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**COMMISSION STAFF WORKING DOCUMENT**

**EU4Health Programme**

**Performance Monitoring and Evaluation Framework**

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## 1. INTRODUCTION TO THE EU4HEALTH PROGRAMME

The EU4Health Programme (2021-2027)<sup>1</sup> (also referred to as ‘the Programme’) was adopted in March 2021 in the wake of the COVID-19 pandemic with a budget of about EUR 5.7 billion over 7 years. It has four general objectives: (a) improving and fostering health in the EU; (b) protecting people in the EU from serious cross-border threats to health; (c) improving the availability, accessibility and affordability of medicinal products and medical devices and crisis-relevant products; and (d) strengthening health systems. The Programme finances actions that implement existing and upcoming legislative and non-legislative EU health initiatives, including their preparatory work, and is delivered through annual work programmes. The actions included in the annual work programmes must fulfil at least one of the Programme’s 10 specific objectives and are structured under five strands<sup>2</sup>: crisis preparedness and response; health promotion and disease prevention; cancer; health systems and health workforce; and digital. The annual work programmes are adopted by the European Commission after consultation with relevant stakeholders and Member State representatives in the EU4Health Steering Group, and based on a positive opinion of the Member States representatives in the EU4Health Programme Committee.

The EU4Health Programme’s objectives are closely interlinked with the objectives of the legislative and non-legislative EU health initiatives that aim at building the European Health Union and supporting its associated initiatives. The Programme’s objectives are deliberately broad to allow for the financing of all relevant EU health policy priorities and related actions, including related preparatory work during the 2021-2027 multiannual financial framework (MFF). Some of the EU health policy priorities are covered by one or more specific objectives.

The EU4Health Programme also supports activities under the extended mandates of the European Medicines Agency (EMA)<sup>3</sup> and the European Centre for Disease Prevention and Control (ECDC)<sup>4</sup>. The EU4Health Programme works, where relevant, in synergy with, and in a manner that complements other EU instruments, programmes and funds<sup>5</sup>, such as the Digital Europe Programme, Horizon Europe, the rescEU reserve and the ESF+.

The EU4Health Programme established by Regulation (EU) 2021/522<sup>6</sup> (also referred to as ‘the Regulation’) provides that the Commission is to present an interim evaluation of the Programme no later than 31 December 2024. The interim evaluation will be the basis for adjusting the implementation of the Programme, as appropriate. A final evaluation is due no

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<sup>1</sup> [Regulation \(EU\) 2021/522](#) of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union’s action in the field of health (‘EU4Health Programme’) for the period 2021-2027, and repealing Regulation (EU) No 282/2014.

<sup>2</sup> The ‘strand’ is a communication tool that brings together actions that implement related policies.

<sup>3</sup> [Regulation \(EU\) 2022/123](#) of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p.1).

<sup>4</sup> [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.

<sup>5</sup> Article 24 of the [EU4Health Regulation \(EU\) 2021/522](#).

<sup>6</sup> Article 20 of the [EU4Health Regulation \(EU\) 2021/522](#).

later than end of 2031. The Commission will communicate the conclusions of both the interim and final evaluations accompanied by its observations, to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

## **2. THE AIM OF THE EU4HEALTH PERFORMANCE MONITORING AND EVALUATION FRAMEWORK**

According to the Commission Communication on the performance framework for the EU budget under the 2021-2027 MFF<sup>7</sup>, the aim of any performance monitoring and evaluation framework is to ensure that data, information and knowledge is available to measure progress in the Programme's performance every year, and guide the data collection and analysis for the interim and *ex post* evaluations.

The EU4Health performance monitoring and evaluation framework will be used for the interim and final evaluation by Directorate-General for Health and Food Safety (DG SANTE), the Commission's Health Emergency Preparedness and Response Authority (HERA), the Health and Digital Executive Agency (HaDEA), evaluators, and the contractors supporting the evaluation and other interested parties.

## **3. THE PROGRAMME PERFORMANCE MONITORING AND EVALUATION FRAMEWORK**

The EU4Health Programme performance monitoring and evaluation framework includes the intervention logic, a set of sound indicators to collect data, the monitoring, reporting and evaluation arrangements, and the data, information and knowledge management. The EU4Health performance monitoring and evaluation framework was developed in line with the monitoring and evaluation provisions of the EU4Health Regulation<sup>8</sup>.

### **3.1. The EU4Health intervention logic**

The intervention logic reflects the complex interlinkages between the EU4Health Programme's specific objectives as adopted by the co-legislators and the main EU health policies in place on that date or adopted by the EU up to January 2024. To simplify and facilitate communication, the components of the intervention logic – problems and needs, general and specific objectives, and inputs – are discussed below highlighting the main EU health priorities, the Programme's specific objectives, and the relevance of the COVID-19 pandemic in defining the EU4Health intervention. The intervention logic is structured by strand to reflect the approach that is used to communicate with beneficiaries and stakeholders.

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<sup>7</sup> [COM \(2021\) 366 final](#).

<sup>8</sup> Article 19 of the EU4Health Regulation (EU) 2021/522.



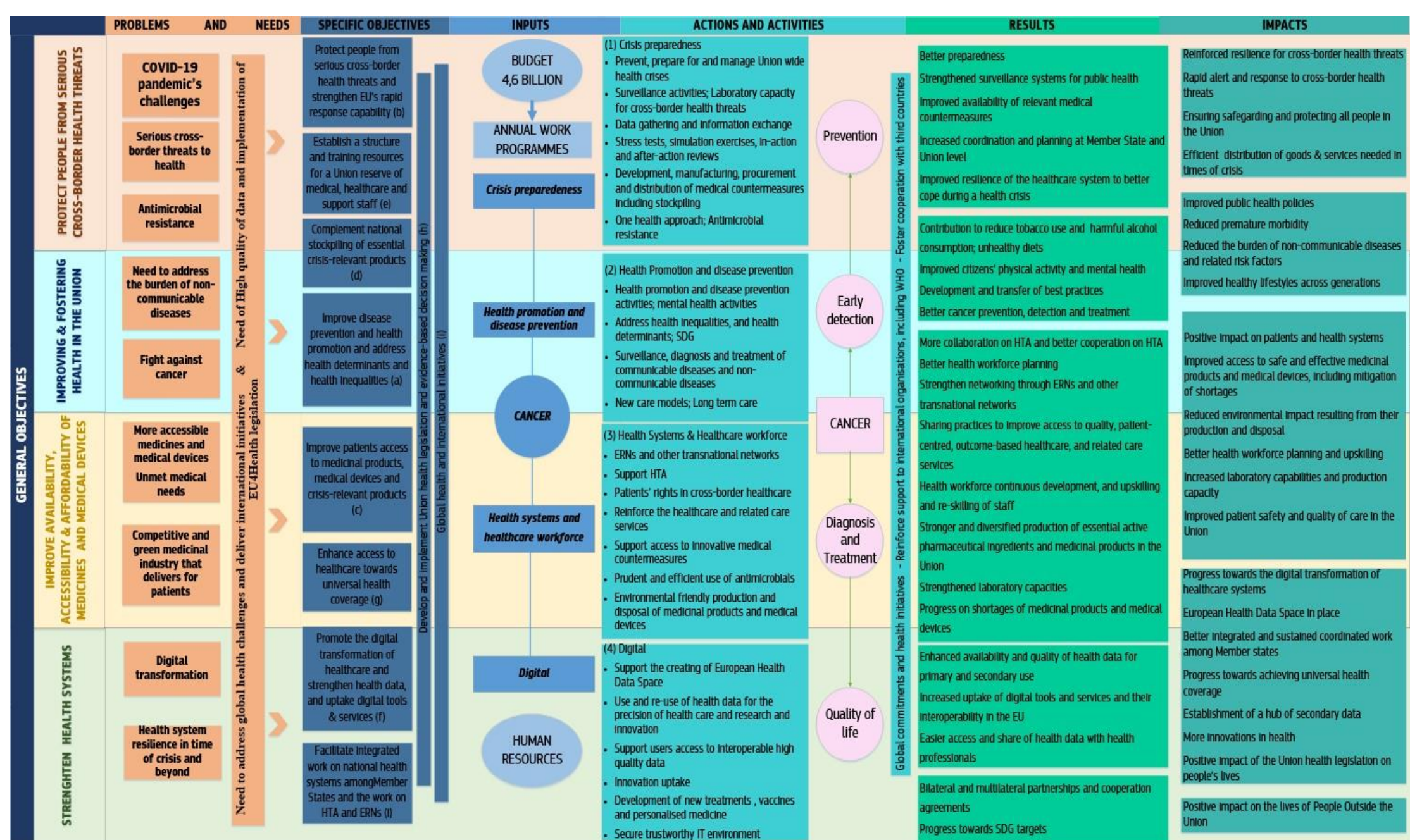


Figure 1 – EU4Health intervention logic

## Problems and needs

### *COVID-19 pandemic challenges and the need to improve the preparedness and response for serious cross-border health threats*

Early in 2020, at the onset of the COVID-19 pandemic, it was clear that existing cooperation and coordination practices among EU Member States in addressing serious cross-border health threats was insufficient. The capabilities to prevent, prepare for and respond to health crises were not optimal and have put to the test the EU's resilience and Member States ability to cope with the COVID-19 pandemic. This prompted broad political support for an enhanced, EU-wide, and national cross-sectoral crisis prevention, preparedness, and surveillance approach. The magnitude of the pandemic also revealed the need to improve the EU's preparedness and response capabilities including by setting up a structure and putting in place training resources for a reserve of medical, healthcare and support staff, and to complement national stockpiling of essential crisis-relevant products. The EU's legal framework on human health<sup>9</sup> with a crisis management structure applying a 'one health'<sup>10</sup> approach was already in place before COVID-19. This built on the experience acquired during the pandemic influenza outbreak of 2009. In addition, the Joint Procurement Agreement was signed by the first countries in 2014 and extensively used during the COVID-19 pandemic.

The COVID-19 pandemic reduced life expectancy across the EU and around the world. It led to a reduction of more than 1 year in life expectancy in the EU in 2021 compared with the pre-pandemic level – the largest drop observed in most EU Member States since World War 2. By the end of October 2022, more than 1.1 million COVID-19 deaths had been reported across the 27 EU Member States as described in 'Health at a Glance: Europe 2022 – State of Health in the EU Cycle'<sup>11</sup>. The pandemic revealed the acute need to increase, through cross-border regional cooperation, the availability of intensive care beds and treatment to relieve over-burdened hospitals. The pandemic also had a profound impact on patients and vulnerable groups. For example, the suspension of non-COVID-19 care affected chronic disease patients, who would have benefited from better integrated work and more effective management of chronic diseases during that challenging time. For instance, the number of people screened for breast cancer decreased, and the number of days on a waiting list increased for hip and knee replacements in 2020, as compared to 2019. The pandemic also highlighted significant health inequalities between patient and social groups and the need to protect people in vulnerable situations and ensure their access to healthcare.

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<sup>9</sup> [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.

<sup>10</sup> 'One Health approach' means a multisectoral approach which recognises that human health is connected to animal health and to the environment, and that actions to tackle threats to health must take into account those three dimensions; Article 2 of the EU4Health Regulation (EU) 2021/522

<sup>11</sup> OECD/EU (2022) [Health at a glance: Europe 2022](#) OECD Publishing, Paris.



### *Antimicrobial resistance*

In 2019, the World Health Organization (WHO) declared antimicrobial resistance (AMR) as one of the top 10 global public health threats facing humanity<sup>12</sup>. AMR<sup>13</sup> is responsible for more than 35 000 deaths every year in the EU/EEA. AMR also has significant costs, including for healthcare systems.

