis Consultation activities: Targeted survey Interviews	Section 4.3.3 (Relevance of EU4Health to the objectives of existing European Health Union initiatives)

ANNEX IV. OVERVIEW OF BENEFITS AND COSTS AND, WHERE RELEVANT, TABLE ON SIMPLIFICATION AND BURDEN REDUCTION

Table 1. Overview of costs and benefits identified in the evaluation[222]

		Citizens/Consumers		Businesses		Administrations		Beneficiaries of the programme including	
		Quantitative in EUR million	Comment	Quantitative in EUR million	Comment	Quantitative in EUR million	Comment	Quantitative in EUR million	Comment
Cost or Benefit description:									
COSTS:									
Direct compliance costs – administrative costs	**Type:** **one-off or recurrent** impossible to distinguish							63.6	Admin labour cost associated with reporting on implementation, coordination of tasks; The value represents the admin cost not covered by EU4Health.

Direct costs	**Type:** **one-off or recurrent** impossible to distinguish					1390	EU4Health committed budget	135.7	Beneficiary's co-funding. Total co-funding for the whole project duration.
Enforcement costs: (costs associated with activities linked to the implementation of an initiative such as monitoring, inspections and adjudication/litigation)	**Type:** **one-off or recurrent**	None	n/a	None	n/a	None	n/a		
Costs: **Indirect costs** (indirect compliance costs or other indirect costs such as transaction costs)	**Type:** **one-off or recurrent** impossible to distinguish							10.87	Unrecognised overhead costs based on stakeholders' estimates, not covered by the EU4Health

[222] Where there is a prior impact assessment, the table should contain as a minimum the costs/benefits identified in the IA with the information gathered on the actual cost/benefit. As available, the table should include the monetisation (€) of the costs/benefits based on any quantitative translation of the data (time taken, person days, number of records/equipment/staff etc. affected or involved represented in monetary value – see Standard cost model, for example). For all information presented, it should be included in the comments section whether it relates to all Member States or is drawn from a subset. An indication of the robustness of the data should be provided in Annex II on Methodology and analytical models used.

BENEFITS									
Benefits: **Direct benefits** (such as improved wellbeing: changes in pollution levels, safety, health, employment; market efficiency)			Increased access of Ukrainian refugees to first-aid psychological and mental health. Faster and more effective solutions that target major NCDs and address environmental threats. More and deeper knowledge of AMR facilitates more accurate identification and mitigations of risks. Analysis of the needs and stockpiling of critical medicines improves the speed and effectiveness of actions in pandemic situations. Improved ability of early warning systems to foresee health threats.				Country health profiles for all EU Member States, Iceland, and Norway supporting better health policymaking. Support to 22 European countries (including 20 Member States) to improve digital health systems and data access. Doubling in the Member States' participation in the EDHS from 7 in	Not quantifiable	Improved health outcomes as a result of implementing best practices. Improved international collaboration and more effective sharing of best practices thanks to leveraged EU networks. Establishment of the EU FAB network to ensure sufficient and agile manufacturing capacities for different vaccine types. Capacity building and increased training/education, with improved

			Increased capabilities, coordination and data exchange among the Member States via the 1 619 clinical centres within the framework of the ERNs. Double increase in the number of patients diagnosed and treated by the members of ERNs – from 1 million in 2020 to 2.24 million in 2023. Investments in the development of the EDHS facilitates the even and simultaneous implementation of the EHDS directive, whose objective is to provide EU citizens with cross-border healthcare services. Greater cooperation of the EU research and academia leads to the development of new treatments and covering unmet				2020 to 15 in 2024.		healthcare knowledge. Alignment of funding with activities contributing to the Global Health Strategy. Better international coordination and collaboration with EU institutions and Member States. Identified 32 antibiotics for EU stockpiling.

			medical needs, especially for the medicines for rare diseases and children. Measures on identification and stockpiling 32 critical antibiotics contributes to the better crisis preparedness. Support to 22 European countries to improve digital health systems and data access.						
Indirect benefits (such as wider economic benefits, macroeconomic benefits, social impacts, environmental impacts)			Long-term welfare benefits: Reduced health inequalities through improved health promotion, and increased health access for rare diseases patients.						

			Implemented practices in health promotion, disease practices and reduction of health inequality in 25 Member States would contribute to the healthy behaviours and creation of supportive environments for health. Advanced training focused on paediatric oncology and the needs of displaced cancer patients facilitates more targeted and customised care for these patient groups. Improved vaccine-coverage – the purchase of 334 540 doses of vaccine improved coverage leading to reduced risk for public health and outbreak of Mpox. The cumulative effect of the actions brings						Improvement of country knowledge in the field of health sets a basis for better understanding of the national characteristics and their better consideration in planning health initiatives at EU level. Improved collaboration with NGOs/IGOs and Member States. Adoption of best practices in cancer, tobacco control, physical exercise, nutrition, cardiovascular disease and diabetes. EU-level production of new knowledge on

			better protection of the population against cross-border health threats. Easier access to (innovative) treatment for patients, including rare diseases patients. Enhanced quality of health services through European guidelines. and quality assurance for breast cancer. Increased availability of safe and performant medical devices. Improved expertise, access to specialised care and patient outcomes due to ERNs. Strengthening Member State health systems to benefit EU citizens and patients. Improved protection against health crises.						health threats, specifically AMR.

TABLE 2:* S*implification and burden reduction (savings already achieved)

*Report any simplification, burden reduction and cost savings **achieved already** by the intervention evaluated, including the points of comparison where available (e.g. REFIT savings predicted in the IA or other sources).*

	Tenderers for procurements covering business or NGOs		Tenderers for grants covering national administrations only		Tendering process covering all applicants and executive agency	
	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment
Direct compliance costs **recurrent**	Not quantified	Integrating framework contracts into a new e-procurement system that includes e-contracting to launch, sign and implement contracts. This speeds up and makes the management of contracts smoother. In October 2023, the Funding and Tender Portal was activated. It is more user-friendly, is a single contact point for economic operators contacting with contracting authorities and allows for more efficient handling of questions asked by the economic operators. Calls are published earlier in a given year, allowing the				

		operators to plan better their activities. Moving fully to using qualified electronic signature speeds up the awarding process.				
Indirect cost savings **recurrent**			Not quantified	Use of the e-grants system allows the speeding up the granting process. The e-grant tool is more user-friendly and replaces paper-based procedures. Guides for applicants for grants are available online in the Funding and Tender Portal. This allows the applicants to easily find the information they need. EU4Health grant management templates are the same as for all other e-grants programmes. The beneficiaries can act more efficiently.		
Indirect cost savings **recurrent**					Not quantified	All EU4Health projects and their non-sensitive deliverables (once approved) are publicly available through the Funding and Tenders Portal, making them more accessible for applicants,

						beneficiaries and other stakeholders. This can help to better identify and thus increase synergies between proposals and thus projects, once funded.
Compliance costs **recurrent**					Not quantified	Since February 2024, applicants have been using a simplified budget table in the proposal preparation phase. This has reduced the administrative burden on applicants, the granting authority and evaluators; and reduced the risk of errors.
Compliance cost **recurrent**			Not quantified	Member States can nominate more than one competent authority in the case of joint actions. This makes it possible to reduce the number of affiliated entities. Affiliated authorities do not have full access to grants' IT systems. Part of their financial reporting therefore had to be done by competent authorities, and this was a burden for them. Moreover, having fewer affiliated authorities simplifies the process of establishing joint action consortia.		

Indirect cost **recurrent**						Internal platforms used by the executive agency (HaDEA) enable more efficient handling of online opening sessions and the participation of interested tenderers.
Indirect cost **recurrent**						HaDEA has (by providing more information via information sessions, publishing guidelines and attending kick-off meetings) intensified its efforts to support the applicants during calls for proposals, grant agreement preparation and project implementation.

PART II: II <u>Potential</u> simplification and burden reduction (savings)

*Identify further potential simplification and savings **that could be achieved** with a view to make the initiative more effective and efficient without prejudice to its policy objectives*[223].

	Citizens/Consumers/ Workers	Businesses	Administrations	MS national administrations, NGOs academia _ specify

[223] This assessment is without prejudice to a possible future Impact Assessment.

	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment
Description								
Type: One-off / recurrent (select)			Expected reduction of man-hours for application and reporting. Quantification not possible due to lack of data.	Time for the preparation of the proposal – simplify templates. Reporting on the progress – move from preparation of reports to encoding data by the beneficiaries directly into the Commission's IT systems (thus avoiding having to go through the Member States). Increase the use of the framework			Expected reduction of man-hours for application and reporting. Quantification not possible due to lack of data.	Time for the preparation of the proposal – simplify templates. Reporting on the progress – move from preparation of reports to encoding data by the beneficiaries directly into the Commission's IT systems of, thus avoiding having to go through the Member States. Increase the use of the framework contracts in procurement. Standardising procedures and aligning requirements across

				contracts in procurement. Standardising procedures and aligning requirements across EU funding programmes. Modernising procurement by integrating framework contracts into a new e-procurement system that includes e-contracting, thus digitising contract management [IN PROGRESS]. Offering e-translation and AI-based tools to simplify translation, reporting and				EU funding programmes Modernising procurement by integrating framework contracts into a new e-procurement system that includes e-contracting, thus digitising contract management [IN PROGRESS]. Offering e-translation and AI-based tools to simplify translation, reporting, and monitoring [IN PROGRESS] Introducing a two-tier selection process where complex and detailed budget information only needs to be provided for

				monitoring [IN PROGRESS]. Introducing a two-tier selection process where complex and detailed budget information only needs to be provided for proposals above a minimum threshold. Revised and reduced the number of deliverables and the frequency of reporting by NGO recipients of operating grants. Standardising procedures and aligning requirements				proposals above a minimum threshold. Revised and reduced the number of deliverables and the frequency of reporting by NGO recipients of operating grants. Standardising procedures and aligning requirements across programmes (e.g. Horizon Europe) could reduce duplication of administrative actions and streamline operations. Recording staff activity via timesheets is seen as cumbersome. Stakeholders suggest adopting simplified cost models (action-based costs) similar

				across programmes (e.g. Horizon Europe) could reduce duplication of administrative actions and streamline operations. Recording staff activity via timesheets is seen as cumbersome. Stakeholders suggest adopting simplified cost models (action-based costs) similar to those in Horizon Europe. Multiannual work programme planning also helps in better				to those in Horizon Europe. Multiannual work programme planning also helps in better preparation for future calls. Modification of the requirements of the current tendering process to make team formation more flexible and clearer.

				preparation for future calls. Modification of requirements of the current tendering process to make team formation more flexible and clearer.				

ANNEX V. STAKEHOLDERS CONSULTATION - SYNOPSIS REPORT

Introduction

This report provides an overview of the consultation activities carried out in the context of the interim evaluation of the EU4Health Programme. It provides an outline of the consultation strategy, lists the consultation activities, and provides key results for each of them.

The following consultations took place:

- feedback on the call for evidence[224] (from 5 December 2023 to 9 January 2024);
- targeted stakeholder survey (from 11 April 2024 to 17 May 2024);
- interviews (from 11 April 2024 to 25 May 2024);
- focus groups on joint actions (10 June 2024) and operating grants (11 June 2024).

The Commission carried out the first consultation, but the external contractor analysed the replies to the call for evidence. The other three consultations were carried out entirely in the context of the external study underpinning this evaluation.

The key objectives of the consultations were to gather input from the impacted stakeholders in order to assess the effectiveness, efficiency, coherence, EU added value and relevance of the EU4Health Programme.

The following stakeholder groups were identified and involved in different consultation activities: intergovernmental organisations; competent authorities in the Member States; governmental public health organisations; NGOs; research and academia; businesses and consultancy; social partners[225]; and the general public[226].

The consulted groups represent the stakeholders that were targeted for funding under EU4Health (potential beneficiaries), as well as those benefiting from the effects of EU4Health on health-related areas (potential final beneficiaries).

Representatives of DG SANTE, HERA and HaDEA were also consulted via interviews. Stakeholder groups were consulted in the same way.

Call for evidence feedback

The call for evidence for the evaluation was published on the Commission's Have Your Say website [227]. 30 replies were submitted during the consultation. 22 replies came from NGOs and 5 replies came from the representatives of the general public. 1 reply each came from the representatives of competent authorities in the Member States; research and academia; and businesses and consultancy. 11 replies to the call for evidence were sent by stakeholders from Belgium; 5 by stakeholders from France; 3 by stakeholders from Italy; 2 by stakeholders from

224 EU4Health call for evidence, 2023-2024.
225 For example, industry associations and trade unions.
226 This stakeholder group was only directly consulted in the call for evidence feedback.
227 EU4Health Programme interim evaluation – call for evidence.

the Netherlands; and 1 each by stakeholders from Cyprus, Denmark, Germany, Ireland, Luxembourg, Poland, Romania, Slovakia and the United Kingdom.

Targeted surveys

The surveys resulted in a satisfactory sample of respondents. 3 352 beneficiaries were targeted through the first survey and **262 responses** were received from successful applicants (an 8% response rate). 669 stakeholders were targeted through the second survey and **24 responses** were received from unsuccessful applicants (a 4% response rate).

Table V.1 Number of respondents per survey and stakeholder group

Stakeholder group	Number of survey responses (beneficiaries) (%)	Number of survey responses (unsuccessful applicants) (%)
1. Intergovernmental organisations	6 (3%)	0 (0%)
2. EU institutions and agencies	n/a	n/a
3. National authorities[228]	88 (37%)	3 (13%)
4. Non-governmental organisations	43 (18%)	10 (43%)
5. Research and academia	68 (29%)	5 (22%)
6. Businesses and consultancy	11 (5%)	1 (4%)
7. Social partners	2 (1%)	0 (0%)
8. Other [229]	17 (7%)	4 (17%)
Total respondents	**235**	**23**

Table V.2 Country of respondents per survey

Country	Number of beneficiaries	Number of unsuccessful applicants	Total per country
Austria	12	1	13
Belgium	18	2	20
Bosnia and Herzegovina		1	1
Bulgaria	4		4
Croatia	9	2	11
Cyprus	4		4
Czechia	7	1	8
Denmark	5	1	6
Estonia	3		3
Finland	5	1	6
France	13		13
Germany	9		9
Greece	13		13
Hungary	3		3
Iceland	1		1
Ireland	7	1	8
Italy	23	3	26
Latvia	2	1	3
Lithuania	6		6
Luxembourg	4		4
Malta	3		3
Netherlands	12	1	13
Norway	1		1
Poland	5	1	6
Portugal	11	1	12
Romania	12	2	14

[228] These are competent authorities in the Member States and governmental public health organisations.

[229] This category is made up of the respondents that did not identify their organisation as belonging to any of the other groups.

Slovakia	4		4
Slovenia	9		9
Spain	24	1	25
Sweden	4	1	5
Uganda		1	1
Ukraine	2	1	3
Total respondents	**235**	**23**	**258**

Interviews

Seven scoping interviews were undertaken with international organisations (the WHO and the European Observatory on Health Systems and Policies); EU institutions and agencies (HaDEA and DG SANTE); and national authorities (national contact points from the Member States).

Targeted interviews were conducted to complement the broader survey data. The qualitative information obtained from these interviews was used to enrich the analysis, offering examples and contextual understanding.

54 interviews were conducted, involving 75 individuals. The overall response rate was 61%. The interviews were distributed across stakeholder groups as shown in Table V.3.

Table V.3 Number of interviewees per stakeholder group

Stakeholder group	Number of interviews (attendees) (%)
1. Intergovernmental organisations	8 (12) (15%)
2. EU institutions and agencies	10 (14) (19%)
3. National authorities[230]	16 (24) (30%)
4. Non-governmental organisations	10 (14) (19%)
5. Research and academia	4 (4) (7%)
6. Businesses and consultancy	5 (6) (9%)
7. Social partners[231]	1 (1) (2%)
Total interviewees	**54**

Focus groups

Two focus groups were held on the funding instruments of operating grants and joint actions.

Table V.5 Participating organisations in the 2 FGDs

FGD1: Joint actions	FGD2: Operating grants
• JAVNA AGENCIJA REPUBLIKE SLOVENIJE ZA ZDRAVILA IN MEDICINSKE PRIPOMOCKE (Slovenia) • NARODOWY FUNDUSZ ZDROWIA (Poland) • TERVISEAMET (Estonia) • MINISTERE DE LA SANTE ET DE LA PREVENTION (France) • NORWEGIAN MINISTRY OF HEALTH (Norway)	• BREAST INTERNATIONAL GROUP (Belgium) • EUROPEAN ASSOCIATION FOR PALLIATIVE CARE (Ireland) • EUROPEAN PUBLIC HEALTH ALLIANCE (Belgium) • TB EUROPE COALITION (Ukraine) • SMOKE FREE PARTNERSHIP COALITION (Portugal, Belgium)

230 These are competent authorities in the Member State and governmental public health organisations.
231 For example, industry associations and trade unions.

- TERVISEAMET (Estonia)
- STATE INSTITUTION PUBLIC HEALTH CENTER OF THE MINISTRY OF HEALTH OF UKRAINE (Ukraine)
- AGENCE NATIONALE DE SANTE PUBLIQUE (France)
- STATNI USTAV PRO KONTROLU LECIV (Czechia)
- AGENZIA NAZIONALE PER I SERVIZI SANITARI REGIONALI (Italy)
- HEALTH SERVICE EXECUTIVE (Ireland)
- FUNDACION PARA LA INVESTIGACION BIOMEDICA DEL HOSPITAL UNIVERSIATRIO LA PAZ (Spain)
- FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS (Belgium)
- ETHNIKOS ORGANISMOS DIMOSIAS YGEIAS (Greece)
- CHILDHOOD CANCER INTERNATIONAL - Europe (Austria)
- AIDS Action Europe (Germany)
- CORRELATION EUROPEAN HARM REDUCTION NETWORK
- EUROPEAN FOOD INFORMATION COUNCIL (Belgium)

Results per evaluation criteria

Relevance

Most survey respondents considered that the general objectives of the EU4Health Programme were relevant in the EU over the implementation period (2021-2024). 66% or more of the responses indicated that each objective was relevant to a very large or to a large extent[232].

The positive aspects that were highlighted were the appropriate level of focus on health promotion and disease prevention (16 respondents); improved EU vaccine manufacturing capacity; improved digital literacy for healthcare workers; and progress in cancer screening.

Overall, the survey respondents considered that all 10 specific objectives were relevant during the implementation period. More than 50% of the responses indicated that each objective was relevant to a very large or to a large extent[233]. They overall considered that all 10 specific objectives would continue to be relevant in the near future.

It emerged from the interviews that the stakeholders broadly acknowledged the relevance of the Programme's objectives, especially in the light of recent health crises. However, they expressed concern about an overemphasis on certain areas (e.g. cancer), which might overshadow other crucial aspects like mental health, digital health tools and public health infrastructure. There is a call for greater flexibility within the Programme to ensure that it aligns better with the Member States' differing needs. Concerns were also expressed about the balance of funding and the transparency of prioritisation processes. Stakeholders called for a more nuanced approach to effectively address both long-term health challenges and emerging threats.

232 The survey responses from beneficiaries and unsuccessful applicants were combined because no significant differences between the answers of these two groups were identified.

233 The survey responses from beneficiaries and unsuccessful applicants were combined because no significant differences between the answers of these two groups were identified.

The stakeholders recognised Programme's significant role in managing health crises, such as the COVID-19 pandemic. However, they identified a need to shift from a crisis-centric focus to enhancing long-term health resilience. The Programme effectively addresses immediate health needs, but there is a growing call for more attention to be paid to emerging areas like mental health and digital health, as well as to address health inequalities. The stakeholders also highlighted the need for improved transparency in priority-setting and budget allocation. They considered that it is essential to ensuring the Programme's flexibility and align resources with evolving health needs in order to maintain its effectiveness and address diverse regional challenges.

Effectiveness

The Programme's effectiveness is evident in its focus on crisis preparedness, health inequality, vaccination coverage and the strengthening of health systems. For the four general objectives, the most positive result in the survey was that 53% of respondents agreed that the Programme had contributed to a large extent or to a very large extent to improving and fostering health. However, only 40% agreed that the Programme had contributed to a large extent or to a very large extent to improving access to medicinal products and devices and crisis-relevant products.

Overall, the survey highlights the need for improved collaboration, stakeholder engagement and alignment of priorities, as well as improved expertise, data and knowledge within the Member States. The Commission's role as a knowledge broker is also crucial, but its performance in this regard was considered modest.

The stakeholders' considered that EU4Health's success relies on several key factors. These included:

- **Collaboration between Member States**. 84% of stakeholders acknowledged that this is important for achieving the Programme's objectives, but only 52% considered that the current level of collaboration is sufficient.
- **Stakeholders' engagement**. 83% of stakeholders saw this as important for achieving the objectives, but only 49% recognised that how the stakeholder engages now will contribute to EU4Health effectiveness to a large or very large extent.
- **Political will in the Member States**. 84% of stakeholders considered this an important factor, but only 41% considered that it is currently sufficient.
- **Expertise, data and knowledge within Member States**. 84% of stakeholders recognised its overall importance, but only 49% considered that it is currently sufficient.
- **Alignment of national health priorities with EU health priorities**. 85% of stakeholders considered this crucial, but only 45% considered that it is currently at a sufficient level.
- **Synergies between different EU programmes**. 77% of stakeholders considered that synergies (if sufficiently strong) would significantly contribute to EU4Health

effectiveness. 45% of stakeholders considered that the currently observed synergies were satisfactory in this regard.

The EU4Health Programme received positive feedback from stakeholders, particularly for its contribution to specific objectives on disease prevention and health promotion, as well as on international health initiatives and cooperation (54% and 58% respectively reported significant contributions). However, opinions on the Programme's effectiveness varied as regards the alignment of specific objectives with the general objective of protecting people from serious cross-border threats to health. 49% of respondents acknowledged EU4Health's contribution to specific objective prevention, preparedness and response to cross-border health threats. 14% and 18% of respondents respectively assessed the Programme's support for specific objectives that complement the national stockpiling of essential crisis-relevant products and establishing a reserve of medical, healthcare and support staff (including training) as 'limited' or 'not at all'. The Programme received the least recognition for its contribution to the general objective of improving access to medicinal products, medical devices and crisis-relevant products, but 40% of respondents did consider that it contributed significantly to achieving this objective.

EU4Health aims to enhance cross-border health networks, digital health capabilities and health infrastructure. Specific areas of interest include the effectiveness of joint actions and grants, transparency issues and challenges in measuring impact (particularly in addressing health disparities).

The stakeholders have acknowledged the Programme's successes but have also expressed concerns about the Programme's effectiveness. Their criticisms include the lack of concrete results, administrative burdens and difficulties in measuring impact due to incomplete early results and funding constraints. They were also worried about the underfunding of critical areas was affecting the Programme's overall effectiveness.

The Programme has achieved success in managing health crises and fostering collaboration, but there are ongoing concerns about transparency, funding stability and addressing health disparities. To improve effectiveness, there is a need for enhanced data collection, strategic funding allocation and a balanced approach that meets both immediate and long-term health needs.

Efficiency

There are no direct data on administrative costs, but estimates can be derived from survey responses that indicate the percentage of administrative implementation costs. Analysis shows that average administrative costs are 11.8% of total costs for national authorities, 12.5% for EU-level NGOs, 11.5% for national NGOs, 12.6% for research and academia, and 14.4% for other organisations.

Overall, stakeholders consider that the benefits of EU4Health outweigh its costs. 61% view the benefits as exceeding the costs to a large or very large extent. Most groups shared this positive

view, but NGOs and business organisations were more critical and saw the benefits as exceeding costs by a smaller margin than the other groups. In addition, administrative costs are generally at least to some extent, to a large extent or to a very large extent considered to be proportionate for participating by comparison with a reasonable amount for administering an EU-funded action. 39% of stakeholders considered the administrative procedures to be somewhat clear and simple, but 44% had encountered significant difficulties with them. Financial challenges were particularly significant for smaller organisations, NGOs, and countries with a lower gross national income. They were struggling to meet the co-financing requirements, particularly for covering personnel, travel and subcontracting costs. Many stakeholders considered that the structure of reimbursement (with frequent recording and reporting of staff activity through timesheets) was very time-consuming. In addition, unit travel reimbursement costs often do not reflect the actual costs that stakeholders incur before and during the projects.

