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

on the interim evaluation of the EU4Health Programme 2021-2024

{SEC(2025) 304 final} - {SWD(2025) 369 final}

1. Introduction

Health is a precondition for our society and economy to function. The aims of the EU include promoting the well-being of its peoples[1]. A high level of human health protection should be ensured in the drawing up and implementation of all EU policies and activities[2].

Article 168 of the Treaty on the Functioning of the European Union (TFEU) provides that the EU must complement and support national health policies, encourage cooperation between Member States and promote coordination between their programmes. The EU must achieve this while respecting the responsibilities of the Member States for drawing up their own health policies and for the organisation, management and delivery of health services and medical care.

Since 2020, drawing on the lessons from the COVID-19 pandemic, the European Commission has been building the European Health Union, in which all EU Member States: prepare and respond together to health crises; make medical supplies available, affordable and innovative; and work together to improve prevention, treatment and aftercare for diseases such as cancer. The main EU funding programme to deliver the European Health Union is the EU4Health Programme.

2. The EU4Health Programme

The EU4Health Programme was established by Regulation (EU) 2021/522[3] ('EU4Health Regulation') to improve human health throughout the EU and to ensure a high level of human health protection in all EU policies and activities.

The Programme's objectives[4] are broad, aligned with the priorities of the European Health Union[5], and closely interlinked with the objectives of the EU's legislative and non-legislative health initiatives that the Programme supports financially. The four general objectives are:

a) improving and fostering health in the Union to reduce the burden of communicable and non-communicable diseases, by supporting health promotion and disease prevention, by reducing health inequalities, by fostering healthy lifestyles and by promoting access to healthcare;

b) protecting people in the Union from serious cross-border threats to health and strengthening the responsiveness of health systems and coordination among the Member States in order to cope with serious cross-border threats to health;

c) improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, and supporting innovation regarding such products;

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1 Article 3(1) of the Treaty on European Union (TEU).

2 Articles 9 and 168 TFEU and Article 35 of the Charter of Fundamental Rights of the European Union.

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

4 The health objectives from the initial proposal put forward in the European Social Fund Plus (ESF+) programme were retained with priority given to the EU's and Member States' response and crisis preparedness to future health crises in the aftermath of the COVID-19 pandemic.

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

d) *strengthening health systems by improving their resilience and resource efficiency, in particular through: (i) supporting integrated and coordinated work between Member States; (ii) promoting the implementation of best practices and promoting data sharing; (iii) reinforcing the healthcare workforce; (iv) tackling the implications of demographic challenges; and (v) advancing digital transformation.*

The general objectives referred to in Article 3 of the EU4Health Regulation are pursued through the following specific objectives, ensuring a high level of human health protection in all EU policies and activities, and pursuing the One Health approach:

a) in synergy with other relevant Union actions, supporting actions for disease prevention, for health promotion and for addressing health determinants, including through the reduction of damage to health resulting from illicit drug use and addiction, supporting actions to address inequalities in health, to improve health literacy, to improve patient rights, patient safety, quality of care and cross-border healthcare, and supporting actions for the improvement of the surveillance, diagnosis and treatment of communicable and non-communicable diseases, in particular cancer and paediatric cancer, as well as supporting actions to improve mental health, with special attention given to new care models and the challenges of long term care, in order to strengthen the resilience of the health systems in the Union;

b) strengthening the capability of the Union for prevention of, preparedness for, and rapid response to, serious cross- border threats to health in accordance with relevant Union legislation, and improving the management of health crises, particularly through the coordination, provision and deployment of emergency healthcare capacity, supporting data gathering, information exchange, surveillance, the coordination of voluntary stress testing of national healthcare systems, and the development of quality healthcare standards at national level;

c) supporting actions to enhance the availability, accessibility and affordability of medicinal products, medical devices and crisis-relevant products by encouraging sustainable production and supply chains and innovation in the Union, while supporting the prudent and efficient use of medicinal products, in particular antimicrobials, and actions to support the development of medicinal products that are less harmful for the environment, as well as the environmentally friendly production and disposal of medicinal products and medical devices;

d) in synergy with other Union instruments, programmes and funds, without prejudice to Member State competences, and in close cooperation with relevant Union bodies, supporting actions complementing national stockpiling of essential crisis-relevant products, at Union level, where needed;