### *The need to address the burden of non-communicable diseases*

Health promotion and disease prevention across sectors are key tools to improve public health and address non-communicable diseases (NCDs). Cardiovascular diseases and cancer are the first and second leading causes of premature mortality in the EU, respectively. For example, improved health promotion and disease prevention can reduce the prevalence of NCDs by as much as 70%<sup>14</sup>. While in 2018, the amount spent on prevention was no more than 2.8% of the total health expenditure in the EU, the costs of treating NCDs are high<sup>15</sup>. In addition, mental illness, neurological disorders, chronic respiratory diseases and diabetes represent major causes of disability. Before the COVID-19 pandemic, 1 in 6 people in the EU suffered from mental health issues, but the situation has worsened since then<sup>16</sup>. Together with ill-health, health-related retirement and premature death in the EU, these health challenges have had a considerable social and economic impact. The significant burden of chronic diseases in the EU has been exacerbated by the COVID-19 pandemic. This had led to the need for more coordinated efforts in the EU to tackle the underlying causes of diseases and to promote best practices in managing them.

### *The fight against cancer*

Cancer is the second leading cause of mortality in EU Member States after cardiovascular diseases. Every year, 2.6 million people are diagnosed with the disease and it kills another 1.2 million people - as mentioned in the Europe's Beating Cancer Plan adopted in February 2021<sup>17</sup>.

### *Health system resilience in times of crisis and beyond*

The COVID-19 pandemic has further revealed the fragility of health systems. The health systems' resilience and resources were challenged by insufficient access to safe, high-quality and affordable medicinal products and medical devices for patients due to high costs and shortages, notably for vulnerable people.

Other challenges to health systems are linked to the need to use resources efficiently, to the rising healthcare demand, and the fragmentation of the internal market for medicinal products and medical devices for patients.

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<sup>12</sup> [Antimicrobial resistance](#), World Health Organisation.

<sup>13</sup> [ECDC Press release](#) 35 000 annual deaths from antimicrobial resistance in the EU/EEA, 17 Nov 2022.

<sup>14</sup> OECD/EU (2016), [Health at a Glance: Europe 2016](#) – State of Health in the EU, OECD Publishing, Paris

<sup>15</sup> Fradgley EA, Paul CL, Bryant J. A systematic review of barriers to optimal outpatient specialist services for individuals with prevalent chronic diseases: what are the unique and common barriers experienced by patients in high income countries [Int J Equity Health 2015; 14: 52](#).

<sup>16</sup> [COM\(2023\) 298 final](#).

<sup>17</sup> [COM/2021/44 final](#).



### *Unmet medical needs*

Unmet medical needs, especially those of vulnerable populations, remain unaddressed. There is a need for innovation and to unlock its potential including through stimuli, to make the best use of research results, and to scale up and deploy health innovations in national healthcare systems and clinical practice. Efforts in this area should build on clinical and real-world evidence to enable the development, authorisation, and evaluation of effective medicinal products.

### *More accessible medicines and medical devices and a competitive and green medicinal industry that delivers for patients*

The Pharmaceutical Strategy for Europe<sup>18</sup>, adopted in 2020, stressed that a new EU approach is needed to ensure a strong, fair, competitive and green industry that delivers for patients, and which draws on the potential of the digital transformation of health and care. It further emphasised that well-functioning international supply chains and a well performing single market for pharmaceuticals is necessary. The available evidence has shown that pharmaceuticals have adverse effects on the environment. There is therefore a need to address the environmental risks associated with the production, use and disposal of medicinal products.

### *Digital transformation*

The COVID-19 pandemic created an unexpected opportunity to advance with the digital transformation of health systems and healthcare, and to improve prevention, diagnosis, treatment, monitoring and management of health-related issues, and to monitor and manage lifestyle-habits that impact health. Innovative digital health and care driven by technological advances in fields such as artificial intelligence and health data interoperability are necessary to improve access to care and its quality, as well as to increase the overall efficiency of the health sector. The preparatory actions for the upcoming regulation to set up the European Health Data Space<sup>19</sup>, and accompanying Communication from the Commission ‘A European Health Data Space: harnessing the power of health data for people, patients and innovation’<sup>20</sup>, published in May 2022, demonstrated the importance of digital services in the health domain.

### *Global health challenges and international initiatives*

The significant global challenges are accompanied by a massive unfinished global agenda and a slow progress towards the health Sustainable Development Goals that has even reversed in many countries<sup>21</sup>. Collectively countries have only achieved about one quarter of what is needed to reach health targets by 2030<sup>22</sup>. At the same time, it is essential to strengthen

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<sup>18</sup> [COM/2019/128 final](#).

<sup>19</sup> [COM/2022/197 final](#).

<sup>20</sup> [COM\(2022\) 196 final](#).

<sup>21</sup> [The Sustainable Development Goals Report 2023](#): Special Edition - Towards a Rescue Plan for People and Planet; United Nations.

<sup>22</sup> [Incentivizing collaboration towards the health-related Sustainable Development Goals](#), Joint News Release, 2022.

global health security swiftly and comprehensively, to better prevent future pandemics and other threats and to increase resilience. The EU's leading role in fighting the COVID-19 pandemic has shown that it can make a major contribution to the global objectives with the 'Team Europe' approach. The EU Global Health Strategy<sup>23</sup> published in November 2022 emphasised that the pandemic has severely disrupted the progress on the Sustainable Development Goals.

#### *EU health legislation implementation, high-quality data needs, synergies across programmes*

Valid, reliable, and comparable high-quality data are necessary for evidence-based decision-making, as well as for the development, sound implementation and monitoring of new and existing health initiatives. Moreover, the existing EU health regulatory framework needs to be managed and evaluated, and synergies need to be developed between the Programme and other EU programmes (e.g. Digital Europe, Horizon Europe, the European Regional Development Fund, the European Social Fund Plus, InvestEU, and the Recovery and Resilience Facility) while avoiding duplication of activities and double funding, and further optimising the use of financial resources.

### **General objectives**

The four general objectives of the EU4Health Regulation<sup>24</sup>, which correspond to the Programme's ambitions, are:

**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<sup>25</sup>;

**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;

**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;

**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;

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<sup>23</sup> European Commission, Directorate-General for Health and Food Safety, [EU global health strategy – Better health for all in a changing world](#), Publications Office of the European Union, 2022.

<sup>24</sup> Article 3 of the EU4Health Regulation (EU) 2021/522.

<sup>25</sup> The letter indicates the correspondence with the general objectives (a), (b), (c) or (d) in Article 3 of the [EU4Health \(EU\) Regulation 2021/522](#).

- (iv) tackling the implications of demographic challenges; and
- (v) advancing digital transformation.

## Specific objectives

The four general objectives (*in italics*) are pursued through the following 10 specific objectives<sup>26</sup>:

### 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)<sup>27</sup>;**
- **Establish a structure and training resources for a Union reserve of medical, healthcare and support staff (e);**
- **Complement national stockpiling of essential crisis-relevant products at EU level (d);**

### Improving and fostering health in the Union

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

### 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);**

### Strengthening health systems

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

### Horizontal specific objectives

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

<sup>26</sup> The specific objectives are presented without the areas of the intervention mentioned in Article 4 of the EU4Health Regulation (EU) 2021/522.

<sup>27</sup> The letter indicates the correspondence with the specific objectives (a), (b), (c), (d), (e), (f), (g), (h), (i) or (j) from the Article 3 of the EU4Health Regulation (EU) 2021/522.

- **Support global commitments and health initiatives (j).**

## Inputs

The total financial allocation for the implementation of the EU4Health Programme initially amounted to **EUR 5.7 billion**. Under the European Health Union, funds were allocated to the extended mandates of ECDC and the EMA. Moreover, the revision of the 2021-2027 MFF redeployed funds across the EU budget, including EUR 1 billion from the EU4Health Programme. As a result, the remaining EU4Health Programme budget stands at EUR 4.6 billion. The Programme must invest at least 20% of its budget in health promotion and disease prevention. It 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<sup>28</sup>. These allocations are monitored on the EU4Health dashboard.

The EU4Health Programme is implemented through **annual work programmes** adopted by the Commission following a positive opinion of the Member States in the EU4Health Programme Committee and building on their and other stakeholders' views. The annual work programmes are structured under five overarching '**strands**', namely:

***Strand 1 Crisis preparedness** covering specific objectives (b), (d), (e), and (j),*

***Strand 2 Health promotion and disease prevention** covering specific objective (a),*

***Strand 3 Health systems and healthcare workforce** covering specific objectives (c), (e), (g), and (i)*

***Strand 4 Digital** covering specific objective (f).*

***Strand 5** the fight against **Cancer** covering specific objective (a), (c), (f), (g), (h), (i), (j)*

The fight against cancer is a major transversal strand that cuts across the other four strands and specific objectives with specific actions such as cancer screening and other prevention actions (health promotion and disease prevention), some European Reference Networks – ERNs (health systems), imaging diagnostic tools (digital), and actions addressing the consequences of the de-prioritisation of cancer-related actions during health crises (crisis preparedness). The strands illustrate the main health priorities at the preparatory stage of the annual work programmes and may change in the future programming.

The five strands are complemented by **horizontal actions** in support of improving evidence-based legislation (*specific objective (h)*) and global health (*specific objective (j)*).

The EU co-financing rate varies for grants, depending on their type, and must not exceed 60%. However, the rate may rise as high as 80% in case of exceptional utility<sup>29</sup>. In specific

<sup>28</sup> Article 5(4) of the [EU4Health Regulation \(EU\) 2021/522](#).

<sup>29</sup> Article 8 (3) of the [EU4Health Regulation \(EU\) 2021/522](#).

cases the co-funding may be up to 100% of the eligible costs<sup>30</sup>, i.e. direct grants to the ERNs or other transnational networks<sup>31</sup> set out in accordance with EU law (e.g. the network of EU reference laboratories for high-risk *in vitro* diagnostic medical devices, the network of Public Health EU reference laboratories<sup>32</sup>, and direct grants to the WHO). Furthermore, prizes and the actions delivered by the international organisations through contribution agreements (indirect management) and services acquired from commercial operators through procurement are also financed at 100% of the eligible costs.

DG SANTE and HERA are responsible for the annual programming of their respective budgets. The European Health and Digital Executive Agency (HaDEA) implements the annual work programme as delegated by DG SANTE and HERA. A limited number of procurements and all the funds disbursed under indirect management are managed by the parent DGs.

## **Actions and activities**

### ***Strand 1: Crisis preparedness***<sup>33</sup>

Under the ***crisis preparedness*** strand, the EU4Health Programme finances actions that help to strengthen the EU 's capability to prevent, prepare for and respond to health crises by supporting coordinated public health measures at EU level to address different aspects of serious cross-border threats to health. The specific aim is to support the implementation of Regulation (EU) 2022/2371 on serious cross-border threats to health<sup>34</sup>. This strand supports surveillance, including by building laboratory capacity for cross-border health threats, as well as exercises and training to improve the management and response capacity of actors at EU and Member State levels. The coordinated EU public health measures are supported by data gathering on serious cross-border health threats and medical countermeasures, and information exchange. Furthermore, the Programme supports the creation of an EU prevention, preparedness and response plan, which should be updated regularly. This plan will undergo stress tests, simulation exercises and in-action and after-action reviews with Member States<sup>35</sup>.

The Programme also supports activities that fall under the remit of DG HERA. These actions aim to ensure the development, manufacturing, procurement and equitable distribution of key medical countermeasures in line with the Commission Communication introducing HERA<sup>36</sup>, the Commission Decision establishing HERA<sup>37</sup> and HERA's annual work plans<sup>38</sup>.

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<sup>30</sup> Article 8(4) of the [EU4Health Regulation \(EU\) 2021/522](#).

<sup>31</sup> Article 100(5) of [Regulation \(EU\) 2017/746](#).

<sup>32</sup> Article 15(3) of [Regulation \(EU\) 2022/2371](#).

<sup>33</sup> Covers specific objectives in Article 4, points (b), (d) and (e), of the [EU4Health Regulation \(EU\) 2021/522](#).

<sup>34</sup> [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.

<sup>35</sup> [EUR-Lex – 32022R2371 – EN – EUR-Lex \(europa.eu\)](#).

<sup>36</sup> [COM\(2021\) 576 final](#).

<sup>37</sup> [C\(2021\) 6712 final](#).

<sup>38</sup> [HERA Work Plan 2022](#).



The Programme is also used to procure and supply essential crisis-relevant products as well as to support the national stockpiling of such products.