87% of the survey respondents viewed financial resources as crucial for EU4Health's success, but only 55% considered them sufficient. Similarly, 86% rated human resources as vital at the national level, but only 40% considered them sufficient. At the EU level, 79% considered human resources important, but only 46% considered them sufficient. The recent 20% budget cut could further limit Member States' ability to handle health emergencies and affect research, potentially jeopardising the Programmes' ability to achieve its objectives.

Coherence

73% of the survey's respondents considered that the EU4Health Programme's objectives, priorities and actions were internally coherent. Only a small percentage (3%, distributed evenly across stakeholder groups) considered that coherence was limited. The opinions shared in response to the call for evidence appreciated the broad scope of the Programme, but some diseases were seen as overrepresented – to the detriment of other health challenges. This suggests that the Programme's design and implementation are generally coherent, but there may be some room to enhance its overall coherence.

The results on coherence between the EU4Health and other EU funding programmes were more nuanced. A majority of respondents (51%) considered EU4Health and Horizon Europe to be well aligned. Responses to the call for evidence included appreciation of the alignment with the EU's Beating Cancer Plan. There was, however, a noticeable lack of awareness about the Programme's overall external coherence. A significant percentage of respondents (ranging between 69% and 80%) chose the 'do not know' option when asked whether the Programme is coherent with other EU funding programmes (e.g. the Innovation Fund, the Recovery and Resilience Facility, the Technical Support Instrument and the Single Market programme). This lack of awareness may indicate that the Programme's external coherence is not well-communicated or understood by stakeholders.

Stakeholders during the interviews generally expressed their appreciation of the Programme's alignment with EU priorities, but they also expressed concerns about complexity, potential overlaps and inefficiencies. These issues include duplication of efforts and inadequate

structural mechanisms for coordination. There is a call for clearer mission statements and improved integration with other EU initiatives (e.g. Horizon Europe) in order to avoid redundancy and enhance overall effectiveness.

58% of the survey participants considered to a very large extent or to a large extent that the Programme's objectives are well aligned with the health priorities of the Member States and national stakeholders in health. However, a significant proportion (33%, mostly national authorities, NGOs and academia) felt that the coherence is only to some extent or to a limited extent present. This suggests that there may be scope to better align the Programme with national priorities.

The interviewed representatives of the Member States authorities were more critical than the stakeholders taking part in the surveys as regards the coherence of EU4Health actions with national challenges. They considered that the actions proposed in the annual work programmes are too generalised and insufficiently tailored to national-level or regional-level needs.

Many survey respondents felt that EU4Health complements international commitments to a large or very large extent. This was particularly the case for the SDGs and International Health Regulations, where a large majority of respondents (65% and 70% respectively) considered that EU4Health complements these international commitments. The results of the call for evidence present the same picture.

A significant percentage of respondents were unsure or did not know how the Programme aligns with certain international commitments (e.g. TRIPS and the Convention for the Rights of the Child). This highlights the need for increased awareness and understanding of the Programme's alignment with international commitments and obligations.

EU added value

The stakeholders participating in the surveys overwhelmingly indicated that the Programme delivers results that go beyond what could reasonably be expected from Member States acting independently. The survey results show that a significant majority of stakeholders (54%) believe that the Programme delivers added value to a large or very large extent. National authorities and NGOs operating at EU level believe this particularly strongly. The results of interviews are consistent with these findings. Rare diseases and cross-border threats to health were mentioned as examples of challenges that EU4Health addresses better than the individual Member States could by themselves. In the event of a crisis, however, the Programme's potential is seen as constrained by funding limitations and differing national commitments.

The survey's results also highlight the perceived benefits of EU4Health actions compared with those of national health policy actions. A significant proportion of respondents (33%) believe that EU4Health-financed actions deliver more value for money. They cite benefits such as the sharing of best practices, leveraging funding to address health issues, and sustained funding for long-term actions at the EU level. In addition, the Programme promotes collaboration between

Member States, thus increasing knowledge, innovation and support for implementing evidence-based interventions and good practices.

However, a significant proportion of survey respondents (34%) had no view on the value for money provided by EU4Health actions. This highlights a need for increased awareness and understanding of the Programme's impact. Furthermore, a small but noteworthy proportion of respondents (4%) believed that EU4Health actions offer less value for money – citing concerns related to funding, administrative challenges and implementation.

The survey's results also provide insights into the perceived effectiveness of EU4Health actions in achieving the Programme's objectives. Most respondents (66%) believe that the objectives of EU4Health related to protecting people from cross-border threats to health are best met through action at EU level. However, there is a significant difference of views when it comes to the objectives related to access to medicinal products, medical devices and crisis-relevant products – 16% of respondents expressed uncertainty.

This disparity in opinions highlights the need for a more nuanced understanding of the Programme's impact and effectiveness in achieving its objectives. It also underscores the importance of effective communication and stakeholder engagement in increasing awareness and understanding of the added value and impact of EU4Health.

This finding is consistent with the opinions expressed by the Member States' authorities in the interviews. They recognised the added value of EU level coordination, such as fostering cross-border cooperation and sharing best practices. However, some argued that the Programme's unique benefits are unclear, especially in cases where the Member States also apply their own robust approach. There was a call for better showcasing of the Programme's impact through data and case studies, particularly as regards health resilience and preparedness.

The survey's results suggest that the Programme is seen as a valuable complement to national health policy actions. 29% of respondents believe that EU4Health actions provide similar value for money. This highlights the Programme's role in supporting and enhancing national health policy initiatives, rather than duplicating or replacing them.

Overall, the results of stakeholders' consultations constitute a positive assessment of EU4Health's added value and impact. They highlight the Programme's role in delivering results that go beyond what could reasonably be expected from Member States acting independently. However, the results also highlight areas for improvement (including the need for increased awareness and understanding of the Programme's impact) and the importance of effective communication and stakeholder engagement.

ANNEX VI. EU4HEALTH LIST OF INDICATORS FROM THE PROGRAMME PERFORMANCE MONITORING AND EVALUATION FRAMEWORK

Indicator name	Definition	Notes
Number of actions contributing to the reduction of avoidable mortality in the area of non-communicable diseases and risk factors	The number of actions contributing to the reduction of avoidable (preventable and treatable) mortality in the area of NCDs and associated risk factors and delivering the policy objectives of the 'Europe's Beating Cancer Plan' and the 'Healthier together – EU non-communicable diseases' initiatives. The actions considered are those that address the following causes of avoidable mortality from cancer: health determinants; cardiovascular diseases; diabetes; chronic respiratory diseases; mental health and neurological disorders; external causes of death; alcohol and drugs effects; and other related causes of avoidable mortality. The actions that contribute to reducing avoidable mortality of NCDs and risk factors (tobacco, alcohol, healthy lifestyles, screening, vaccination), including those related to cancer will be included under the relevant indicators (12, 13, 14) referred to in Annex 2 to the EU4Health Regulation	Relative proxy indicator; static indicator in some years; uncertain target and milestone because the number of actions depends on the programming process that involves Member States; the 'Healthier together' initiative presented in June 2022 is being implemented and the decision to roll out a particular best practice resides with the Member States; projects supporting work in the area of NCDs and Europe's Beating Cancer Plan are mutually complementary. The actions considered under this indicator are aimed at improving health promotion and disease prevention via the reduction of avoidable mortality in the area of NCDs and risk factors.
Number of Member States implementing best practices regarding health promotion, disease prevention and addressing health inequalities – KEY PERFORMANCE INDICATOR	The number of Member States implementing 'best' and 'promising' practices that are rolled-out at the national level with EU funding support and addressing health promotion, disease prevention and health inequalities. The 'best' and 'promising' practices counted are those selected by the Expert Group on Public Health established by the Commission (C(2022) 8816 final).	Relative proxy indicator; static indicator in some years; uncertain target and milestone; the 'Healthier together' initiative presented in June 2022 is under development and the decision to roll out a particular best practice resides with the Member States.
Vaccination coverage for measles – (sub-indicator 7.1)	The number of EU Member States having reached 95% coverage for both the first	Relative proxy indicator; uncertain targets and milestones; no direct causal link, any progress is an achievement. To

	and the second dose of the measles vaccine for eligible individuals.	operationalise it, indicator 7 Vaccination coverage by age for vaccine-preventable diseases such as measles, seasonal influenza, human papillomaviruses (HPV) and coronavirus COVID-19 referred to in Annex 2 to the EU4Health Regulation has been broken down into its four components (7.1, 7.2, 7.3 and 7.4). The actions on vaccination contribute to disease prevention.
Vaccination coverage for seasonal influenza – (sub-indicator 7.2)	The number of EU Member that have reached 75% coverage for the seasonal influenza vaccine in older age groups.	Relative proxy indicator, baseline from 2018, last time when data were collected; uncertain targets and milestones; no direct causal link, any progress is an achievement. The public health target, set in the Council Recommendation on seasonal influenza from 2009, is for all Member States to reach 75% coverage for the seasonal influenza vaccine in older age groups, extending, if possible, this coverage rate to other at-risk groups. To operationalise it, indicator 7 Vaccination coverage by age for vaccine-preventable diseases such as measles, seasonal influenza, human papillomaviruses (HPV) and coronavirus COVID-19 referred to in Annex 2 to the EU4Health Regulation it has been broken down into its four components (7.1, 7.2, 7.3 and 7.4). The actions on vaccination contribute to disease prevention
Vaccination coverage for human papillomaviruses (HPV – (sub-indicator 7.3)	The number of EU Member having reached at least 90% coverage for a full vaccination course (last dose) in eligible girls.	n/a
Age-standardised five-year net survival rate for paediatric cancer (to the extent available) – (indicator 9)	Percentage of the population covered by Cancer Registries reporting information on rates of European children (aged 0–14 years) that have survived five-years post cancer diagnosis.	This indicator is still under construction and more details are expected by early 2025; static indicator in some years; data not available earlier than 2025; data analysis might be influenced by the low number of cases. Monitoring the survival rate allows investigations into the causes of higher or lower survival rates supporting health promotion by identifying specific needs.
Breast cancer screening coverage74 – (sub-indicator 10.1)	Number of Member States that have achieved a breast cancer screening examination coverage of over 70%. The coverage level is calculated as the number of women aged 50-69 who have received a bilateral mammography within the past 2 years (or according to the specific	This indicator envisages ongoing annual data collection. As this was voluntary until 2020, only partial coverage is provided. The first year with data available for all Member States is 2021. Eurostat releases the data in July every year as of 2023. These administrative data are collected by the competent authorities of Member States indicating the screening coverage (uptake) within organised programmes. To operationalise it, indicator 10 ‘Screening

	screening frequency recommended in each country) divided by the number of women aged 50-69 eligible for an organised screening programme (for programme-based data); the data are reported by the competent authorities of Member States indicating the screening coverage (uptake) within organised programmes.	coverage for breast, cervical and colorectal cancer screening programmes, by type, target population, and Member State' referred to in Annex 2 to the EU4Health Regulation has been broken down into its three components (10.1, 10.2 and 10.3).
Cervical cancer screening coverage75 – (sub-indicator 10.2)	Number of Member States that have achieved a cervical cancer screening examination coverage of 70%. The coverage level is calculated as the number of women aged 20-69 who have been screened for cervical cancer within the past 3 years (or according to the specific screening frequency recommended in each country) divided by the number of women aged 20-69 eligible for an organised screening programme (for programme-based data).	This indicator envisages ongoing annual data collection. As this was voluntary until 2020, only partial coverage is provided. The first year with data available for all Member States is 2021. Eurostat releases the data in July every year as of 2023.These administrative data are collected by the competent authorities of Member States indicating the screening coverage (uptake) within organised programmes. To operationalise it, indicator 10 'Screening coverage for breast, cervical and colorectal cancer screening programmes, by type, target population, and Member State' referred to in Annex 2 to the EU4Health Regulation has been broken down into its three components (10.1, 10.2 and 10.3)
Colorectal cancer screening coverage – (sub-indicator 10.3)	Number of Member States that have achieved a colorectal cancer screening examination coverage of 45%. The coverage level is calculated as the number of men and women aged 50-74 who have been screened for colorectal cancer within the past 3 years (or according to the specific screening frequency recommended in each country) divided by the number of men and women aged 50-74 eligible for an organised screening programme (for programme-based data).	Indicator 10 'Screening coverage for breast, cervical and colorectal cancer screening programmes, by type, target population, and Member State' from Annex 2 to the EU4Health Regulation has been broken down into its three components (10.1, 10.2 and 10.3) to operationalise it.
Percentage of population covered by Cancer Registries reporting information on cervical, breast, colorectal and paediatric cancer stage at diagnosis – (indicator 11)	Percentage of population covered by Cancer Registries reporting information on cervical, breast, colorectal and paediatric cancer stage at diagnosis, which is computed as the ratio between the population	The above cancer registries record information on cervical, breast, colorectal and paediatric cancer cases. The more representative the coverage is, and the more detailed the information, the easier it is to identify and tackle underlying causes, for example for a high number of late-stage diagnoses. Thus, the results assessed

	covered by the cancer registry/ies (residents in a specific area) over the total population of the Member State.	contribute to health promotion and disease prevention.
Number of Member States reporting information on cervical, breast, colorectal and paediatric cancer stage at diagnosis	Number of Member States with at least one cancer registry (for the countries with regional registries) having submitted the stage at diagnosis for cervical, breast, colorectal and paediatric cancer for the respective data call.	n/a
Number of actions addressing the prevalence of major chronic diseases per Member State, by disease, gender, and age – (indicator 12)	The sum of actions addressing the prevalence of major chronic diseases - cancer, cardiovascular diseases, diabetes, chronic respiratory diseases, mental health and neurological disorders - and delivering the policy objectives of the Europe's Beating Cancer Plan and of the 'Healthier together' EU NCD initiative per Member State, by disease. Actions that address prevalence through various activities, in particular related to health promotion and prevention and early detection, will be counted, including tobacco-related actions.	Static indicator in some years; uncertain target and milestone because the number of actions depends on the programming process that involves Member States; the actions delivered are across gender and age category and data cannot be properly disaggregated; action-level indicators to collect data related to gender will be designed and data collected after the launch of the actions.
Number of actions addressing the age prevalence of tobacco use, if possible, differentiated by gender – (indicator 13)	Sum of actions addressing the prevalence of use of tobacco and related products, if possible, differentiated by gender and age and delivering the policy objectives of the relevant tobacco legislation, Europe's Beating Cancer Plan and of the 'Healthier together' EU NCD initiative. Actions that address the age prevalence of tobacco use, in particular the activities related to health promotion and prevention and early detection, will be counted.	Uncertain target and milestone because the number of actions depends on the programming process that involves Member States; actions on tobacco use may directly or indirectly address tobacco use with a primary focus on young people. Therefore, this indicator aims to differentiate by age and gender. Action level indicator to differentiate by gender and age will be defined.
Number of actions addressing the prevalence of harmful use of alcohol, if possible,	The sum of actions addressing the prevalence of harmful use of alcohol and	Uncertain target and milestone because the number of actions depends on the programming process that involves Member

differentiated by gender and age – (indicator 14)	delivering the policy objectives of the Europe's Beating Cancer Plan and the 'Healthier together' EU NCD initiative. Actions addressing the prevalence of the harmful use of alcohol will be counted.	States; differentiation by age and gender may not always be possible; indicators will be defined at action level to collect data by gender.
Number of actions addressing environmental risk factors for health – (indicator 23)	The sum of actions contributing to addressing environmental risk factors for health and delivering the policy objectives of the Europe's Beating Cancer Plan and the 'Healthier Together' – EU non-communicable diseases initiative. Actions that address environmental risk factors for health will be counted.	Uncertain target and milestone because the number of actions depends on the programming process that involves Member States.
Preparedness and response planning of the Union and of Member States for serious cross-border threats to health – (sub-indicator 1.1) KEY PERFORMANCE INDICATOR	Number of Member States and associated countries participating in more than one Union action aiming to improve prevention, preparedness, and response planning for serious cross-border threats to health excluding capacity-building activities to improve integrated surveillance.	The value for the target will increase in the future with the number of countries associated to the EU4Health Programme.
Number of Member States participating in the prevention, preparedness and response planning joint action – (sub-indicator 1.2)	Number of National Competent Authorities in Member States and associated countries participating in the joint action on prevention, preparedness and response planning according to the Article 7-11 of Cross-border health threats Regulation (EU) 2022/2371.	The joint action is expected to be launched towards the end of the MFF at earliest in 2026. static indicator in some years; relative proxy indicator; targets and milestones will be set in line with Regulation 2022/2371 on serious cross-border threats to health and expected to be available at the end of 2023 when the reporting is due.
Number of Member States with improved integrated surveillance systems – (sub-indicator 1.3)	Number of Member States and associated countries with improved integrated epidemiological surveillance systems (including wastewater) as reflected by the final reports of the direct grants co-financed by EU4Health.	Indicators based on Article 13 of Regulation 2022/2371 – epidemiological surveillance. It monitors joint actions from the 2021 annual work programme (JA UNITED4SURVEILLANCE) and direct grants to Member States from the 2023 annual work programme. The data also includes the data from JA EU-WISH from the 2023 annual work programme. Static indicator in some years; relative proxy indicator; uncertain targets and milestones.

Number of new capacity-building activities (EU, Member States) for improved integrated surveillance systems (sub-indicator 1.4)	Number of new capacity building activities (EU, Member States) for improved integrated epidemiological surveillance systems	Indicators based on Article 13 of Regulation 2022/2371 - Epidemiological surveillance; relative proxy indicator; uncertain targets and milestones due to ongoing needs analysis for surveillance based on the results of a joint action that started in January 2023. The joint actions from the 2021 annual work programme (JA UNITED4SURVEILLANCE) that started in February 2023 will provide information to define target and milestone. In addition, the JA EU-WISH that will kick-off in February 2024 (EU contribution is from the 2023 annual work programme) will also provide relevant information.
Number of Member States with improved preparedness and response planning (sub-indicator 6.1)	The number of Member States that reported an increased level of preparedness and response planning assessed against the indicator levels (1-5) described in COMMISSION IMPLEMENTING REGULATION (EU) 2023/1808	Uncertain targets and milestones; no direct causal link; the grants provided are only one part of the total financial contribution to improving preparedness and response planning by the Member States, any progress is an achievement.
Number of Member States with improved preparedness and response planning with regard to medical countermeasures (sub-indicator 6.2)	Number of Member States that reported an increased level of preparedness and response planning with regard to medical countermeasures compared to the baseline. assessed against the indicators A 6.8 to A 6.13 described in the COMMISSION IMPLEMENTING REGULATION (EU) 2023/1808 ()	Uncertain targets and milestones; no direct causal link, any progress is an achievement. Increased level of preparedness and response planning with regard to medical countermeasures is monitored through Member States' participation in EU4Health actions related to medical countermeasures.
Number of actions addressing the fight against communicable diseases (indicator 22)	Number of actions contributing to address the fight against communicable diseases.	Static indicator in some years; uncertain targets and milestones due to the programming process that involves the Member States.
Number of Member States and associated countries with increased laboratory and diagnostic capacity for cross-border health threats, contributing to the mission of HERA	Total number of Member States and associated countries with additional laboratory and diagnostic capacity for cross-border health threats supported with EU funding contributing to the mission of HERA excluding EURLs and EU LabCap survey.	Static indicator in some years; "Laboratory capacity for cross-border health threats" refers to the ability to detect and respond to public health threats through laboratory testing, from threat detection, evolutionary analysis and threat characterisation, taking a One Health approach, This indicator will rely on the actions' final reporting outputs (including deliverables and milestones), against the baseline defined by the initial proposals, focusing exclusively on the EU4Health actions contributing to the mission of HERA.

Number of countries where One Health surveillance programmes were successfully implemented	Number of countries where One Health surveillance programmes were successfully implemented following implementation of the grants.	Static indicator; relative proxy indicator.
Number of Member States and associated countries with improved procurement procedures for medical countermeasures during health crisis	This indicator measures the number of Member States and associated countries with newly designed and improved processes that have a direct impact on their procurement procedures for emergencies therefore strengthening preparedness and response to cross border health threats on the basis of data sharing, better coordination and exchange of best practices.	Static indicator in some years; uncertain targets and milestones; no direct causal link, any progress is an achievement. It is not possible to provide a general definition of "improved procurement procedures", which needs to be assessed on a case-by-case basis, considering the specific baseline in a given Member State.
Access to centrally authorised medicinal products, for example the number of existing and new orphan authorisations, advanced therapy medicinal products (ATMPs), medicinal products for paediatric use or vaccines, for unmet needs – (indicator 2)	Number of medicines, (i.e. orphan authorisations, advanced therapy medicinal products, medicinal products for paediatric use, vaccines with a single marketing authorisation issued by the Commission and valid across the EU).	Relative proxy indicator; the baseline (86) represents the annual average between 2017 and 2021. It is expected that the current trend where about half of the medicines authorised every year are orphan medicines will continue in the future. The availability of medicinal products can be measured by how many medicines are authorised centrally.
Number of certificates issued by notified bodies under the Medical Device Regulation (MDR)	The number of MDR certificates issued by notified bodies under Regulation (EU) 2017/745 on medical devices	The number of certificates for medical devices is an indicator to measure the number of devices placed on the market under the MDR and contributes to monitoring the transition of devices to the new rules.
Number of certificates issued by notified bodies under the In Vitro Diagnostic Medical Devices Regulation (IVDR)	The number of IVDR certificates issued by notified bodies under Regulation (EU) 2017/746 for medium- and high-risk IVDs	The number of certificates for in vitro diagnostic medical devices is an indicator to measure the number of devices placed on the market under the IVDR and contributes to monitoring the transition of devices to the new rules.
EU Laboratory capacity index (EULabCap) – (indicator 8)	The EULabCap monitoring tool combines 60 indicators to assess the capability and capacity of microbiology laboratories to provide essential public health functions, as defined in EU policies and action plans, international health	ECDC will revise the format of the survey including the indicators in 2023/2024. Comparability needs to be seen by the time.

	regulations, and technical standards. The target measures are aggregated into the EULabCap Country system index, with 10 being the maximum score. The methodology is described in further detail in the EULabCap report (ECDC, 2018). – see details ECDC.	
Number of reported shortages of medicinal products in the Member States through the single point of contact network – (indicator 15)	This indicator measures the level of monitoring and reporting on relevant shortages of human and veterinary medicines by measuring the number of shortages of medicines that were reported and identified as critical given their impact on human/animal health, by the SPOC (single point of contact) at EMA.	Relative proxy indicator; uncertain targets and milestones; no direct causal link, given that an increase in reported shortages can either be due to better reporting and monitoring or due to an increase in the number of actual shortages even if a one joint action on shortages contributes to strengthening the structure and reporting in the Member States, any progress is an achievement; the values for this indicator may increase in the short term (2020 - mid-2024) until the forthcoming Pharmaceutical package starts to take effect. The initial increase in numbers would be linked to a higher level of reporting and monitoring.
Number of actions aimed at increasing the security and continuity of the global supply chains and addressing dependence on imports from third countries for the production of essential active pharmaceutical ingredients and medicinal products in the Union – (indicator 16) – KEY PERFORMANCE INDICATOR	Number of actions contributing to increasing the security and continuity of the global supply chains and addressing dependence on imports from third countries for the production of essential active pharmaceutical ingredients and medicinal products.	Static indicator in some years; relative proxy indicator; uncertain targets and milestones because the number of actions depends on the programming process that involves Member States.
Number of production facilities with enhanced capacities in increasing security and continuity of supply for medical countermeasures, raw materials, and components at EU level – KEY PERFORMANCE INDICATOR	Number of new producers and producers with enhanced capacities in increasing security and continuity of supply of medical countermeasures, raw materials, and components in the Union, including ever-warm capacities.	n/a