e) in synergy with other Union instruments, programmes and funds, without prejudice to Member State competences and in close cooperation with the ECDC [European Centre for Disease Prevention and Control], establishing a structure and training resources for a reserve of medical, healthcare and support staff allocated voluntarily by Member States for its mobilisation in the event of a health crisis;

f) strengthening the use and re-use of health data for the provision of healthcare and for research and innovation, promoting the uptake of digital tools and services, as well as the digital transformation of healthcare systems, including by supporting the creation of a European health data space;

g) enhancing access to quality, patient-centred, outcome-based healthcare and related care services, with the aim of achieving universal health coverage;

h) supporting the development, implementation and enforcement and, where necessary, the revision of Union health legislation and supporting the provision of valid, reliable and comparable high-quality data for evidence-based decision-making and monitoring, and promoting the use of health impact assessments of other relevant Union policies;

i) supporting integrated work among Member States, and in particular their health systems, including the implementation of high-impact prevention practices, supporting work on HTA [health technology assessment], and strengthening and scaling up networking through ERNs [European Reference Networks] and other transnational networks, including in relation to diseases other than rare diseases, to increase the coverage of patients and improve the response to low prevalence and complex communicable and non- communicable diseases;

j) *supporting global commitments and health initiatives by reinforcing the Union's support for actions by international organisations, in particular actions by the WHO [World Health Organization], and fostering cooperation with third countries.*

The **initial budget of EUR 5.8 billion** for years 2021-2027 provided for in Article 5 of the EU4Health Regulation was **reduced to EUR 4.6 billion**[6] when the 2021-2027 multiannual financial framework (MFF) was revised[7]. The redeployed funds were allocated to, among other things, catering for Ukraine's immediate needs, recovery and support for its European path; addressing the needs related to migration pressures; strengthening global partnerships; and responding to emergencies.

Under the EU4Health Regulation, at least 20% of the Programme's budget must be reserved for health promotion and disease prevention. The Programme should invest no more than 12.5% in procurement to complement national stockpiling of essential crisis-relevant products, no more than 12.5% to support global commitments and international health initiatives, and a maximum of 8% to cover administrative expenses[8].

The EU4Health Programme budget is implemented through **annual work programmes**[9] adopted by the Commission following a positive opinion from the Member States in the

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6 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.

7 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).

8 Article 5(4) of Regulation (EU) 2021/522.

9 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 to the Commission implementing decision.

EU4Health Programme Committee and building on relevant stakeholders' views. The annual EU4Health programming is based on the Commission's analysis of the gap between the current state of implementation and the Programme's objectives. The annual work programme priorities and strategic orientations take into account the stakeholders' input and are developed in consultation with the Member States to ensure the Programme's implementation the EU's overall health policy objectives.

The Programme is implemented mainly through **direct management** with the Member States' authorities, academia and education establishments, research institutes, hospitals, civil society and other public or private entities. Some budget implementation tasks are entrusted through **indirect management** to bodies such as international organisations or their agencies (the WHO, the International Federation of Red Cross and Red Crescent Societies, the Organisation for the Economic Cooperation and Development (OECD)), the European Investment Bank and other organisations[10]. The Programme may provide funding in any of the forms laid down in the Financial Regulation, in particular grants, prizes and procurement.

For **grants** the **co-financing rate** is **up to 60%** and, **in case of exceptional utility, up to 80%**. In the case of direct grants to the **ERNs, other transnational networks** set out under EU law and the **WHO**, such grants may be **up to 100 % of eligible costs**.

Public procurement contracts may be awarded to any legal entity that satisfies the requirements set out in the applicable legal framework.

The eligible beneficiaries of the Programme are amongst others, national or regional (health) administrations of Member States or associated countries, research bodies, educational institutes, private and non-profit entities[11].

The **Commission has signed EU4Health Programme association agreements with Ukraine, Moldova, Montenegro and Bosnia and Herzegovina,** which allow these countries to access EU4Health funding. The association of **Norway** and **Iceland** (EEA EFTA countries) to the EU4Health Programme is governed by Protocol 31 to the Agreement on the European Economic Area on cooperation in specific fields outside the four freedoms.

