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Proposal for a

# REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

## on the establishment of a Programme for the Union's action in the field of health –for the period 2021-2027 and repealing Regulation (EU) No 282/2014 ("EU4Health Programme")

(Text with EEA relevance)

# EXPLANATORY MEMORANDUM

## 1. CONTEXT OF THE PROPOSAL

This proposal provides for a date of application as of 1 January 2021 and is presented for a Union of 27 Member States.

- **Reasons and objectives**

"We will stop at nothing to save lives," said President von der Leyen, speaking to the European Parliament on 26 March 2020, the COVID-19 crisis is the biggest challenge the European Union (EU) has faced since the Second World War, and it has demonstrated that if each country tries to tackle pandemics on its own, the EU will be as weak as the weakest link. Every health system has struggled in tackling this crisis, and this has affected every citizen in one way or another.

Europe needs to give a higher priority to health, to have health systems ready to provide state of the art care, and to be prepared to cope with epidemics and other unforeseeable health threats in line with the International Health Regulations (IHR)[1]. Whilst the overall framework for preparedness, early warning and response is already in place under Decision 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health, COVID-19 has shown the need to significantly boost the EU's capability to respond effectively to such major health threats. An ambitious self-standing Programme, to be called the EU4Health Programme, will be the key instrument for delivering it.

The new Programme will be essential in making sure that the EU remains the healthiest region in the world, has all possible tools available to address health challenges at national and EU level and is prepared for any new emerging health threat that may endanger the population of the EU.

Embedded in the 'One health' approach, which recognises the interconnection between human health and animal health and more broadly with the environment, the EU4Health Programme can support Member States in the transition to better preparedness and the reinforcement of their health systems and support them in achieving the health-related United Nations Sustainable Development Goals (SDGs). It provides for new actions, which will fill in gaps that this pandemic has revealed in terms of the development and manufacturing of medicinal products, the adequate supply of equipment in hospitals and sufficient medical human resources, the uptake of digital tools and services that enable continuity of care, and the need to maintain access to essential goods and services in times of crisis. This will allow the EU to have more tools to take quick, decisive and coordinated action with the Member States in both preparing for and managing crises.

Beyond the required level of preparedness and response, there are a number of further challenges in the areas of health security and health systems impeding their overall functioning, and rendering an adequate crisis response overall more demanding, in particular:

[1] International Health Regulations (2005), World Health Organization.

- inequalities in health status among population groups, countries and regions, and access to affordable, preventive and curative health care of good quality;
- burden from non-communicable diseases, including cancer, mental health, rare diseases and risks from health determinants;
- uneven distribution of health care systems capacity, including health care workers;
- obstacles to the wide uptake and best use of digital innovations as well their scaling up;
- growing health burden from environmental degradation and pollution, in particular air, water and soil quality, and also from demographic changes.

The EU4Health Programme will set out key action areas such as improvement of national health systems, measures against communicable and non-communicable diseases, availability and affordability of medicines and other crisis relevant products. As many of the new and innovative suggestions are closely related to the functioning of health systems, the Commission will work closely with the Member States to make sure that the support provided by the EU4Health Programme is based on national needs. The Commission will also work with third countries and international partners in the implementation of the EU4Health Programme actions.

The Programme will need to be dynamic and flexible to adapt to emerging new challenges, and to serve the EU and the Member States in their evolving needs and priorities. It needs to address inequalities by benchmarking, providing support and closing identified gaps between countries, regions, population groups and citizens. It should help reduce gaps in life expectancy and access to care and services. It will provide tools for enhanced solidarity in preparedness and crisis response, as well as in finding common ground to improve prevention and in addressing non-communicable diseases, and in particular cancer, and for better coordinating between different policies, tools and financial instruments. Finally, it will contribute to tackling the negative impact of climate change and environmental degradation on human health.

Funding for health under the next Multiannual Financial Framework (MFF) includes several instruments such as the European Social Fund Plus (ESF+), the European Regional Development Fund, and Horizon Europe, the Digital Europe Programme, and the Connecting Europe Facility 2. Working across programmes, and having shared objectives between policies will be key considerations to channel health funds across policies and support the achievement of their objectives more effectively than before.

Article 168 of the Treaty on the Functioning of the European Union (TFEU) provides the legal basis for the EU's actions in the field of health. Whilst the Member States are responsible for the functioning of their health systems, there are specific areas where the EU can legislate, and others where the Commission can support Member States' efforts. There is already a comprehensive regulatory framework for medical products and technologies (medicinal products, medical devices and substances of human origin), as well as on tobacco legislation, patients' rights in cross-border healthcare and serious cross-border health threats.

The EU4Health Programme will support actions to enable the Commission to complement the necessary regulatory framework and contribute to addressing the significant structural needs identified in the COVID-19 crisis.

The EU agencies, the European Centre for Disease Prevention and Control, the European Medicines Agency, the European Food Safety Authority, the European Chemicals Agency, and the European Safety and Health at Work Agency have a key role to play in Europe's defence against serious cross border health threats and pandemics, both on the prevention and on the crisis management front.

- **Consistency with existing policy provisions**

  The EU4Health Programme supports policies and priorities which aim to promote health. It will support the implementation of the principles of the European Pillar of Social Rights[2], the European Semester as far as the health area is concerned to ensure that the Union and Member States reach the targets of the 3rd SDG, to 'Ensure healthy lives and promote well-being for all at all ages' and other SDGs related to health. In the areas of national competence, the Commission and the Member States will need to collaborate more closely, earlier, and more inclusively in setting priorities for this EU4Health Programme, defining the best ways to use the instruments and in the subsequent implementation of the Programme.

- **Consistency with other Union policies**

  The EU4Health Programme, while much larger than its predecessor, still represents only about one third of all health investments of the next MFF. In many cases, health expenditure under different programmes and funds needs to be implemented in a closely co-ordinated way to be fully effective and avoid duplication. The Commission is committed to ensure operational synergies with other Union programmes, notably to address policy needs and to enable the pursuit of common objectives and common areas for activities. Building on the principle of 'Health in all Policies', these programmes[3] will provide financial support to reforms and investments that will have a lasting impact on the growth potential and resilience of the economy of the Member States. They will also address challenges identified in the European Semester and contribute to the objectives of the EU4Health Programme. The EU4Health Programme will also contribute to the Commission's priorities, including responding to the challenges from migration and the Green Deal.