Antimicrobial consumption for systemic use ATC (group J01) – (indicator 18)	The indicator measures the total consumption (community and hospital sectors) of antibacterials for systemic use (ATC group J01) expressed as defined daily dose'(DDD) per 1 000 inhabitants per day'. It has been selected as the primary harmonised outcome indicator by ECDC, the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA) to describe total antimicrobial consumption (AMC) in humans, combining both the community and hospital sectors. AMC data were collected using the Anatomical Therapeutic Chemical (ATC)classification system and analysed using the defined daily dose (DDD) methodology developed by the World Health Organization (WHO).	This indicator is based on one of the targets agreed under Council Recommendation of 13 June 2023 on stepping up EU actions to combat antimicrobial resistance taking a One Health approach, where the baseline is set in 2019 as defined in the Council Recommendation because 2020/2021 is not representative for AMC due to the effects of the COVID-19 pandemic; no direct causal link, any progress is an achievement. The target is defined by the Council Recommendation; the milestones are policy proposals that assume a linear trajectory of reduction to the target.
Number of audits conducted in the EU and in third countries to ensure good manufacturing practices and good clinical practices (Union control) – (indicator 17) - KEY PERFORMANCE INDICATOR	The number of audits conducted in the EU and in third countries, including candidate countries, to ensure good manufacturing practices and good clinical practices (EU control). This indicator shows to what extent the EU ensures high quality medicines and proper implementation of the Clinical Trial Regulation and supports the implementation of the legislation.	n/a
Number of Member States participating in actions aimed at supporting innovation, uptake and access to market of medical countermeasures supported at EU and global level for better preparedness and response	This indicator measures the number of Member States that participate in actions contributing at supporting innovation, uptake, and access to market of medical countermeasures in EU and global level and therefore to increasing availability and accessibility of new or repurposed medical countermeasures for priority threats that are closer or have gained access to the market	Static indicator in some years; relative proxy indicator; uncertain targets and milestones.

	to improve preparedness and response.	
Number of actions complementing national stockpiling of essential crisis-relevant products	This indicator measures the number of actions aimed at complementing national stockpiling, these could be purchases intended to increase the national stockpile or actions intended to gather information to strengthen national or EU stockpiles.	Static indicator in some years; relative proxy indicator; uncertain targets and milestones because the number of actions depends on the programming process that involves Member States
Number of Member States participating in stockpiling activities	Total number of Member States participating in the Joint Action on stockpiling foreseen in the EU4Health 2024 annual work programme and contributing to the development and implementation of activities outlined in the EU stockpile strategic approach and vision. The involvement of the EU Member States, participating in the Joint Action on stockpiling foreseen in the EU4Health annual work programme for 2024, will be assessed by looking at the various reports and deliverables of the Joint Action	Uncertain targets and milestones because the number of actions depends on programming processes that involves Member States.
Number of healthcare and public health staff trained (Article 11 of the CHBT Regulation and Decision establishing HERA) - KEY PERFORMANCE INDICATOR	Number of participants in training actions (regardless of the implementing mode - e.g. eLearning, in person training) on preparedness and response to cross-border health threats targeting healthcare staff and public health staff (Article 11 of Regulation 2022/2371, train the-trainers) and addressing medical countermeasures	Static indicator in some years; relative proxy indicator; uncertain targets and milestones.
Stakeholders' satisfaction rate in HERA training programmes	Percentage of participants to any training activity supported by the EU Health Preparedness training Programme / the HERA Training Programme that report positive feedback on	Uncertain baseline; training activities starting in 2024

	content and organisation of the event; satisfactory feedback corresponds to a score equal or higher to 70 out of 100; feedback collected via surveys or questionnaires after each training activity	
Number of actions contributing to the digital transformation of healthcare systems and the implementation of the European Health Data Space (EHDS)	This indicator measures the number of actions included under EU4Health work programmes (including grants and procurements) to support the digital transformation of healthcare systems and the implementation of the EHDS (cumulative).	n/a
Number of Member States participating in the European Health Data Space – (indicator 5) - KEY PERFORMANCE INDICATOR	This indicator measures the number of Member States connected to MyHealth@EU and/or to the cross-border infrastructure for secondary uses (cumulative).	n/a
Progress on setting up health data access bodies in the EU	This indicator measures the number of Member States that have set up or are in the process of setting up a health data access body (cumulative).	n/a
Number of actions producing guidance for improving access to healthcare services	The sum of EU4Health actions that produce guidelines or recommendations for Member States on how to assess and improve access to healthcare services. These may include guidelines or recommendations on affordable access to healthcare, access to mental healthcare, access to healthcare for vulnerable groups, as well as information about new indicators for measuring access to healthcare	The milestone and target are the same because it is highly unlikely that similar actions could be prioritised in the coming years. The three actions included in the annual work programmes for 2021, 2022 and 2023 are expected to address the most relevant challenges in this area.
Number of measures taken by Member States to improve access to healthcare services	The sum of measures taken by Member States supported by EU4Health Programme to improve access to healthcare on the basis of guidance provided by EU4Health projects. This may include measures regarding	n/a

	affordability of healthcare, access to mental health care, access to healthcare for vulnerable groups, as well as new indicators for measuring access to healthcare.	
Number of impact assessments of Union policies	Number of published impact assessments and supporting reports and staff working documents of EU health policies supported by the Programme.	Static indicator in some years; uncertain milestones and targets a target for 2027 may be set only in 2025 after the new College sets out defines its priorities.
Number of studies supporting the evaluations of legislative and non-legislative health Union policies – KEY PERFORMANCE INDICATOR	Number of studies published supporting the evaluations, monitoring the implementation and assessing the functioning of legislative and non-legislative policies	Static indicator in some years; data are collected from the Interinstitutional-Studies Database, which is revised depending on needs and political priorities; uncertain targets and milestones because of the political priorities of the Commission and the regulatory cycle.
Number of Health Technology Assessment (HTA) reports jointly carried out – (indicator 20)	Number of joint clinical assessments on medicinal products and on medical devices in the context of the new HTA Regulation (EU) 2021/2282	HTA Regulation (EU) 2021/2282 is to apply from January 2025; the 'number of joint clinical assessments' depends on the number of newly filed marketing authorisation requests for medical products by the industry and then, on the collaboration of Member States in conducting Joint Clinical Assessments in the context of the corresponding marketing authorisation processes; uncertain targets and milestones which may need to be revised in 2025 depending on the state-of-play on implementation.
Number of healthcare units involved in ERNs – (sub-indicator 19.1)	Number of healthcare units involved in ERNs	The milestone is not expected change unless another call to enlarge the ERNs takes place; the number of hospital units involved in ERNs is at this stage mostly stable and is not expected to change substantially. To operationalise it, the indicator 19 Number of healthcare units involved in European Reference Networks (ERNs) and of patients diagnosed and treated by the members of ERNs referred to in Annex 2 to the EU4Health Regulation has been broken down into its two components (19.1 and 19.2).
Number patients diagnosed and treated by the members of ERNs – (sub-indicator 19.2) - KEY PERFORMANCE INDICATOR	The sum of the number of patients referred to ERNs whose cases are reviewed by ERNs	To operationalise it, the indicator 19 Number of healthcare units involved in European Reference Networks (ERNs) and of patients diagnosed and treated by the members of ERNs referred to in Annex 2 to the EU4Health Regulation has been broken down into its two components (19.1 and 19.2).

Number of actions and contribution agreements supporting global commitments and health initiatives concluded with global partners	Number of contribution agreements and actions supporting global commitments and health initiatives concluded with global partners including the organisations pillar assessed.	Milestone and target will be available at the end of 2023 given that this is a new initiative, and the actions are in the making; uncertain target and milestone because the number of actions depends on the programming process that involves Member States.
Number of areas where EU and WHO collaborate	Number of areas where EU and WHO align policies and/or actions (such as crisis preparedness and response, health promotion, disease prevention, health systems, healthcare workforce, digital and cancer).	Only the actions supported by the EU4Health Programme are relevant to this indicator; actions funded by other EU funding programmes are excluded.
Areas of coordination between EU and relevant global partners and EU Member States	Number of areas of coordination between EU and relevant global partners such as crisis preparedness and response, health promotion and disease prevention, cancer, health systems and health workforce, digital infrastructure and digital skills and cancer.	Only the actions supported by the EU4Health Programme are relevant to this indicator. Actions funded by other EU funding programmes are excluded.

ANNEX VII. POINTS OF COMPARISON: BASELINES, EXPECTED ACHIEVEMENTS AND TARGETS PER EU4HEALTH WORK PROGRAMME STRAND AND SPECIFIC OBJECTIVES AND DATA FROM 2021, 2022, AND 2023 (WHERE AVAILABLE)

Crisis preparedness and response

2020 baseline

The 2020 ***crisis preparedness*** baseline was framed legally by Decision No 1082/2013/EU[234] on serious cross-border threats to health and other relevant legal acts. During the baseline period, the Commission stepped up relevant EU-level action in three ways. Firstly, it adopted *recommendations* (such as those for a common EU testing approach for COVID-19[235]) on COVID-19 testing strategies, including the use of rapid antigen tests[236]. Secondly, it adopted *legal proposals*: for a Regulation on serious cross-border threats to health[237]; and to extend the mandates of both the European Medicines Agency[238] and that of the European Centre for Disease Prevention and Control[239]. Thirdly, it adopted relevant *communications* such as the Communication 'Building a European Health Union: preparedness and resilience' that accompanied the legal proposals[240]. These actions have built on the existing health security framework established in 2013 to: protect EU citizens; promote coordination between Member States and with neighbouring countries; and respond to the increasing threat of communicable diseases[241]. Valuable experience had already been acquired by the EU following: the pandemic influenza outbreak of 2009; the completion of the joint procurement agreement signed by the first countries in 2014[242]; and experience in the fight against three epidemics (HIV/AIDS, viral hepatitis B and C, and tuberculosis). The Commission took stock of the fight against these three epidemics in 2018 when it became clear that: investment in prevention was key; there was no one-size-fits-all solution; and each situation required a thorough and targeted analysis, involving all stakeholders in the implementation of preventive and treatment measures[243]. By the end of the baseline period, it was possible to identify the related challenges and needs confronting countries, the EU, and the world more generally. Some of these challenges had already been addressed by the end of the baseline period thanks to urgent actions, while for

234 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).

235 EU health preparedness: Recommendations for a common EU testing approach for COVID-19.

236 Commission recommendation of 28.10.2020 on COVID-19 testing strategies, including the use of rapid antigen tests.

237 Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU, COM(2020)727 final.

238 Proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, COM(2020)725 final.

239 Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control (OJ L 314, 6.12.2022).

240 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*, COM(2020)724 final.

241 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).

242 European Health Union: HERA signs Joint Procurement contract for Pandemic Influenza Vaccine.

243 Commission Staff Working Document on Combating HIV/AIDS, viral hepatitis and tuberculosis in the European Union and neighbouring countries - State of play, policy instruments and good practices, SWD(2018)387 final.

other challenges, measures were progressively rolled out and the implementation started during the baseline period.

The ambition of the EU4Health Programme's intervention (as set out in the milestones) and end results (targets) were drawn from existing and upcoming EU health policies and legislation.

Current situation and actions planned

Under the ***crisis preparedness*** strand, the EU4Health Programme supports the implementation of: Regulation (EU) 2022/2371 on serious cross-border threats to health[244]; the Commission Communication introducing HERA[245]; the Commission Decision establishing HERA[246]; and (iv) HERA's annual work plans[247]. Help from the EU4Health Programme in these areas include support for: coordinated public health measures at EU level related to serious cross-border threats to health; the surveillance of those health threats; training activities; data gathering and analysis; and information exchange. Furthermore, the Programme supports: the creation of an EU plan for preventing, preparing for and responding to serious cross-border threats to health; upcoming regular updates and stress tests of the Programme itself; and simulation exercises and reviews with the Member States[248]. Under this crisis-preparedness strand, the Programme also supports actions to ensure the development, manufacturing, procurement and equitable distribution of key medical countermeasures; procure and supply essential crisis-relevant products; and support the national stockpiling of such products.

The EU4Health Programme supports actions that take a **One Health** approach, where applicable, and these actions include the development of new medical countermeasures against **AMR**. Some of the upcoming actions are expected to deliver on the June 2023 Council Recommendation on stepping up EU action to combat AMR in the areas of human health, animal health and the environment[249].

2020 baseline

AMR remained a major public health concern in the European region and worldwide[250]. The EU has prioritised efforts against AMR for over two decades now. More recent EU action on **AMR** has been driven by the European One Health action plan against AMR (the '2017 AMR action plan')[251]. This plan outlines over 70 actions covering human health, animal health and the environment. In addition, the EU guidelines for the prudent use of antimicrobials in human health adopted by the Commission in June 2017 helped Member States to draw up their own

244 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 (OJ L 314, 6.12.2022).

245 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union*, COM(2021)576 final.

246 Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority (OJ C 393I, 29.9.2021).

247 HERA Work Plan 2022, HERA Work Plan 2023, HERA Work Plan 2024.

248 As stipulated by Article 5(5) of 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 (OJ L 314, 6.12.2022).

249 Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach, 2023/C 220/01.

250 See Section 2.1 'Problems and needs.'

251 A European One Health Action Plan against Antimicrobial Resistance (AMR), 2017.

national guidelines and recommendations. In February 2020, the fourth progress report[252] on the implementation of the 2017 AMR action plan highlighted substantial progress made since mid-2019. This progress included meetings of both the AMR One Health Network and the Health Security Committee to improve cooperation and coordination on AMR, as well as 'One Health' visits to Member States to support the implementation of national One Health action plans. Other milestones include the publication of two overview reports. The first of these overview reports was published in 2017 on measures to tackle AMR through the prudent use of antimicrobials in animals. The second was published in 2018 on a series of audits carried out in order to evaluate the monitoring and reporting of AMR in zoonotic and commensal bacteria in certain food-producing animal populations and food. The publication in December 2020 of the fifth progress report[253] on the implementation of the 2017 AMR action plan detailed the further action that had been taken on AMR. For example, in May 2020 the Commission adopted the EU 'farm to fork' strategy[254], which contained a target aiming to reduce by 50% overall EU sales of antimicrobials for farmed animals and in aquaculture by 2030. In addition, by December 2020 work was ongoing on implemented and delegated acts for the implementation of the recently adopted Regulations on Veterinary Medicinal Products[255] and Medicated Feed[256]. Commission Implementing Decision (EU) 2020/1729[257] on the monitoring and reporting of AMR in zoonotic and commensal bacteria was in place in December 2020 and the pharmaceutical strategy for Europe[258] – adopted in November 2020 – also flagged the fight against AMR as a key objective. The EU4Health programme also played a crucial role in addressing AMR by funding the EU-JAMRAI joint action with EUR 6.9 million (originally set out in the 2017 annual work programme) to help EU Member States develop and implement effective One Health national action plans against AMR and healthcare-associated infections (HCAIs).

In 2020, the baseline was set (value 0) for eight Programme indicators characterising the crisis preparedness strand and monitoring the implementation of the specific objectives (b), (d) and (e). In 2022, the baseline was set (value 0) for two other Programme indicators. And in 2023, the baseline was set (value 0) for four other Programme indicators to monitor the progress made in implementing the Regulation on serious cross-border threats to health and AMR actions. For more on the setting of these baselines, see Section 2.1, Figure 2.

Current situation and actions

252 AMR: Commission publishes its [4th] progress report on Action Plan.

253 AMR: Commission publishes its [5th] progress report on the EU's Action Plan.

254 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system*, COM(2020)381 final.

255 Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019).

256 Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019).

257 Commission Implementing Decision (EU) 2020/1729 of 17 November 2020 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria and repealing Implementing Decision 2013/652/EU (OJ L 387, 19.11.2020).

258 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions *Pharmaceutical Strategy for Europe*, COM(2020)761 final.

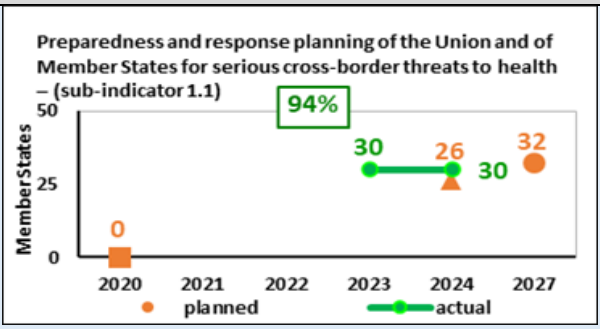
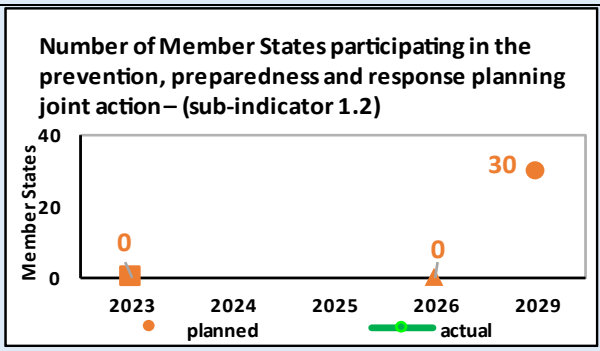
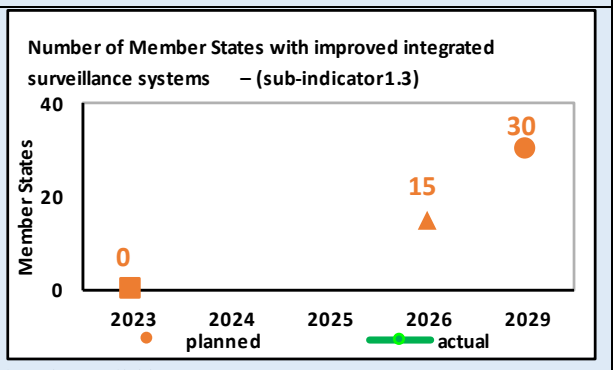
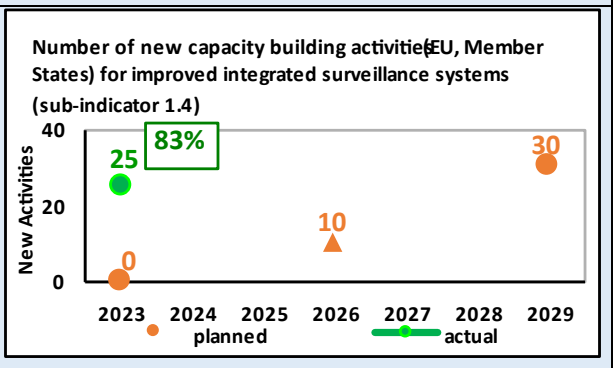
The EU4Health Programme supports actions that take a **One Health** approach, where applicable, and these actions include the development of new medical countermeasures against **AMR**. Some of the forthcoming actions under the Programme are expected to deliver on the June 2023 Council Recommendation on stepping up EU action to combat antimicrobial resistance in the areas of human health, animal health and the environment[259].

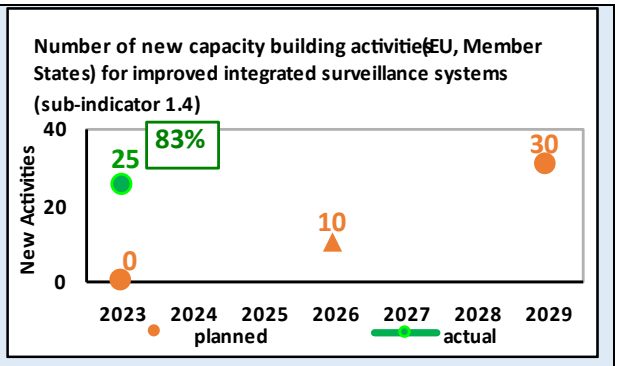
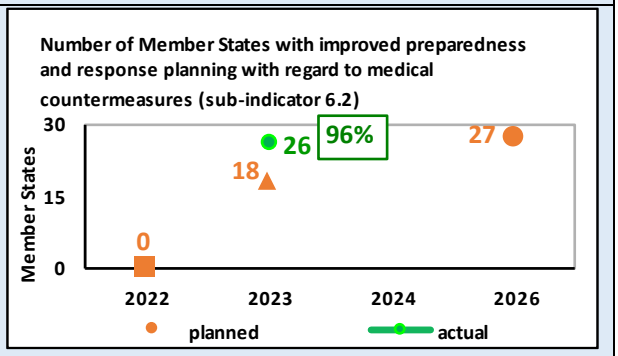
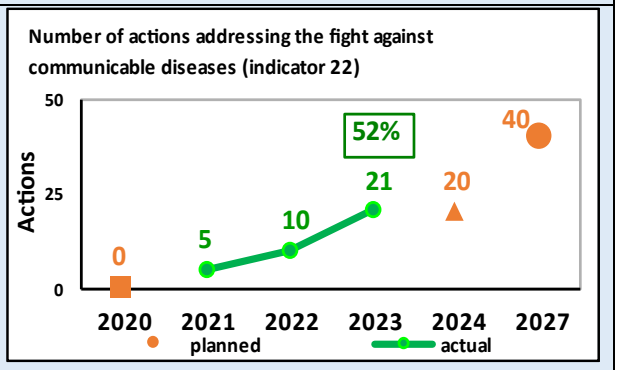
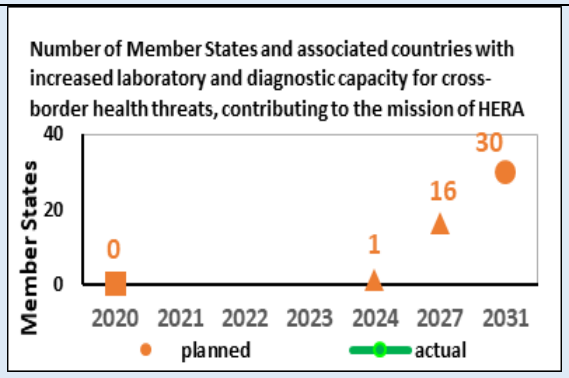
Expected Programme milestones and targets

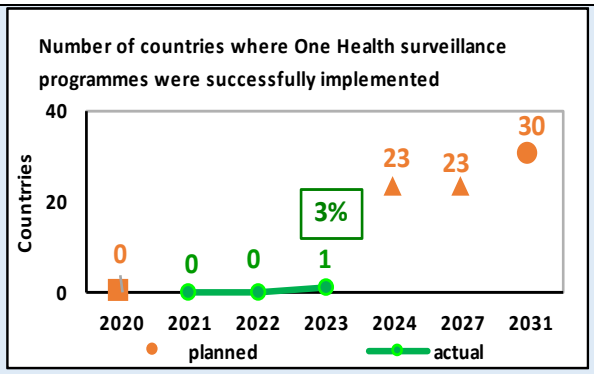
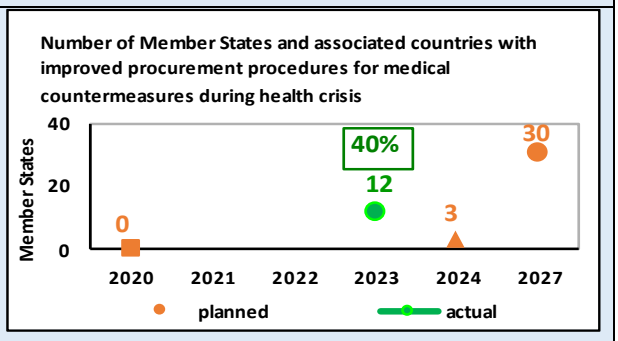
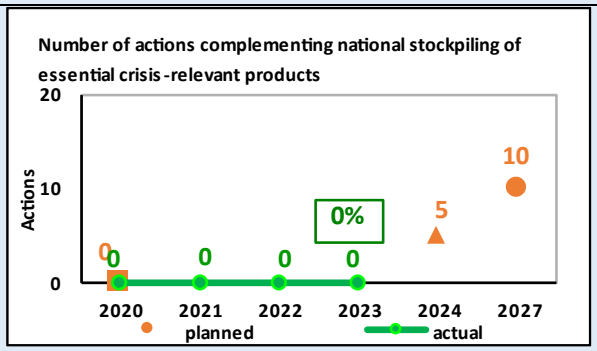
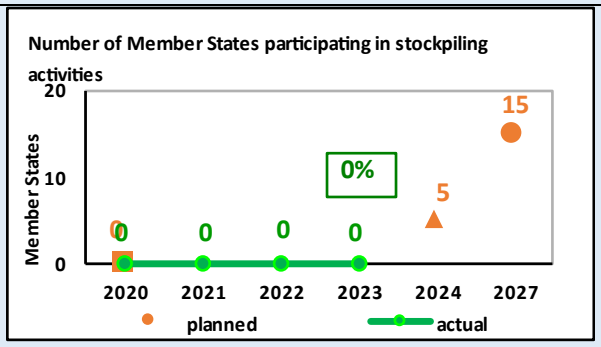
The expected 2024 achievements and 2027 targets for the Programme indicators for the crisis preparedness strand and its three specific objectives (b, d and e) are illustrated in the below figure.