3. Interim evaluation approach and methodology

Evaluation criteria and context

The interim evaluation report of the EU4Health Programme is a legal obligation in line with Article 20 of the EU4Health Regulation and is accompanied by a staff working document presenting the available evidence. The interim evaluation assesses: the Programme's **effectiveness** and **efficiency**; the **coherence** within the Programme and with other relevant EU funding initiatives and relevant policies; the **EU added value** of the funded actions; and the

The European Commission adopts implementing decisions pursuant to Article 17(2) of the EU4Health Regulation on 'Implementation of the Programme'.

[10] Article 62(1) (c) of Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union (recast), (OJ L, 2024/2509, 26.9.2024).

[11] Article 13 of Regulation (EU) 2021/522.

relevance of the Programme objectives. The interim evaluation provides insights for the ongoing implementation of the EU4Health Programme, sets the scene for the forthcoming final evaluation, and informs the reflections on a potential successor Programme for the next MFF.

The evaluation period

The interim evaluation measures the Programme's progress from 1 January 2021 to 30 April 2024 (cut-off date), across the 27 Member States and 6 non-EU countries associated to the Programme[12].

The evaluation methodology

The interim evaluation, as outlined in Article 20(2) of the EU4Health Regulation[13], builds on output and results data from a limited number of actions completed by the cut-off date. Consequently, there were only limited data available on results and no data at all on impacts. EU public health interventions often involve multiple components and stakeholders and complement those of the Member States. This can make it difficult to isolate the effects of specific actions and evaluate their impact accurately. Establishing a causal link between inputs, outputs, results, and impacts in an EU public health intervention is difficult because of the complex and multifaceted nature of such interventions, where multiple variables and external factors can influence outcomes.

The evaluation draws on additional evidence provided by an external study 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 and a literature review. The data analysis includes a comparison against baseline and targets, a cost-benefit analysis 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.

4. Main findings of the interim evaluation

At the time of the interim evaluation, the available data are limited to early results from the financed actions, and the impacts of these actions are yet to materialise. The initial findings from 26 grants and 136 procurements show that the data collection approach is reliable, and that the evaluation methodology provides a strong basis to deliver the final evaluation.

Effectiveness and efficiency

The EU4Health Programme governance was established in a timely manner and allowed the programming process to unfold swiftly and efficiently during the COVID-19 pandemic. The EU4Health programming process has been a critical enabler in aligning the Programme's activities with its overarching objectives. Coordination between the two parent Directorates-General (DGs), the Directorate-General for Health and Food Safety (DG SANTE) and the Health Emergency Preparedness and Response Authority (HERA), the European

[12] Bosnia and Herzegovina, Iceland, Moldova, Montenegro, Norway and Ukraine.
[13] Regulation (EU) 2021/522.

Health and Digital Executive Agency (HaDEA), as well as the active participation of the 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 annual work programmes have been effective in translating the EU4Health Programme's broad objectives into concrete actions, with clear allocation of resources to priority areas such as crisis preparedness, digital health (eHealth), and disease prevention. The first annual work programme for 2021 was adopted about three months after the EU4Health Regulation had been adopted. The programming processes were run in parallel for the 2021 and 2022 work programmes, which were adopted after a roughly ten months preparatory period. Programming in 2023 and 2024 adhered to more regular programming cycles, with timely adoption of work programmes and an effective amendment process.

All actions programmed for 2021, 2022 and 2023 delegated to HaDEA by the parent DGs were successfully launched. Consequently, 726 contracts (covering all these actions for these three years) were signed with 1 274 legal entities such as: health ministries; national, regional and other public authorities; healthcare and health research organisations; and non-profit and private entities. Most of the EU4Health funds were disbursed through grants and procurement. Additionally, contribution agreements were used to support global health priorities. By April 2024, about EUR 2.63 billion of the total EU4Health budget (of EUR 5.8 billion for the years 2021-2027) had been programmed and EUR 1.39 billion had been effectively committed.

The EU4Health work programme consists of **four overarching 'strands'**: *crisis preparedness*; *health promotion and disease prevention*; *health systems and healthcare workforce*; and *digital*. *Cancer* is considered to be a horizontal strand.

The grants beneficiaries from 22 countries[14] 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.).