  Complementary to and in synergy with the EU4Health Programme other programmes may provide support for health policy actions, including the implementation of solutions tailored to specific national/regional contexts/needs, as well as bilateral and interregional initiatives. In particular:

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2 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2017:251:FIN

3 Horizon Europe programme; the common agricultural policy; the European Regional Development Fund; the European Social Fund Plus; the Single Market Programme; the Programme for Environment & Climate Action ; the Connecting Europe Facility; the Digital Europe Programme; the Erasmus Programme; the InvestEU Fund; and the external action instruments (Neighbourhood, Development and International Cooperation Instrument and Instrument for Pre-accession Assistance.

- Through the enhanced Union Civil Protection Mechanism (UCPM/rescEU) capacities, the EU and the Member States will be better prepared for and able to react quickly and flexibly in a future crisis. The upgraded UCPM and in particular its emergency rescEU capacities will also endow the Union with enhanced preparedness and a proficient logistic infrastructure that can cater for different types of emergency, including those with a medical emergency component. Where the UCPM will focus on the direct crisis response capacities which will have to be immediately ready and available in case of an emergency, the EU4Health Programme will include structural, large-scale reserves, including a reserve of ready medical staff and experts, and the underlying resilience of the health care systems and necessary structures. Those resources will be crucial for a coordinated crisis response at Union level
- The European Regional Development Fund (ERDF) will support the health care systems capacity in the regions in terms of infrastructures, modernisation of the public and private healthcare sectors, and (inter)regional cooperation networks. The ERDF also provides investments in research and innovation, uptake of advanced technologies and innovative solutions, and in digitalisation, including in health. Further, it supports capacity building, technical assistance and cross-border cooperation.
- The European Social Fund Plus (ESF+) will create synergies and complementarities with the EU4Health Programme by supporting, among other, skills development for health staff and improved access to health care for people in socio-economic vulnerable situations, and long term care. The challenges identified through the European Semester will be particularly relevant.
- The Recovery and Resilience Facility will provide financial support to reforms and investments that will have a lasting impact on the growth potential and resilience of the economy of the Member States and will address challenges identified in the European Semester.
- Horizon Europe will finance research and innovation in health: health throughout the life; environmental and social health determinants; non-communicable and rare diseases; infectious diseases; tools, technologies and digital solutions for health and care and healthcare systems are the areas of intervention in the Commission's proposal for a 'Health' cluster. The EU4Health Programme will help to ensure best use of research results and facilitate the uptake, scale-up and deployment of health innovation in healthcare systems and clinical practice.
- The Digital Europe Programme will support the deployment of digital infrastructure underpinning the wide use of digital technologies in areas of public interest. The programme will support, amongst other elements, tools and data infrastructures supporting data spaces in different sectors. Building on that infrastructure and pilot implementations in different sectors supported by the DEP Programme, the EU4Health Programme will focus on delivering data sharing and citizen platform applications covering areas such as secure and effective management of personal health data across borders; better data for research, disease prevention

and personalised health and care; and use of digital tools for citizen empowerment and for person-centred care, in compliance with data protection rules.

- The Connecting Europe Facility Programme 2 Digital (CEF Digital) will fund highly resilient Gigabit networks to connect socio-economic drivers, including hospitals and medical centres, in areas where no such networks exist or are planned to be deployed in the near future; this will enable critical applications such as tele-operated surgery as well as the sharing of medical data. It will also bring connectivity to households to enable remote patient monitoring in a secure manner and in compliance with data protection legislation.

## 2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

  The legal basis for the proposal is Article 168(5) TFEU, which provides for the adoption of incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol.

  Under Article 168 TFEU the Union is to complement and support national health policies, encourage cooperation between Member States and promote the coordination between their programmes, in full respect of the responsibilities of the Member States for the definition of their health policies and the organisation and delivery of health services and medical care.

  The EU4Health Programme laid down in the proposal, implemented under direct and indirect management, covers actions and incentive measures aimed at preventing health risks and protecting and improving human health.

- **Subsidiarity (for non-exclusive competence)**

  Pursuant to point (a) of Article 6 TFEU, the Union shall have competence to carry out actions to support, coordinate or supplement the actions of the Member States for the protection and improvement of human health. Under Article 168 TFEU the Union is to complement and support national health policies.

  The objectives of this Regulation are to protect people in the Union from serious cross-border threats to health; to contribute to a high level of protection of public health by supporting actions which promote health, prevent diseases, strenghten health systems,improve availability and affordability in the Union of medicines and other crisis relevant products and support integrated and cordinated work and exchange of best practices in this respect.

  Given the measures envisaged under the proposal, the objectives of the EU4Health Programme cannot be sufficiently achieved by the Member States alone but rather can better be achieved at Union level, and therefore the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union.

The EU4Health Programme will be implemented with full respect to the responsibilities of the Member States, for the definition of their health policy and for the organisation and delivery of health services and medical care as stated in Article 168 TFEU.

The subsidiarity principle is therefore respected.

- **Proportionality**

In accordance with the principle of proportionality, this proposal does not go beyond what is necessary to achieve its goals. The principle of proportionality has guided the Commission's design of the EU4Health Programme, which proposes to identify and enable synergies with other programmes and to strengthen collaboration with the Member States in defining priorities for it.

The proposal is proportionate and seeks to increase participation of Member States in the actions it supports by lowering as much as possible the barriers to participation, and provides for a reduction of administrative burden on the Union and on the national authorities that has been limited to what is necessary for the Commission to exercise its responsibility for implementing the Union budget.

- **Choice of the instrument**

The choice of instrument is a Regulation of the European Parliament and of the Council to establish the EU4Health Programme.

## 3. RESULTS OF RETROSPECTIVE EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

– The Health Programme 2014-2020

**Strengths:** The mid-term evaluation confirmed the EU added value of actions, notably in the form of:

(i) increased capacity in the Member States to address serious cross-border health threats;

(ii) technical guidelines and recommendations for cancer, HIV/AIDS and TB prevention;

(iii) additional support for EU health legislation on medicinal products and medical devices, as well as the eHealth Network activities and Health Technology Assessment.

The evaluation also recognised the added value of tools to control healthcare-associated infections and to step up coordinated efforts to fight against antimicrobial resistance, and of the extensive groundwork pursued through Joint Actions to identify and transfer best practices for the prevention and management of diseases. It also recognised the positive contribution of actions to increase the interoperable and standardised cross-border exchange of health data, and of those efforts to set up EU-wide digital infrastructures for that purpose.