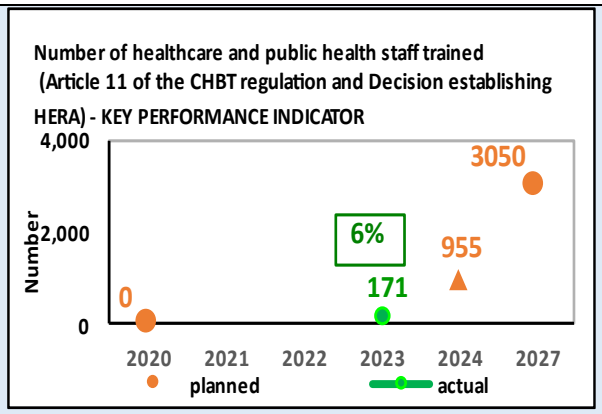
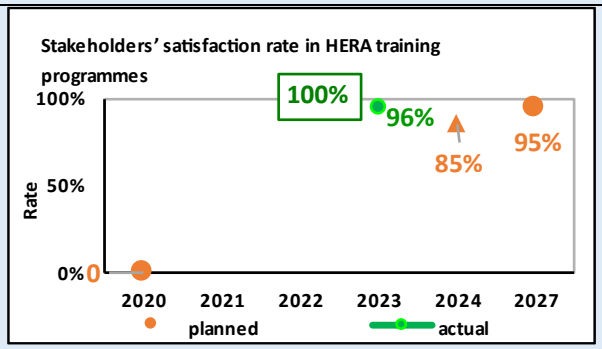
[259] Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach, (OJ C 220, 22.6.2023).249

Figure: Baselines, milestones and targets for the crisis preparedness strand and its three specific objectives (b, d and e) - Legend: ■ baseline; ▲ milestone; ● target; ● actual.

Indicator	Graph based on recorded values
Preparedness and response planning of the Union and of Member States for serious cross-border threats to health – (sub-indicator 1.1) – KEY PERFORMANCE INDICATOR – monitoring specific objective (b).	 *Percentage indicates the progress towards 2027 target.
Number of Member States participating in the prevention, preparedness and response planning joint action – (sub-indicator 1.2) – monitoring specific objective (b).	 *No data available.
Number of Member States with improved integrated surveillance systems – (sub-indicator 1.3) – monitoring specific objective (b).	 *No data available.
Number of new capacity building activities (EU, Member States) for improved integrated surveillance systems (sub-indicator 1.4) – monitoring specific objective (b).	 *Percentage indicates the progress towards 2029 target.

Number of Member States with improved preparedness and response planning (sub-indicator 6.1) – monitoring specific objective (b).	 *No data available.
Number of Member States with improved preparedness and response planning with regard to medical countermeasures (sub-indicator 6.2) – monitoring specific objective (b).	 *Percentage indicates the progress towards 2026 target.
Number of actions addressing the fight against communicable diseases (indicator 22) – monitoring specific objective (b).	 *Percentage indicates the progress towards 2027 target.
Number of Member States and associated countries with increased laboratory and diagnostic capacity for cross-border health threats, contributing to the mission of HERA – monitoring specific objective (b).	 *No data available yet.

Number of countries where One Health surveillance programmes were successfully implemented – monitoring specific objective (d).	 *Percentage indicates the progress towards 2031 target.
Number of Member States and associated countries with improved procurement procedures for medical countermeasures during health crisis– monitoring specific objective (d).	 *Percentage indicates the progress towards 2027 target.
Number of actions complementing national stockpiling of essential crisis-relevant products – monitoring specific objective (d).	 *Percentage indicates the progress towards 2027 target.
Number of Member States participating in stockpiling activities – monitoring specific objective (d).	 *Percentage indicates the progress towards 2027 target.

Number of healthcare and public health staff trained (Article 11 of the CHBT regulation and Decision establishing HERA)- KEY PERFORMANCE INDICATOR - monitoring specific objective (e).	 *Percentage indicates the progress towards 2027 target.
Stakeholders' satisfaction rate in HERA training programmes - monitoring specific objective (e).	 *Percentage indicates the progress towards 2027 target.

2020 baseline

The baseline for the ***health promotion and disease prevention*** strand and related action was framed by several successive 2011 and 2010 Council conclusions on action against cancer; Council Conclusions on the European pact for mental health and well-being[260]; Council Conclusions on innovative approaches for chronic diseases in public health and healthcare systems[261]; and earlier Council recommendations such as a 2003 Recommendation on cancer screening[262]. The Commission and EU Member States' health authorities have collaborated on non-communicable diseases for many years. This collaboration has covered: cancer screening (e.g. European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis[263]); mental health (e.g. joint action ImpleMENTAL[264]); depression care and suicide prevention (e.g. the EAAD-Best project[265]); cardiovascular diseases (e.g. the YOUNG50 Stay Healthy

260 Council conclusions on the European Pact for Mental Health and Well-being: results and future action, (OJ C 202, 8.7.2011).

261 Council conclusions 'Innovative approaches for chronic diseases in public health and healthcare systems' (OJ C 74, 8.3.2011).

262 Council Recommendation of 2 December 2003 on cancer screening (2003/878/EC).

263 European Commission: Directorate-General for Health and Consumers, Karsa, L., Holland, R., Broeders, M., Wolf, C. et al., European guidelines for quality assurance in breast cancer screening and diagnosis – Fourth edition, supplements, Karsa, L.(editor), Holland, R.(editor), Broeders, M.(editor), Wolf, C.(editor), Perry, N.(editor) and Törnberg, S.(editor), Publications Office, 2013, https://data.europa.eu/doi/10.2772/13196.

264 JA on Implementation of Best Practices in the Area of Mental Health.

265 EAAD-Best.

project[266]); and improving physical activity (e.g. the EUPAP project[267])[268]. In 2018, the Commission launched an online portal on best practices, which detailed best practices collected by previous health programmes. The portal also enabled stakeholders to submit their own practices for evaluation. As of 2020, more than 10 best practices selected by the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases[269] had been taken up in 75% of Member States. The areas covered by these best practices 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.

In 2018, the baseline for 1 Programme indicator (value 0) was set. In 2020, seven Programme indicators (value 0) characterising the health promotion and disease prevention strand and monitoring the implementation of specific objective (a) was set. And in 2021, the baseline for another Programme indicator was set (value 1). For more on the setting of these baselines, see Section 2.1, Figure 3.

Current situation and actions

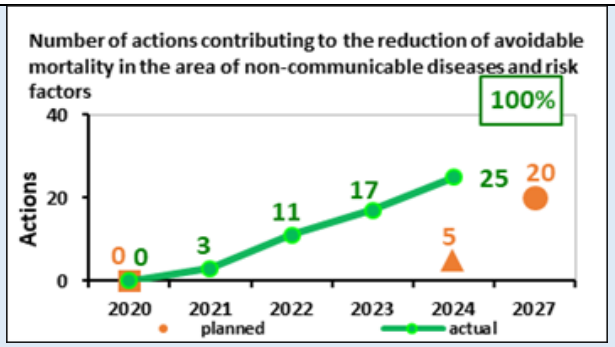
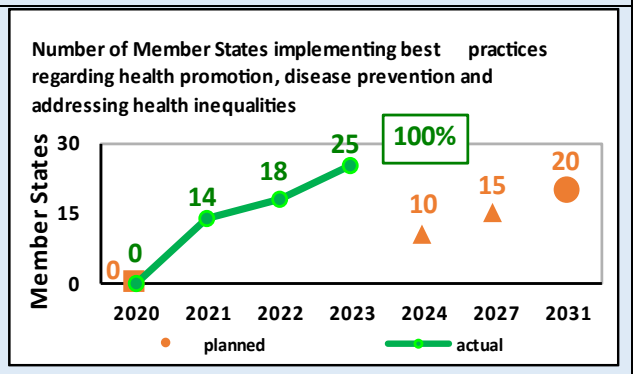
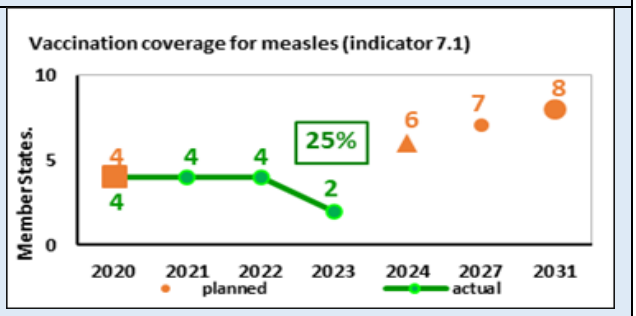
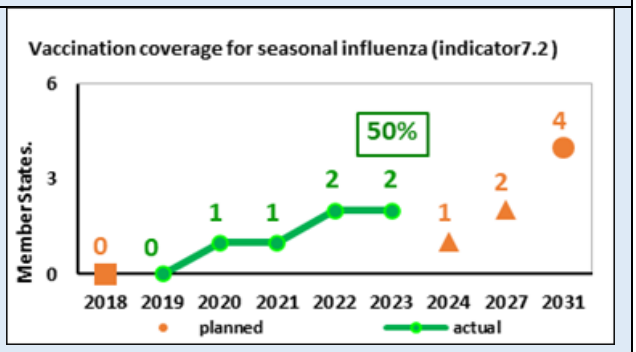
Under the ***health promotion and disease prevention*** strand, the EU4Health Programme supports actions that: focus on reducing the burden of NCDs and relevant health determinants; and address health inequalities, as outlined by 'Healthier together' – the EU NCD initiative[270]. The EU4Health Programme also supports: the promotion of good mental health; the prevention of mental health problems; and the treatment and care of mental health problems, throughout the lifetime of an individual, and through a comprehensive prevention-oriented approach to mental health[271]. This strand will also help the Member States to reach the UN SDGs and targets[272] in this area, as well as the relevant WHO global NCD targets for 2025[273].

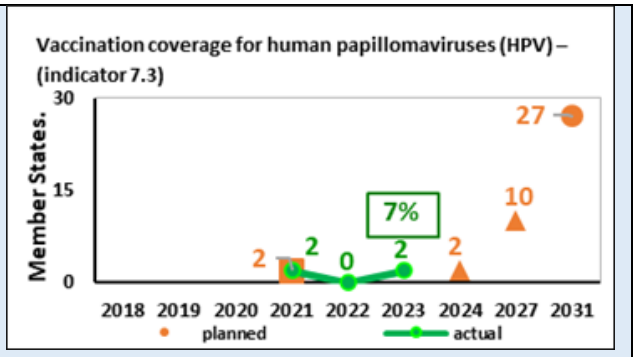
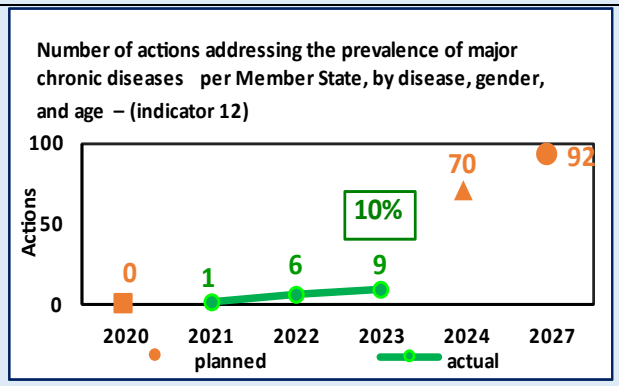
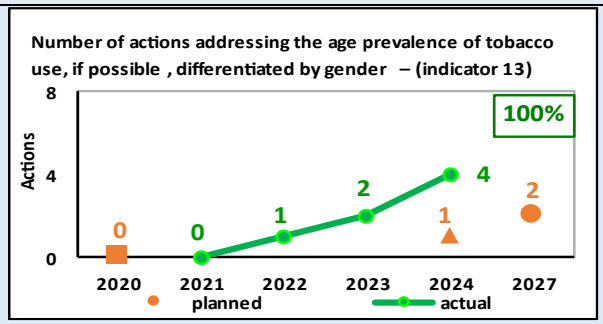
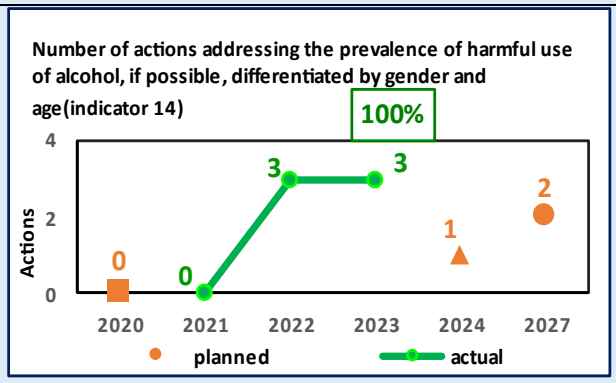
The EU4Health Programme may also fund actions to improve the surveillance, diagnosis, and treatment of communicable and non-communicable diseases. The Programme gives special attention to both the development of innovative care models and addressing the challenges of long-term care to strengthen the resilience of health systems in the EU.

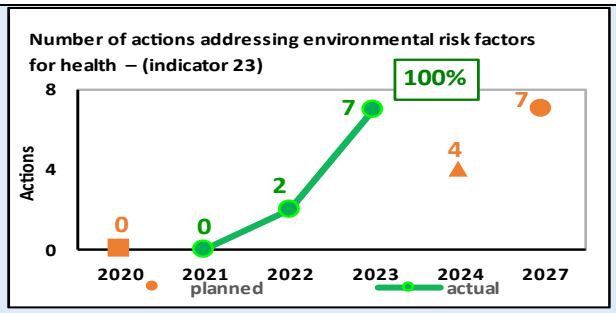
Expected Programme milestones and targets.

Indicator	**Graph based on recorded values**

266 YOUNG50 #Stay Healthy – Cardiovascular Risk Prevention.
267 EUPAP – A European Physical Activity on Prescription model.
268 Healthier Together EU Non-Communicable Diseases Initiative.
269 In December 2022, the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases was replaced by Expert group on public health.
270 The Healthier Together EU Non-Communicable Diseases Initiative.
271 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on a comprehensive approach to mental health, COM(2023)298 final.
272 UN resolution of 25 September 2015. In particular, Sustainable Development Goal 3 'Ensuring healthy lives and promote well-being for all at all ages' and its Target 3.4, namely, to reduce premature mortality from non-communicable diseases by one third by 2030 through prevention and treatment and promote mental health and well-being.
273 Set of nine voluntary global NCD targets for 2025, World Health Organization 2022.

Number of actions contributing to the reduction of avoidable mortality in the area of non-communicable diseases and risk factors – monitoring specific objective (a).	 *Percentage indicates the progress towards 2027 target.
Number of Member States implementing best practices regarding health promotion, disease prevention and addressing health inequalities – KEY PERFORMANCE INDICATOR – monitoring specific objective (a).	 *Percentage indicates the progress towards 2031 target.
Vaccination coverage for measles (indicator 7.1) – monitoring specific objective (a).	 *Percentage indicates the progress towards 2031 target.
Vaccination coverage for seasonal influenza – (indicator 7.2) – monitoring specific objective (a).	 *Percentage indicates the progress towards 2031 target.

Vaccination coverage for human papillomaviruses (HPV)– (indicator 7.3) – monitoring specific objective (a).	 *Percentage indicates the progress towards 2031 target.
Number of actions addressing the prevalence of major chronic diseases per Member State, by disease, gender, and age – (indicator 12) – monitoring specific objective (a).	 *Percentage indicates the progress towards 2027 target.
Number of actions addressing the age prevalence of tobacco use, if possible, differentiated by gender – (indicator 13) – monitoring specific objective (a).	 *Percentage indicates the progress towards 2027 target.
Number of actions addressing the prevalence of harmful use of alcohol, if possible, differentiated by gender and age – (indicator 14) – monitoring specific objective (a).	 *Percentage indicates the progress towards 2027 target.

Number of actions addressing environmental risk factors for health – (indicator 23) – monitoring specific objective (a).	 *Percentage indicates the progress towards 2027 target.

Health systems and healthcare workforce

2020 baseline

The ***health systems and healthcare workforce*** strand covers multiple areas, so baselines apply to each of these areas separately. On the healthcare workforce, the baseline was set in the 2012 Commission action plan for the EU health workforce. This action plan identified various actions where the EU could add value to address challenges faced by the health workforce. These actions include: (i) health workforce planning; (ii) the anticipation of skills requirements; (iii) recruitment and retention; and (iv) ethical international recruitment[274]. The baseline was further influenced by the COVID-19 pandemic, which put the spotlight on shortages of healthcare workers and the problem of well-being in the health workforce. Evidence-based policymaking in the area of health systems and the healthcare workforce was supported by the recurrent 'State of Health in the EU' project cycle. This project cycle has been carried out by a partnership between the Commission, the European Observatory on Health Systems and Policies, and the Organisation for Economic Cooperation and Development. Every two years since 2016, the project provides a regular update of indicators and statistics on the performance of EU health systems, with related publications released every year[275]. The most recent 'State of Health in the EU' report[276] identifies healthcare as a sector facing critical labour shortages.

Health technology assessment (HTA) is an important part of evidence-based decision-making on health in most EU countries, and the Commission has supported cooperation projects in this field for decades. In particular, the EUnetHTA project was set up in 2006 and led to the establishment of both and EU HTA network and the scientific-technical EUnetHTA joint actions[277]. The EUnetHTA joint actions ran from 2010 until 2021. In 2021, a call for tender was launched to continue EU cooperation on HTA beyond the end of the EUnetHTA joint action 3. As a result, the EUnetHTA 21 consortium was created. It ran from 2021 to 2023, supporting the preparatory phase for the implementation of the HTA Regulation, which finally came into application in January 2024.

274 Commission staff working document on an Action Plan for the EU Health Workforce, SWD(2012)93 final.
275 State of Health in the EU.
276 OECD/European Commission (2024), Health at a Glance: Europe 2024: State of Health in the EU Cycle, OECD Publishing, Paris, https://doi.org/10.1787/b3704e14-en.
277 EUnetHTA joint actions Behind the HTA regulation - European Commission

The 24 ***European reference networks*** *(ERNs)* were already set up in March 2017 under Directive 2011/24/EU on patients' rights in cross-border healthcare[278]. These ERNs brought together European hospital centres of expertise and reference to tackle rare, low-prevalence and complex diseases and conditions requiring highly specialised healthcare. In 2017, the ERNs included 956 highly specialised healthcare units from 313 hospitals in 26 countries (25 EU Member States plus Norway). Following a call for new members on 30 September 2019, 620 new applicants joined. In addition, Directive 2011/24/EU meant that patients could travel to another EU country to receive medical care and reimbursement.

In 2020, the baseline for a Programme indicator on the patients diagnosed and treated by ERN members (value 1 million) was set. In 2021, the baseline was set for a Programme indicator (value 1139) for the number of ERN healthcare units. And in 2025, the baseline was set for three Programme indicators monitoring the implementation of the HTA and ERN actions implementing specific objective (i) for the HTA.

The EU's actions and regulatory framework on increasing the availability, accessibility and affordability of **medicinal products, medical devices and crisis-relevant products** were advanced when the pharmaceutical strategy for Europe[279] was adopted in November 2020. That strategy, a key action of the European Health Union, is the largest reform in over 20 years aiming to modernise the pharmaceutical sector with a patient-centred approach that supports an innovative and competitive pharmaceutical industry. Prior to the introduction of this strategy, the EU had already a comprehensive pharmaceuticals system in place (e.g. Directive 2001/83/EC[280], Regulation (EC) 726/2004[281], the Orphan Medicinal Products Regulation[282] and the Paediatric[283] Regulation). This comprehensive pharmaceutical system covered the development and authorisation of medicines as well as their post-authorisation monitoring. The Commission, the European Medicines Agency (EMA), and the medicines regulatory authorities in the Member States and the European Economic Area now work together in the European Medicines Regulatory Network to ensure that patients have access to high-quality, effective and safe medicines. Together with other public and private actors, the strong and competitive pharmaceutical industry in the EU has served public health well and acts as a driver of job creation, trade and science[284]. However, concerns remained that investment was not necessarily focusing on the greatest ***unmet needs***. Many unmet and pressing medical needs do

278 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).

279 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Pharmaceutical Strategy for Europe, COM(2020)761 final.

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

281 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union 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).

282 Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 018 22.1.2000).

283 Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006).

284 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Pharmaceutical Strategy for Europe, COM(2020)761 final.

not attract commercial interest or are affected by limitations in the science, and only about 5% of those needs are addressed.

Since 2017, ***medical devices and in vitro diagnostic medical devices*** (IVDs) have been regulated in the EU/EEA by Regulation (EU) 2017/745[285] (the Medical Device Regulation or MDR) and Regulation (EU) 2017/746[286] (the In Vitro Diagnostic Medical Devices Regulation or IVDR) respectively. These Regulations aim to create a robust, transparent and sustainable regulatory framework that maintains a high level of safety, while supporting innovation. To achieve these objectives, the Regulations impose more stringent rules across the lifecycle of developing, certifying and monitoring medical devices and IVDs. All new devices as well as devices already placed on the market must comply with these more stringent rules.

It was already possible for Member States to apply the MDR and IVDR on a voluntary basis before their dates of application became applicable in 2021 and 2022 respectively. For this reason, some parts of infrastructure set out by the Regulations for building in the future were already partly delivered by the beginning of 2021. By February 2021, 18 notified bodies were designated under the MDR, and 4 notified bodies were designated under the IVDR. By the beginning of 2021, the Commission had also made progress on developing the European database on medical devices by making available the first versions of three out of the planned six inter-connected modules. Similarly, a first version of the European Medical Device Nomenclature was released in May 2021 and made available free of charge to manufacturers and other stakeholders required by the Regulations to use that nomenclature.

At the end of the baseline period: the number of single marketing authorisations of specific medicines valid across the EU was 86; the total number of medical devices certificates issued by notified bodies under Regulation (EU) 2017/745 on medical devices intended to be placed on the EU market was 502; the number of in vitro diagnostic medical devices issued by notified bodies under Regulation (EU) 2017/746 for medium- and high-risk devices intended to be placed on the EU market was 31; and the level of monitoring and reporting on relevant shortages of human and veterinary medicines to reach maturity showed that this level of shortages remained under control. At the end of the baseline period, actions were also being drawn up to increase the security and continuity of global supply chains and address dependence on imports from third countries for the production of essential active pharmaceutical ingredients and medicinal products. Similarly, the actions to support innovation in, uptake of, and access to the market for medical countermeasures at EU and global level were at an early stage. In total, 11 audits had been conducted in the EU and in third countries, including candidate countries, to ensure good manufacturing practices and good clinical practices (EU control). Improvements were expected on increasing access to healthcare with the aim of achieving universal health coverage.

The baseline for two Programme indicators monitoring the implementation of the actions improving the availability, accessibility and affordability of medicinal products, medical devices and crisis-relevant products was set in 2019 (value above 0). The baselines for five such Programme indicators (values of 0 or above 0) were set in 2020. And the baselines for

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

[286] 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).

three such indicators were set in 2021 (values above 0). For more on the setting of these baselines, see Section 2.1, Figure 4.

Achieving ***universal access to healthcare*** is one of the targets of the UN's Sustainable Development Goal 3 – Ensure healthy lives and promote well-being for all at all ages. The European Pillar of Social Rights action plan[287], published in 2021, contained measures to improve access to healthcare. The European strategy for the rights of persons with disabilities[288], also published in 2021, entails commitments to provide guidelines to Member States on how to improve access to healthcare for persons with disabilities. The EU's third health programme, which ran from 2014-2020 and was a precursor to the EU4Health Programme, supported an action on access to healthcare, which showed the need for more robust indicators to measure and explain the hurdles experienced by more vulnerable groups, who experience specific challenges in accessing healthcare[289].