During 2021-2024, 255 NGOs received action grants and participated in 55 projects, absorbing EUR 41.2 million. In addition, 27 NGOs received operating grants, absorbing EUR 23.2 million.

A total of 94 legal entities from 18 Member States[15] benefited from funds through procurement between 2021 and 2024. The largest procurement of services was made under the crisis preparedness strand. This procurement includes ensuring ever-warm facilities (the EU FAB project) for vaccine production and IT development to enhance early warning systems, modelling, simulation and forecasting[16]. Of the total budget amounting to EUR 396.4 million, six Member States[17] have absorbed most of the procurement funds with at least EUR 22 million per Member State.

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

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

[16] ATHINA – the Advanced Technology for Health INtelligence and Action IT System.

[17] Belgium, Denmark, Ireland, the Netherlands, Luxembourg and Spain.

The grants and procurement for services have enabled targeted actions under all strands of the work programme. The overall budget committed by the cut-off date amounts to EUR 1.39 billion. Direct management includes grants of EUR 741.84 million and procurement of EUR 420.44 million. Indirect management comprises the remaining EUR 227.72 million. The joint actions and other direct grants to Member States bring together national authorities facilitating and enhancing collaboration, capacity building and knowledge transfer. The procurement of services involves private sector providers mainly from the Member States, and in a few cases from other countries[18], international organisations[19] or Commission services[20]. Contribution agreements with international organisations have facilitated the implementation of initiatives including beyond the EU's borders, such as addressing the health consequences of Russia's war of aggression against Ukraine or crisis preparedness actions to address emerging cross-border health threats at the place of origin, such as in Africa in the case of the Mpox virus.

By the cut-off date, the **joint actions enabled 499 organisations to collaborate across European countries, with 40% of all organisations participating in more than one joint action.** The *exceptional utility criteria* have demonstrated their relevance as a funding mechanism in the EU4Health Programme, providing increased financial support (an EU contribution of up to 80%) for actions involving at least 14 Member States of which at least 4 are countries whose gross national income (GNI) per inhabitant is less than 90% of the EU average[21] or where 30% of the action budget is directed to such countries.

Administrative burdens remain a significant challenge, particularly for smaller Member States and NGOs. This includes 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.

The **Programme has already made significant progress at this interim stage.**

The Programme contributes to **disease prevention and health promotion** by supporting very effectively the delivery of the **Healthier together – EU non-communicable diseases (NCD) initiative[22],** as demonstrated by, among other things, the joint work of the Member States[23]. Moreover, the legal obligation to allocate a minimum of 20% of the total Programme budget to disease prevention and health promotion actions has been fulfilled until 2024[24]. **There has been a substantial progress in improving healthcare networks.** The ERNs, which provide specialised care for rare diseases, now include 1 619 healthcare providers, marking by the cut-off date a 40% increase compared to 2021. This expansion has had a tangible impact, as by

18 The United States.
19 The WHO; grant for the African Society for Laboratory Medicine.
20 The Joint Research Centre.
21 Article 8(3) of the EU4Health Regulation.
22 Healthier together – EU non-communicable diseases initiative.
23 Joint Action Prevent Non-Communicable Diseases (JA PreventNCD) and Joint Action on Cardiovascular diseases and Diabetes (JACARDI).
24 Article 5 of the EU4Health Regulation budget includes provisions to reserve a minimum of 20% of the total EU4Health budget for health promotion and disease prevention actions.

2024, 2.24 million rare disease patients have received expert advice on the most appropriate diagnoses and treatments. **Digital health initiatives are also advancing**, through the implementation of MyHealth@EU, the infrastructure enabling cross-border continuity of care by providing access to Patient Summaries and ePrescirptions and is paving the way for the European Health Data Space. This work has been made possible through 44 key projects funded by the Programme, ensuring better access to – and management of – health data across the EU. **Innovation and accessibility** in medical countermeasures have been further supported by a EUR 104 million investment aimed at fostering advancements in the field, including incentives to ensure access to antibiotics. In addition, under EU FAB, six economic operators have secured manufacturing capacities to ensure that vaccines can be fully produced within the EU in case of an emergency. Meanwhile, in the fight against cancer the Member States are adapting and adopting the European guidelines on breast cancer screening and diagnosis, and the questions and answers scheme has been completed and ready for implementation after being tested across nine Member States. A crucial step following the 2022 Council recommendation on cancer screening. Moreover, in response to the increasing risk of cross-border pathogens, in January 2024, 23 Member States began implementing a **One Health surveillance system**, reinforcing the EU's preparedness against health threats that transcend national borders. Similarly, the joint action EU wastewater integrated surveillance for public health (EU-WISH) initiative has also brought together 26 countries to boost their ability to prevent, prepare for, and respond rapidly to serious cross-border health threats through wastewater surveillance.