The EU4Health Programme supports actions that take a ‘one health’ approach, where applicable. For example, the prudent and efficient use of medicinal products and of antimicrobials, in the transition to better preparedness and the reinforcement of national health systems. To this end, the EU4Health Programme supports the development of new medical countermeasures against AMR, based on gap analysis and needs assessment conducted in the Member States. 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<sup>39</sup>. AMR is one of the top three serious cross-border health threat categories identified that require coordination of measures at EU level on the availability of medical countermeasures. AMR poses one of the greatest risks to human health, causing an annual estimate of over 1.2 million deaths globally<sup>40</sup>. This figure underlines the need to support effective policies to tackle AMR, including on the optimal use of existing antimicrobial medicines, as well as the need for incentives for innovative antimicrobials.

### ***Strand 2: Health promotion and disease prevention<sup>41</sup>***

The Programme supports actions that focus on ***health promotion and disease prevention***, to reduce the burden of NCDs and relevant health determinants, and address health inequalities, as outlined by the ‘Healthier together’ – EU NCD Initiative<sup>42</sup>. It supports the promotion of good mental health and the prevention of mental health problems and their treatment and care, throughout the lifetime of an individual, through a comprehensive prevention-oriented approach to mental health<sup>43</sup>. This strand will help the Member States to reach the UN Sustainable Development Goals and targets<sup>44</sup> and the WHO global NCD targets for 2025<sup>45</sup>.

The Programme may also fund actions for the improvement of the surveillance, diagnosis and treatment of communicable and non-communicable diseases, and gives special attention to innovative care models and the challenges of long-term care to strengthen the resilience of the health systems in the EU.

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<sup>39</sup> [2023/C 220/01](#).

<sup>40</sup> Tang KWK, Millar BC, Moore JE. [Antimicrobial Resistance \(AMR\). Br J Biomed Sci. 2023 Jun 28;80:11387.](#)

<sup>41</sup> Covers specific objective (a) from Article 4 of the [EU4Health Regulation \(EU\) 2021/522](#).

<sup>42</sup> [Healthier Together EU Non-Communicable Diseases Initiative](#).

<sup>43</sup> [Mental health \(europa.eu\)](#) – Commission Communication on a comprehensive approach to mental health.

<sup>44</sup> [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.

<sup>45</sup> [Set of nine voluntary global NCD targets for 2025](#), World Health Organisation 2022 <https://www.who.int/multi-media/details/set-of-nine-voluntary-global-ncd-targets-for-2025>.

### **Strand 3: Health systems and healthcare workforce**<sup>46</sup>

Under the **health systems and healthcare workforce** strand, the Programme finances actions that help strengthen national health systems and the health workforce by improving their resilience and resource efficiency. To that end, the Programme supports networking through ERNs and other transnational networks, the work on HTA, and the Directive on patients' rights in cross-border healthcare<sup>47</sup>. It contributes to reinforcing the healthcare workforce, and to advancing the digital transformation of health systems. This strand also supports actions that enhance access to quality, patient-centred, outcome-based healthcare, and related care services, with the aim of achieving universal health coverage. It supports access to health and care services for people with disabilities and other vulnerable or disadvantaged population groups.

The Programme also supports actions to increase the availability, accessibility and affordability of innovative products, including therapeutics, vaccines, medical devices and crisis-relevant medical countermeasures, by encouraging sustainable production and supply chains and innovation (in synergy with Horizon Europe) in the EU, aligned to the measures proposed in the Communication to tackle medicine shortages in the EU<sup>48</sup>. Some of the specific projects in this strand will help to deliver on the policy actions described in the Commission Communication on shortages of medicines. The EU4Health Programme also supports actions contributing to the prudent and efficient use of medicinal products, in particular antimicrobials, and actions contributing to 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. The implementation of EU regulatory frameworks such as for pharmaceuticals, medical devices and substances of human origin is supported by specific actions and activities.

Other actions are expected to increase the capacity building of Member States and strengthen the collaboration with the EMA.

### **Strand 4: Digital**<sup>49</sup>

To advance the digital transformation of health systems and the creation of a European Health Data Space, the EU4Health Programme under the **digital** strand supports actions that strengthen the use and re-use of health data for the provision of healthcare and for research and innovation and regulatory and policymaking activities. The 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 re-use of health data.

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<sup>46</sup> Covers specific objectives (c), (e), (g), and (i) from Article 4 of the [EU4Health Regulation \(EU\) 2021/522](#).

<sup>47</sup> [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.

<sup>48</sup> [COM\(2023\) 672 final](#).

<sup>49</sup> Covers specific objective (f) from Article 4 of the [EU4Health Regulation \(EU\) 2021/522](#).

## **Strand 5: Cancer**

The fight against **cancer** is driven by Europe's Beating Cancer Plan and its four key action areas: prevention; early detection; diagnosis and treatment; and quality of life improvement for cancer patients, survivors, and carers. The Plan also addresses cross-cutting topics such as research, innovation and digitalisation, inequalities and paediatric cancer. The **cancer** strand of the EU4Health Programme supports the 10 flagship initiatives of Europe's Beating Cancer Plan: the Knowledge Centre on Cancer; Cancer Diagnostic and Treatment for All initiative; the European cancer imaging initiative; the European initiative to understand cancer; eliminate cancers caused by human papillomavirus; better life for cancer patients initiative; EU cancer screening scheme; European Cancer Inequalities Registry; EU network of national comprehensive cancer centres and the helping children with cancer initiative<sup>50</sup>. Many other supporting actions described in the list of actions<sup>51</sup> annexed to the Plan are supported by the EU4Health Programme and other EU funding programmes such as Horizon Europe and its Cancer Mission and the Digital Europe programme.

### ***Horizontal actions***<sup>52</sup>

The Programme supports actions for the *development, implementation and enforcement and, where necessary, the revision of Union health legislation*. It finances the provision of valid, reliable and comparable high-quality data for evidence-based decision-making and monitoring and promotes the use of health impact assessments of other relevant EU policies. The Programme, in cooperation with relevant bodies such as the EMA and ECDC, should provide high-quality, comparable, and reliable data, including real-world healthcare data, to support policymaking and monitoring, set targets and develop tools to measure progress.

The EU has a central role to play in tackling *global health challenges* and the EU4Health Programme consolidates EU support for international health initiatives and cooperation, for initiatives by the WHO, with the aim of improving health, addressing health inequalities, and increasing preparedness against global health threats. The 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. With regard candidate countries, the Programme will also support the alignment of their respective health systems with EU health standards. The Programme supports strengthen the global health emergency response architecture in the area of medical countermeasures by collaborating with EU and international partners, with the implementation of actions like the global consortium for wastewater surveillance, clinical trials, AMR, sequencing and environmental surveillance capacities, enhancing data collection and exchanges.

The Programme supports *recurrent actions and activities*, such as communication activities, the organisation of events in the field of health, logistical support to meetings of expert groups and similar entities as well as of relevant scientific committees (e.g. the Scientific

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<sup>50</sup> [Beating Cancer Plan flagship initiatives](#).

<sup>51</sup> [COM\(2023\) 298 final](#).

<sup>52</sup> Covers specific objectives (h) and (j) from Article 4 of the [EU4Health Regulation \(EU\) 2021/522](#).

Committee on Consumer Safety, Scientific Committee on Health, Environmental and Emerging risks, etc.) in the field of risk assessment for health, environment, emerging risks and consumers safety. The communication activities are addressed to the public or to specific groups of people or professionals, to promote healthy lifestyles and prevent disease, to disseminate best practices, to counter misinformation and disinformation on the prevention, cause and treatment of diseases, to address vaccine hesitancy and to support efforts to strengthen altruistic behaviour, such as organ and blood donation, in a manner that complements national campaigns on those matters. The Programme also supports interaction with stakeholders and synergies among different stakeholder groups including through the EU Health Policy Platform.

## Results

Results of *crisis preparedness* actions are expected to include: better preparedness; strengthened surveillance systems for public health; improved availability and accessibility of relevant medical countermeasures; increased coordination and planning at Member State, EU and global level for future health emergencies; and improved resilience of healthcare systems in the event of a health crisis.

The *health promotion and disease prevention* actions will contribute to reducing the burden of major NCDs and related risk factors, including socio-economic risk factors, use of tobacco and related products, harm due to alcohol use, unhealthy diet, physical inactivity, and environmental risk factors for health.

Furthermore, those actions are expected to contribute to improving mental health, identifying and extending best practices for disease prevention and health promotion, and supporting an integrated response to communicable and non-communicable diseases. To that end, they will focus on the exchange of knowledge and best practices for health promotion, disease prevention and on addressing health inequalities.

The actions on *cancer* are expected to result in better cancer prevention through reducing exposure to and raising awareness of relevant risk factors, access to high-quality healthcare and related care services, improvement of vaccination coverage rates for vaccine-preventable diseases, increased screening coverage for certain cancers and a comprehensive information system on cancer.

The *health systems and healthcare workforce* actions are expected to increase the collaboration on HTA, contribute to better health workforce planning, strengthen networking through ERNs and other transnational networks, and improve access to quality, patient-centred, outcome-based healthcare, and related care services including for people with disabilities, vulnerable and disadvantaged population groups via sharing best practices and other approaches. The continuous professional development of the health workforce will be enhanced via training including upskilling and re-skilling of staff.

The actions to improve the availability, accessibility and affordability of medicinal products, medical devices and crisis-relevant products are expected to result, for example, in a stronger

and diversified production of essential active pharmaceutical ingredients and medicinal products in the EU, contribute to mitigate shortages, strengthened laboratory capacity in the EU and progress towards an EU system for the monitoring, reporting and notification of shortages of medicinal products and the availability of medical devices. Some actions will also bring about a safe, effective, and innovative medicinal products and medical devices and will encourage environmentally friendly and sustainable production and supply chains and innovation in the EU, as well as a rational use of medicinal products. Some specific actions are designed to contribute to delivering on the policy actions described in the Commission Communication on shortages of medicines<sup>53</sup>. Finally, the actions should enable sustainable production and supply chains, innovation and the efficient use of medicinal products and medical devices in the EU in the future, and contribute to public health.

The *digital* actions are expected to increase the availability and quality of health data for primary and secondary use at European level, among other results. This should in turn contribute to increasing the uptake of digital tools and services and their interoperability in the EU. The aim is easier access to and sharing of patient health data with health professionals, with less need to re-do tests unnecessarily while maintaining high security and data standards. Researchers, innovators, regulators and policymakers will be given access to untapped health data for innovation and research, and policymaking and regulatory activities.

Outside the EU, the EU4Health Programme funded actions on global health will strengthen the health security architecture including early detection of cross-border health threats and availability of medical countermeasures, promote good health for all and support high-quality public health principles, standards and legislation through bilateral and multilateral partnerships and cooperation agreements. Progress is expected on reaching the targets of the UN 2030 Agenda for Sustainable Development.

Communication activities supported by the Programme will increase awareness among health professionals and specific population groups such as vulnerable people on, for example, promoting health and healthy lifestyles, and preventing diseases. Such activities are expected to help counter misinformation and disinformation on the prevention, the cause and treatment of diseases. The aim is to address vaccine hesitancy and support efforts to strengthen altruistic behaviour, such as organ and blood donation, in a way that complements national campaigns.

## Impacts

The crisis preparedness strand is expected to lead to better safeguards to protect people in the EU from serious cross-border threats to health. It aims to enhance prevention and preparedness so as to promptly and efficiently address and manage all types of serious cross-border health threats, including outbreaks of infectious diseases and pandemics, health risks due to climate change or man-made disasters, and to boost capabilities to react to and manage such crises. Other expected impacts are improved EU resilience to cross-border health threats

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<sup>53</sup> [COM\(2023\) 672 final](#).



including through timely response thanks to rapid alerts and the availability of and timely distribution of adequate medical countermeasures in times of crisis.

On health promotion and disease prevention, the funded actions will set in motion improved public health policies – specifically: healthier lifestyles across generations; decreased morbidity and premature mortality from NCDs; better prevention and preparedness in the event of pandemics and epidemics; healthier environments; and better protection of people in vulnerable situations including those with mental health problems. The financed actions are also expected to reduce inequalities in healthcare - both within and between Member States - and reduce cancer mortality, in particular for paediatric cancer.