The baseline for two Programme indicators monitoring the implementation of the actions on universal access to healthcare and specific objective (g) were set in 2020 (value 0). For more on the setting of these baselines, see Section 2.1, Figure 4.

Current situation and actions

Under the ***health systems and healthcare workforce*** strand, the EU4Health Programme finances actions to help strengthen national health systems and the health workforce by improving their resilience and resource efficiency. To that end, the Programme funds: networking through ERNs and other transnational networks; the work on HTA; and other measures implementing the Directive on patients' rights in cross-border healthcare[290]. The Programme helps to strengthen the healthcare workforce and advance the digital transformation of health systems. This strand also supports actions to improve access to quality, patient-centred, outcome-based healthcare, and related care services, with the aim of achieving universal health coverage. It also supports access to health and care services for people with disabilities and other vulnerable or disadvantaged population groups. In addition, the EU4Health Programme supports actions to increase the availability, accessibility, and affordability of medicinal products, medical devices, crisis-relevant products and medical countermeasures (these devices, products and countermeasures include diagnostic tools, **therapeutics, and vaccines)** including through the development and uptake of innovative products. The actions: encourage sustainable production and supply chains and innovation in the EU, in synergy with Horizon Europe; contribute to the implementation of the Commission Communication on tackling medicine shortages in the EU[291]; and are also aligned with the

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287 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *The European Pillar of Social Rights Action Plan*, COM(2021)102 final.

288 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Union of Equality: Strategy for the Rights of Persons with Disabilities 2021-2030*, COM(2021) 101 final.

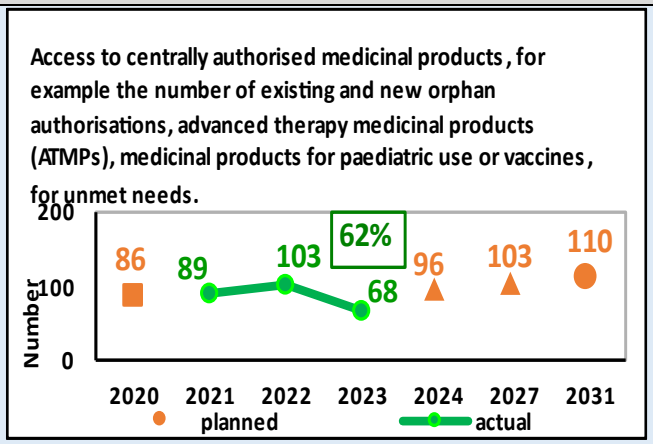
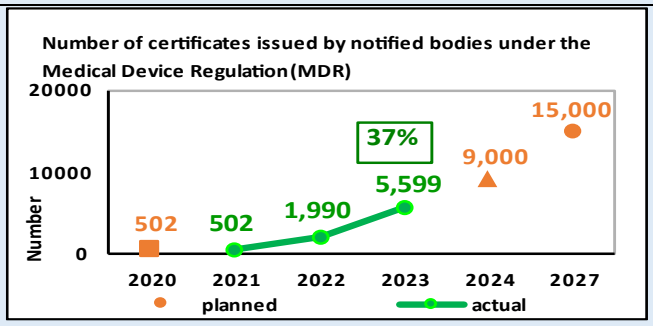
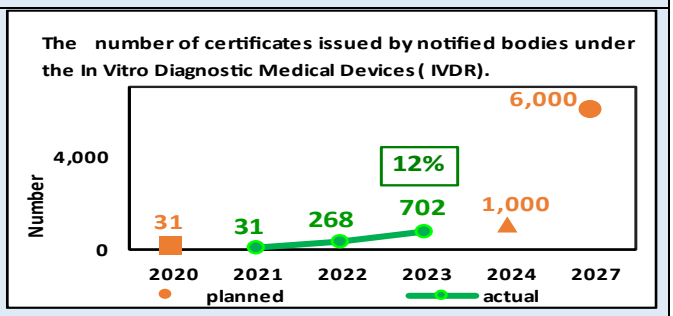
289 Study 'Report on the comparative assessment of the accessibility of healthcare services: comparability of indicators on unmet needs for medical examination or treatment across EU Member States'.

290 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).

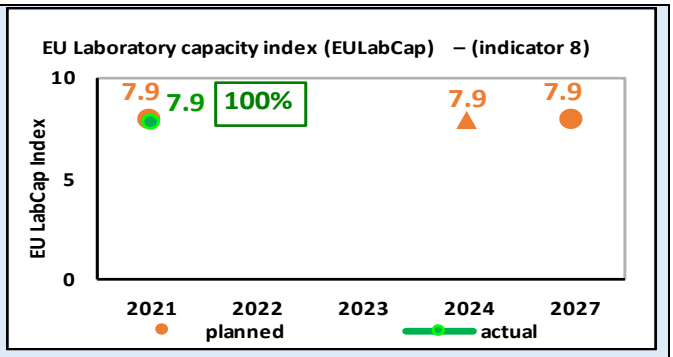
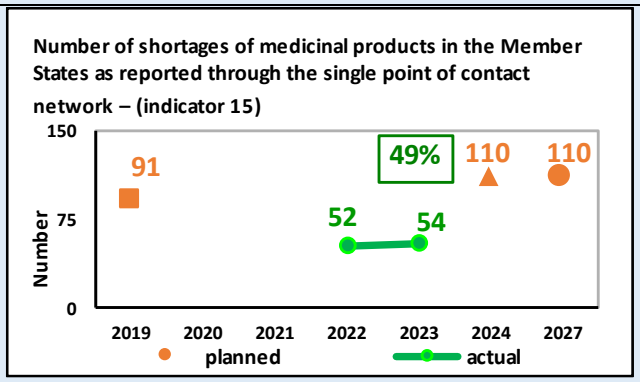
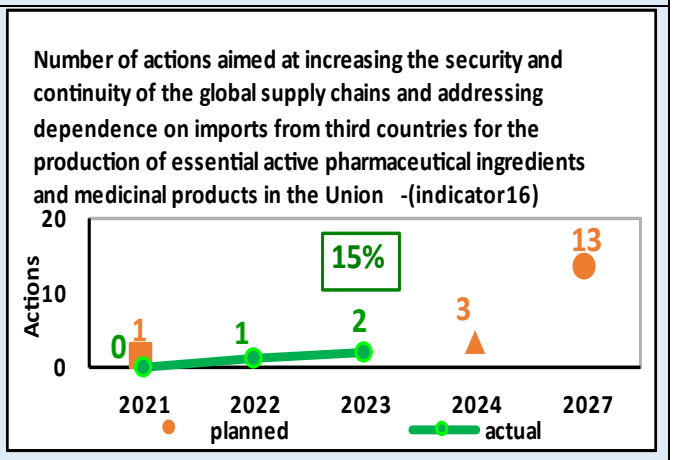
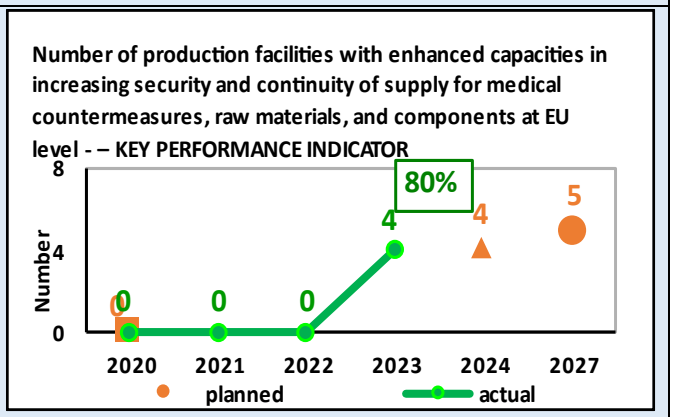
291 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Addressing medicine shortages in the EU*, COM(2023)672 final.

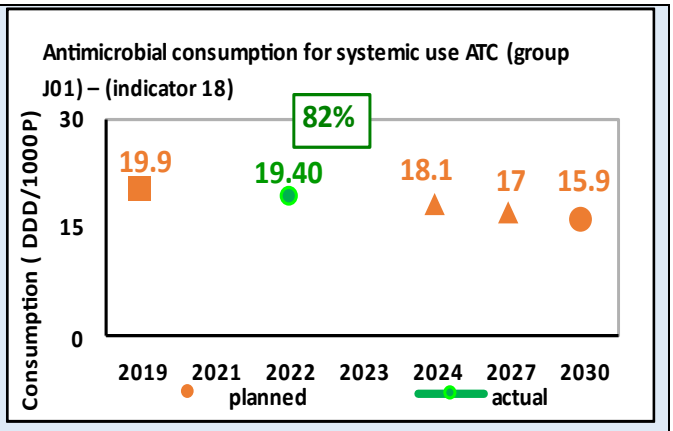
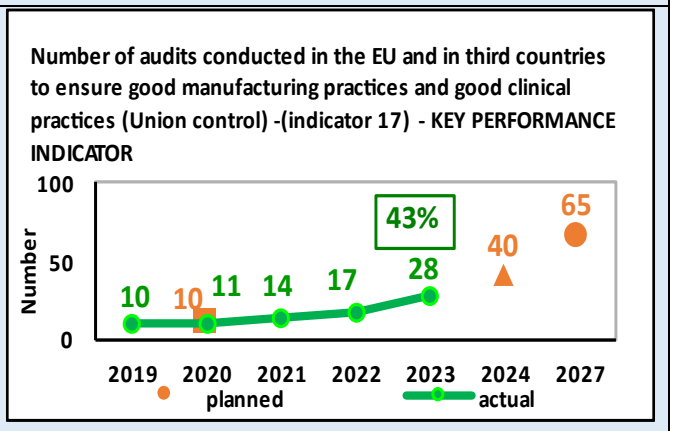
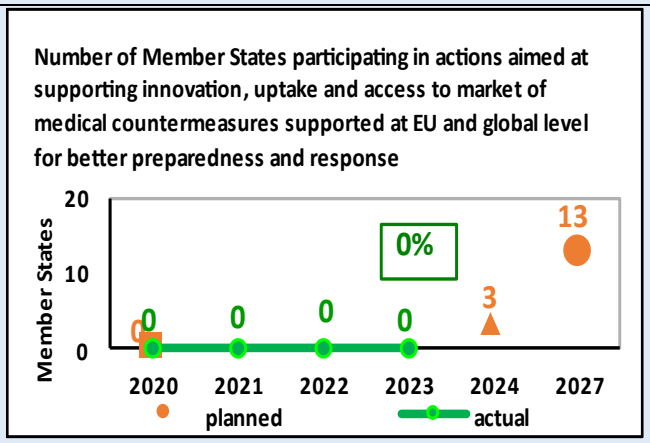
measures proposed in HERA's annual work plans[292]. The EU4Health Programme also supports: actions contributing to the prudent and efficient use of medicinal products, in particular antimicrobials; actions contributing to the development of medicinal products that are less harmful for the environment; and the environmentally friendly production and disposal of medicinal products and medical devices. The implementation of EU regulatory frameworks, such as those for pharmaceuticals, medical devices and substances of human origin (SoHO), is also supported by specific actions and activities. Other actions financed under this strand are expected to increase the capacity building of Member States and strengthen collaboration between the Member States and the EMA.

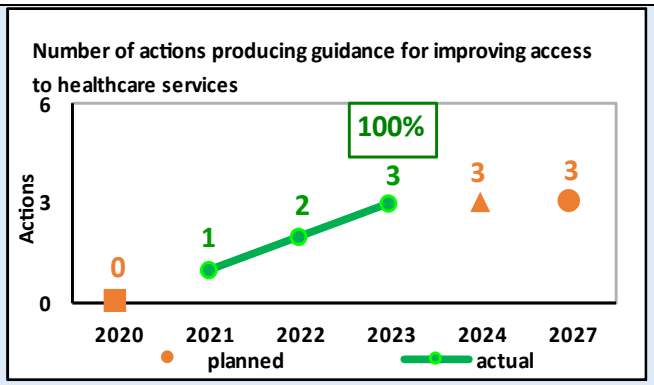
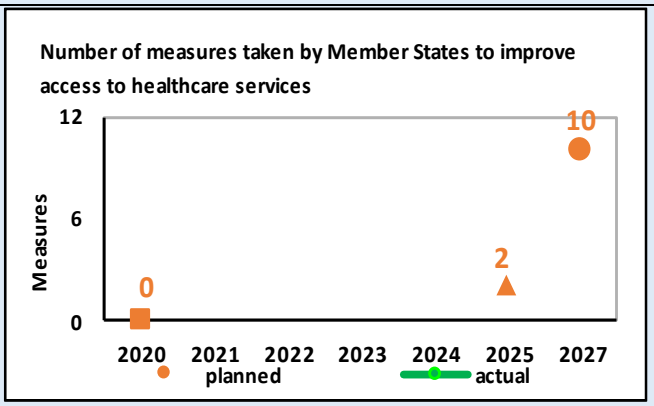
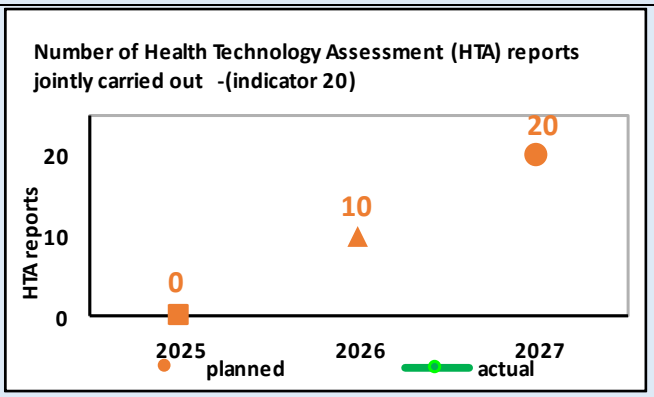
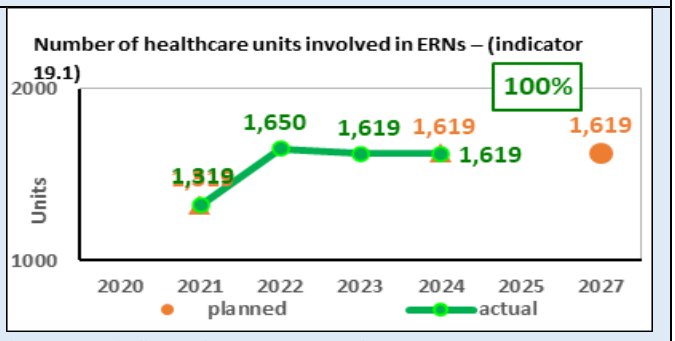
Expected Programme milestones and targets

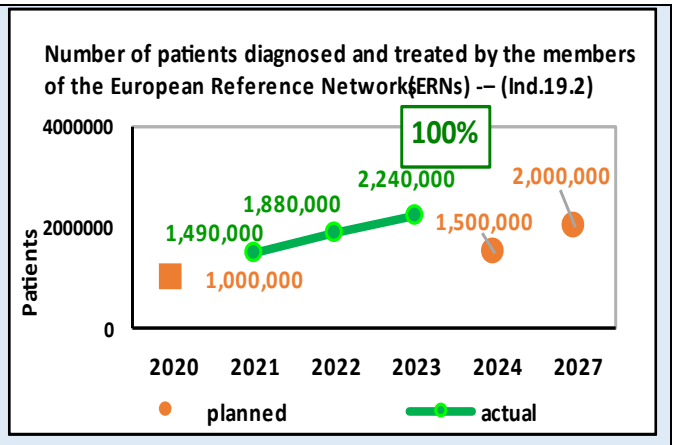
Indicator	**Graph based on recorded values**
Access to centrally authorised medicinal products, for example the number of existing and new orphan authorisations, advanced therapy medicinal products (ATMPs), medicinal products for paediatric use or vaccines, for unmet needs- (indicator 2) – monitoring specific objective (c).	 *Percentage indicates the progress towards 2031 target.
Number of certificates issued by notified bodies under the Medical Device Regulation (MDR) – monitoring specific objective (c).	 *Percentage indicates the progress towards 2027 target.
Number of certificates issued by notified bodies under the In Vitro Diagnostic Medical Devices Regulation (IVDR) – monitoring specific objective (c).	 *Percentage indicates the progress towards 2027 target.

[292] HERA Work Plan 2022, HERA Work Plan 2023, HERA Work Plan 2024.

EU Laboratory capacity index (EULabCap)– (indicator 8) – monitoring specific objective (c).	 *Percentage indicates the progress towards 2027 target.
Number of reported shortages of medicinal products in the Member States through the single point of contact network – (indicator 15) – monitoring specific objective (c).	 *Percentage indicates the progress towards 2027 target.
Number of actions aimed at increasing the security and continuity of the global supply chains and addressing dependence on imports from third countries for the production of essential active pharmaceutical ingredients and medicinal products in the Union -(indicator 16) – KEY PERFORMANCE INDICATOR – monitoring specific objective (c).	 *Percentage indicates the progress towards 2027 target.
Number of production facilities with enhanced capacities in increasing security and continuity of supply for medical countermeasures, raw materials, and components at EU level – KEY PERFORMANCE INDICATOR – monitoring specific objective (c).	 *Percentage indicates the progress towards 2027 target.

Antimicrobial consumption for systemic use ATC (group J01) – (indicator 18) – monitoring specific objective (c).	 *Percentage indicates the progress towards 2030 target.
Number of audits conducted in the EU and in third countries to ensure good manufacturing practices and good clinical practices (Union control) (indicator 17) – KEY PERFORMANCE INDICATOR – monitoring specific objective (c).	 *Percentage indicates the progress towards 2027 target.
Number of Member States participating in actions aimed at supporting innovation, uptake, and access to market of medical countermeasures supported at EU and global level for better preparedness and response – monitoring specific objective (c).	 *Percentage indicates the progress towards 2027 target.

Number of actions producing guidance for improving access to healthcare services – monitoring specific objective (g).	 *Percentage indicates the progress towards 2027 target.
Number of measures taken by Member States to improve access to healthcare services – monitoring specific objective (g).	 *NO data available yet.
Number of Health Technology Assessment (HTA) reports jointly carried out -(indicator 20) – monitoring specific objective (i).	 *NO data available yet.
Number of healthcare units involved in ERNs (indicator 19.1) – monitoring specific objective (i).	 *Percentage indicates the progress towards 2027 target.

Number of patients diagnosed and treated by the members of the European Reference Networks (ERNs) (Indicator 19.2) – KEY PERFORMANCE INDICATOR – monitoring specific objective (i).	 *Percentage indicates the progress towards 2027 target.

Digital

2020 baseline

The ***digital*** strand baseline consisted of the eHealth Network, set up under Article 14 of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare. The eHealth Network was the main forum for cooperation since its inception in the early 2010s. Over the years, the work of the eHealth Network has focused mostly on digital health and health interoperability matters. An existing eHealth Digital Service Infrastructure (eHDSI) computer system was already ensuring continuity of care for European citizens when they travelled abroad within the EU. The eHDSI gave EU countries the possibility of exchanging health data in a secure, efficient, and interoperable way. Citizens could easily recognise the availability of the services under the brand *'MyHealth@EU'*. Two electronic cross-border health services were available in some EU/EEA countries and were in the process of being introduced in all EU countries: ePrescription and eDispensation. Much of the groundwork for these two services was funded through joint actions under the EU4Health Programme's predecessor, the EU's third Health programme (JASeHN[293] and eHAction[294]), which ran from 2014 to 2020. By 2020, seven Member States were connected to these two services, and supported by funding from the Connecting Europe Facility (Telecom) programme[295]. Moreover, the 2019 mission letter of the Health Commissioner Stella Kyriakides underlined the need to make the most of the potential of e-eHealth to provide high-quality healthcare and reduce inequalities by creating the European Health Data Space.

Fragmentation in the infrastructure for the reuse of health data persisted in the EU in 2020, with only 13 Member States having centralised their health data authorities dedicated to the secondary use of health data[296]. This fragmentation continued to hamper the seamless sharing and analysis of health data, which is needed for research and improving health outcomes. For example, in 2021, only 64% of EU Member States had put in place national regulations on the

293 Commission Staff Working Document Accompanying the document Report from the Commission to the European Parliament and the Council Implementation of the third programme of Union action in the field of health, SWD/2020/256 final.

294 Joint Action Supporting the eHealth Network.

295 CEF Telecom.

296 European Parliament resolution of 17 September 2020 on the shortage of medicines – how to address an emerging problem, (2020/2071(INI)).

cross-border sharing of EHR data. Furthermore, only 68% of EU Member States had allocated specific budgets for their digital health strategies, and only 43% had incorporated cloud services into their health systems' infrastructure[297].

In 2020, when the EU4Health Programme was developed, there were already preparatory actions underway for the upcoming regulation to set up the EHDS[298]. The supporting studies[299] for this upcoming regulation showed that people faced difficulties in controlling the sharing of – and access to – their health data. Healthcare professionals also faced difficulties accessing health records and making decisions regarding individual patient's health, particularly in cross-border settings. Moreover, the lack of a consistent framework for the sharing of health data inhibited the reuse of health data by researchers, innovators, regulators, and policy makers for secondary purposes to support their activities. In addition, the COVID-19 pandemic highlighted even further the importance of electronic health data for the development of policy in response to health emergencies. In this context, plans to develop the EHDS were included under the EU4Health Programme to improve the use and reuse of health data.

The baseline for three Programme indicators characterising the digital strand and monitoring the implementation of specific objective (f) were set in 2020 (value 0 and above 0). For more on the setting of these baselines, see Section 2.1, Figure 5.

Current situation and actions

To advance both the digital transformation of health systems and the creation of a European Health Data Space Regulation, the EU4Health Programme is taking several actions under the ***digital*** strand. These actions strengthen the use and reuse of health data for: the provision of healthcare; research and innovation; and regulatory and policymaking activities. The EU4Health Programme is also funding actions that promote the uptake of validated digital tools and services. Some actions will improve users' access to interoperable high-quality data, and facilitate policymaking and regulatory activities, including health research and innovation. They will also provide the foundations for secure and trustworthy access to – and reuse of – health data.

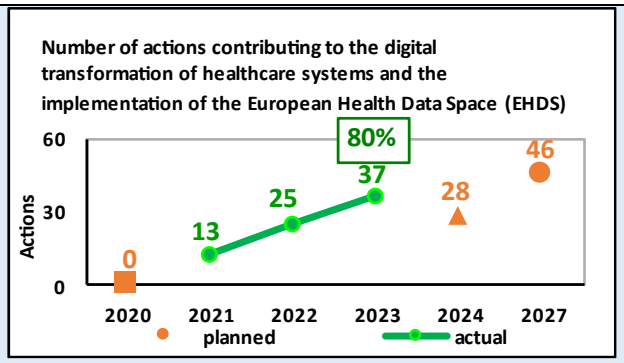
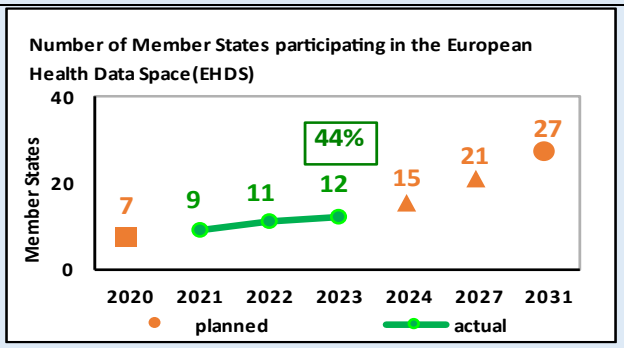
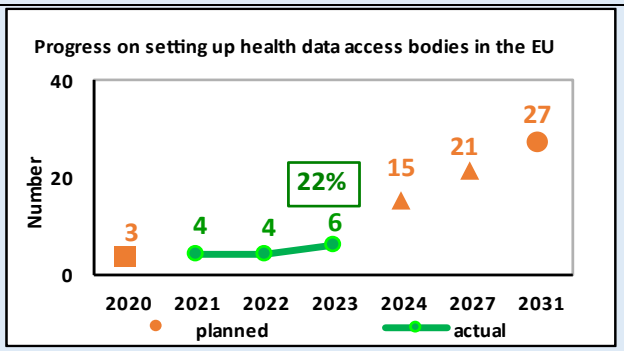
Expected Programme milestones and targets

Indicator	**Graph based on recorded values**

[297] European Parliament resolution of 17 September 2020 on the shortage of medicines – how to address an emerging problem, (2020/2071(INI)).