The Programme data collection is enabled by 52 indicators, which are described in the EU4Health Programme performance monitoring and evaluation framework (PPMEF)[25]. The indicators monitor inputs, outputs, results, and impacts. Nine designated *key performance indicators* are related to flagship health policies and serve to reflect the key achievements in the annual performance reporting[26].

The 2023 annual performance analysis (the latest available before the interim evaluation cut-off date 30 April 2024) indicates that the overall Programme performance is on track to achieve its objectives.

The progress of the *nine key performance indicators* is illustrative. The 2027 target has already been exceeded in 2024 for the indicator related to ERNs and for the indicator on the number of Member States implementing best practices on health promotion and disease prevention. Almost all Member States and associated countries (30) have taken steps to develop their preparedness and response plans for serious cross-border health threats. The 2024 milestone is close to being met for the key performance indicator 'Number of healthcare and public health staff trained' and on track to be met for four other indicators[27].

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25 See Annex I to the Commission Staff Working Document EU4Health Programme Performance Monitoring and Evaluation Framework SWD(2024)223 final.

26 See Annex 2 to SWD(2024)223 final.

27 For information on performance results of EU4Health indicators see (2024) 2021-2027 Performance Data Tables.

The 2024 milestones, for example, have been reached and even exceeded under different strands. As the Programme's implementation advances, significant progress has been made on several indicators towards meeting the 2027 targets in key areas such as: crisis preparedness and response; health promotion and disease prevention; cancer; and addressing the needs of rare disease patients through ERNs.

Coherence

The design of the EU4Health Regulation is sound overall, and the objectives are coherent. All the Programme's general and specific objectives accurately and comprehensively reflect the EU's health needs and challenges. The comprehensive specific objectives allow for the financing of the implementation of existing EU health policy priorities, including existing EU health legislation.

The Programme is consistent with other EU funding programmes such as Horizon Europe, the Digital Europe programme, European Social Fund+ the Union Civil Protection Mechanism (rescEU), the European Regional Development Fund, **the Recovery and Resilience Facility, the Technical Support Instrument, and the Neighbourhood, Development and International Cooperation Instrument – Global Europe (NDICI-GE)**. Horizon Europe advances health research and innovation through its Cluster 1 initiatives and the EU Cancer Mission, addressing disease prevention and promoting synergies with public health policies. It funds research in areas like infectious diseases and cancer and helps to incorporate digital technologies into healthcare and promotes global health cooperation. Partnerships within Horizon Europe, such as those focusing on transforming health systems and rare diseases, bolster Europe's health innovation ecosystem. The Digital Europe programme improves digital skills in health and is helping to set up the European Health Data Space for better data access and interoperability. Additionally, funds like the European Regional Development Fund, European Social Fund+, ERASMUS+ the Recovery and Resilience Facility, the Technical Support Instrument, support health infrastructure, eHealth, and workforce skills development.

The coherence of the EU4Health Programme with other EU funds is also ensured through inter-service consultation on the annual work programmes and organisation of joint stakeholder events to present projects on specific thematic areas (e.g. mental health). Coherence between EU4Health and Horizon Europe is most prominent in the case of cancer actions[28]. This stems from the close alignment of Horizon Europe's EU Cancer Mission with EU4Health's cancer strand, which is ensured through the joint governance of the EU Cancer Mission and Europe's Beating Cancer Plan.

There is also potential for synergy between the European Green Deal and EU4Health. 15 actions representing EUR 23.5 million, directly support Green Deal priorities.

[28] For more overview on coherence between EU4Health and Horizon Europe, see section 4.1.3 Crisis preparedness in accompanying Staff Working Document.

EU added value

Actions under the EU4Health Programme have provided significant EU added value through capacity building, strategic planning, and the setting of priorities and actions to upscale and promote innovation and make the best use of research results.