More effective, resilient, and accessible health systems should have a positive impact on patients and healthcare systems. In addition, an increase in the availability and timely access to safe, effective medicinal products, medical devices and crisis-relevant products, including vaccines, that are affordable and have a lower environmental impact resulting from their production and disposal is expected, which will increase patients' safety and health. Health workforce planning is expected to improve, as is the upskilling of the health workforce including their digital skills. Increased laboratory capabilities and production capacity, and improved patient safety and quality of care in the EU are all expected in the long-term.

On the digital transition, the expected impact is progress towards the digital transformation of healthcare systems and the creation of a European Health Data Space. This in turn is expected to lead to better integrated and more coordinated work among the Member States and progress on achieving universal health coverage. Furthermore, the EU is expected to be a hub of secondary health data which can lead to more innovation in health.

EU health legislation has an immediate impact on public health, on the lives of people, on the efficiency and resilience of health systems and on the proper functioning of the internal market.

### **3.2. Indicators for Programme performance monitoring and evaluation**

The Programme's annual performance and progress towards its objectives will be monitored over 2021-2027 with the help of input, output, results and impact indicators. At least one 'output' indicator and one 'results' indicator<sup>54</sup> have been designed for each specific objective of the EU4Health Programme<sup>55</sup> (see Annex 1).

Nine indicators related to flagship health policies<sup>56</sup> and designated *key performance indicators* serve as a stable reference for the annual performance reporting and will showcase

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<sup>54</sup> [MFF Performance Results Reports](#).

<sup>55</sup> Article 4 of the [EU4Health Regulation \(EU\) 2021/522](#).

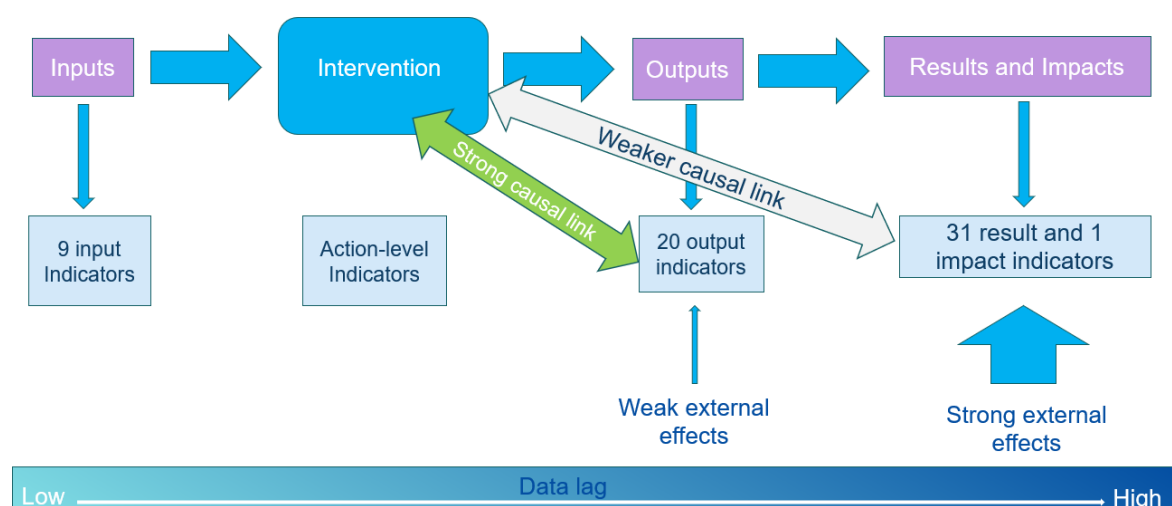
<sup>56</sup> [Healthier Together Initiative](#), [Cross-border threats to health Regulation \(EU\) 2022/2371](#), Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union ([COM/2021/576 final](#)), the Pharmaceutical Strategy ([COM/2020/761 final](#)), the planned European Health Data Space ([COM/2022/197 final](#)), the European Reference Networks ([C/2019/5470](#)), etc.

the annual implementation status of the EU4Health Programme in the Programme Performance Statement (see Annex 2).

The Programme indicators cover each strand (see Annex 3) and are complemented by **action-level indicators** that are available to monitor the outputs and results of each action funded through grants, procurement, prizes and contribution agreements.

The EU4Health dashboard includes several **other indicators** such as number of actions per specific objective, number of and type of eligible beneficiaries per country, etc. and will be used to monitor inputs.

The current set of indicators may be adjusted following the Programme's interim evaluation and in line with relevant unexpected events such as changes in the Commission's political priorities.



**Figure 2: The types of EU4Health indicators** (adapted figure from the Better Regulation toolbox #43)

### Input indicators (9)

The relevant inputs for the EU4Health intervention are the financial and human resources allocated. The nine input indicators enable the collection of data related to the investments made per annual work programme, per specific objective and per area of action (annual programme strand, policy area) at both action and project level. Additional input indicators are available on the EU4Health dashboard and collect data such as: the number of financed projects per action and per policy area; the number of actions per specific objective; the number of financed projects per specific objective; and the number of beneficiaries per eligible country, per strand, per policy area and per specific objective (see Annex 1).

## **Output indicators (20)**

Data related to outputs, for example, the number of programmed actions in a particular area of intervention (strand) and the number of activities (e.g. training, guidelines prepared, studies, contribution agreements, etc.) are collected with the help of the 20 output indicators. Other indicators inform the monitoring on outputs, such as: the number of Member States participating in the prevention, preparedness and response planning joint action; the number of new capacity building activities (EU, Member States) for improved integrated surveillance systems; or the number of Member States participating in stockpiling activities. At least one output indicator has been defined for each specific objective of the Programme.

## **Results indicators (31)**

The immediate and medium-term direct effects of the EU4Health initiative and its actions are monitored by 31 results indicators that cover all of the Programme's specific objectives and actions.

## **Impact indicators (1)**

One impact indicator will be used to collect quantitative data for the Programme performance assessment.

## **Contextual indicators**

Relevant contextual indicators will be selected, depending on the needs that emerge during the analysis of the data and performance assessment, from those published by Eurostat<sup>57</sup> or by relevant European Core Health Indicators (ECHI) on the demographic and socio-economic situation, health status, health determinants, health services or health promotion, etc.

## **Action-level indicators**

All the actions financed by the EU4Health Programme include indicators. These are designed to monitor the outputs and results of the funded actions (grants, procurements and contribution agreements). Some of the action-level indicators are used to monitor the implementation of the Programme. That is the case where a particular specific objective of the Programme is implemented via a single action and/or a limited number of very similar actions that should use the same types of indicators or very similar indicators.

### **3.3. Monitoring, reporting and evaluation arrangements**

#### **Monitoring overview**

Monitoring is a systematic process to track progress and generate information for performance assessment and evaluation. Arrangements therefore need to be set up for

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<sup>57</sup> [Key figures on Europe 2022 edition.](#)

collecting, processing, and using and reusing data. The EU4Health monitoring system benefits from a comprehensive and balanced set of indicators and processes that enable the collection of data on inputs, outputs, results, and impacts and report on the Programme's progress towards achieving its objectives. These indicators enable an annual performance assessment and a deeper analysis of performance in the interim and *ex post* evaluations of the programmes. The results of these assessments are an essential input to inform upcoming programming, decision-making on the budget and the design of future programmes.

As the effects of the funded actions are not always immediately clear, monitoring beyond the end of the 2021-2027 MFF may be necessary.

The actors involved in the programming and implementation of the EU4Health annual work programme are involved in data collection exercises, and the relevant contracting authority<sup>58</sup> is responsible for appropriate data collection, processing, validation and storage.

### **Annual Programme performance monitoring and reporting**

The Programme Performance Statement<sup>59</sup> 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. It includes concrete examples of achievements, the rationale and design of the annual work programme, the contribution to the Commission's general priorities, and the budget performance implementation and outcomes.

### **Monitoring of contract implementation**

In line with their contractual obligations, beneficiaries report to the contract authority periodically with deliverables, interim reports, or final reports and the action-level indicators for each contract. These are assessed by HaDEA, DG SANTE or HERA, and if accepted, are the basis of a payment. In addition, the beneficiaries have the obligation to report on the action-level indicators periodically. The appropriate data are collected, processed, validated and stored by the relevant contracting authority<sup>60</sup> and will inform the annual Programme performance assessment and the evaluations.

## **3.4. Evaluation arrangements**

The Programme performance interim evaluation, and the final evaluation will be carried out according to the Commission Communication on Better Regulation<sup>61</sup>, the relevant guidelines<sup>62</sup> and toolbox<sup>63</sup>. The evaluations will address the relevance, coherence, efficiency, effectiveness and EU added value of the EU4Health Programme.

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<sup>58</sup> DG SANTE, HERA or HaDEA.

<sup>59</sup> [EU4Health Programme – Performance: EU Programme for a Healthier and Safer Union.](#)

<sup>60</sup> Ibid 59.

<sup>61</sup> [Better Regulation: Joining forces to make better laws.](#)

<sup>62</sup> [Better Regulation Guidelines.](#)

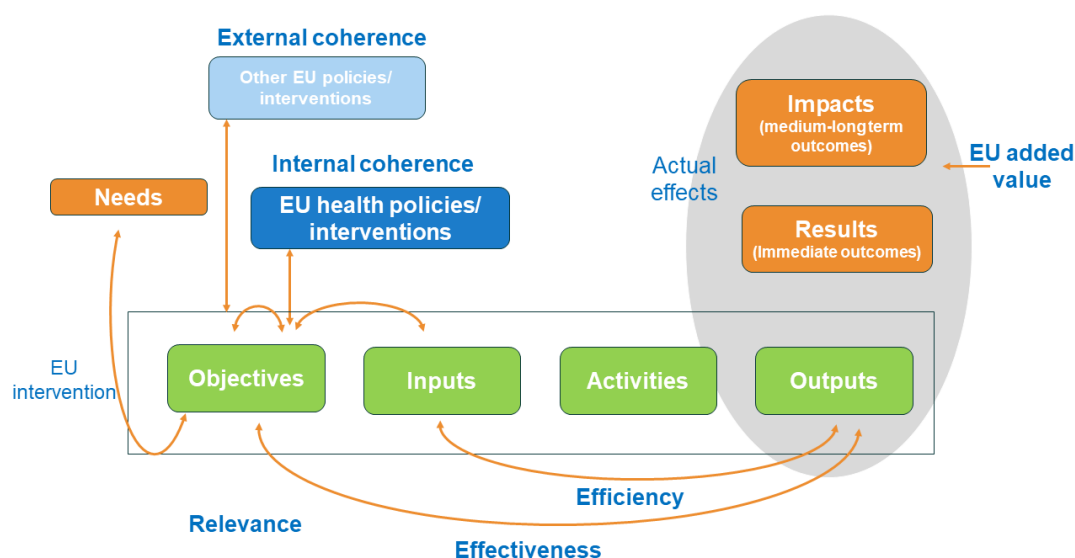
<sup>63</sup> [Better Regulation Toolbox.](#)

## Interim evaluation

The interim evaluation will assess the relevance of the specific objectives and actions of the EU4Health Programme, including whether it remains relevant to emerging needs. It will measure whether the Programme delivered effectively and efficiently on its intended objectives by the cut-off date and to the extent results are already available. The interim evaluation will be the basis for possible adjustments to the implementation of the Programme and the results will feed into the decision-making process, including for the next MFF, as appropriate. The cut-off date for collecting data for the interim evaluation is April 2024, to allow sufficient time for processing and analysis of the data before the publication of its results at the end of 2024. As by the cut-off date only a limited number of actions will have reached completion, the data required to assess the effectiveness and efficiency of the Programme is expected to be limited to actions that were already completed by that date.

The interim evaluation will review the coherence of the actions within the EU4Health Programme and with other relevant EU initiatives and the EU added value of the programmed and implemented actions.

The interim evaluation will cover all Member States and participating non-EU countries. It will cover the EU4Health Programme's implementation period and its annual work programmes for 2021, 2022, 2023 and 2024, until April 2024. The interim evaluation will be supported by a study, and the five evaluation criteria and associated questions<sup>64</sup> will structure the analysis.