**Weaknesses:** In non-legislative areas where actions can be more open-ended or broadly defined, the mid-term evaluation revealed that there is a danger of

those actions being less focused. There is scope to streamline the added-value criteria to focus on three key areas: addressing serious cross-border health threats, improving economies of scale, and fostering the exchange and implementation of best practices. There were also some inefficiencies and inadequacies with the monitoring of implementation of data, which can make it harder for programme managers to keep an up-to-date overview of the programme's achievements.

- **Stakeholder consultations**

  Under the initial proposal for the next MFF, health was included under the European Social Fund Plus (ESF+). A series of stakeholder consultations were carried out at the time with the main organisations and institutions in the EU working in the field of social and employment policy and relevant public authorities at all levels of government, social partners, civil society organisations, funding beneficiaries and end-users as well as citizens across the EU. The general conclusions, which are also relevant for the new programme, were related to the need for streamlining the exchange of knowledge between countries and regions, simplifying and reducing the administrative burden on beneficiaries including less burdensome requirements on collecting data from participants. There was a call to strengthen synergies and avoid duplication and overlaps between EU instruments.

  Notably, it was concluded that public health issues could only be effectively dealt with through collaboration at EU level. It was stated that there is an added value in the EU addressing common challenges such as health inequalities, migration, an ageing population, patient safety, high quality health care, tackling serious health threats including non-communicable diseases, infectious diseases and antimicrobial resistance.

- **External expertise**

  N.A.

- **Impact assessment**

  The proposal for the European Social Fund Plus (ESF+) programme under the next Multiannual Financial Framework, including health, was supported by an impact assessment examined by Regulatory Scrutiny Board under the Single Market MFF Programme on 18 April 2018 and issued a positive opinion. All health objectives from the initial proposal are retained with priority given to the EU’s and Member States’ response and crisis preparedness to future health crises in the aftermath of COVID-19 pandemic. The general and specific objectives have been aligned with the political priorities of the Commission regarding pharmaceuticals and cancer.

- **Simplification**

  N.A.

- **Fundamental rights**

  The EU4Health Programme will contribute to the Charter of Fundamental Rights of the European Union as it aims to improve access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. The new Programme is also aligned with the Charter’s objective that a high level of human health protection is to

be ensured in the definition and implementation of all the Union's policies and activities.

## 4. BUDGETARY IMPLICATIONS

The total budget allocated for the EU4Health Programme amounts to EUR 10 397 614 000 (in current prices) for the 2021-2027 period.

1. EUR 1 946 614 000 shall derive from heading 5 “Resilience, Security and Defence” of the MFF 2021-2027;
2. EUR 8 451 000 000 shall derive from proceeds of the European Union Recovery Instrument [/Regulation xxx], constituting external assigned revenues according to Article 21.5 of the Financial Regulation.

## 5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

  The proposed EU4Health Programme will be mainly implemented by direct management, using in particular grants, prizes and procurement, as well as indirect management.

  Part of the EU4Health Programme is expected to be implemented by executive agencies.

  The Programme’s results and outputs will be assessed regularly through defined indicators for the specific work plans to monitor the implementation. Special focus will be put on monitoring the coordination of relevant health spending programmes to ensure there will be no double funding and that synergies will be made.

  The Commission will carry out a mid-term and a final evaluation of the Programme in order to assess its efficiency, effectiveness, relevance, coherence and value added, in conformity with Article 34, paragraph 3, of the Financial Regulation.

- **Detailed explanation of the specific provisions of the proposal**

  Chapter I - General provisions

  The Regulation establishes the EU4Health Programme for Union action in the field of health for the period 2021-2027.

  The Programme’s general objectives are laid down in Article 3 of the Regulation and are as follows:

  (1) protect people in the Union from serious cross-border threats to health;

  (2) the availability in the Union of medicines, medical devices and other crisis relevant products, contribute to their affordability, and support innovation;

  (3) strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, sustained implementation of best practice and data sharing, to increase the general level of public health.

Article 4 provides for the Programme's specific objectives.

The budget of the Programme and rules on resources coming from amounts made available through Regulation [European Union Recovery Instrument] are laid down in Articles 5 and 6.

Participation to the Programme is open to legal entities established in a Member State or in a participating non-EU country, with no further restrictions on access to the Programme.

Chapter II - Funding

The Programme will be implemented through direct or indirect management and will make use of the most commonly used spending mechanisms of the Union budget, including public procurement, prizes and grants. Specific provisions for emergency procurement, the possibility of blending, and rules on cumulative funding are provided in Articles 8 and 9.

Chapter III - Actions

This Chapter lays down rules on eligible actions, entities and costs.

A non exhaustive list of actions that may be funded through the Programme is provided in Annex I to the Regulation. Actions are deemend to be eligible insofar as they implement the objectives laid down in Articles 3 and 4.

As regards costs, Article 15 provides for the possibility, under conditions, to consider as eligible costs incurred prior to the date of submission of the grant application, in the case of actions contributing to the protection of people in the Union from serious threats to health and in other exceptional cases. In similarly exceptional cases, and again under conditions, costs incurred in relation to a cross border crisis by entities established in non-associated countries can also be considered as eligible.

In order to achieve maximal simplification, the Regulation stipulates either additional conditions or derogations from the Financial Regulation concerning eligibility requirements for entities, exceptions from the requirement of call for proposals, co-financing rules, eligible costs, etc.

Chapter IV – Governance

This Chapter provides for an obligation for the Commission to consult the health authorities of the Member States on the work plans for the Programme, on its priorities and strategic orientations and on its implmentation.

Chapter V – Programming, monitoring, evaluation and control

A list of Programme indicators is included in Annex II to the Regulation, complemented by a list of more specific indicators to be used to monitor the performance of the Programme. The Commission will be empowered to adopt delegated acts in order to amend the list of indicators where necessary.

Interim and final evaluations will be carried out.

Chapter VI - transitional and final provisions

This Chapter requires the Commission to implement communication and information activities directed at multiple audiences on the programme and on its actions (as also specified in Annex I).

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## on the establishment of a Programme for the Union's action in the field of health –for the period 2021-2027 and repealing Regulation (EU) No 282/2014 ("EU4Health Programme")

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(5) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[4],

Having regard to the opinion of the Committee of the Regions[5],

Acting in accordance with the ordinary legislative procedure[6],

Whereas:

(1) According to Article 3(1) of the Treaty on the European Union, amongst the aims of the Union is to promote the well-being of its peoples.

(2) In accordance with Articles 9 and 168 of the Treaty on the Functioning of the European Union (TFEU) and Article 35 of the Charter of Fundamental Rights of the European Union (the Charter), a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities.