The EU4Health Programme launched actions worth EUR 623 million on *crisis preparedness and health security*, between January 2021 and the cut-off date of the interim evaluation (30 April 2024). These actions improved the EU's ability to better prevent, be better prepared and respond to health emergencies. They also ensured the EU's ability to ensure access to medical countermeasures. Examples include activities on medical countermeasures development and procurement; European reference laboratories; surveillance and intelligence gathering capabilities; and early warning and response systems. Such actions are crucial for counteracting future cross-border threats to health in the EU.

EUR 27 million has been made available to support intelligence gathering through open sources, wastewater surveillance systems and sequencing capacities and epidemic intelligence gathering at global level.

The Programme has made considerable investments to directly support *health promotion and disease prevention* (EUR 155.4 million), particularly concerning NCDs (including cancer), mental health, cardiovascular diseases, diabetes, respiratory diseases and to promote healthier lifestyles that are expected to have positive impacts on the long-term health of EU citizens. The actions from other strands also include health promotion and disease prevention activities. Together with the direct support in this area of intervention, EUR 536.7 million has now been programmed for health promotion and disease prevention. This meets the 20% legal commitment made under the EU4Health Regulation.

600 000 displaced people from Ukraine received psychological first aid and mental health services in 22 Member States and 3 non-EU countries

The EU4Health Programme has deployed EUR 239 million on actions *to strengthen national health systems*, for example: through the CIRCE joint action transferring best practices in primary healthcare among EU Member States; by increased financing of the European Reference Networks (EUR 100.5 million), and by increasing the resilience of the healthcare workforce, building on the outcomes of the previous health programmes. Established in 2017, the European Reference Networks have continued to facilitate and enhance collaboration between healthcare providers and gave advice on the most appropriate diagnosis and the best treatment available to rare disease patients. The Programme has also improved healthcare workforce preparedness through targeted training and capacity-building initiatives, ensuring that Member States are better equipped to manage surges in demand for healthcare.

Between November 2023 and April 2024, 15 medicines had their electronic product information published as part of their marketing authorisation procedure, paving the way for the wider digitalisation of the regulatory network.

The *digital transformation of healthcare systems* (EUR 124.96 million) across the EU has advanced through the preparatory work and the development of the European Health Data Space infrastructure supported by the EU4Health Programme. This allows health data to be exchanged across borders and improves access to quality healthcare. EU citizens now have easier access to their health records and can receive continuous care when travelling between Member States. Member States are also better connected, leading to 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 leader in medical research and healthcare innovation. The actions from other strands include digital transformation activities that contribute together to the EU's cross-cutting priorities.

22 European countries, including 20 EU Member States, received support for the digitalisation of their health systems and increased the geographic coverage of MyHealth@EU services, interoperability and/or patient access to their own health data.

The *investments supporting implementation of Europe's Beating Cancer Plan* (EUR 220 million) include key actions to reduce cancer risk factors, improve vaccination and screening coverage, and improve cancer registries by enhancing data collection, thus contributing effectively to early detection and more effective treatment strategies. Progress has been made in several other areas, including on the European Commission Knowledge Centre on Cancer[29], the European cancer inequalities registry[30], and the EU Network linking recognised National Comprehensive Cancer Centres and new networks of expertise. The EU Network taps into the entire European oncology community for specific, challenging cancer areas that could benefit from cross-border cooperation.

In December 2023, 29 country cancer profiles from all EU Member States and Iceland and Norway were published, highlighting the key achievements and challenges in cancer prevention and care.

29 Knowledge Centre on Cancer.
30 ECIR - European Cancer Inequalities Registry.

The support to the EU's *Global Health Strategy*[31] amounts to EUR 61.5 million[32], of which about EUR 50 million has been committed to actions such as strengthening preparedness and response to cross-border threats to health at global level. An ongoing study aims to design and test a monitoring framework to assess the progress and outcomes of the EU's Global Health Strategy's implementation. Supported by EU4Health Programme financing, Member States and associated countries are strengthening the EU's role in global health by improving the coordination of actions between Member States and EU institutions. The global commitments and health initiatives concluded with international partners such as the WHO and the Red Cross and Red Crescent Societies have addressed, among other issues, the health consequences of Russia's war of aggression in Ukraine and the needs of refugees.