**Figure 3 Simplified view of the intervention and the five key evaluation criteria**

(source: adapted from the Better Regulation toolbox TOOL #47.)

<sup>64</sup> [Better Regulation Tool # 47.](#)



Figure 3 shows the interplay between the evaluation criteria and the main elements of the intervention logic. This guides the development of the ‘evaluation matrix’, data collection and analysis. The evaluation criteria and the Programme and evaluation indicators are closely connected (Annex 4). For example, the data collected using the output indicators will inform the relevance criteria and the input, results and impact indicators will inform the assessment of the Programme’s effectiveness and efficiency. The evaluation matrix will identify the sub-question, judgement criteria, indicators, and data sources for each evaluation question.

### **Ex post evaluation**

The ex-post evaluation will use a similar approach to the interim evaluation and will build on its results. Where relevant, those results will be used as point of comparison for assessing the performance after the end of the Programme’s implementation period.

## **4. DATA, INFORMATION AND KNOWLEDGE MANAGEMENT**

The EU4Health Programme performance monitoring and evaluation framework will be in line with the Commission’s Data Governance and Data Policies<sup>65</sup>.

### **Data collection**

Data are collected by the Commission, HaDEA and beneficiaries of the EU4Health funds throughout the 2021-2027 MFF. They can be collected through surveys or acquired from third parties. Data are mainly collected at the proposal stage or the evaluation, grant agreement / procurement contract and reporting stages, through the EU4Health dashboard that supports the entire life cycle of the Programme. Most data are provided by the beneficiaries through forms (proposals template, periodic reporting template, final reporting template) and supplemented through the Programme’s life cycle with other information (evaluation, financing, etc.).

Data are collected to progressively monitor the Programme’s contribution to crosscutting policy objectives such as addressing climate change, the digital transition, gender equality and the relevant Sustainable Development Goals (SDG 3).

### **The EU4Health dashboard**

The most relevant internal and external data are gathered in one single integrated database, which forms the basis of the EU4Health dashboard. That database builds on the Horizon Europe e-Grants system<sup>66</sup> and specific dashboard IT applications, and facilitates the visualisation of the collected information. Beside grants, the EU4Health dashboard (currently in the production stage) will include information on prizes, procurements and contribution agreements. A public version of the EU4Health dashboard is planned to be deployed during 2024. In addition, the general public can find information about the projects and the related

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<sup>65</sup> [Data governance and data policies at the European Commission.](#)

<sup>66</sup> [Horizon Dashboard.](#)

documents in the [EU Funding & Tenders Portal](#)<sup>67</sup>, and users in the Commission members can mine unstructured text documents stemming from the e-Grants suite (SEDIA) with CORTEX<sup>68</sup>.

### **Data analytics**

Relevant data on grants (calls, applicants, proposals, evaluations, grants, participants, project results, etc.) is collected and aggregated in CORDA (Common Research Data). The Funding & Tenders Portal<sup>69</sup> provides information about the calls that have been launched, the details of funded projects and their results. The EU4Health dashboard enables the analysis and visualisation of inputs (budget) per specific objective of the Programme and per strand, year, form of funding, etc.

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<sup>67</sup> [EU Funding & Tenders Portal CORDIS](#).

<sup>68</sup> [CORTEX Database](#).

<sup>69</sup> [Funding & Tenders Portal](#).

## Annex 1: Programme indicators and their distribution per specific objective

The set of EU4Health indicators is presented below, broken down per specific objective of the Programme. Each indicator's metadata mentions, among other things, the type of indicator: output, results or impact. Several milestones and targets stem from Annex 2 to the EU4Health Regulation and others are set by the EU health policies and priorities, legislative and/or non-legislative. The indicators below that originate from Annex 2 to the EU4Health Regulation include a reference (i.e. indicator #number) to their respective number mentioned in that annex.

### Specific objective (a) Supporting actions for disease prevention, for health promotion and for addressing health determinants

Indicator name	Number of actions contributing to the reduction of avoidable mortality in the area of non-communicable diseases and risk factors
Definition	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.
Type of indicator	Quantitative; output
Data sources	Annual work programmes –
Frequency of measurement	Annual
Baseline <sup>70</sup> (2020)	0
Milestone (mid-2024)	5
Target (2027)	20
Notes	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
Indicator name	Number of Member States implementing best practices regarding health promotion, disease prevention and addressing health inequalities – KEY PERFORMANCE INDICATOR

<sup>70</sup> The baseline is set by default to 2020 as the year of reference. It may be set earlier, in cases where the data is not available for that year and/or the last available data was collected in another year, or it may be set later when the implementation of a particular priority or legislation starts later than the year of reference.

Definition	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 ( <a href="#">C(2022) 8816 final</a> ).
Type of indicator	Quantitative; result
Data sources	e-Grants projects; CORDA – DG SANTE
Frequency of measurement	Annual
Baseline 2020)	0
Milestone (mid-2024)	10
Milestone (2027):	15
Target (mid-2031)	20
Comments	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.
<b>Indicator name</b>	<b>Vaccination coverage for measles<sup>71</sup></b> (sub-indicator 7.1)
Definition	The number of EU Member States having reached 95% coverage for both the first and the second dose of the measles vaccine for eligible individuals
Type of indicator	Quantitative; result
Data sources	Reports – ECDC and WHO
Frequency of measurement	Annual
Baseline (2020)	5
Milestone 2024)	6
Milestone (2027)	7
Target (2030 or mid-2031)	8
Comments	Relative proxy indicator; uncertain targets and milestones; no direct causal link, any progress is an achievement. To operationalise it, indicator 7 <i>Vaccination coverage by age for vaccine-preventable diseases such as measles, seasonal influenza, human papillomaviruses (HPV) and coronavirus COVID-19</i> 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.
<b>Indicator name</b>	<b>Vaccination coverage for seasonal influenza<sup>72</sup></b> – (sub-indicator 7.2)
Definition	The number of EU Member that have reached 75% coverage for the seasonal influenza vaccine in older age groups.
Type of indicator	Quantitative; result
Data sources	Reports – ECDC
Frequency of measurement	Annual
Baseline (2018)	0
Milestone (mid-2024)	1
Milestone (2027)	2
Target (2030 or mid-2031)	4
Comments	Relative proxy indicator, baseline from 2018, last time when data were

<sup>71</sup> The indicators 7.1, 7.2, 7.3 and 7.4 are sub-indicators of indicator 7 ‘Vaccination coverage by age for vaccine-preventable diseases such as measles, seasonal influenza, human papillomaviruses (HPV) and coronavirus COVID-19’ from Annex 2 to the [EU4Health Regulation \(EU\) 2021/522](#).

<sup>72</sup> Ibid 56.

	collected; uncertain targets and milestones; no direct causal link, any progress is an achievement. The public health target, set in the <a href="#">Council Recommendation on seasonal influenza from 2009</a> , 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 <i>Vaccination coverage by age for vaccine-preventable diseases such as measles, seasonal influenza, human papillomaviruses (HPV) and coronavirus COVID-19</i> 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.
<b>Indicator name</b>	<b>Vaccination coverage for human papillomaviruses (HPV)<sup>73</sup></b> – (sub-indicator 7.3)
Definition	The number of EU Member having reached at least 90% coverage for a full vaccination course (last dose) in eligible girls.
Type of indicator	Quantitative; result
Data sources	Reports – ECDC/WHO
Frequency of measurement	Annual
Baseline (2021)	1
Milestone (mid-2024)	2
Milestone (2027)	10
Link with specific objective	
Target (2030 or mid-2031)	27
Comments	Relative proxy indicator; no direct causal link, any progress is an achievement. The public health goal, set in the <a href="#">Europe's Beating Cancer Plan</a> , is for all Member States to have vaccinated at least 90% of the EU target population of girls and to significantly increase the vaccination of boys by 2030 or mid-2031. As completed by the forthcoming Council recommendation on HPV vaccination. To operationalise it, the indicator 7 <i>Vaccination coverage by age for vaccine-preventable diseases such as measles, seasonal influenza, human papillomaviruses (HPV) and coronavirus COVID-19</i> 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.
<b>Indicator name</b>	<b>Age-standardised five-year net survival rate for paediatric cancer (to the extent available)</b> – (indicator 9)
Definition	Percentage of population covered by Cancer Registries reporting information on rates of European children (aged 0–14 years) that have survived for five years post cancer diagnosis.
Type of indicator	Quantitative composite; impact
Data sources	Reports – EURO CARE and European Cancer Information System
Frequency of measurement	Annual
Baseline (2022)	Number; to be defined
Milestone (mid-2024)	Number; to be defined
Milestone (2027)	Number; to be defined
Target (2030 or mid-2031)	Number; to be defined
Comments	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. The cancer registries are recording the survival rates for paediatric cancer. Monitoring the survival rate allows investigations into the causes of higher or lower survival rates supporting health promotion by identifying specific needs.

<sup>73</sup> Ibid 56.



<b>Indicator name</b>	<b>Breast cancer screening coverage<sup>74</sup> – (sub-indicator 10.1)</b>
Definition	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 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.
Type of indicator	Quantitative; result
Data sources	Eurostat: Preventive cancer screenings – programme data ( <a href="https://ec.europa.eu/eurostat/databrowser/view/hlth_ps_prev/default/table?lang=en">https://ec.europa.eu/eurostat/databrowser/view/hlth_ps_prev/default/table?lang=en</a> ); partially available (not for all EU Member States) from 2000 to 2020 full availability for all EU Member States that have screening programmes from 2021.
Frequency of measurement	Annual
Baseline (2021)	6
Milestone (mid-2024)	6
Milestone (2027)	7
Target (2030)	12
Comments	<p>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.</p> <p>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).</p>
<b>Indicator name</b>	<b>Cervical cancer screening coverage<sup>75</sup> – (sub-indicator 10.2)</b>
Definition	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).
Type of indicator	Quantitative; result
Data sources	<p>Eurostat; partially available (not for all EU Member States) from 2000 to 2020 full availability for all EU Member States with screening programmes from 2021.</p> <p>Eurostat: Preventive cancer screenings – programme data (<a href="https://ec.europa.eu/eurostat/databrowser/view/hlth_ps_prev/default/table?lang=en">https://ec.europa.eu/eurostat/databrowser/view/hlth_ps_prev/default/table?lang=en</a>)</p>
Frequency of measurement	Annually (administrative data)
Baseline (2021)	5
Milestone (mid-2024)	5
Milestone (2027)	6

<sup>74</sup> The indicators 10.1, 10.2. and 10.3 are sub-indicators of the 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 \(EU\) 2021/522](#).

<sup>75</sup> Ibid 57.

Target (2030)	10
Comments	<p>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.</p> <p>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)</p>
<b>Indicator name</b>	<b>Colorectal cancer screening coverage<sup>76</sup> – (sub-indicator 10.3)</b>
Definition	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).
Type of indicator	Quantitative; result
Data sources	Eurostat: Preventive cancer screenings - programme data ( <a href="https://ec.europa.eu/eurostat/databrowser/view/hlth_ps_prev/default/table?lang=en">https://ec.europa.eu/eurostat/databrowser/view/hlth_ps_prev/default/table?lang=en</a> )
Frequency of measurement	Annually (administrative data)
Baseline (2021)	9
Milestone (mid-2027)	9
Target (2033)	13
Comments	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.
<b>Indicator name</b>	<b>Percentage of population covered by Cancer Registries reporting information on cervical, breast, colorectal and paediatric cancer stage at diagnosis – (indicator 11)</b>
Definition	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 covered by the cancer registry/ies (residents in a specific area) over the total population of the Member State.
Type of indicator	Quantitative; result
Data sources	European Network of Cancer Registries - DG JRC
Frequency of measurement	Annual
Baseline (2015)	Cervical cancer 48%; breast 48%; colorectal 48%; paediatric 54% (first time data available in 2022)
Milestone (mid-2024)	60% for each type of cancer
Target (2027)	70% for each type of cancer
Comments	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 contribute to health promotion and disease prevention.
<b>Indicator name</b>	<b>Number of Member States reporting information on cervical, breast, colorectal and paediatric cancer stage at diagnosis</b>

<sup>76</sup> Ibid 57.