(3) Article 168 TFEU provides that the Union is to complement and support national health policies, encourage cooperation between Member States and promote the coordination between their programmes, in full respect of the responsibilities of the Member States for the definition of their health policies and the organisation and delivery of health services and medical care.

(4) Continued actions have been taken in particular under the previous programmes of Union action in the field of public health to meet the requirements set out in Article 168 TFEU[7].

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4 OJ C […], […], p. […].

5 OJ C […], […], p. […].

6 Position of the European Parliament of .... and decision of the Council of ….

(5) On 11 March 2020 the World Health Organization (WHO) declared the novel coronavirus (COVID-19) outbreak a global pandemic. That pandemic has *caused* an unprecedented *worldwide* health *crisis* with severe socio-economic consequences and human suffering.

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity[8]. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.

(7) It is therefore appropriate to establish a new Programme for the Union's action in the field of health, called EU4Health Programme ('the Programme') for the period 2021 - 2027. In line with the goals of the Union action and its competences in the area of public health the Programme should place emphasis on actions in relation to which there are advantages and efficiency gains from collaboration and cooperation at Union level and actions with an impact on the internal market.

(8) This Regulation should lay down a financial envelope for the Programme for the Union's action in the field of health which is to constitute the prime reference amount, within the meaning of point 16 of the Proposal for an Interinstitutional Agreement between the European Parliament, the Council and the Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management as adopted by the said Institutions[9].

(9) In accordance with Regulation [European Union Recovery Instrument] and within the limits of resources allocated therein, recovery and resilience measures under the Programme should be carried out to address the unprecedented impact of the COVID-19 crisis. Such additional resources should be used in such a way as to ensure compliance with the time limits provided for in Regulation [European Union Recovery Instrument].

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No

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7 Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008) (OJ L 271, 9.10.2002, p.1); Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-13) (OJ L 301, 20.11.2007, p. 3); Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union''s action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC (OJ L 86, 21.3.2014, p. 1).

8 Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

9 COM/2018/323 final.

1082/2013/EU of the European Parliament and of the Council[10] and other relevant mechanisms and structures established at Union level. This could include strategic stockpiling of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the "One Health" approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

(11) As in the time of health crisis emergency health technology assessment as well as clinical trials can contribute to the rapid development of medical countermeasures the Programme should provide support to facilitate such actions. The Commission has adopted a proposal[11] on Health Technology Assessment (HTA) to support cooperation on health technology assessment at Union level.

(12) With a view to protect people in vulnerable situations, including those suffering from mental illnesses and chronic diseases, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups.

(13) The COVID-19 crisis has highlighted many challenges in ensuring the supply of medicines, medical devices as well as personal protective equipment needed in the Union during the pandemics. The Programme therefore should provide support to actions which foster the production, procurement and management of crisis relevant products ensuring complementarity with other Union instruments.

(14) In order to minimise the public health consequences of serious cross-border threats to health it should be possible for actions supported under the Programme to cover coordination of the activities which strengthen the interoperability and coherence of Member States' health-systems through benchmarking, cooperation and exchange of best practices and ensure their capability to respond to health emergencies, that includes contingency planning, preparedness exercises and the upskilling of health care and public health staff and the establishment of mechanisms for the efficient monitoring and needs-driven distribution or allocation of goods and services needed in time of crisis.

(15) Experience from the COVID-19 crisis has indicated that there is a general need for the support to structural transformation of and systemic reforms of health systems across the Union to improve their effectiveness, accessibility and resilience. In the context of such transformation and reforms, the Programme should promote, in synergy with the Digital Europe Programme, actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide new care models and to deliver integrated services, from the community and primary health care

[10] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

[11] Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU, COM(2018) 51 final of 31.01. 2018.

to the highly specialised services, based on people's needs and ensure an efficient public health workforce equipped with the right skills, including digital skills. The development of a European health data space would provide health care systems, researchers and public authorities with means to improve the availability and quality of healthcare. Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006[12] the Programme should support actions ensuring the universality and inclusivity of health care, meaning that no-one is barred access to health care, and those ensuring that patients' rights, including on the privacy of their data, are duly respected.

(16) Keeping people healthy and active longer and empowering them to take an active role in managing their health will have positive effects on health, health inequalities, quality of life, productivity, competitiveness and inclusiveness, while reducing pressures on national budgets. The Commission has committed to help Member States to reach the sustainable development targets set in the 'UN 2030 Agenda for Sustainable Development' in particular Sustainable Development Goal 3 "Ensure healthy lives and promote well-being for all at all ages".[13] The Programme therefore should contribute to the actions taken towards reaching these goals.

(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and behavioural factors. Such non-communicable diseases as cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors and policy fields, combined with efforts to strengthen health systems.

(18) The Programme therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of illicit drugs. The Programme should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits and physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also therefore contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.

(19) Cancer is the second leading cause of mortality in the Member States after cardiovascular diseases. It is also one of non-communicable diseases that share common risk factors and the prevention and control of which would benefit the

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12 Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

13 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Next steps for a sustainable European future. European action for sustainability COM (2016) 739 final of 22.11.2016.

majority of citizens. In 2020 the Commission announced the 'Europe's Beating Cancer Plan' which would cover the entire cycle of the disease starting from prevention and early diagnosis to treatment and quality of life of patients and survivors. The measures should benefit from the Programme and from Horizon Europe's Mission on Cancer.

(20) The Programme will work in synergy and complementarity with other EU policies, programmes and funds such as actions implemented under the Digital Europe Programme, Horizon Europe, rescEU reserve under the Union Civil Protection Mechanism, Emergency Support Instrument, European Social Fund+ (ESF+, including as regards synergies on better protecting the health and safety of millions of workers in the EU), including the Employment and Social Innovation Strand (EaSI), the InvestEU fund, Single Market Programme, European Regional Development Fund (ERDF), Recovery and Resilience Facility including the Reform Delivery Tool, Erasmus, European Solidarity Corps, Support to mitigate Unemployment Risks in an Emergency (SURE), and EU external action instruments, such as the Neighbourhood, Development and International Cooperation Instrument and the Instrument for Pre-accession Assistance III. Where appropriate, common rules will be established in view of ensuring consistency and complementarity between funds, while making sure that specificities of these policies are respected, and in view of aligning with the strategic requirements of these policies, programmes and funds, such as the enabling conditions under ERDF and ESF+.