Relevance

The findings of the evaluation's supporting study published together with this report indicate that **all general and specific objectives of the EU4Health Programme were highly relevant**, reflecting accurately and comprehensively the health needs and challenges in existence in 2021, when the Programme was created. The study found that the specific objectives were well-aligned with the EU 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[33].

During the period 2021-2024, the **EU4Health Programme remained very relevant with regards to European Health Union priorities** such as: health crisis prevention, preparedness and response; implementation of Regulation (EU) 2022/2371 on serious cross-border threats to health[34]; Europe's Beating Cancer Plan[35]; the 'Healthier Together' initiative[36]; Europe's pharmaceutical strategy[37]; supporting health technology assessment work and building the European Health Data Space[38].

The actions funded in the 2021, 2022, 2023 and 2024 annual work programmes were highly relevant for implementing all general and specific objectives. A mapping exercise and further analysis of the annual work programmes confirmed that all four general objectives and the ten specific objectives were largely and adequately covered. In line with this, most

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

32 For this interim evaluation, financial support for the EU's Global Health Strategy is meant as total budget of actions implementing specific objective (j) of EU4Health – supporting global commitments and health initiatives.

33 Mission letter from Ursula von der Leyen, President of the European Commission, to the Commissioner for Health and Food Safety, 1 December 2019.

34 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).

35 Europe's Beating Cancer Plan.

36 Healthier Together EU Non-Communicable Diseases Initiative.

37 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.

38 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).

stakeholders agreed that the actions in the 2021-2024 annual work programmes were relevant for all four general and all ten specific objectives.

The **continued relevance** of the Programme during the implementation period is underscored by the high opinion of stakeholders expressed via surveys and during targeted interviews in April and May 2024: 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. Stakeholder-targeted interviews confirmed a consensus across all stakeholder groups that the EU4Health Programme's general and specific objectives remained relevant over the Programme's implementation period from January 2021 until April 2024.

The **health challenges that the EU4Health Programme was designed to address, remain relevant for the years to come,** in particular in relation to: the increased risk of outbreaks and epidemics or pandemics; growing antimicrobial resistance; increased longevity which, in the absence of further action, is associated with an increased prevalence of NCDs. These health challenges will require EU level action and commensurate resources. Such action includes:

1. continuing to build a One Health approach;
2. upscaling innovation across health policies;
3. improving regulatory frameworks for pharmaceuticals and medical devices, including critical medicines;
4. laying the groundwork for the digital transition;
5. mitigating workforce shortages;
6. improving access to healthcare;
7. stepping up prevention of NCDs;
8. enabling healthy ageing through a comprehensive and lifelong approach to health promotion and disease prevention, including cardiovascular diseases, and the continued fight against cancer;
9. reducing health damage due to illicit drug use and addiction, including information and prevention; amplifying threat detection activities and supporting new medical countermeasures against outbreaks;
10. improving the security of supply of critical medicines and medical countermeasures;
11. developing health biotechnologies.

The EU4Health Programme remains relevant because it finances the implementation of the Union health *acquis* and facilities collaboration and coordination with Member States to **build the European Health Union**. The EU4Health Programme is the main EU fund that underpins the development of a strong European Health Union, including both its internal and external dimensions. It finances actions to build the European Health Union by implementing health priorities and policies such as:

1. crisis preparedness and response;
2. Europe's Beating Cancer Plan;
3. the reform of EU pharmaceutical legislation;

4. a comprehensive approach to mental health[39];
5. HTA;
6. the European Health Data Space;
7. medical devices[40];
8. in vitro diagnostic medical devices[41];
9. rules on substances of human origin[42].

The EU4Health Programme also supports activities under the extended mandates of the European Medicines Agency and the European Centre for Disease Prevention and Control. It furthermore supports the EU's Global Health Strategy and helps the Member States meet the UN Sustainable Development Goals and targets. The EU4Health Programme supports the EU health priorities and the development and evaluation of legal acts.