Definition	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.
Type of indicator	Quantitative; result
Data sources	European Network of Cancer Registries – DG JRC
Frequency of measurement	Annual
Baseline (2015)	<ul style="list-style-type: none"> <li>- Number of Member States reporting cervical cancer stage at diagnosis: 20</li> <li>- Number of Member States reporting breast cancer stage at diagnosis: 20</li> <li>- Number of Member States reporting colorectal cancer stage at diagnosis: 20</li> <li>- Number of Member States paediatric: 26 (first time data available in 2022)</li> </ul>
Milestone (mid-2024)	24 (for each type of cancer); 26 (for paediatric cancer)
Target (2027)	27 (for each type of cancer)
Comments	n/a
<b>Indicator name</b>	<b>Number of actions addressing the prevalence of major chronic diseases per Member State, by disease, gender, and age – (indicator 12)</b>
Definition	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.
Type of indicator	Quantitative; output
Data sources	e-Grants; CORDA – DG SANTE
Frequency of measurement	Annual
Baseline (2020)	0
Milestone (mid-2024)	70
Target (2027)	92
Comments	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.
<b>Indicator name</b>	<b>Number of actions addressing the age prevalence of tobacco use, if possible, differentiated by gender – (indicator 13)</b>
Definition	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.
Type of indicator	Quantitative; output
Data sources	e-Grants; CORDA – DG SANTE
Frequency of measurement	Annual
Baseline (2020)	0
Milestone (mid-2024)	1
Target (2027)	2
Comments	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.
<b>Indicator name</b>	<b>Number of actions addressing the prevalence of harmful use of alcohol, if</b>

	<b>possible, differentiated by gender and age – (indicator 14)</b>
Definition	The sum of actions addressing the prevalence of harmful use of alcohol and 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.
Type of indicator	Quantitative; output
Data sources	e-Grants; CORDA – DG SANTE
Frequency of measurement	Annual
Baseline (2020)	0
Milestone (mid-2024)	1
Target (2027)	2
Comments	Uncertain target and milestone because the number of actions depends on the programming process that involves Member States; differentiation by age and gender may not always be possible; indicators will be defined at action level to collect data by gender.
<b>Indicator name</b>	<b>Number of actions addressing environmental risk factors for health – (indicator 23)</b>
Definition	The sum of actions addressing environmental risk factors for health and delivering the policy objectives of the Europe’s Beating Cancer Plan and the ‘Healthier together’ EU NCD initiative. Actions that address environmental risk factors for health will be counted.
Type of indicator	Quantitative; output
Data sources	e-Grants; CORDA – DG SANTE
Frequency of measurement	Annual
Baseline (2020)	0
Milestone (mid-2024)	4
Target (2027)	7
Comments	Uncertain target and milestone because the number of actions depends on the programming process that involves Member States.

### Specific objective (b) Prevention, preparedness & response to cross-border health threats

<b>Indicator name</b>	<b>Preparedness and response planning of the Union and of Member States for serious cross-border threats to health – (sub-indicator<sup>77</sup> 1.1) KEY PERFORMANCE INDICATOR</b>
Definition	Number of Member States and associated countries participating in more than one EU action aimed at improving prevention, preparedness and response planning for serious cross-border threats to health excluding capacity building activities to improve integrated surveillance.
Type of indicator	Quantitative; output
Data sources	e-Grants – DG SANTE and HERA
Frequency of measurement	Every 3 years
Baseline (2020)	0
Milestone (2024)	26
Target (2027)	32
Comments	The value for the target will increase in the future with the number of countries associated to the

	EU4health Programme.
<b>Indicator name</b>	<b>Number of Member States participating in the prevention, preparedness and response planning joint action</b> – (sub-indicator 1.2)
Definition	Number of national competent authorities in Member States and associated countries participating in the joint action on prevention, preparedness and response planning according to Articles 7-11 of the Cross-border Health Threats Regulation (EU) 2022/2371.
Type of indicator	Qualitative; output
Data sources	Member State reports – DG SANTE
Frequency of measurement	Annual
Baseline (2023)	0
Milestone (2026)	0
Target (2029)	30
Comments	The joint action is expected to be launched towards the end of the MFF, and at the 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.
<b>Indicator name</b>	<b>Number of Member States with improved integrated surveillance systems</b> – (sub-indicator 1.3)
Definition	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
Type of indicator	Qualitative; result
Data sources	ECDC reports, DG SANTE and HERA
Frequency of measurement	Annual
Baseline (2023)	0
Milestone (2026)	15
Target (2029)	30
Comments	Indicators based on Article 13 of Regulation 2022/2371 - Epidemiological surveillance; it monitors joint actions from the 2021 annual work programme (JA UNITED4SURVEILLANCE), direct grants to Member States from the 2023 annual work programme; the data 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.
<b>Indicator name</b>	<b>Number of new capacity building activities (EU, Member States) for improved integrated surveillance systems</b> (sub-indicator 1.4)
Definition	Number of new capacity building activities (EU, Member States) for improved integrated epidemiological surveillance systems.
Type of indicator	Qualitative; output
Data sources	Member State reports – DG SANTE and HERA
Frequency of measurement	Annual
Baseline (2023)	0

Milestone (2026)	10
Target (2029)	30
Comments	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 for setting targets and milestones. 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.
<b>Indicator name</b>	<b>Number of Member States with improved preparedness and response planning</b> (sub-indicator 6.1)
Definition	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 <sup>78</sup> .
Type of indicator	Quantitative; output
Data sources	Early Warning and Response System (EWRS)
Frequency of measurement	Every 3 years
Baseline (2022)	0
Milestone (2023)	27
Target (2026)	27
Comments	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.
<b>Indicator name</b>	<b>Number of Member States with improved preparedness and response planning with regard to medical countermeasures</b> (sub-indicator 6.2)
Definition	Number of Member States that reported an increased level of preparedness and response planning regarding medical countermeasures compared to the baseline, assessed against the indicators A 6.8 to A 6.13 described in in Commission Implementing Regulation (EU) 2023/1808 <sup>79</sup>
Type of indicator	Quantitative; output
Data sources	e-Grants; CORDA –HERA
Frequency of measurement	Annual
Baseline (2022)	0
Milestone (2023)	18
Target (2026)	27

<sup>78</sup> Commission Implementing Regulation (EU) 2023/1808 of 21 September 2023 setting out the template for the provision of information on prevention, preparedness and response planning in relation to serious cross-border threats to health in accordance with Regulation (EU) 2022/2371 of the European Parliament and of the Council C/2023/6280 OJ L 234, 22.9.2023, p. 105–141.

<sup>79</sup> Ibid 79.



Comments	Uncertain targets and milestones; no direct causal link, any progress is an achievement. Increased level of preparedness and response planning regarding medical countermeasures is monitored through Member States' participation in EU4Health actions related to medical countermeasures.
<b>Indicator name</b>	<b>Number of actions addressing the fight against communicable diseases (indicator 22)</b>
Definition	Number of actions contributing to address the fight against communicable diseases.
Type of indicator	Quantitative; output
Data sources	e-Grants; CORDA – DG SANTE and HERA
Frequency of measurement	Annual
Baseline (2020)	0
Milestone (mid-2024)	20 (tbc)
Target (2027)	40 (tbc)
Comments	Static indicator in some years; uncertain targets and milestones due to the programming process that involves the Member States.
<b>Indicator name</b>	<b>Number of Member States and Associated Countries with increased laboratory and diagnostic capacity for cross-border health threats, contributing to the mission of HERA</b>
Definition	Number of Member States and Associated Countries with additional or better equipped laboratory or diagnostic capacities for cross-border health threats supported with EU funding contributing to the mission of HERA, excluding EURLs and EU LabCap survey.
Type of indicator	Quantitative; result
Data sources	e-Grants; CORDA – HERA
Frequency of measurement	Annual
Baseline (2020)	0
Milestone (mid-2024)	1
Milestone (2027)	16
Target (2030 or mid-2031)	30
Comments	Static indicator. '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.
<b>Indicator name</b>	<b>Number of countries where One Health surveillance programmes were successfully implemented</b>
Definition	Number of countries where 'one health' surveillance programmes were successfully implemented with the support of the grants.
Type of indicator	Quantitative; output
Data sources	e-Grants; CORDA – DG SANTE

Frequency of measurement	At midterm and end term of grants
Baseline (2023)	0
Milestone (mid-2024)	23
Milestone (2027)	23
Comments	Static indicator in some years; relative proxy indicator
<b>Indicator name</b>	<b>Number of Member States and associated countries with improved procurement procedures for medical countermeasures during health crisis</b>
Definition	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.
Type of indicator	Quantitative; result
Data sources	e-Grants; CORDA – DG SANTE and HERA
Frequency of measurement	Annual
Baseline (2020)	0
Milestone (mid-2024)	3
Target (2027)	30
Comments	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.

**Specific objective (c) Enhancement of availability, accessibility & affordability of medicinal products, medical devices and crisis-relevant products**

<b>Indicator name</b>	<b>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)</b>
Definition	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 European Commission and valid across the European Union).
Type of indicator	Quantitative; result
Data sources	European Commission register of authorised medicines – DG SANTE and HERA
Frequency of measurement	Biennial
Baseline (2020)	86
Milestone (mid-2024)	96
Milestone (2027)	103
Target (2030 or mid-2031)	110

Comments	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.
<b>Indicator name</b>	<b>Number of certificates issued by notified bodies under the Medical Device Regulation (MDR)</b>
Definition	The number MDR certificates issued by notified bodies under Regulation (EU) 2017/745 on medical devices intended to be placed on the EU market
Type of indicator	Quantitative; result
Data sources	Reports – DG SANTE
Frequency of measurement	Annual
Baseline (2020)	502 MDR certificates
Milestone (mid-2024)	≥ 9 000 MDR certificates
Target (2027)	≥ 15 000 MDR certificates
Comments	The number of certificates for <i>in vitro</i> diagnostic 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.
<b>Indicator name</b>	<b>Number of certificates issued by notified bodies under the <i>In Vitro</i> Diagnostic Medical Devices Regulation (IVDR)</b>
Definition	The number of IVDR certificates issued by notified bodies under Regulation (EU) 2017/746 for medium- and high-risk devices intended to be placed on the EU market
Type of indicator	Quantitative; result
Data sources	Reports – DG SANTE
Frequency of measurement	Annual
Baseline (2020)	31 IVDR certificates
Milestone (mid-2024)	1 000 IVDR certificates
Target (2027)	6 000 IVDR certificates
Comments	The number of certificates for <i>in vitro</i> 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.
<b>Indicator name</b>	<b>EU Laboratory capacity index (EULabCap) – (indicator 8)</b>
Definition	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 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). – <a href="#">see details ECDC</a> .
Type of indicator	Quantitative; result
Data sources	Reports – ECDC
Frequency of measurement	Every 2 years
Baseline (2021)	7.9 The EU/EEA public health microbiology system performance showed continuous improvement over the survey years. The mean EULabCap index reached 7.9/10 for the EU/EEA in 2021, which is a 14% increase since the survey on 2013 system outputs <sup>80</sup>

Milestone (2024)	No decreases in score, and increases for countries with low or intermediate score – compared to baseline (survey ongoing in 2024, to be published in 2025)
Target (2027)	No decreases in score, and increases for countries with low or intermediate score – compared to Milestone mid-2024
Comments	ECDC will revise the format of the survey including the indicators in 2023/2024. Comparability needs to be seen by the time.
<b>Indicator name</b>	<b>Number of reported shortages of medicinal products in the Member States through the single point of contact network – (indicator 15)</b>
Definition	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.
Type of indicator	Quantitative; result
Data sources	Reports; EMA
Frequency of measurement	Annual
Baseline (2019)	91
Milestone (mid-2024)	110
Target (2027)	110
Comments	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.
<b>Indicator name</b>	<b>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</b>
Definition	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.
Type of indicator	Quantitative; output
Data sources	Annual work programmes – HERA, DG GROW and DG SANTE
Frequency of measurement	Annual
Baseline (2021)	1
Milestone (mid-2024)	3
Target (2027)	13
Comments	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.
<b>Indicator name</b>	<b>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</b>
Definition	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 EU, including ever-warm capacities.
Type of indicator	Quantitative; result