(21) In accordance with Article 114 TFEU, a high level of health protection should be ensured in the legislation adopted by the Union for the establishment and the functioning of the internal market. On the basis of Article 114 TFEU and point (c) of Article 168(4) TFEU, a considerable body of Union acquis was developed which guarantees the high standards of quality and safety for medicinal products and medical devices. Given the rising healthcare demand, Member States' healthcare systems face challenges in the availability and affordability of medicines and medical devices. To ensure a better public health protection as well as the safety and empowerment of patients in the Union, it is essential that patients and health systems have access to high quality healthcare products and can fully benefit from them.

(22) The Programme should therefore support actions to monitor shortages of medicines, medical devices and other healthcare products and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet medical needs, the Programme should provide support to clinical trials so as to speed up the development, authorisation and access to innovative and effective medicines, promote incentives to develop such medicinal products as antimicrobials and foster the digitial transformation of healthcare products and platforms for monitoring and collecting information on medicines.

(23) As the optimal use of medicines and antimicrobials in particular yields benefits for individuals and health systems, the Programme should promote their prudent and efficient use. In line with the European One Health Action Plan against Antimicrobial Resistance[14], adopted in June 2017 following the request from Member States, and given the experience with the bacterial secondary infections related to COVID 19, it is

[14] Communication from the Commission to the Council and the European Parliament 'A European One Health Action Plan against Antimicrobial Resistance (AMR)', COM(2017)0339 final of 29.6.2017.

essential that the Programme supports actions aimed at the prudent use of antimicrobials in humans, animals and crops, in the framework of an integrated policy on patient safety and prevention of medical errors.

(24) Since environmental pollution caused by human and veterinary pharmaceutical substances is an emerging environmental problem that can impact on public health, the Programme should foster measures to strengthen the assessment and appropriate management of environmental risks associated with the production, use and disposal of medicinal products, in line with the European Union Strategic Approach to Pharmaceuticals in the Environment[15].

(25) The Union health legislation has an immediate impact on public health, the lives of citizens, the efficiency and resilience of the health systems and the good functioning of the internal market. The regulatory framework for medical products and technologies (medicinal products, medical devices and substances of human origin), as well as for tobacco legislation, patients' rights in cross-border healthcare and serious cross-border threats to health is essential to health protection in the Union. The Programme therefore should support the development, implementation and enforcement of Union health legislation and provide high quality, comparable and reliable data to underpin policymaking and monitoring.

(26) Cross-border cooperation in the provision of healthcare to patients moving between Member States, collaboration on health technology assessments (HTA), and European Reference Networks (ERNs) are examples of areas where integrated work among Member States has shown to have strong added value and great potential to increase the efficiency of health systems and thus health in general. The Programme should therefore support activities to enable such integrated and coordinated work, which also serves to foster the implementation of high-impact practices that are aimed at distributing in the most effective way the available resources to the concerned population and areas so as to maximise their impact.

(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council[16] are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider the extension of ERNs beyond rare diseases to communicable and non-communicable diseases such as cancer.

(28) Regulation (EU, *Euratom*) 2018/1046 of the European Parliament and of the Council [17] (the 'Financial Regulation') applies to this Programme. It lays down rules on the

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15 Communication of the Commission to the European Parliament, the Council and the European economic and Social Committee 'European Union Strategic Approach to Pharmaceuticals in the Environment', COM(2019)128 final of 11.03.2019.

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

17 Regulation (EU, *Euratom*) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013,

implementation of the Union budget, including the rules on grants, prizes, procurement, indirect implementation, financial assistance, financial instruments and budgetary guarantees.

(29) The types of financing and the methods of implementation under this Regulation should be chosen on the basis of their ability to achieve the specific objectives of the actions and to deliver results, taking into account, in particular, the costs of controls, the administrative burden, and the expected risk of non-compliance. This should include consideration of the use of lump sums, flat rates and unit costs, as well as financing not linked to costs as envisaged in Article 125(1) of the Financial Regulation.

(30) In order to optimise the added value and impact from investments funded wholly or in part through the budget of the Union, synergies should be sought in particular between the Programme for the Union's action in the field of health and other Union programmes, including those under shared-management. To maximise those synergies, key enabling mechanisms should be ensured, including cumulative funding in an action from the Programme for the Union's action in the field of health and another Union programme, as long as such cumulative funding does not exceed the total eligible costs of the action. For that purpose, this Regulation should set out appropriate rules, in particular on the possibility to declare the same cost or expenditure on a pro-rata basis to Programme for the Union's action in the field of health and another Union programme.

(31) Given the specific nature of the objectives and actions covered by the Programme, the respective competent authorities of the Member States are best placed in some cases to implement the related activities. Those authorities, designated by the Member States themselves, should therefore be considered to be identified beneficiaries for the purpose of Article 195 of the Financial Regulation and the grants be awarded to such authorities without prior publication of calls for proposals.

(32) The ERNs are approved as Networks by the Board of Member States of the European Reference Networks, following the approval procedure set out in Commission Implementing Decision 2014/287/EU of 10 March 2014[18]. Those networks, should therefore be considered to be identified beneficiaries for the purpose of Article 195 of the Financial Regulation and the grants to the ERNs be awarded without prior publication of calls for proposals. Direct grants should also be awarded to other entities designated in accordance with Union rules (for example reference laboratories and centres, centres of excellence and transnational networks).

(33) Given the common agreed values of solidarity towards equitable and universal coverage of quality health services as a basis for the Union's policies in this area and that the Union has a central role to play in accelerating progress on global health challenges[19], the Programme should support the Union's contribution to international

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(EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, *Euratom*) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

[18] Commission Implementing Decision 2014/287/EU of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks (OJ L 147, 17.5.2014, p. 79).

[19] Council conclusions on the EU role in Global Health, 3011th Foreign Affairs Council meeting, Brussels, 10 May 2010.

and global health initiatives with a view to improve health, address inequalities and increase protection against global health threats.

(34) In order to maximise the effectiveness and efficiency of actions at Union and international level, cooperation should be developed with relevant international organisations such as the United Nations and its specialised agencies, in particular the WHO, the World Bank, as well as with the Council of Europe and the Organisation for Economic Co-operation and Development (OECD) to implement the Programme. Pursuant to Article 94 of Council Decision 2013/755/EU[20], persons and entities established in Overseas Countries and Territories (OCTs) are eligible for funding subject to the rules and objectives of the Programme and possible arrangements applicable to the Member State to which the relevant OCTs are linked.

(35) Third countries which are members of the European Economic Area (EEA) may participate in Union programmes in the framework of the cooperation established under the EEA agreement, which provides for the implementation of the programmes by a decision under that agreement. A specific provision should be introduced in this Regulation to grant the necessary rights for and access to the authorising officer responsible, the European Anti-Fraud Office (OLAF) as well as the European Court of Auditors (ECA) to comprehensively exert their respective competences.