5. Conclusions and lessons learned

Conclusions

The EU4Health Programme's governance and programming processes were set up successfully and have proven to be effective for the timely adoption of the annual work programmes and the necessary amendments. The consultation process with stakeholders is well-established. The work programmes have been effective in translating the EU4Health Programme's broad objectives into concrete actions, with clear allocation of resources to priority areas such as crisis preparedness, digital health, and disease prevention. The first work programme in 2021 was adopted about three months after the EU4Health Regulation was adopted. The programming processes were run in parallel for the 2021 and 2022 work programmes, which were adopted over a record period of roughly ten months.

The implementation processes are effective and were adapted in a timely manner to accommodate large increase of the budget by the newly created HaDEA. The executive agency is instrumental and essential for the implementation of the Programme and its annual work programmes. The programmed actions are designed to provide **significant EU added value** upon delivery through strategic planning of EU priorities and actions to upscale and promote innovation and capacity building and make the best use of research results across Europe. Subsequently, the Programme contributed substantially to the EU's cross-cutting priorities,

39 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.

40 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).

41 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).

42 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).

such as the digital transition, gender equality and green budgeting by committing funds to relevant EU4Health actions.

The EUR 1 billion redeployment in 2024, had no impact on the programming for the 2021, 2022, 2023 and 2024 annual work programme. However, this major budget cut to the EU4Health Programme will have an impact on the programming from 2025 onwards. Nevertheless, is important to ensure sufficient support to both ongoing and new initiatives and commitments.

The **joint actions** continue to provide crucial funding to national authorities, including those of countries with a lower GNI through the exceptional utility criteria. They also enable collaboration that addresses common European health challenges and implement effective solutions at national level. **The main beneficiaries**, in terms of both received EU contribution and number of projects, are public entities, such as health ministries, national health agencies, institutes, laboratories, university hospitals and research organisations. NGOs benefited from both operating and action grants, with 27 NGOs having benefited from operating grants and 255 NGOs from action grants in the 2021-2024 period.

The Programme's performance is as it was expected to be at this interim stage when only a limited number of actions have reached completion and delivered results. The impacts of these results are expected to unfold in the years to come and will be analysed in the final evaluation, due by the end of 2031. The EU4Health Programme also 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 and disease prevention and tackle environmental risk factors to health.

Looking ahead

In the programming phase, **setting strategic and thematic priorities for periods longer than one year** may enable stakeholders to plan for a longer time frame. Where appropriate, in some specific areas (e.g. health systems and healthcare workforce) the strategic grouping of actions within specific instruments could also be explored. 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.

In addition, **fostering political ownership** and engagement within Member States in joint actions can help realise the full potential of these initiatives and ultimately improve health outcomes across the EU. The success of health actions at national level requires the active engagement of the Member States' authorities, which play a key role in implementing impactful initiatives. Closer collaboration and alignment of priorities at both EU and national/regional level are essential to assign clear roles and responsibilities in joint actions (e.g. coordinator and affiliated entities).

Enhancing administrative efficiency by simplifying complex procurement procedures and flexible tendering, reducing reporting burdens, and streamlining grant application processes, could significantly ease the workload for beneficiaries. Moreover, standardising procedures and aligning requirements across EU funding programmes could reduce duplication of administrative actions and streamline operations, particularly in areas like audit certificates, where differing rules add complexity. Coherence across initiatives could be further improved by aligning administrative requirements with other EU programmes, such as Horizon Europe, to avoid duplication of efforts and harmonising procedures. In addition, the simplification of administrative requirements for funding application, reducing co-financing burdens, and streamlining monitoring and reporting processes could improve efficiency and attract broader participation. The identified measures for reducing administrative burden in the EU4Health Programme can potentially enhance effectiveness and efficiency of its implementation, while actively contributing to the new Commission's priority of enhancing simplification across all policies.

The possibility to adjust **co-funding rates**, when justified, and to provide **more flexibility**, including full coverage of eligible costs, could be considered. This would be helpful because most of the actions in the Programme, with the exception of the ERNs[43], only partially cover their eligible costs. In addition, by expanding partnerships with **other funding mechanisms**, such as InvestEU[44], the Technical Support Instrument[45], the European Regional Development Fund[46], and the European Social Fund Plus[47], there would be opportunities to further amplify the Programme's impact.

By investing 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 health policy priorities and objectives.

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

44 InvestEU.

45 Technical Support Instrument.

46 European Regional Development Fund.

47 European Social Fund Plus.