Data sources	Reports – HERA, DG SANTE and EMA
Frequency of measurement	Annual
Baseline (2020)	0
Milestone (mid-2024)	4
Target (2027)	5
Comments	n/a
<b>Indicator name</b>	<b>Antimicrobial consumption for systemic use ATC<sup>81</sup> (group J01) – (indicator 18)</b>
Definition	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 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 WHO.
Type of indicator	Quantitative, result
Data sources	Reports – ECDC
Frequency of measurement	Annual
Baseline (2019)	19.9
Milestone (mid-2024)	18.1
Milestone (2027)	17.0
Target (2030)	15.9
Comments	This indicator is based on one of the targets agreed under the 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.
<b>Indicator name</b>	<b>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</b>
Definition	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.
Type of indicator	Quantitative; results
Data sources	European Commission database – DG SANTE
Frequency of measurement	Annual
Baseline (2020)	10
Milestone (mid-2024)	40
Milestone (2027)	65
Comments	n/a
<b>Indicator name</b>	<b>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</b>
Definition	This indicator measures the number of Member States that participate in actions to support innovation, uptake and access to the market of medical countermeasures at EU and global level, and therefore to increasing the

<sup>81</sup> Therapeutic subgroup of the Anatomical Therapeutic Chemical Classification System - ATC code J01.

	availability and accessibility of new or repurposed medical countermeasures for priority threats that are closer or that have gained access to the market to improve preparedness and response.
Type of indicator	Quantitative; output
Data sources	e-Grants; CORDA – HERA
Frequency of measurement	Occasional/targeted
Baseline (2020)	0
Milestone (mid-2024)	3
Milestone (2027)	13
Comments	Static indicator in some years; relative proxy indicator; uncertain targets and milestones.

### Specific objective (d) Complementing national stockpiling of essential crisis-relevant products

<b>Indicator name</b>	<b>Number of actions complementing national stockpiling of essential crisis-relevant products</b>
Definition	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.
Type of indicator	Quantitative; output
Data sources	e-Grants; CORDA – HERA
Frequency of measurement	Occasional/targeted; the data are collected for the years when relevant actions are included in the annual work programme.
Baseline (2020)	0
Milestone (mid-2024)	5
Target (2027)	10
Comments	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
<b>Indicator name</b>	<b>Number of Member States participating in stockpiling activities</b>
Definition	Total number of Member States participating in the joint action on stockpiling envisaged in the EU4Health 2024 annual work programme and contributing to the development and implementation of the activities outlined in the EU strategic stockpile approach and vision. The involvement of the EU Member States participating in the joint action on stockpiling included in the EU4Health annual work programme for 2024, will be assessed by looking at the various reports and deliverables of the joint action
Type of indicator	Quantitative; output
Data sources	e-Grants; CORDA - HERA
Frequency of measurement	annual
Baseline (2020)	0
Milestone (mid-2024)	5
Target (2027)	15
Comments	Uncertain targets and milestones because the number of actions depends on programming processes that involve Member States.



**Specific objective (e)** Establishing a structure and training resources for a reserve of medical, healthcare and support staff

<b>Indicator name</b>	<b>Number of healthcare and public health staff trained</b> (Article 11 of the CHBT Regulation and Decision establishing HERA) - KEY PERFORMANCE INDICATOR
Definition	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
Type of indicator	Quantitative; result
Data sources	Reports – Member States, DG SANTE and HERA
Frequency of measurement	Annual
Baseline	0
Milestone (mid-2024)	955
Target (2027)	3050
Comments	Static indicator in some years; relative proxy indicator; uncertain targets and milestones.
<b>Indicator name</b>	<b>Stakeholders' satisfaction rate in HERA training programmes</b>
Definition	Percentage of participants to any training activity supported by the EU Health Preparedness training Programme / the HERA Training Programme that report positive feedback on 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.
Type of indicator	Qualitative; result
Data sources	Reports HERA
Frequency of measurement	Annual
Baseline (2020)	0
Milestone (mid-2024)	85
Target (2027)	95
Comments	Uncertain baseline; training activities starting in 2024

**Specific objective (f) Strengthening health data, digital tools & services, digital transformation of healthcare**

<b>Indicator name</b>	<b>Number of actions contributing to the digital transformation of healthcare systems and the implementation of the European Health Data Space (EHDS)</b>
Definition	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).
Type of indicator	Quantitative; output
Data sources	e-Grants; CORDA – SANTE
Frequency of measurement	Annual
Baseline (2020)	0
Milestone (mid-2024)	28
Target (2027)	46
Comments	n/a
<b>Indicator name</b>	<b>Number of Member States participating in the European Health Data Space – (indicator 5) - KEY PERFORMANCE INDICATOR</b>
Definition	This indicator measures the number of Member States connected to MyHealth@EU and/or to the cross-border infrastructure for secondary uses (cumulative).
Type of indicator	Quantitative; result
Data sources	Reports – DG SANTE
Frequency of measurement	Annual
Baseline (2020)	7
Milestone (mid-2024)	15
Milestones (2027)	21
Target (2031)	27
Comments	n/a
<b>Indicator name</b>	<b>Progress on setting up health data access bodies in the EU</b>
Definition	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).
Type of indicator	Quantitative; result
Data sources	Reports – DG SANTE
Frequency of measurement	Annual
Baseline (2020)	3
Milestone (mid-2024)	15
Milestones (2027)	21
Target (2031)	27
Comments	n/a

**Specific objective (g)** Enhancing access to healthcare with the aim of achieving universal health coverage

Indicator name	Number of actions producing guidance for improving access to healthcare services
Definition	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.
Type of indicator	Quantitative; output
Data sources	Annual work programmes – DG SANTE
Frequency of measurement	Annual
Baseline (2020)	0
Milestone (mid-2024)	3
Target (2027)	3
Comments	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.
Indicator name	Number of measures taken by Member States to improve access to healthcare services
Definition	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 on the affordability of healthcare, access to mental healthcare, access to healthcare for vulnerable groups, as well as new indicators for measuring access to healthcare.
Type of indicator	Quantitative; result
Data sources	Reports – Social Protection Committee, European Social Policy Network, ‘State of Health in the EU’ project, Health Systems Policy Monitor ( <a href="https://eurohealthobservatory.who.int/monitors/health-systems-monitor">https://eurohealthobservatory.who.int/monitors/health-systems-monitor</a> )
Frequency of measurement	Annual between 2025 and 2027
Baseline (2020)	0
Milestone (2025)	2
Target (2027)	10
Comments	n/a

**Specific objective (h)** Developing and implementing EU health legislation and evidence-based decision-making, monitoring, and promoting the use of health impact assessments of other relevant Union policies

Indicator name	Number of impact assessments of Union policies
Definition	Number of published impact assessments and supporting reports and staff working documents of EU health policies supported by the Programme.
Type of	Quantitative; output

indicator	
Data sources	EUR-lex and Inter-institutional Studies Database – DG SANTE and HERA
Frequency of measurement	Annual
Baseline (2020)	0
Milestone (2022)	0
Milestone (end-2024)	2
Target (2027)	2
Comments	Static indicator in some years; uncertain targets and milestones; a target for 2027 may be set only in 2025 after the new College sets out its priorities.
<b>Indicator name</b>	<b>Number of studies supporting the evaluations of legislative and non-legislative health Union policies – KEY PERFORMANCE INDICATOR</b>
Short title	Health Union policies' evaluation
Definition	Number of studies published supporting the evaluations, monitoring the implementation and assessing the functioning of legislative and non-legislative policies.
Type of indicator	Quantitative; output
Data sources	Inter-institutional Studies Database – DG SANTE and HERA
Frequency of measurement	Annual
Baseline (2020)	0
Milestone (End 2024)	14
Target (2027)	25
Comments	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.

### Specific objective (i) Integrated work among Member States' health systems

<b>Indicator name</b>	<b>Number of Health Technology Assessment (HTA) reports jointly carried out – (indicator 20)</b>
Definition	Number of joint clinical assessments on medicinal products and on medical devices in line with the new HTA Regulation (EU) 2021/2282.
Type of indicator	Quantitative; output
Data sources	Reports – DG SANTE
Frequency of measurement	Annual between 2026 and 2028
Baseline (2025)	0
Milestone (2026)	10
Target (2027)	20
Comments	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 line with 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 .
<b>Indicator name</b>	<b>Number of healthcare units involved in ERNs<sup>82</sup></b> – (sub-indicator 19.1)
Definition	Number of healthcare units involved in ERNs
Type of indicator	Quantitative; result
Data sources	e-Grants; CORDA – DG SANTE
Frequency of measurement	Annual
Baseline (2021)	1139
Milestone (mid-2024)	1619
Target (2027)	1619
Comments	The milestone is not expected change unless another call to enlarge the ERNs is; 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 <i>Number of healthcare units involved in European Reference Networks (ERNs) and of patients diagnosed and treated by the members of ERNs</i> referred to in Annex 2 to the EU4Health Regulation has been broken down into its two components (19.1 and 19.2).
<b>Indicator name</b>	<b>Number patients diagnosed and treated by the members of ERNs<sup>83</sup></b> – (sub-indicator 19.2) - KEY PERFORMANCE INDICATOR
Short title	Patients referred to ERNs
Definition	The sum of the number of patients referred to ERNs whose cases are reviewed by ERNs.
Type of indicator	Quantitative; result
Data sources	e-Grants; CORDA – DG SANTE
Frequency of measurement	Annual
Baseline (2020)	1 million
Milestone (mid-2024)	1.5 million
Target (2027)	2 million
Comments	To operationalise it, the indicator 19 <i>Number of healthcare units involved in European Reference Networks (ERNs) and of patients diagnosed and treated by the members of ERNs</i> referred to in Annex 2 to the EU4Health Regulation has been broken down into its two components (19.1 and 19.2).

### Specific objective (j) International health initiatives & cooperation

<b>Indicator name</b>	<b>Number of actions and contribution agreements supporting global commitments and health initiatives concluded with global partners</b>
Definition	Number of contribution agreements and actions supporting global commitments and health

<sup>82</sup> Indicators 19.1 and 19.2 are sub-indicators of 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 \(EU\) 2021/522](#).

<sup>83</sup> Ibid 60.

	initiatives concluded with global partners including the organisations pillar assessed.
Type of indicator	Quantitative; output
Data sources	Annual work programmes – DG SANTE and HERA
Frequency of measurement	Annual
Baseline (2020)	0
Milestone (mid-2024)	19
Target (2027)	28
Comments	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.
<b>Indicator name</b>	<b>Number of areas where EU and WHO collaborate</b>
Short title	EU and WHO aligned policies and/or actions
Definition	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) .
Type of indicator	Quantitative; results
Data sources	Annual work programmes – DG SANTE and HERA
Frequency of measurement	Annual
Baseline (2022)	0
Milestone (mid-2024)	9
Target (2027)	13
Comments	Only the actions supported by the EU4Health Programme are relevant to this indicator; actions funded by other EU funding programmes are excluded.
<b>Indicator name</b>	<b>Areas of coordination between EU and relevant global partners and EU Member States</b>
Short title	Coordination with global partners and EU Member States
Definition	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.
Type of indicator	Quantitative; result
Data sources	e-Grants; CORDA – DG SANTE and HERA
Frequency of measurement	Annual
Baseline	0
Milestone (mid-2024)	4
Target (2030)	6
Comments	Only the actions supported by the EU4Health Programme are relevant to this indicator. Actions funded by other EU funding programmes are excluded.



### **Additional indicators**

The following input indicators are available on the EU4Health dashboard<sup>84</sup> to collect additional data:

- Total budget per Programme strand
- Total budget per policy area
- Total budget per action
- Total budget per project
- Average budget per project (*for actions implemented through multiple projects*).

### **Other available indicators**

The following indicators are available on the EU4Health dashboard:

- Number of actions per strand
- 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 specific objective
- Number of financed projects per specific objective
- Number of beneficiaries per eligible country, per strand, per policy area and per specific objective.