(36) Cooperation with third countries should be strengthened on the exchange of knowledge and best practices in health systems preparedness and response.

(37) In accordance with the Financial Regulation, Regulation (EU, *Euratom*) No 883/2013 of the European Parliament and of the Council[21], Council Regulation (EC, *Euratom*) No 2988/95[22], Council Regulation (*Euratom*, EC) No 2185/96[23] and Council Regulation (EU) 2017/1939[24], the financial interests of the Union are to be protected by means of proportionate measures including measures relating to the prevention, detection, correction and investigation of irregularities, including fraud, to the recovery of funds lost, wrongly paid or incorrectly used and, where appropriate, to the imposition of administrative penalties. In particular, in accordance with Regulations (*Euratom*, EC) No 2185/96 and (EU, *Euratom*) No 883/2013, the European Anti-Fraud Office has the power to carry out administrative investigations, including on-the-spot checks and inspections with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union. The European Public Prosecutor's Office (EPPO) is empowered in accordance with Council Regulation (EU) 2017/1939 to investigate and prosecute criminal

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[20] Council Decision 2013/755/EU of 25 November 2013 on the association of the overseas countries and territories with the European Union ( 'Overseas Association Decision' ) (OJ L 344, 19.12.2013, p. 1).

[21] Regulation (EU, *Euratom*) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (*Euratom*) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).

[22] Council Regulation (EC, *Euratom*) No 2988/95 of 18 December 1995 on the protection of the European Communities financial interests (OJ L 312, 23.12.1995, p. 1).

[23] Council Regulation (*Euratom*, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

[24] Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office ('the EPPO') (OJ L 283, 31.10.2017, p. 1).

offences affecting the financial interests of the Union, as provided for in Directive (EU) 2017/1371 of the European Parliament and of the Council[25].

(38) In accordance with the Financial Regulation, any person or entity receiving Union funds is to fully cooperate in the protection of the financial interests of the Union, grant the necessary rights and access to the Commission, OLAF, the Court of Auditors and in respect of those Member States participating in enhanced cooperation, the EPPO pursuant to Regulation (EU) 2017/1939, and ensure that any third parties involved in the implementation of Union funds grant equivalent rights. .

(39) Horizontal financial rules adopted by the European Parliament and the Council on the basis of Article 322 TFEU apply to this Regulation. These rules are laid down in the Financial Regulation and determine in particular the procedure for establishing and implementing the budget through grants, procurement, prizes, indirect implementation, and provide for checks on the responsibility of financial actors. Rules adopted on the basis of Article 322 TFEU also concern the protection of the Union's budget in case of generalised deficiencies as regards the rule of law in the Member States, as the respect for the rule of law is an essential precondition for sound financial management and effective EU funding.

(40) Reflecting the importance of tackling climate change in line with the Union's commitments to implement the Paris Agreement and the United Nations Sustainable Development Goals, this Programme will contribute to mainstream climate action in the Union's policies and to the achievement of an overall target of 25 % of the EU budget expenditures supporting climate objectives. Relevant actions will be identified during the Programme's preparation and implementation, and reassessed in the context of its mid-term evaluation.

(41) The policy objectives of this Programme may be also addressed through financial instruments and budgetary guarantees under the InvestEU Fund. Financial support should be used to address market failures or sub-optimal investment situations, in a proportionate manner and actions should not duplicate or crowd out private financing or distort competition in the internal market. In general, actions should have a clear European added value.

(42) The implementation of the Programme should be such that the responsibilities of the Member States, for the definition of their health policy and for the organisation and delivery of health services and medical care, are respected.

(43) Given the nature and potential scale of cross-border threats to human health, the objective of protecting people in the Union from such threats and to increase crisis prevention and preparedness cannot be sufficiently achieved by the Member States acting alone. In accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union, action at Union level can also be taken to support Member States' efforts in the pursuit of a high level of protection of public health, to improve the availability and affordability in the Union of medicines, medical devices and other crisis relevant products, to support innovation and to support integrated and coordinated work and implementation of best practices among Member States, and to address inequalities in access to health throughout the EU in a manner that creates efficiency gains and value-added impacts that could not be generated by action taken

[25] Directive (EU) 2017/1371 of the European Parliament and of the Council of 5 July 2017 on the fight against fraud to the Union's financial interests by means of criminal law (OJ L 198, 28.7.2017, p. 29).

at national level while respecting the Member States' competence and responsibility in the areas covered by the Programme. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(44) In order to allow for possible adjustments necessary to achieve the Programme's objectives, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the review, amendment and addition of the indicators set out in Annex II to this Regulation When exercising these delegated powers, it is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016[26]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council are to receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(45) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt rules on technical and administrative arrangements necessary for the implementation of the actions of the Programme and and on uniform templates for the collection of data necessary to monitor the implementation of the Programme. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of European Parliament and of the Council. [27]

(46) As the third Programme for the Union's action in the field of health (2014-2020), established by Regulation (EU) No 282/2014, comes to an end, that Regulation becomes obsolete and should be repealed.

(47) It is appropriate to ensure a smooth transition without interruption between the previous programme in the field of health (2014-2020) and the Programme, and to align the duration of the Programme with Regulation[28] (new MFF). Therefore, the Programme should apply from 1 January 2021.

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26 OJ L 123, 12.5.2016, p. 13.

27 Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

28 ……..

HAVE ADOPTED THIS REGULATION:

# CHAPTER I

# GENERAL PROVISIONS

*Article 1*

***Subject matter***

This Regulation establishes the EU4Health Programme ("the Programme").

It lays down the objectives of the Programme, its budget for the period from 1 January 2021 to 31 December 2027, the forms of Union funding of the Programme and the rules for providing such funding.