[298] Proposal for a regulation of the European Parliament and of the Council on the European Health Data Space, COM(2022)197 final.

[299] European Health Data Space - European Commission (europa.eu).

Number of actions contributing to the digital transformation of healthcare systems and the implementation of the European Health Data Space (EHDS) – monitoring specific objective (f).	 *Percentage indicates the progress towards 2027 target.
Number of Member States participating in the European Health Data Space (EHDS) (indicator 5) – monitoring specific objective (f).	 *Percentage indicates the progress towards 2031 target.
Progress on setting up health data access bodies in the EU – monitoring specific objective (f).	 *Percentage indicates the progress towards 2031 target.

Cancer

2020 baseline

In 2019, **cancer** became one of the main political priorities of the von der Leyen Commission, and a European plan to fight cancer and support Member States in improving cancer control and care was announced in President von der Leyen's political guidelines. The 2019 mission letter to the Health Commissioner Stella Kyriakides asked her to draw up a European plan to beat cancer, which was adopted in February 2021. Europe's Beating Cancer Plan (the Cancer Plan) was the first all-encompassing plan at EU level to tackle the whole disease pathway, a holistic plan bringing together scientists, patients, researchers and further stakeholders for the first time, strengthening the Commission's political commitment to beating cancer. The baseline for the cancer strand of the EU4Health Programme is broadly described in the Cancer Plan. The EU has now been working to tackle cancer for decades, and its actions, for example on tobacco control and protection from hazardous substances, have saved and prolonged

lives[300]. The final evaluation of the EU's third Health Programme[301] highlights that about EUR 19 million was invested in a variety of cancer-related actions over the course of the Programme (which ran from 2014-2020). These actions included: support for screening programmes in the Member States; improving the quality of patients' lives; addressing survivorship issues; assessing the impact of cancer research; and facilitating the uptake of innovative treatments. More than half of this amount, EUR 11 million, was allocated to addressing major risk factors of cancer and other chronic diseases, i.e. alcohol and tobacco control, physical activity and nutrition. By 2020, 6 Member States were implementing the European accreditation scheme for breast cancer services, a decrease from 10 in 2018. By 2019, the European Quality Assurance scheme was developed in a harmonised, evidence-based, and flexible way to grant equal and quality-benchmarked healthcare treatment to patients. The activities of the European Network of Cancer Registries coordinated by the Joint Research Centre (JRC) provided a data-brokering service to ensure the integrity of a single European dataset for different purposes. The European Cancer Information System (ECIS) hosting data from128 cancer registries in 29 European countries has now been set up (including on breast, colorectal and cervical cancers) providing data from more than 25.9 million records and giving access to researchers and specialised healthcare professionals as tools for: improving and accelerating diagnostics; and providing patients with more tailored treatments[302].

The baselines for two Programme indicators characterising the cancer strand and monitoring the implementation of the specific objective (a) were set in 2015 (values above 0), and the baseline for three such indicators were set in 2015 (values above 0). The baseline for one indicator is under development. For more on the setting of these baselines, see Section 2.1, Figure 6.

Current situation and actions

The ***cancer*** strand supports the nine flagship initiatives of the Cancer Plan: the Knowledge Centre on Cancer; the Cancer Diagnostic and Treatment for All initiative; the European cancer imaging initiative; the initiative to eliminate cancers caused by human papillomavirus (HPV); the initiative to ensure a better life for cancer patients; the EU cancer screening scheme; the European Cancer Inequalities Registry; the EU network of national comprehensive cancer centres; and the initiative on helping children with cancer[303]. The EU contributes to the Cancer Plan through many other actions, described in the list of actions[304], which are supported by the EU4Health Programme and other EU funding programmes such as Horizon Europe (and its EU Cancer Mission), and the Digital Europe programme.

Expected Programme milestones and targets

Indicator	**Graph based on recorded values**

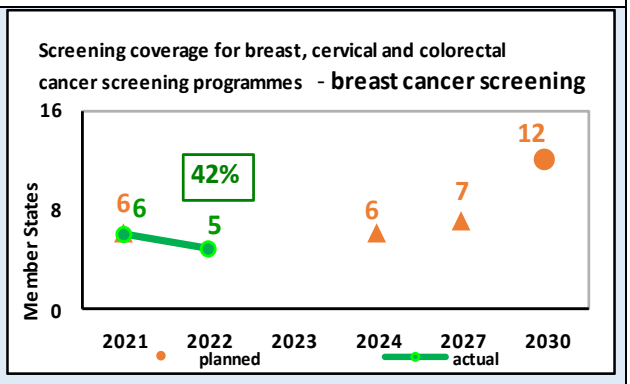
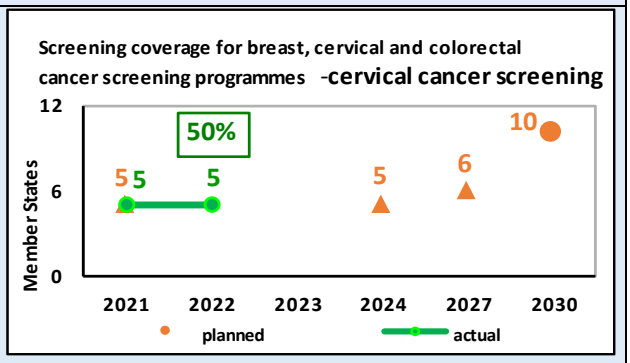
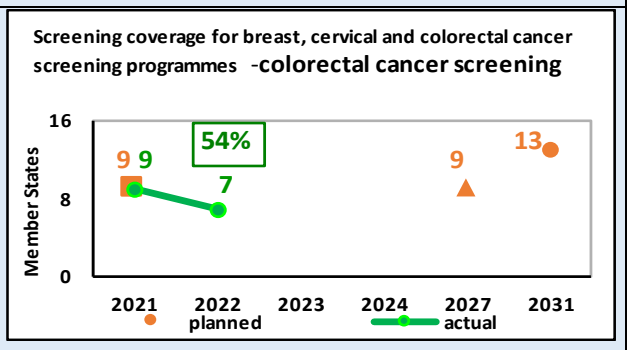
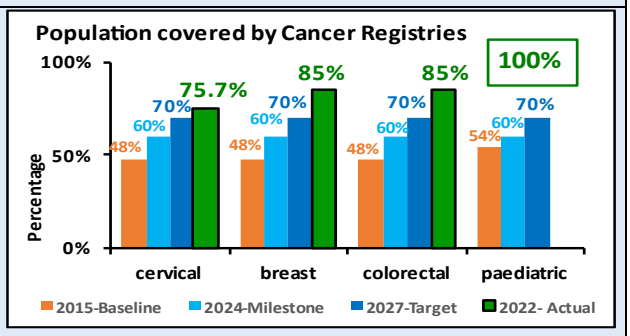
300 Communication from the Commission to the European Parliament and the Council Europe's Beating Cancer Plan, COM(2021)44 final.

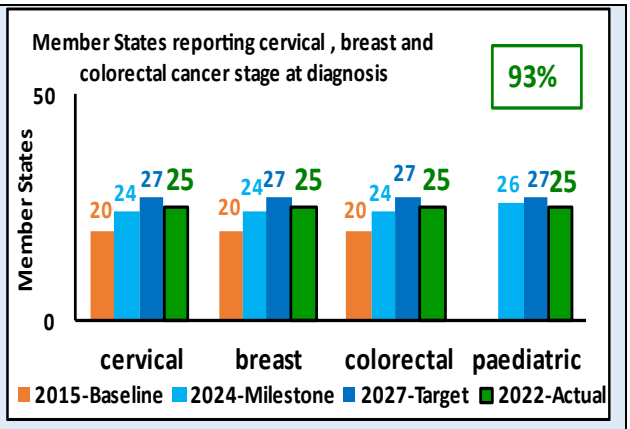
301 Commission report – Final evaluation of the third Health Programme 2014-2020.

302 Staff Working Document on Ex-Post Evaluation of third Health Programme SWD(2023) 369 final.

303 Factsheet – Europe's Beating Cancer Plan flagship initiatives.

304 Annexes to the European Commission communication on Europe's Beating Cancer Plan, COM(2021)44 final ANNEX.

Age-standardised five-year net survival rate for paediatric cancer (to the extent available) – (indicator 9) – monitoring specific objective (a).	Not available/not defined yet.
Screening coverage for breast, cervical and colorectal cancer screening programmes – Breast cancer screening coverage – (sub-indicator 10.1) monitoring specific objective (a).	 *Percentage indicates the progress towards 2030 target.
Screening coverage for breast, cervical and colorectal cancer screening programmes – Cervical cancer screening coverage – (sub-indicator 10.2) monitoring specific objective (a).	 *Percentage indicates the progress towards 2030 target.
Screening coverage for breast, cervical and colorectal cancer screening programmes – Colorectal cancer screening coverage – (sub-indicator 10.3) monitoring specific objective (a).	 *Percentage indicates the progress towards 2031 target.
Percentage of population covered by Cancer Registries reporting information on cervical, breast, colorectal and paediatric cancer stage at diagnosis – (indicator 11) – monitoring specific objective (a).	 *Percentage indicates the progress towards 2027 target.

Number of Member States reporting information on cervical, breast, colorectal and paediatric cancer stage at diagnosis – monitoring specific objective (a).	 *Percentage indicates the progress towards 2027 target.

General cross-cutting actions (covering specific objective (h)) and **global health initiatives** (specific objective (j)).

2020 baseline

The **development, implementation, enforcement and revision of EU health legislation** was already supported by the EU4health Programme's predecessor, the third Health programme, which ran from 2014 to 2020 and funded studies, evaluations and impact assessments.

Ensuring that all existing and new EU health legislation is soundly developed and properly implemented requires continued support from the EU4Health Programme. This support covers the delivery of studies informing impact assessment, activities by Commission expert groups, the creation of databases and IT tools, etc.

The baseline for two Programme indicators monitoring the implementation of actions supporting the development, implementation, enforcement and revision of EU health legislation and of specific objective (h) were set in 2020 (value 0). For more on the setting of these baselines, see Section 2.1, Figure 7.

Before the EU Global Health Strategy was adopted in 2022, and even before EU4Health actions were deployed in the summer of 2021, **EU action in global health** was guided by policy set in 2010[305, 306], which drew up the principles for a stronger EU vision, voice, and action on global health. These principles were: leadership, universal coverage, coherence of EU policies, and knowledge. The EU has long supported the World Health Organization as the leading authority on global health in the United Nations system, and the EU speaks with one voice in the WHO's governing bodies. The Commission cooperates with the WHO Secretariat on health security, R&D, noncommunicable diseases, health inequalities, health systems and health information. The EU also supports other global health multilateral processes, and in particular: the UN Human Rights Council; the UN General Assembly initiative on Non-Communicable Diseases; the health-related Sustainable Development Goals; the Framework Convention on Tobacco Control; and the post-2015 development agenda[307].

305 Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, *The EU Role in Global Health*, COM(2010)128 final.

306 Council conclusions on the EU role in Global Health, 2010.

307 The EU in Global Health.

The baseline for one Programme indicator was set in 2020 (value 0). And the baselines for two Programme indicators (one of which was to monitor the implementation of actions supporting the international health initiatives and cooperation, and the other was to monitor specific objective (j)) were set in 2022 (value 0). For more on the setting of these baselines, see Section 2.1, Figure 7.

Current situation and actions

The EU has a central role to play in tackling ***global health challenges*** and the EU4Health Programme consolidates EU support for the EU Global Health Strategy, international health initiatives and cooperation with the WHO. The EU4Health Programme also supports cooperation with non-EU countries, in particular the exchange of knowledge and best practices to improve health systems' preparedness and response capacity. For EU candidate countries, the EU4Health Programme will help to align their respective health systems with EU health standards. The Programme helps to strengthen the global structures for responding with medical countermeasures to health emergencies. It does this in by financing both: the collaboration between EU and international partners; and the implementation of a variety of actions (such as the global consortium for wastewater surveillance, clinical trials, AMR initiatives, sequencing and environmental surveillance capacities, and enhancing data collection and exchanges).

The EU4Health Programme works in synergy with other EU funding instruments, for example the EU research and innovation framework programme, Horizon Europe, where many actions on health research have results and outputs taken up by health policies and healthcare systems. These actions on health research include Cluster 1 'Health', the Cancer Mission[308] and various European partnerships (such as the partnership on transforming health and care systems[309], the partnership on personalised medicine, the partnership on rare diseases, etc.).

The Joint Transnational Call 2023 'Healthcare of the Future' is an EU-funded call for tenders that aims to: (i) encourage research on optimising patient care pathways; and (ii) contribute to the transition towards more sustainable, efficient, resilient, ethical, high-quality, and accessible person-centred healthcare systems. The 2024 Joint Transnational Call 'Innovate to Prevent' will fund projects to support the implementation of innovative person-centred health and care models addressing prevention strategies, with help from existing IT and digital technologies and services.

The EU4Health Programme supports ***cross-cutting actions*** for the development, implementation, enforcement and, where necessary, evaluation and revision of EU health legislation. It finances the provision of valid, reliable, and comparable high-quality data for evidence-based decision-making and monitoring. It also promotes health impact assessments of other relevant EU policies.

The EU4Health Programme also supports ***recurrent actions*** and activities, such as: communication activities; the organisation of health-related events; and logistical support for meetings of expert groups and relevant scientific committees[310] in the field of risk assessment

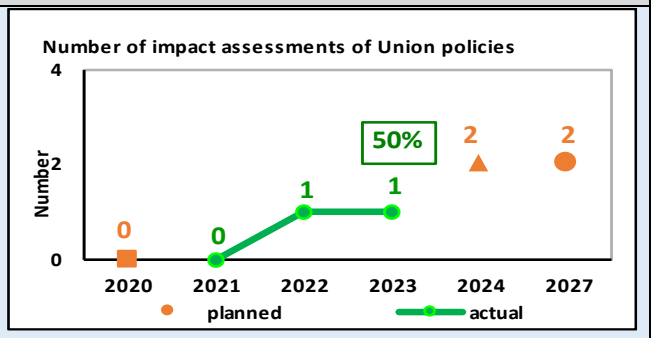
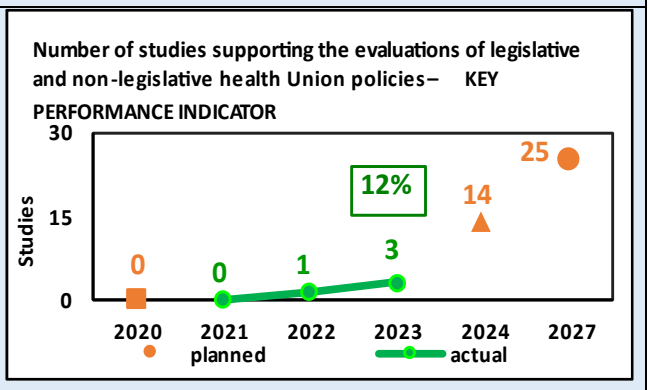
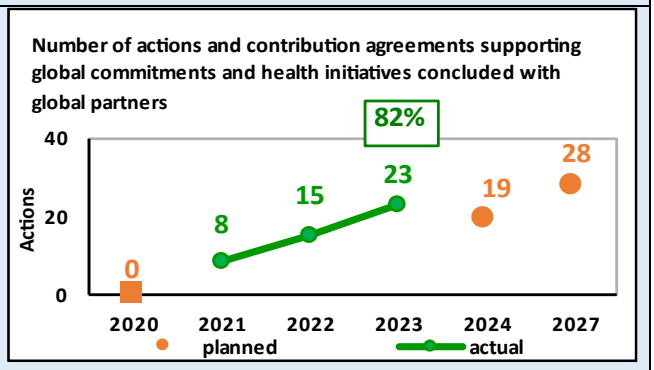
308 EU Mission: Cancer.

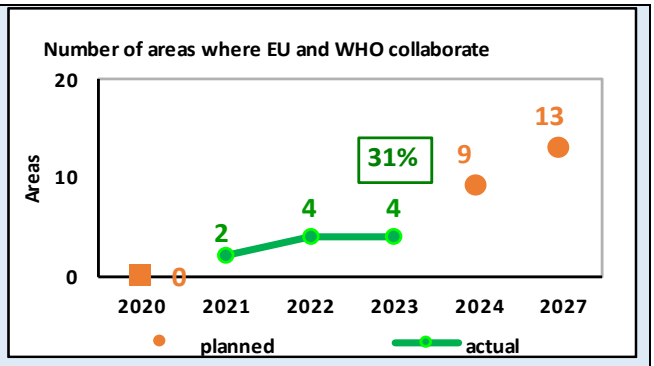
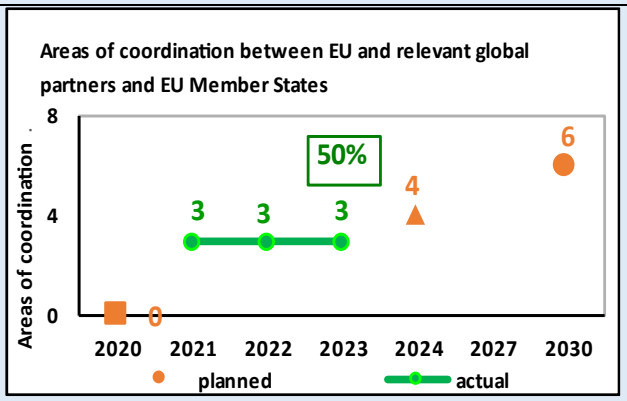
309 European Partnership on transforming health and care systems.

310 For example, the Scientific Committee on Consumer Safety, Scientific Committee on Health, Environmental and Emerging risks, etc. cover specific objectives (h) and (j) from Article 4 of the EU4Health Regulation.

for health, environment, emerging risks, and consumer safety. Lastly, the EU4Health Programme also supports interaction with stakeholders and synergies among different stakeholder groups including through the EU Health Policy Platform.

Expected Programme milestones and targets

Indicator	Graph based on recorded values
Number of impact assessments of Union policies.	 *Percentage indicates the progress towards 2027 target.
Number of studies supporting the evaluations of legislative and non-legislative health Union policies – KEY PERFORMANCE INDICATOR.	 *Percentage indicates the progress towards 2027 target.
Number of actions and contribution agreements supporting global commitments and health initiatives concluded with global partners.	 *Percentage indicates the progress towards 2027 target.

Number of areas where the EU and WHO collaborate.	 *Percentage indicates the progress towards 2027 target.
Areas of coordination between EU and relevant global partners and EU Member States.	 *Percentage indicates the progress towards 2030 target.

ANNEX VIII. CURRENT STATE OF PLAY – PROGRAMME PERFORMANCE, CONTRIBUTION TO EU'S CROSS-CUTTING PRIORITIES

Programme performance 2021-2023 in a nutshell[311]

By early 2024, all 593 actions of the annual work programme for 2021 and 2022 had been launched, and almost all the actions from 2023 had been launched. By early 2024, the implementation of the 2024 annual work programme was also on schedule, with 22 actions launched[312].

- ✓ *Contribution to EU cross-cutting priorities.* The EU4Health Programme has contributed to gender equality with EUR 178.1 million in funding, and to the digital transition with EUR 349.6 million in funding. Additional investment in gender equality and the digital transition is planned in the 2024 annual work programme (EUR 25.75 million). The funds allocated by the EU4Health Programme to 'One Health' actions vary over the year. The total committed EU4Health budget over the 2021-2024 period contributing indirectly to green budgeting priorities is about EUR 314 million.

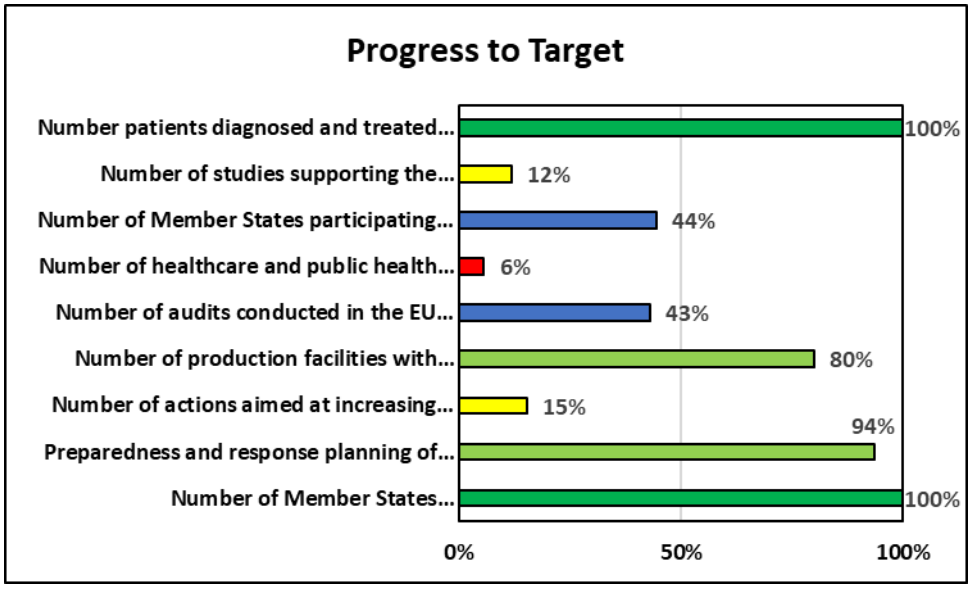


Figure 4: EU4Health key performance indicators.

311 EU4Health Programme – Programme Performance Statement, 2024.

312 The Programme Performance Statement, as part of the Commission's strategic planning and programming cycle, is a key tool for annual reporting on the results achieved, challenges encountered and areas for possible improvement.

Out of 9 **key performance indicators**[313] related to flagship health policies[314] the target for 2 indicators has been achieved. Policies are on track for 4 indicators, while moderate progress has been achieved for 2 others. Attention is still needed for one indicator.

The programmed budget vs the committed budget[315]

The EU4Health Programme has well-established governance programming and implementation processes in place. Employing these processes, the parent DGs have *programmed* about EUR 2.63 billion in four annual work programmes (2021, 2022, 2023 and 2024). This represents more than half (57.2%) of the EUR 4.6 billion total revised EU4Health budget. About 90% of the EU4Health Programme's programmed budget is implemented under direct management through grants, prizes and procurement (i.e. EUR 2.37 billion), and the remaining 10% is implemented under indirect management through contribution agreements and co-delegation with other Commission DGs[316] (i.e. EUR 0.26 billion).

The contracting authority[317] has *committed* about EUR 1.39 billion by signing 726 contracts, which represents more than half (53%) of the programmed budget in years 2021 to 2024. Most of the committed budget, i.e. EUR 1.16 billion, was assigned under direct management, while EUR 0.23 billion was assigned under indirect management (see Figure 8).

About two thirds of the direct management commitments (EUR 742 million) were accomplished through *grants*, and almost a third (EUR 420 million) were accomplished through *procurement*. Prizes were used once in 2021 work programme and the amount allocated through that form of funding was EUR 0.4 million.

313 See Annex 2 of the PPMEF.

314 Healthier Together Initiative, Cross-border threats to health Regulation (EU) 2022/2371, Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union (COM(2021)576 final), the pharmaceutical strategy for Europe (COM(2020)761 final), the planned European Health Data Space (COM(2022)197 final), the European Reference Networks (C/2019/5470), etc.

315 Programmed amounts refer to budgetary allocations planned within a EU funding work programme actions, whereas committed amounts are those already formally obligated through legal contracts or agreements when implementing those actions.