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<sup>84</sup> See Section 4. DATA, INFORMATION AND KNOWLEDGE MANAGEMENT.

## Annex 2: Programme KEY PERFORMANCE INDICATORS and their distribution per strand and per specific objective

### Strand 1 **Crisis preparedness** (covering specific objective (b), (d) and (e))

Preparedness and response planning of the Union and of Member States for serious cross-border threats to health – (sub-indicator 1.1)
Number of new trainings for healthcare staff, public health staff (Article 11 of the CHBT Regulation and Decision establishing HERA)

### Strand 2 **Health promotion and disease prevention** (covering specific objective (a))

Number of Member States implementing best practices regarding health promotion, disease prevention and addressing health inequalities
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### Strand 3 **Health systems and healthcare workforce** (covering specific objectives I, (g) and (i))

Number of production facilities with enhanced capacities in increasing security and continuity of supply for medical countermeasures, raw materials, and components at EU level
Number of audits conducted in the EU and in third countries to ensure good manufacturing practices and good clinical practices (Union control) – (indicator 17)
Number patients diagnosed and treated by the members of ERNs <sup>80</sup> – (sub-indicator 19.2)

### Strand 4 **Digital** (covering specific objective (f))

Number of Member States participating in the European Health Data Space – (indicator 5) - KEY PERFORMANCE INDICATOR
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### Strand 5 **Cancer** (covering specific objective (a), (c), (f), (g), (h), (i), (j))

n/a
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### **Horizontal actions** (covering specific objective (h)) and **global health** (specific objective (j))

Number of studies supporting the evaluations of legislative and non-legislative health Union policies
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### Annex 3: Programme indicators and their distribution per strand

#### *Strand 1 Crisis preparedness (covering specific objective (b), (d), and (e))*

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 participating in the prevention, preparedness and response planning joint actions – (sub-indicator 1.2)
Number of Member States with improved integrated surveillance systems – (sub-indicator 1.3)
Number of new capacity building activities (EU, Member States) for improved integrated surveillance systems (sub-indicator 1.4)
Number of Member States with improved preparedness and response planning (indicator 6.1)
Number of Member States with improved preparedness and response planning with regard to medical countermeasures (indicator 6.2)
Number of actions addressing the fight against communicable diseases – (indicator 22)
Increased laboratory and diagnostic capacity for cross-border health threats, contributing to the mission of HERA (new indicator.)
Number of countries where One Health surveillance programmes were successfully implemented (new indicator)
Number of Member States with improved procurement procedures for medical countermeasures during health crisis (new indicator)
Number of actions complementing national stockpiling of essential crisis-relevant products (new indicator)
Number of Member States participating in stockpiling activities (new indicator)
Number of new trainings for healthcare staff, public health staff (Article 11 of the CHBT Regulation and Decision establishing HERA) - KEY PERFORMANCE INDICATOR (new indicator)
Stakeholders' satisfaction rate in HERA training programmes (new indicator)

#### *Strand 2 Health promotion and disease prevention (covering specific objective (a))*

Number of actions contributing to the reduction of avoidable mortality in the area of non-communicable diseases and risk factors (new indicator)
Number of Member States implementing best practices regarding health promotion, disease prevention and addressing health inequalities – KEY PERFORMANCE INDICATOR (new indicator)
Vaccination coverage for measles <sup>85</sup> (indicator 7.1)
Vaccination coverage for seasonal influenza <sup>86</sup> – (indicator 7.2)

<sup>85</sup> Indicators 7.1, 7.2, 7.3 and 7.4 are sub-indicators of 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 \(EU\) 2021/522](#).

Vaccination coverage for human papillomaviruses (HPV) <sup>87</sup> – (indicator 7.3)
Vaccination coverage for COVID-19 <sup>88</sup> – (indicator 7.4)
Number of actions addressing the prevalence of major chronic diseases per Member State, by disease, gender, and age – (indicator 12)
Number of actions addressing the age prevalence of tobacco use, if possible, differentiated by gender – (indicator 13)
Number of actions addressing the prevalence of harmful use of alcohol, if possible, differentiated by gender and age – (indicator 14)
Number of actions addressing environmental risk factors for health – (indicator 23)

*Strand 3 Health systems and healthcare workforce (covering specific objectives (c), (g), and (i))*

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 Medical Device Regulation (MDR) certificates issued by notified bodies under the Medical Device Regulation
Number of <i>In Vitro</i> Diagnostic Medical Devices Regulation (IVDR) certificates issued by notified bodies under the IVDR
EU Laboratory capacity index (EULabCap) – (indicator 8)
Number of shortages of medicinal products in the Member States as reported through the single point of contact network – (indicator 15)
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 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
Antimicrobial consumption for systemic use ATC (group J01) – (indicator 18)
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
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
Number of actions producing guidance for improving access to healthcare services

<sup>86</sup> Ibid 56.

<sup>87</sup> Ibid 56.

<sup>88</sup> Ibid 56.

Number of measures taken by Member States to improve access to healthcare services
Number of Health Technology Assessment reports jointly carried out – (indicator 20)
Number of healthcare units involved in ERNs <sup>79</sup> – (sub-indicator 19.1)
Number patients diagnosed and treated by the members of ERNs <sup>80</sup> – (sub-indicator 19.2) - KEY PERFORMANCE INDICATOR

***Strand 4 Digital (covering specific objective (f))***

Number of actions contributing to the digital transformation of healthcare systems and the implementation of the European Health Data Space (EHDS)
Number of Member States participating in the European Health Data Space – (indicator 5) - KEY PERFORMANCE INDICATOR
Progress on setting up health data access bodies in the EU

***Strand 5 Cancer (covering specific objective (a), (c), (f), (g), (h), (i), (j))***

Age-standardised five-year net survival rate for paediatric cancer (to the extent available) – (indicator 9)
Breast cancer screening coverage <sup>89</sup> – (sub-indicator 10.1)
Cervical cancer screening coverage <sup>90</sup> – (sub-indicator 10.2)
Colorectal cancer screening coverage <sup>91</sup> – (sub-indicator 10.3)
Percentage of population covered by Cancer Registries reporting information on cervical, breast, colorectal and paediatric cancer stage at diagnosis – (indicator 11)
Number of Member States reporting information on cervical, breast, colorectal and paediatric cancer stage at diagnosis

***Horizontal actions (covering specific objective (h)) and global health (specific objective (j))***

Number of impact assessments of Union policies
Number of studies supporting the evaluations of legislative and non-legislative health Union policies – KEY PERFORMANCE INDICATOR

<sup>89</sup> Indicators 10.1, 10.2. and 10.3 are sub-indicators of 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 \(EU\) 2021/522](#).

<sup>90</sup> Ibid 57.

<sup>91</sup> Ibid 57.

Number of actions and contribution agreements supporting global commitments and health initiatives concluded with global partners
Number of areas where EU and WHO collaborate
Areas of coordination between EU and relevant global partners and EU Member States



## Annex 4: Evaluation criteria and examples of indicators

Evaluation criteria	Example of indicators	Examples of data sources
<p><b>Relevance</b> looks at the relationship between the needs and problems at the time of introducing the intervention (2021) and during its implementation (2021- mid-2031). Relevance should also look at the relationship between the current and future needs and problems in the EU and the objectives of the EU4Health Programme.</p>	<ul style="list-style-type: none"> <li>• Oversubscription rate per action, call, topic, etc.</li> <li>• Distribution of applications (e.g. geographic, thematic, organisations)</li> <li>• Stakeholders' satisfaction levels on programme design</li> <li>• Stakeholder perception on the relevance of the 10 specific objectives and their exhaustiveness</li> <li>• Consultation of stakeholders to identify the needs, problems to be addressed</li> <li>• Number of actions contributing to the reduction of avoidable mortality in the area of non-communicable diseases and risk factors</li> <li>• Number of new capacity building activities (EU, Member States) for improved integrated epidemiological surveillance systems</li> </ul>	<ul style="list-style-type: none"> <li>• Programme documentation (basic act, annual work programmes)</li> <li>• EU4Health dashboard</li> <li>• Interviews</li> <li>• Survey</li> <li>• Case studies</li> <li>• Stakeholder consultation</li> <li>• Projects' reporting</li> <li>• Member State reports</li> </ul>
<p><b>Effectiveness</b> analysis considers how successful an EU4Health Programme has been in implementing EU health priorities and achieving (outputs, results, impacts) or progressing towards its objectives (milestones, targets).</p>	<ul style="list-style-type: none"> <li>• Stakeholder perception on how the annual work programmes address the needs identified by stakeholders</li> <li>• Number of Member States participating in the prevention, preparedness and response planning joint action</li> <li>• Breast cancer screening coverage</li> <li>• Percentage of population covered by Cancer Registries reporting information on cervical, breast, colorectal and paediatric cancer stage at diagnosis</li> <li>• Number of new capacity building activities (EU, Member States) for improved integrated surveillance systems</li> </ul>	<ul style="list-style-type: none"> <li>• Annual work programme</li> <li>• Projects' reporting</li> <li>• Eurostat</li> <li>• Targeted stakeholders consultation</li> <li>• Coverage (gaps) analysis</li> <li>• European Network of Cancer Registries</li> <li>• Member State reports</li> </ul>
<p><b>Efficiency</b> considers the resources used by EU4Health Programme (inputs) for the given changes generated; looks at the</p>	<ul style="list-style-type: none"> <li>• Total budget per Programme strand</li> <li>• Total budget per policy area</li> <li>• Total budget per action</li> </ul>	<ul style="list-style-type: none"> <li>• EU4Health dashboard</li> <li>• SANTE/HaDEA Unit management plans (estimation)</li> </ul>

<p><i>performance of the programming and implementation processes (proposals selection, project management and monitoring, etc.), administrative expenses, funding allocation per objectives and policy areas, types of organisations, countries, etc. Analysis of the costs of the EU intervention as they accrue to different stakeholders cost-effectiveness, simplification and burden reduction.</i></p>	<ul style="list-style-type: none"> <li>• <i>Total budget per project</i></li> <li>• <i>Average budget per project (for actions implemented through multiple projects)</i></li> <li>• <i>Number of FTEs involved in programming and implementation</i></li> <li>• <i>Distribution of grants and funds (e.g. geographic, thematic, organisations)</i></li> <li>• <i>Error rate</i></li> <li>• <i>Time-to-pay, time-to-grant</i></li> <li>• <i>Stakeholders' satisfaction levels on implementation and application process)</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>Surveys and interviews</i></li> <li>• <i>Analysis of programme management and implementation data</i></li> <li>• <i>Interviews</i></li> <li>• <i>Survey</i></li> <li>• <i>Case studies</i></li> </ul>
<p><b>Coherence</b> <i>Looks at the 'internal' and 'external' coherence, involves looking at how well (or not) different EU funding programmes and/or national ones work together; observes complementarities, synergies, gaps and overlaps of EU4Health Programme with other relevant public EU, Member States' initiatives.</i></p>	<ul style="list-style-type: none"> <li>• <i>Complementary funding leveraged through other policies/programmes</i></li> <li>• <i>Systems in place to foster synergies with other programmes</i></li> <li>• <i>EU4Health beneficiaries benefiting from other programmes</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>Analysis of other documentation on other policies/programmes</i></li> <li>• <i>Analysis of relevant programme management and implementation data</i></li> <li>• <i>Interviews</i></li> <li>• <i>Survey</i></li> <li>• <i>Case studies</i></li> </ul>
<p><b>EU added value</b> <i>looks for changes that are due to the EU4Health Programme, over and above what could reasonably have been expected from national actions by the Member States.</i></p>	<ul style="list-style-type: none"> <li>• <i>Scale, speed and scope additionality provided through EU4Health participation in terms of improvements of crisis preparedness, health promotion and disease prevention, national health systems e.g. through digitalisation</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>Programme documentation (basic act, work programmes)</i></li> <li>• <i>Analysis of socio-economic, scientific and technological trends, forecasts and foresight</i></li> <li>• <i>Interviews</i></li> <li>• <i>Survey</i></li> <li>• <i>Case studies</i></li> <li>• <i>Stakeholder consultation</i></li> </ul>