*Article 2*

***Definitions***

For the purposes of this Regulation, the following definitions shall apply:

(1) 'associated country' means a third country which is party to an agreement with the Union allowing for its participation in the Programme, in accordance with Article 7;

(2) 'blending operation' means actions supported by the Union budget, including within blending facilities pursuant to Article 2(6) of Regulation (EU, *Euratom*) No 2018/1046, combining non-repayable forms of support and/or financial instruments from the Union budget with repayable forms of support from development or other public finance institutions, as well as from commercial finance institutions and investors;

(3) 'health crisis' means any crisis or serious incident arising from a threat of human, animal, plant, food or environment origin, having a health dimension and which requires urgent action by authorities;

(4) 'crisis relevant products' means products and substances necessary, in the context of a health crisis, to prevent, diagnose or treat a disease and its consequences, included but not limited to: medicinal products - including vaccines - and their intermediates, active pharmaceutical ingredients and raw materials; medical devices; hospital and medical equipment (such as ventilators, protective clothing and equipment, diagnostic materials and tools); personal protective equipment; disinfectants and their intermediary products and raw materials necessary for their production);

(5) 'One Health approach' means an approach which recognises that human and animal health are interconnected, that diseases may be transmitted from humans to animals and *vice versa* and must therefore be tackled in both, and that the environment links humans and animals;

(6) 'European Reference Networks' means the networks referred to in Article 12 of Directive 2011/24;

(7) 'legal entity' means any natural or legal person created and recognised as such under national law, Union law or international law, which has a legal personality and which may, acting in its own name, exercise rights and be subject to obligations, or an

entity without a legal personality in accordance with Article 197(2)(c) of the Financial Regulation;

(8) 'third country' means a country that is not member of the European Union;

(9) 'serious cross-border threat to health' means a life- threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection;

(10) 'emergency support' means a needs-based emergency response, complementing the response of the affected Member States aimed at preserving life, preventing and alleviating human suffering, and maintaining human dignity wherever the need arises as a result of serious cross-border threats to health referred to in Article 3 (1).

*Article 3*

***General objectives***

The Programme shall pursue the following general objectives, in keeping with the "One Health" approach where relevant:

(1) protect people in the Union from serious cross-border threats to health;

(2) improve the availability in the Union of medicines, medical devices and other crisis relevant products, contribute to their affordability, and support innovation;

(3) strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, sustained implementation of best practice and data sharing, to increase the general level of public health.

*Article 4*

***Specific objectives***

The general objectives referred to in Article 3 shall be pursued through the following specific objectives, in keeping with the "One Health" approach where relevant:

(1) strengthen the capability of the Union for prevention, preparedness and response to serious cross-border threats to health, and the management of health crises, including through coordination, provision and deployment of emergency health care capacity, data gathering and surveillance;

(2) ensure the availability in the Union of reserves or stockpiles of crisis relevant products, and a reserve of medical, healthcare and support staff to be mobilised in case of a crisis;

(3) support actions to ensure appropriate availability, accessibility and affordability of crisis relevant products and other necessary health supplies;

(4) strengthen the effectiveness, accessibility, sustainability and resilience of health systems, including by supporting digital transformation, the uptake of digital tools and services, systemic reforms, implementation of new care models and universal health coverage, and address inequalities in health;

(5) support actions aimed at strengthening health system's ability to foster disease prevention and health promotion, patient rights and cross-border healthcare, and promote the excellence of medical and healthcare professionals;

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer;

(7) foster and support the prudent and efficient use of medicines, and in particular of antimicrobials, and more environmentally friendly production and disposal of medicines and medical devices;

(8) support the development, implementation and enforcement of Union health legislation and provide high-quality, comparable and reliable data to underpin policy making and monitoring, and promote the use of health impact assessments of relevant policies;

(9) support integrated work among Member States, and in particular their health systems, including the implementation of high-impact prevention practices, and scaling up networking through the European Reference Networks and other transnational networks;

(10) support the Union's contribution to international and global health initiatives.

*Article 5*

***Budget***

1. The financial envelope for the implementation of the Programme for the period 2021-27 shall be EUR 1 946 614 000 in current prices.

2. The amount referred to in paragraph 1 may be used for technical and administrative assistance for the implementation of the Programme, such as preparatory, monitoring, control, audit and evaluation activities including corporate information technology systems.

3. Appropriations deriving from activities under point (c) of Article 10 of this Regulation, shall constitute assigned revenue within the meaning of point (a) of paragraph 3 and paragraph 5 of Article 21 of Regulation (EU, *Euratom*) 2018/1046.

4. The budgetary commitments extending over more than one financial year, may be broken down over several years into annual instalments.

5. Without prejudice to the Regulation (EU, *Euratom*) 2018/1046, expenditure for actions resulting from projects included in the first work programme may be eligible as from 1 January 2021.

6. If necessary, appropriations may be entered in the budget beyond 2027 to cover the expenses provided for in paragraph (2) to enable the management of actions not completed by 31 December 2027.

*Article 6*

***Resources from the European Union Recovery Instrument***

Measures referred to in Article 2 of Regulation [European Union Recovery Instrument] shall be implemented under the Programme through an amount of up to EUR 8 451 000 000 in current prices referred to in point (iii) of Article 3(2)(a) of that Regulation, subject to its Article 5(4) and (8).

These amounts shall constitute external assigned revenue in accordance with Article 21(5) of Regulation (EU, *Euratom*) 2018/1046.

*Article 7*

***Third countries associated to the Programme***

The Programme shall be open to the following associated countries:

(1) European Free Trade Association (EFTA) members which are members of the European Economic Area (EEA), in accordance with the conditions laid down in the Agreement on the European Economic Area;

(2) Acceding countries, candidate countries and potential candidates, in accordance with the general principles and general terms and conditions for the participation of those countries in Union programmes established in the respective framework agreements and Association Council decisions, or similar agreements, and in accordance with the specific conditions laid down in agreements between the Union and those countries;

(3) Countries covered by the European Neighbourhood Policy, in accordance with the general principles and general terms and conditions for the participation of those countries in Union programmes established in the respective framework agreements and association council decisions, or similar agreements, and in accordance with the specific conditions laid down in agreements between the Union and those countries;

(4) Third countries, in accordance with the conditions laid down in a specific agreement covering the participation of the third country to any programme, provided that the agreement:

(i) ensures a fair balance as regards the contributions and benefits of the third country participating in the Union programmes;

(ii) lays down the conditions of participation in the programmes, including the calculation of financial contributions to individual programmes and their administrative costs. These contributions shall constitute assigned revenues in accordance with Article 21(5) of Regulation (EU, *Euratom* 2018/1046);

(iii) does not confer to the third country a decisional power;

(iv) guarantees the rights of the Union to ensure sound financial management and to protect its financial interests.

# Chapter II

# FUNDING

*Article 8*

***Implementation and forms of Union funding***

1. The Programme shall be implemented in direct management in accordance with Regulation (EU, *Euratom*) 2018/1046 or in indirect management with the bodies referred to in Article 62(1) (c) of Regulation (EU, *Euratom*) 2018/1046.

2. The Programme may provide funding in any of the forms laid down in Regulation (EU, *Euratom*) 2018/1046, in particular grants, prizes and procurement.