316 DG ECFIN.

317 In most cases HaDEA, and for some procurements and all the contribution agreements the parent DGs.

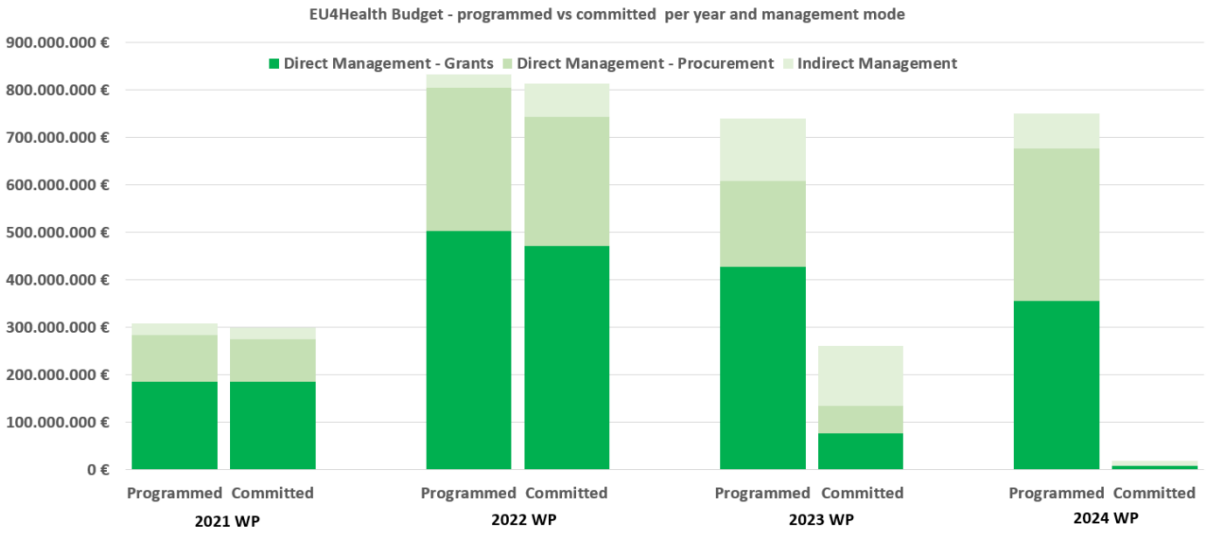


Figure 5 EU4Health budget – programmed vs committed per year and management mode.

During the period covered by this interim evaluation, in direct management, HaDEA commitments were made in four ways. The first way was via action grants following open calls for proposals (EUR 171.36 million). The second way was via operating grants (EUR 23.16 million). The third way was upon invitation for joint actions (EUR 295.79 million). The fourth way was upon invitation for other direct grants (EUR 251.54 million). HaDEA and the parent DGs committed: EUR 62.8 million for procurement open calls for services; EUR 190.61 million for specific contracts under framework contracts; EUR 143.24 million for negotiated procedures and other procurement such as prizes; and EUR 23.30 million for administrative arrangements and service-level agreements.

The EUR 231.70 million in total commitments under indirect management were accomplished by the parent DGs. This includes EUR 121.70 million for contribution agreements with 'pillar-assessed'[318] international organisations and EUR 110 million for co-delegation to DG ECFIN.

Investments and results

The largest investment was made under specific objective (b) on the prevention of and response to cross-border health threats, followed by: specific objective (a) on health promotion and disease prevention; specific objective (i) on integrated work on national health systems; specific objective (f) on digital transformation; specific objective (c) on access to medicines and medical products; specific objective (g) on access to healthcare; specific objective (h) on support for health legislation; specific objective (j) on global health commitments; specific

[318] The purpose of the *ex-ante* assessment ('pillar assessment') is to check whether entities to be entrusted by the Commission with budget implementation tasks under indirect management demonstrate a level of protection of the EU's financial interests equivalent to that existing when the Commission implements the budget itself. It must be guaranteed that the entity or person carrying out the action respects the principles of sound financial management, transparency, non-discrimination and visibility of the EU action (Article 154(2) of Regulation (EU, Euratom) 2018/1046).

objective (d) on EU stockpiling; and specific objective (e) on an EU reserve of medical staff (**see Figure 6**).

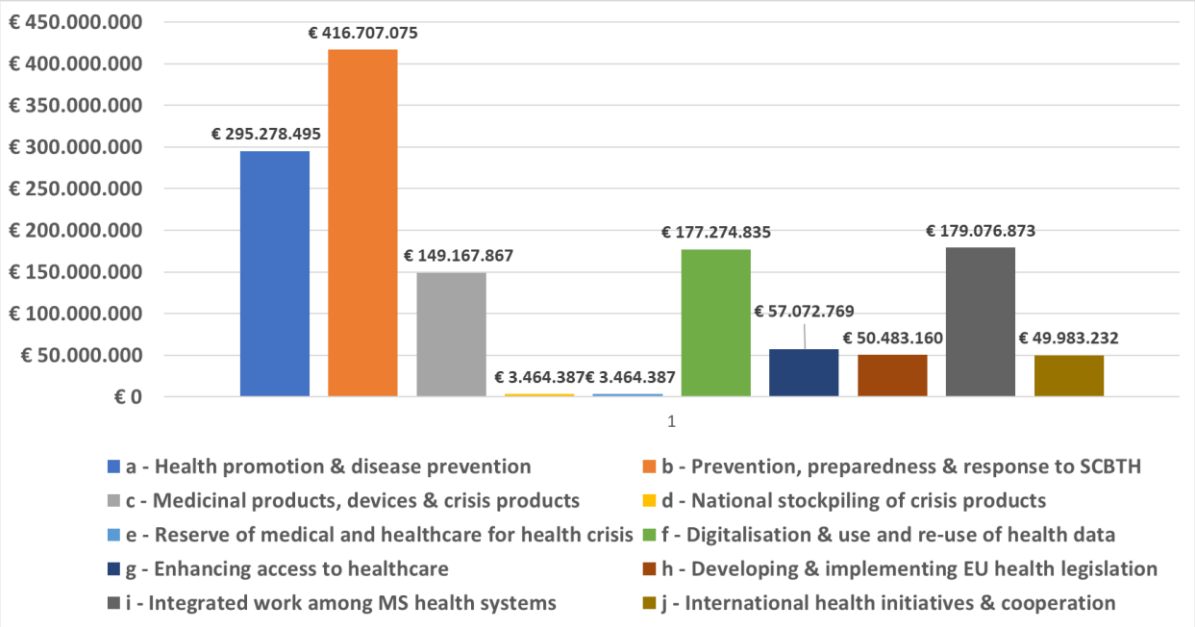


Figure 6 Total EU4Health commitments under each specific objective

The EU4Health Programme strands include actions that implement two or more specific objectives, and almost all strands include actions with a global health dimension.

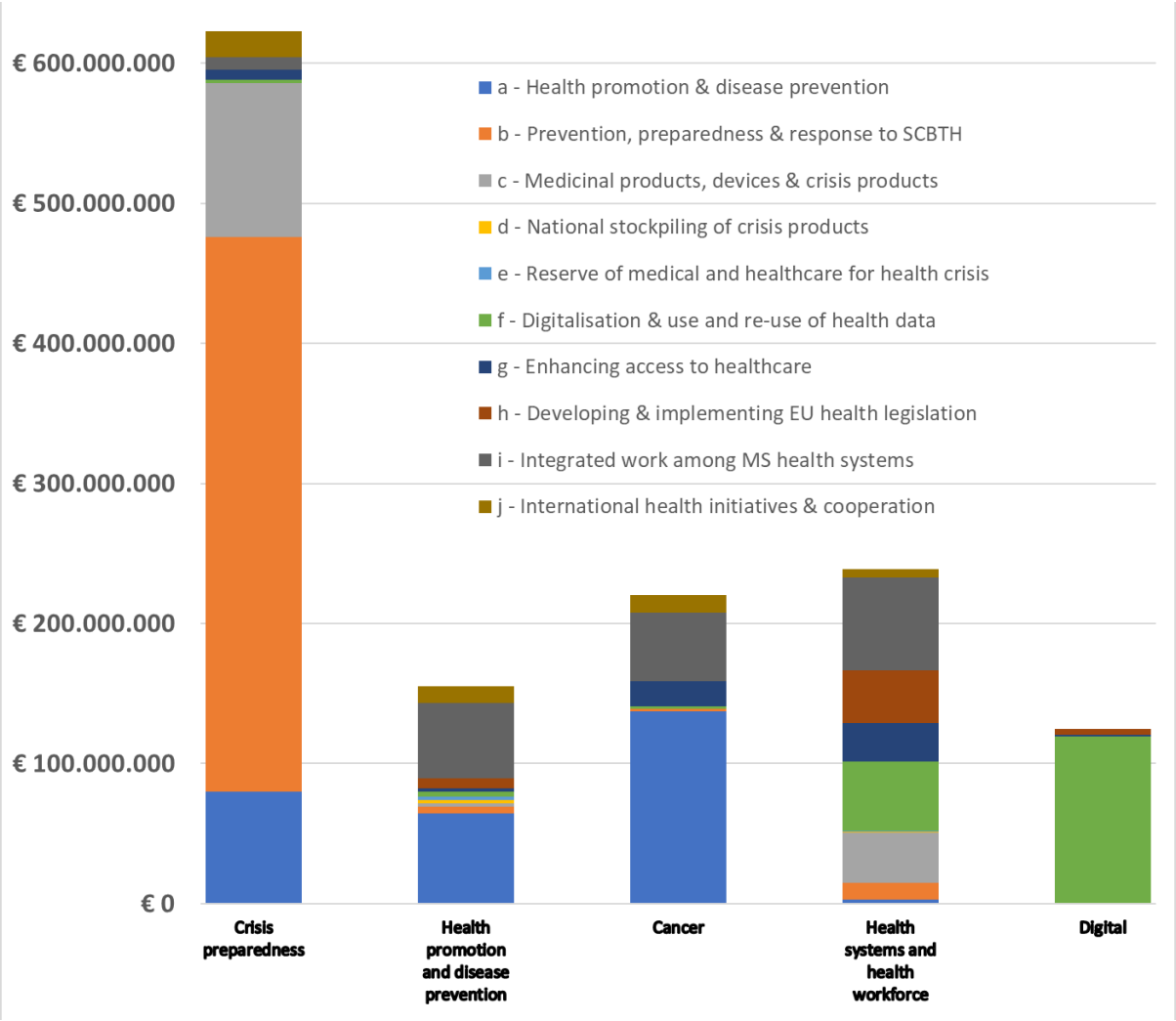


Figure 7 Total commitments by strand and specific objectives

Crisis preparedness

Since the EU4Health implementation began in January 2021, by April 2024, the contracting authorities had committed EUR 623 million and signed 103 actions that contribute to the crisis preparedness strand. EUR 395.69 million was allocated to the specific objectives on prevention and response to cross-border health threats including antimicrobial resistance (b), while EUR 110.41 million was allocated to actions on access to medicines and medical devices (c). In addition, EUR 79.45 million was allocated to actions on health promotion and disease prevention (a), and EUR 18.86 million was allocated to contribute to the international health initiatives (j). There are no programmed actions yet complementing the actions on national stockpiling (d) and the actions on reserve for medical and healthcare staff (e).



Figure 8 The distribution of crisis preparedness investments per specific objective

70.2% of the EU4Health Programme's budget is committed to countermeasure actions, while the remaining 29.8% addresses cross-border threats to health. These commitments also support the first actions to set up a structure and training resources for a reserve of medical, healthcare and support staff.

The largest single investment (EUR 361.7 million) supports: EU FAB, a network of 'ever-warm' production capacities for manufacturing vaccine and medicines; the procurement of vaccines against infectious diseases; and the national action plans on AMR. Other funded actions: ensure fast access to manufacturing capacities in the event of outbreaks of diseases; strengthen the fight against AMR; and improve surveillance of health threats.

In addition, in a joint action (funded with EUR 15 million) 26 Member States are collaborating on the surveillance of their national wastewater[319]. In another action[320] (receiving EUR 7 million

319 EU-WISH.
320 UNITED4Surveillance (January 2023 - December 2025).

in funding), 22 Member States are working to deploy state-of-the-art national and European surveillance systems and a coordinated response among the Member States to any future cross-border threats to health. The EU has strengthened the One Health collaboration including on AMR policies with the WHO and the OECD. The overall committed EU4Health funding for actions tackling AMR amounts to EUR 56.48 million. EU collaboration with partners such as the WHO and the Global Antibiotic Research & Development Partnership strengthens global health security and ultimately ensures better protection against cross-border health threats.

30 EU Member States and associated countries participate in more than one EU action aimed at improving prevention, preparedness and response planning for serious cross-border threats to health. As expected, 171 healthcare staff were trained on preparedness and response to cross-border health threats. One Health surveillance programmes were successfully implemented in eight countries and the total consumption (community and hospital sectors) of antibacterials for systemic use was 19.40 defined daily doses (DDD) per 1000 population and within the expectations. The data for the remaining Programme indicators on prevention and response to cross-border health threats are progressively becoming available.

Health promotion and disease prevention

EUR 155.4 million was committed to 108 health promotion and disease prevention actions (this does not include investments in the fight against cancer). EUR 64.74 million of the budget implements mainly the specific objective on health promotion and disease prevention (b). The health promotion and disease prevention strand also receives: (i) EUR 53.81 million in contributions from actions implementing specific objective (i) on integrated work among Member States health systems; (ii) EUR 12.25 million implementing specific objective (j) on global health initiatives and cooperation; and (iii) smaller amounts from all other specific objectives[321].

[321] The budget of the operating grants has been distributed equally over all specific objectives, given that these types of grants cover usually a broad spectrum of activities.

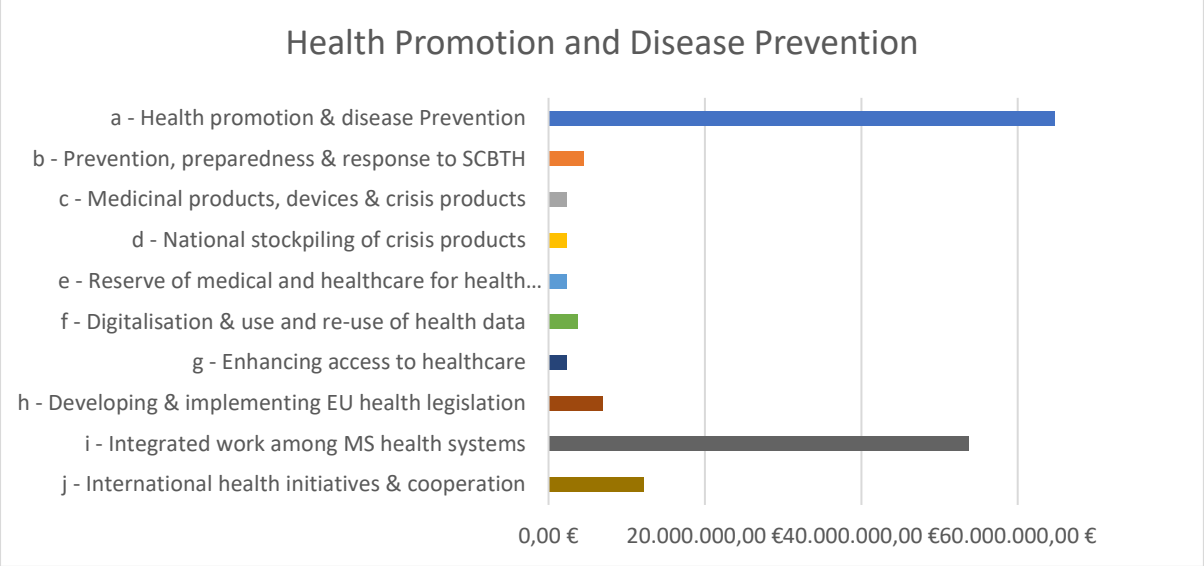


Figure 9 The distribution of investments in the health promotion and disease prevention strand per specific objective

37.1% of the strand's budget was committed to prevention of cardiovascular disease and diabetes. The other policy areas covered are mental health support to Ukraine (16.9%), operating grants (14.9%), mental health in the EU (7.8%), preventive work to improve mental health (4.3%), prevention risk factors (6.2%), HIV and AIDS (4.3%), prevention of NCDs (2.6%), tobacco-related actions (2.4%) chronic respiratory diseases (1.9%) and other related actions (1.6%).

For example, 17 actions contribute to reducing avoidable mortality in the area of NCDs and associated risk factors. 25 Member States implement 'best' and 'promising' practices addressing health promotion, disease prevention and health inequalities, rolling out these practices at the national level with EU funding support. There are three funded actions addressing the prevalence of harmful use of alcohol and seven actions addressing environmental risk factors for health[322]. On vaccination, two EU Member States have reached 95% coverage for both the first and the second dose of the measles vaccine for eligible people, while two EU Member States reached 75% coverage for the seasonal influenza vaccine in older age groups.[323]

Data from the 2022 EU4Health Programme indicators show that Member States are exchanging best and promising practices to reduce the burden of NCDs more than expected. Finally, eight actions contribute to reducing avoidable mortality in the area of non-communicable diseases and risk factors, which is almost twice as many as had been expected.

Health systems and healthcare workforce

322 EU4Health Programme Performance Statement 2024.

EUR 239 million was committed for 288 actions under the strand on *health systems and healthcare workforce.* EUR 66.66 million of that is implementing mainly specific objective (i) on integrated work among Member States health systems, while EUR 49.74 million is going to support the digitalisation, use and reuse of health data (specific objective (f)). In addition: EUR 37.23 million is being allocated to the development and implementation of health legislation (specific objective (h)); EUR 35.75 million is supporting access to medicines and medical devices (specific objective (c)); EUR 27.5 million is going to enhance access to healthcare (specific objective (g)); and EUR 12 million to the specific objective on prevention and response to cross-border threats to health (specific objective (b)). Some of the actions under this strand are benefiting from EUR 5 million to support global health initiatives (specific objective (j)).

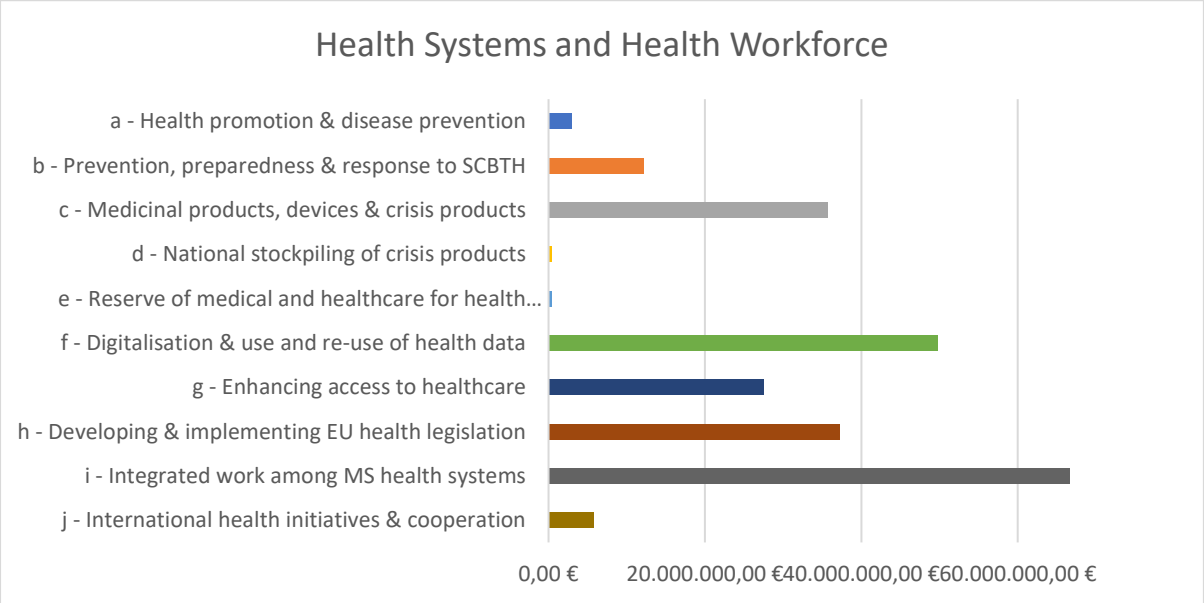


Figure 10 The distribution of investments in the health systems and health workforce strand per specific objective

42.2% of the investments in the strand on health systems and the healthcare workforce are allocated to ERNs and 25% to health system resilience and the healthcare workforce. The remainder is distributed to implementation of the pharmaceutical strategy and related legislation (11.7%), the regulation of medical devices (9.1%), substances of human origin (almost 5.9%), HTA (2.1%), global health (2%), and improving the access of Ukrainian refugees to healthcare (2%) and others.

The work of the ERNs for Rare Diseases has been supported in this strand with EUR 100.47 million[324] to facilitate the exchange of best practices, increase collaboration, and increase the comparability of the ERNs' outputs.

[324] EU4Health Dashboard policy area ERNs.

EUR 52.5 million was allocated under this strand to actions to improve the resilience of health systems by, for example, strengthening primary care systems. To help test the resilience of health systems, a contribution agreement between the OECD and the European Observatory on Health Systems and Policies was carried out. This developed a methodology for testing the resilience of health systems, and this methodology is now publicly available to European health authorities[325].

Medicines and medical devices are specific categories of products available on the single market. Aspects like their manufacturing, certification or access to the market are regulated at EU level. Implementation of the legislation that regulates these aspects is supported by EU4Health funding worth EUR 21.70 million. The funds support: the maintenance of the European Medical Device Nomenclature[326]; the development and maintenance of the EUDAMED database[327]; and the creation of the EU common standard for ePI (electronic medicinal product leaflet information).

Several actions contribute to improving access to healthcare with the aim of achieving universal health coverage. Three actions that will produce guidance for improving access to healthcare services were launched to support policymaking in Member States on measures to improve access to healthcare services. Access to healthcare is one of the principles of the European Pillar of Social Rights[328]. Actions under the EU4Health Programme, with funding worth EUR 24.83 million, help Member States to design better policies for access to healthcare, considering in particular the needs and challenges faced by vulnerable groups. The EU4Health actions in this area present Member States with policy solutions for: more affordable healthcare; the fairer distribution of health benefits; and improving access to healthcare for people with disabilities.

The Programme indicators show that, as expected, 1 619 healthcare units were involved in ERNs by mid-2024, and the number of patients diagnosed and treated by the members of ERNs was 2.24 million, which is 50% more than the 2024 milestone[329].

103 medicines received an EU-wide authorisation in 2022, and this decreased to 68 in 2023. 5 599 certificates[330] were issued in 2023 for new medical devices, which is almost three times more than in 2022, and 702 certificates were issued in 2023 for in vitro diagnostic medical

325 Strengthening Health Systems: A Practical Handbook for Resilience Testing.
326 European Medical Device Nomenclature.
327 EUDAMED – provide a living picture of the lifecycle of medical devices that are made available in the European Union (EU). It will integrate different electronic systems to collate and process information about medical devices and related companies (e.g. manufacturers). In doing so, EUDAMED aims to enhance overall transparency, including through better access to information for the public and healthcare professionals, and to enhance coordination between the different Member States in the EU.
328 Principle 16: Everyone has the right to timely access to affordable, preventive and curative healthcare of good quality.
329 PPS 2024.
330 Issued by notified bodies under Regulation (EU) 2017/745 on medical devices intended to be placed on the EU market.

devices, which is almost twice as many as were approved in 2022[331]. The level of relevant shortages of human and veterinary medicines remained under control.

Two actions in this area help to address dependence on imports from third countries for essential active pharmaceutical ingredients and medicinal products. As planned, 28 audits were conducted in the EU and in third countries, including candidate countries, to ensure good manufacturing practices and good clinical practices (EU control). In addition, EU Member States participated in actions to support innovation in, uptake of and access to the market for medical countermeasures at EU and global level[332].

Digital

Investments of EUR 124.96 million in the strand on ***digital*** are promoting mainly specific objective (f) on digitalisation and the use and reuse of health data. Some of the investment under this strand is funding actions to implement the specific objectives on developing and implementing EU health legislation (specific objective (h)), and the one on enhancing access to healthcare (specific objective (g)).

The investments are balanced between the primary and the secondary use of data. Of the total budget under this strand, 45.6% is invested in the primary use of health data as part of the action MyHealth@EU (an additional EUR 3.8 million is invested in a joint action)[333]. In addition, 3.1% of the budget under this strand is being invested in the primary use of data for patient-facing services, and 2.5% is being invested in databases for EHR systems. The actions on the secondary use of data support the setting up of services by health data access bodies, with 33% of the budget from this strand. The secondary use of health data is also receiving 8.6% of this strand's budget via Healthdata@EU. Consequently, the actions to support the primary use of health data are receiving 58.4% of this strand's budget and the actions to support the secondary use of health data are receiving 41.6% of this strand's budget.

331 Issued by notified bodies under Regulation (EU) 2017/746 for medium- and high-risk devices intended to be placed on the EU market.

332 PPS 2024.

333 Extended EHR@EU Data Space for Primary Use.

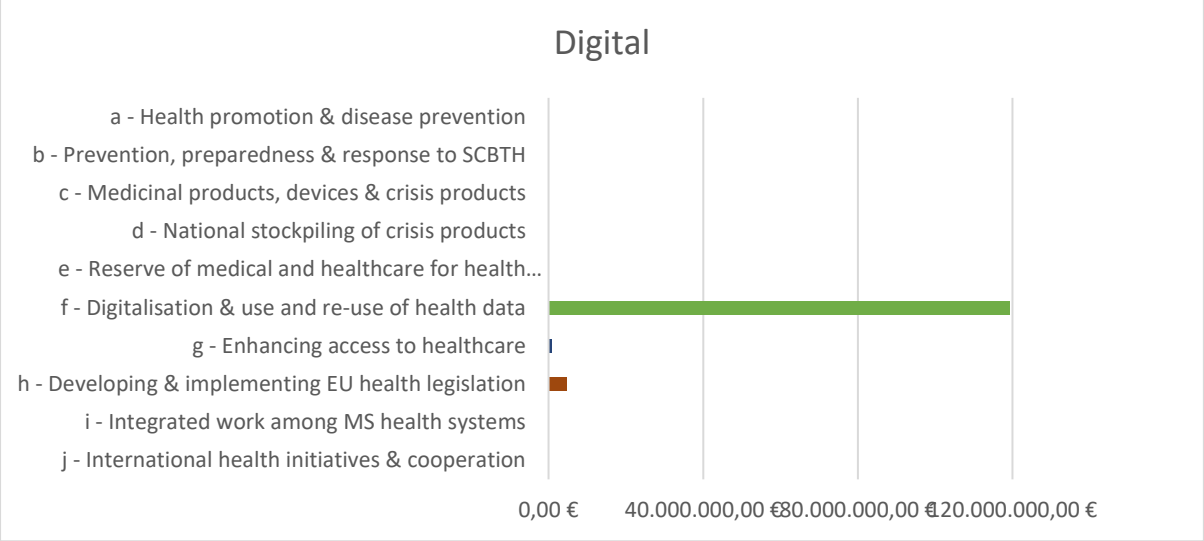


Figure 11 The distribution of digital strand investments per specific objective

The EU4Health Programme indicators reveal that: 37 actions support the digital transformation of healthcare systems and the implementation of the EHDS (cumulative); 12 Member States participate in the EHDS and are connected to MyHealth@EU and/or to the cross-border infrastructure for secondary use; and 6 health data access bodies were set up by the EU Member States.

For example, a joint action[334] under the digital strand (EUR 4.7 million) brings together experts from 25 Member State authorities to lay the groundwork for: the implementation of the European Electronic Health Record Exchange Format; common specifications for electronic health record systems; and the development of MyHealth@EU. An action grant[335] (EUR 5 million) supports the precursors and basis to set up an EU-wide infrastructure for the secondary use of health data.

Cancer

62 actions with a EUR 220 million total budget are included under the **cancer** strand, which supports the implementation of the Cancer Plan and contributes mainly to the achievement of specific objectives (a) on health promotion and disease prevention. This strand also receives considerable contributions from actions implementing specific objective (i) on integrated work among Member States health systems; specific objective (g) on enhancing access to healthcare; and specific objective (j) on global health initiatives.

Almost half of the allocated budget under the cancer strand supports prevention actions against cancer including: actions against HPV, tobacco and alcohol-related diseases (49.3%); followed by screening actions including those on breast, colorectal, cervical, gastric, prostate, liver, and

334 Extended EHR@EU Data Space for Primary Use.
335 HealthData@EU Pilot October 2022 – December 2024.

lung cancer (25%); and treatment including radiation (13.9%), quality of life (6.8%), inequalities (4.6%), and other actions (0.4%).

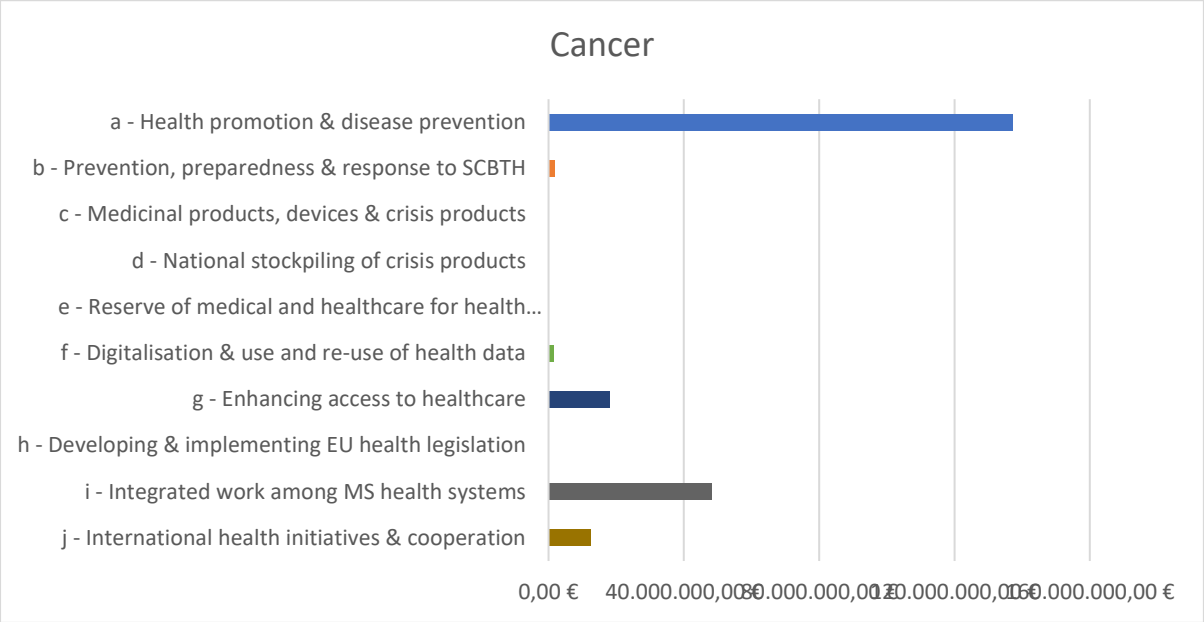


Figure 12 The distribution of Cancer strand investments per specific objective

The ongoing actions are focusing on the prevention of cancer and other NCDs; the creation and transfer of knowledge on cancer screening; targeting cardiovascular diseases and diabetes together with their health determinants; and or identifying and overcoming obstacles to the high uptake of vaccinations. These four areas were funded through joint actions, action grants and procurement instruments. These actions help to: counteract the risk factors for NCDs; promote the early detection of NCDs, including cancer; and protect the EU population from vaccine-preventable diseases. For example, an action grant[336] with a EUR 1.6 million budget was awarded to strengthen the collection of cancer-screening data to update the European Cancer Information System and improve the quality and coverage of cancer-screening programmes across Europe. This action grant made it possible to: identify 19 key performance indicators for breast, cervical, and colorectal cancer screening; determine the relevance of – and feasibility of using – these key performance indicators – with existing cancer screening programmes across Europe; and test these key performance indicators in a pilot programme. The project outcomes will be used for the third EU cancer-screening report, as required by the 2022 Council Recommendation on cancer screening[337]. Also funded under the EU4Health Programme (with EUR 9.1 million in support) is work on improving oncological training. This ongoing project involves developing an inter-speciality training curriculum. The activities linked to the training of trainers will target experts in the fields of clinical oncology, surgery,

336 CanScreen-ECIS September 2022 - February 2024.

337 Council Recommendation on strengthening prevention through early detection: A new EU approach on cancer screening replacing Council Recommendation 2003/878/EC.

radiation oncology, cancer nursing and other specialised staff from at least 100 cancer centres in Europe. These training activities will ensure the future sustainability of the inter-speciality cancer training programme in EU Member States[338] [339]. Recruitment for the training programme began in July 2024.

Funding from the EU4Health Programme made it possible to create the new Knowledge Centre on Cancer, the first ever EU Cancer Inequalities Registry, and the EU Network for Youth Cancer Survivors. All Member States (plus Iceland and Norway) published their country cancer profiles, highlighting key achievements and challenges in cancer prevention and care for each country. In addition, with funding from the EU4Health Programme and development assistance from the JRC, the European guidelines for breast cancer screening and diagnosis were made available, and the corresponding quality assurance scheme for breast cancer was piloted in 20 breast cancer settings in nine Member States. Programme-level data on cancer actions is progressively becoming available.

Global health initiatives

The EU4Health Programme contributes to international health initiatives and cooperation supporting the implementation of the EU Global Health Strategy; global efforts for pandemic preparedness; and the implementation of international health regulations.

By 2024, the EU had concluded 23 contribution agreements and actions supporting global commitments through specific objective (j) on international health initiatives with global partners including the pillar-assessed organisations.

EUR 33.6 million from the EU4Health budget has been already committed via contribution agreements to cooperation on health initiatives with global partners.

Impact assessments and evaluations

The EU4Health Programme funded an impact assessment of published EU health policies along with supporting studies and related staff working documents[340]. In addition, the Programme funded three studies to support the evaluations of, monitor the implementation of, and assess the functioning of legislative and non-legislative policies in the area of the EU's Health Union.

338 INTERACT-EUROPE – Innovative collaboration for Inter-specialty cancer training across Europe. (June 2022 – November 2023).
339 INTERACT-EUROPE 100.
340 Annex I PPMEF; see other references on the previous page.

ANNEX IX. ACTIONS FROM THE 2021-2024 WORK PROGRAMMES (WP) LINKED TO HORIZON EUROPE

Action title	Year	Strand	Funding instrument	Amount allocated within the AWP (in EUR)	Link to Horizon Europe
DP/C-g-10.1.2/3 Direct grants to Member States' authorities: network of Comprehensive Cancer Centres	2021	Cancer	Direct grant to MS authorities	7 million	This action is in line with the Horizon Europe Cancer Mission Board recommendation to establish Comprehensive Cancer Care Networks in MS and network these at the Union level.
DP/C-g-10.1.1 Call for proposals: action grants for 'EU Cancer Treatment Capacity and Capability Mapping' project - Network of Comprehensive Cancer Centres	2021	Cancer	Open call for proposals (action grant)	1.2 million	The action is in line with the Horizon Europe Cancer Mission Board recommendation to establish Comprehensive Cancer Care networks.
CR-g-22-08.01 Direct grants to Member States' authorities: Cancer and other NCDs prevention – action on health determinants	2022	Health promotion and disease prevention	Direct grant to MS authorities (Joint Action)	75 million	Rolled out in close synergy with Horizon Europe's Mission on Cancer.

Action title	Year	Strand	Funding instrument	Amount allocated within the AWP (in EUR)	Link to Horizon Europe
CR-g-22-09.01/02/03 Call for proposals to monitor and strengthen the implementation of innovative approaches to prostate, lung and gastric cancer screening at Union level	2022	Cancer	Open call for proposal	30 million	Rolled out in close synergy with Horizon Europe's Mission on Cancer.
CR-g-22-08.02 Call for proposals on cancer and other NCDs prevention – action on health determinants	2022	Cancer	Open call for proposals (action grant)	11 million	Rolled out in close synergy with Horizon Europe's Mission on Cancer.
CR-g-22-10.01/02/03[341]	2022				Rolled out in close synergy with Horizon Europe' Mission on Cancer.
CR-p-22-11.01 Study on obstacles for cancer survivors to return to work	2022	Cancer	Service	0.5 million	Rolled out in close synergy with Horizon Europe's Mission on Cancer.

[341] This action is listed in the 2022 work programme as being rolled out in close synergy with Horizon Europe, but no further information on the action is available.

Action title	Year	Strand	Funding instrument	Amount allocated within the AWP (in EUR)	Link to Horizon Europe
CR-p-22-13.01 Mapping and evaluating the implementation of the Europe's Beating Cancer Plan	2022	Cancer	Service	1.5 million	Rolled out in close synergy with Horizon Europe's Mission on Cancer.
CP-p-23-15 Support to speed up the development of, access to and/or uptake of innovative technologies and critical medicines (HERA).	2023	Crisis preparedness	Open call(s) for tender for framework contracts and/or service contracts	84 million	This action supports the policy priority to enhance the availability and accessibility of medical countermeasures and support innovation regarding such products to enhance preparedness for future health emergencies in synergy with Horizon Europe.
CR-p-23-43 Study on the quality of life of cancer survivors	2023	Cancer	Open procedure/service	1.5 million	This study builds on the results of 2 Horizon Europe projects: "EUonQoL" and "HORIZON-MISS-2023-CANCER-01-04: Establish best practices and tools to improve the quality of life for childhood cancer

Action title	Year	Strand	Funding instrument	Amount allocated within the AWP (in EUR)	Link to Horizon Europe
					patients, survivors and their families".
CR-g-23-38 Direct grants to Member States' authorities: Implementation of cancer screening programmes	2023	Cancer	A direct grant to MS (Joint Actions)	31 million	This action links to the Horizon Europe Mission on Cancer (e.g., projects funded under the call topic "Develop new methods and technologies for cancer screening and early detection (HORIZON-MISS-2021-CANCER-02-01).
CR-g-23-40.1-2 Direct grants to Member States' authorities: to establish an EU network of Comprehensive Cancer Infrastructures and new networks of expertise on cancers and cancer conditions	2023	Cancer	Two direct grants (JAs)	90 and 40.5 million	This action aims to implement the concepts developed and upscale the initial piloting work in WP2021, which is in line with the Horizon Europe Cancer Mission Board recommendations to establish Comprehensive Cancer Care Networks in MS and network these at the Union level.
DP-g-23-31-01 Direct grants to Member States'	2023	Health promotion	Direct grant to MS (Joint Action)	4 million	This action takes into account the

Action title	Year	Strand	Funding instrument	Amount allocated within the AWP (in EUR)	Link to Horizon Europe
authorities: 'Healthier Together' EU NCD initiative– chronic respiratory diseases (CRDs)		and disease prevention			results of Horizon Europe projects.
DP-g-23-32-01 Direct grants to Member States' authorities: 'Healthier Together' EU NCD initiative – Mental health	2023	Health promotion and disease prevention	Direct grant to MS (Joint Action)	6 million	This action takes into account the results of relevant Horizon Europe projects.
DP-g-23-33-01 Direct grants to Member States' authorities: 'Healthier Together' EU NCD initiative – Dementia and other neurological disorders	2023	Health promotion and disease prevention	Open call for proposals	4 million	This action takes into account the results of relevant Horizon Europe projects.
DP-g-23-32-02 Call for proposals on the prevention of NCDs in the area of mental health including actions supporting vulnerable population groups, such as migrants,	2023	Health promotion and disease prevention	Open call for proposals	2.36 million	With the objective of promoting mental health and reducing the burden of mental health problems, the action will take into account the results of relevant Horizon 2020 and Horizon Europe projects.

Action title	Year	Strand	Funding instrument	Amount allocated within the AWP (in EUR)	Link to Horizon Europe
refugees, Roma people and displaced people from Ukraine.					
CP-p-24-15 Support to speed up the development of access to and/or uptake of medical countermeasures including critical medicines (HERA).	2024	Crisis preparedness	Open call for tender	40 million	This action ultimately enhances preparedness for future health emergencies in synergy with Horizon Europe.
CR-p-24-97 Administrative, logistic and scientific support for the Sub-group on Cancer under the PHEG and for the EU-US Health Task Force (Cancer)	2024	Cancer	Service contract	0.5 million	The sub-group on cancer was set up to facilitate the governance of the implementation of the Europe's Beating Cancer Plan and the Horizon Europe Cancer Mission and to ensure synergies between the two Commission initiatives. The purpose of this action is to provide support services to DG SANTE in its role as secretariat of the Sub-group on Cancer.

Action title	Year	Strand	Funding instrument	Amount allocated within the AWP (in EUR)	Link to Horizon Europe
CR-g-24-36 Direct grants to Member States' authorities: Strengthening digital capabilities including e-health, telemedicine, remote monitoring systems, health data access and health data exchange services in cancer centres in the Union	2024	Cancer	Direct grant to MS (Joint Action)	20 million	With the aim of enhancing the digital capabilities of the cancer centres in the Union, particularly in Eastern Europe, this action makes use of the guidelines, protocols, and best practices, developed under the previous Horizon Europe projects such as UNCAN.eu and European Cancer Patient Digital Centre projects.
CR-g-24-41 Direct grants to Member States' authorities: Personalised Cancer Medicine.	2024	Cancer	Direct grant to MS (Joint Action)	27.9 million	With the objective of strengthening the Personalised Cancer Medicine network within the Union, this action will build on the results of relevant Horizon Europe projects and will improve the collaboration between different institutions/organisations from national, European and international level that are offering personalised cancer medicine including Horizon Europe co-funded projects on

Action title	Year	Strand	Funding instrument	Amount allocated within the AWP (in EUR)	Link to Horizon Europe
					personalised cancer medicine.
CP-g-24-105 Call for proposals to support the development of novel antivirals (HERA)	2024	Crisis preparedness	Open call for proposals (Action Grant)	10 million	With the aim of diversifying and advancing the pipeline of broad-spectrum antiviral candidates, this action will pay attention to complementarity with existing Horizon Europe projects (e.g., HORIZON-HLTH-2023-DISEASE-03-04: Pandemic preparedness and response: Broad spectrum anti-viral therapeutics for infectious diseases with epidemic potential).
CP-g-24-10 Call for proposals on the European Hub for vaccine development (HERA)	2024	Crisis preparedness	Open call for proposals (Action Grant)	102 million	The Hub should establish connections with the future Horizon Europe-funded European Partnership on Pandemic Preparedness (HORIZON-HLTH-2024-DISEASE-12-01) and private manufacturers including through

Action title	Year	Strand	Funding instrument	Amount allocated within the AWP (in EUR)	Link to Horizon Europe
					specific manufacturing agreements such as EUFAB or comparable national models.

ANNEX X. INFORMATION ON THE EU4HEALTH WORK PROGRAMMES ADOPTED.

2021 EU4Health work programme (2nd amendment)

The EU4Health work programme 2021, focuses in part on: addressing the mental health impact of the COVID-19 pandemic; reducing the burden of non-communicable diseases; improving access to healthcare and tackling health inequalities; strengthening health systems and the healthcare workforce; and improving preparedness and response to cross-border health threats. Additionally, the work programme aims to: support the implementation of the Cancer Plan; improve the quality, safety, and availability of substances of human origin; and promote healthy lifestyles.

EU4Health 2022 work programme

The 2022 EU4Health work programme focuses in part on: improving and fostering health in the EU; protecting people from serious cross-border health threats; improving access to medicinal products; and strengthening health systems. The work programme also focuses on cancer prevention and control, mental health, and digital health, with a specific emphasis on addressing the burden of NCDs and reducing health inequalities. Additionally, the work programme aims to support the implementation of the Cancer Plan, the pharmaceutical strategy for Europe, and the Health Union package.

EU4Health 2023 work programme

The 2023 EU4Health work programme addresses health-related emergencies caused by the COVID-19 pandemic and the Russian war of aggression against Ukraine. It also supports emerging policy initiatives by President von der Leyen in the State of the Union Address and in the associated letter of intent with a special focus on mental health, global health, developments in digital health, and medicinal products. The 2023 EU4Health work programme will also address actions related to the recently adopted proposal for a Council recommendation on a new EU approach on cancer screening.

EU4Health 2024 work programme

The 2024 EU4Health work programme addresses issues such as: health-related issues resulting from the COVID-19 pandemic and the Russian war of aggression against Ukraine; and supporting people displaced from Ukraine. It also supports emerging policy initiatives with a special attention on mental health, global health, developments in digital health and medicinal products. In addition, the 2024 EU4Health work programme addresses actions related to the adopted Council recommendation on a new EU approach on cancer screening. The work programme also addresses the challenges identified in the Commission Communication 'Addressing medicine shortages in the EU', especially the challenge of boosting Europe's capacity to produce and innovate in the manufacturing of critical medicines and ingredients. Furthermore, in light of the growing number of health threats emerging globally, the work programme addresses potential new crises, including the Mpox outbreak. The work programme

also aims to ensure that our health systems are resilient and equipped to tackle future challenges effectively.

ENDNOTES

[i] Annex I of the PPMEF: Number of Member States with improved preparedness and response planning with regard to medical countermeasures (sub-indicator 6.2).

[ii] Programme indicator: Number of actions addressing the fight against communicable diseases (indicator 22), Annex I of the PPMEF.

[iii] Programme indicator: Preparedness and response planning of the Union and of Member States for serious cross-border threats to health, Annex I of the PPMEF.

[iv] Annex I of the PPMEF: Number of Member States and associated countries with improved procurement procedures for medical countermeasures during health crisis.

[v] Annex I of the PPMEF: Number of Member States and Associated Countries with increased laboratory and diagnostic capacity for cross-border health threats, contributing to the mission of HERA.

[vi] Annex I of the PPMEF: Number of actions complementing national stockpiling of essential crisis-relevant products.

[vii] Annex I of the PPMEF: Number of healthcare and public health staff trained (Article 11 of the CHBT Regulation and Decision establishing HERA) - KEY PERFORMANCE INDICATOR.

[viii] Annex I of the PPMEF: Stakeholders' satisfaction rate in HERA training programmes.

[ix] Programme indicator: Number of countries where One Health surveillance programmes were successfully implemented, Annex I of the PPMEF.

[x] Annex I of the PPMEF: The indicator measures the total consumption (community and hospital sectors) of antibacterials for systemic use (ATC group J01) expressed as 'defined daily dose (DDD per 1 000 inhabitants per day'. It has been selected as the primary. Therapeutic subgroup of the Anatomical Therapeutic Chemical Classification System - ATC code J01.

[xi] Annex I of the PPMEF: Number of actions contributing to the reduction of avoidable mortality in the area of non communicable diseases and risk factors.

[xii] Annex I of the PPMEF: Number of actions addressing the prevalence of harmful use of alcohol, if possible, differentiated by gender and age – (indicator 14).

[xiii] Annex I of the PPMEF: Number of actions addressing environmental risk factors for health – (indicator 23).

[xiv] Annex I of the PPMEF: Number of healthcare units involved in ERNs – (sub-indicator 19.1).

[xv] Annex I of the PPMEF: Access to centrally authorised medicinal products, for example the number of existing and new orphan authorisations, advanced therapy medicinal products (ATMPs), medicinal products for paediatric use or vaccines, for unmet needs – (indicator 2).

[xvi] Annex I of the PPMEF: Number of certificates issued by notified bodies under the Medical Device Regulation (MDR).

[xvii] Annex I of the PPMEF: The number of certificates issued by notified bodies under the In Vitro Diagnostic Medical Devices(IVDR).

[xviii] Number of reported shortages of medicinal products in the Member States through the single point of contact network – (indicator 15).

[xix] Annex I of the PPMEF: Number of actions contributing to increasing the security and continuity of the global supply chains and addressing dependence on imports from third countries for the production of essential active pharmaceutical ingredients and medicinal products.

[xx] Annex I of the PPMEF: Number of production facilities with enhanced capacities in increasing security and continuity of supply for medical countermeasures, raw materials, and components at EU level – KEY PERFORMANCE INDICATOR.

[xxi] Annex I of the PPMEF: Number of audits conducted in the EU and in third countries to ensure good manufacturing practices and good clinical practices (Union control) – (indicator 17) - KEY PERFORMANCE INDICATOR.

[xxii] Annex I of the PPMEF: Number of Member States participating in actions aimed at supporting innovation, uptake and access to market of medical countermeasures supported at EU and global level for better preparedness and response.

[xxiii] Annex I of the PPMEF: Number of impact assessments of Union policies.

[xxiv] Annex I of the PPMEF: Number of studies supporting the evaluations of legislative and non-legislative health Union policies – KEY PERFORMANCE INDICATOR.

[xxv] Annex I of the PPMEF: Number of actions and contribution agreements supporting global commitments and health initiatives concluded with global partners.

[xxvi] Annex I of the PPMEF: Number of areas where EU and WHO align policies and/or actions.

[xxvii] Annex I of the PPMEF: Areas of coordination between EU and relevant global partners and EU Member States.

[xxviii] See endnote [IX].