3. Contributions to a mutual insurance mechanism may cover the risk associated with the recovery of funds due by recipients and may be considered as sufficient guarantee under Regulation (EU, *Euratom*) 2018/1046. The Commission shall set up specific rules for the operation of the mechanism.

4. Where the Commission implements emergency support operations through non-governmental organisations, the criteria concerning financial and operational capacity shall be deemed to be satisfied where there is a framework partnership agreement in force between that organisation and the Commission pursuant to Regulation (EC) No 1257/96.

*Article 9*

***Grants***

1. Grants under the Programme shall be awarded and managed in accordance with Title VIII of Regulation (EU, *Euratom*) 2018/1046.

2. Grants may be used in combination with financing from the European Investment Bank or national promotional banks or other development and public financial institutions as well as from private-sector finance institutions and private-sector investors, including through public private partnerships.

*Article 10*

***Procurement***

1. Emergency support under this Regulation may be granted in any of the following forms:

   (a) joint procurement with the Member States as referred to in Article 165 (2) of Regulation (EU, *Euratom*) 2018/1046 whereby Member States may acquire, rent or lease fully the capacities jointly procured;

   (b) procurement by the Commission on behalf of the Member States based on an agreement between the Commission and the Member States;

   (c) procurement by the Commission as wholesaler by buying, stocking and reselling or donating supplies and services, including rentals, to Member States or partner organisations selected by the Commission.

2. In the event of a procurement procedure as referred to in point (b) of paragraph 1, the ensuing contracts shall be concluded by either of the following:

   (a) by the Commission whereby the services or goods are to be rendered or delivered to Member States or to partner organisations selected by the Commission;

   (b) by the participant Member States whereby they are to directly acquire, rent or lease the capacities procured for them by the Commission.

3. In the event of procurement procedures as referred to in points (b) and (c) of paragraph 1, the Commission shall follow the rules set out in Regulation (EU, *Euratom*) 2018/1046 for its own procurement.

*Article 11*

***Blending operations***

Blending operations under the Programme shall be implemented in accordance with the [InvestEU regulation] and Title X of the Financial Regulation.

*Article 12*

***Cumulative funding***

An action that has received a contribution from the Programme may also receive a contribution from any other Union programme, including under shared management, provided that the contributions do not cover the same costs.

The rules of each contributing Union programme shall apply to its respective contribution to the action.

The cumulative funding shall not exceed the total eligible costs of the action and the support from the different Union programmes may be calculated on a pro-rata basis in accordance with the documents setting out the conditions for support.

# CHAPTER III

# ACTIONS

*Article 13*

***Eligible actions***

Only actions implementing the objectives referred to in Articles 3 and 4, including those set out in Annex I, shall be eligible for funding.

*Article 14*

***Eligible entities***

1. In addition to the criteria set out in Article 197 of Regulation (EU, *Euratom*) 2018/1046, the following criteria shall apply:
   (a) legal entities established in any of the following countries:
      (i) a Member State or an overseas country or territory linked to it;
      (ii) a third country associated to the Programme;
      (iii) a third country listed in the work programme under the conditions specified in paragraph 2 and 3;
   (b) any legal entity created under Union law or any international organisation;
2. Legal entities established in a third country which is not an associated country are exceptionally eligible to participate where this is necessary for the achievement of the objectives of a given action.
3. Legal entities established in a third country which is not associated to the Programme should in principle bear the cost of their participation.
4. Natural persons are not eligible.
5. Under the Programme, direct grants may be awarded without a call for proposals to fund actions having a clear Union added value co-financed by the competent authorities that are responsible for health in the Member States or in the third countries associated to the Programme, relevant international health organisations or by public sector bodies and non-governmental bodies, acting individually or as a network, mandated by those competent authorities.

6. Under the Programme, direct grants may be awarded without a call for proposals to European Reference Networks. Direct grants may also be awarded to other transnational networks set out in accordance with EU rules.

7. Under the Programme, grants may be awarded without a call for proposals to fund the functioning of non-governmental bodies where financial support is necessary for the pursuit of one or more of the specific objectives of the Programme as long as those bodies fulfil all the following criteria:

   (i) they are non-governmental, non-profit-making and independent of industry, commercial and business or other conflicting interests;

   (ii) they work in the public health area, pursue at least one of the specific objectives of the Programme and play an effective role at Union level;

   (iii) they are active at Union level and in at least half of the Member States, and have a balanced geographical coverage of the Union.

*Article 15*

***Eligible costs***

1. In addition to the criteria set out in Article 186 of Regulation (EU, *Euratom*) 2018/1046, and in accordance with point (a) of the second subparagraph of Article 193 of that Regulation, costs incurred prior to the date of submission of the grant application shall be eligible:

   (a) for actions which implement the objective referred to in point (1) of Article 3;

   (b) for actions implementing other objectives, in duly justified exceptional cases, provided that those costs are directly linked to the implementation of the supported actions and activities.

2. The costs under point (a) of paragraph 1 of this Article, related to measures aiming to address suspected occurrence of a disease that could trigger a cross-border health threat, shall be eligible from the date of notification of the suspected occurrence of the disease to the Commission, provided that that occurrence or presence is subsequently confirmed.

3. In exceptional cases, during a crisis caused by a serious cross-border health threat as defined in Article 3(g) of Decision 1082/2013/EU, costs incurred by entities established in non-associated countries may be considered exceptionally eligible if they are duly justified for reasons of countering the spread of the risk for the protection of the health of people in the Union.

# CHAPTER IV

# GOVERNANCE

*Article 16*

***Joint policy implementation***

The Commission shall consult the health authorities of the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable

Diseases on the work plans established for the Programme and its priorities and strategic orientations and its implementation.

*Article 17*

***Implementation of the Programme***

The Commission may, by means of implementing acts, lay down rules on:

(a) technical and administrative arrangements necessary for the implementation of the actions of the Programme;

(b) uniform templates for the collection of data necessary to monitor the implementation of the Programme.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 23(2).

# CHAPTER V

# PROGRAMMING, MONITORING, EVALUATION AND CONTROL

*Article 18*

***Work programme***

The Programme shall be implemented by work programmes referred to in Article 110 of Regulation (EU, *Euratom*) 2018/1046. Work programmes shall set out, where applicable, the overall amount reserved for blending operations.

*Article 19*

***Monitoring and reporting***

1. Indicators to report on progress of the Programme towards the achievement of the general and specific objectives set out in Articles 3 and 4 are set out in Annex II.

2. The Commission is empowered to adopt delegated acts in accordance with Article 24 concerning amendments to Annex II to amend and supplement the indicators where considered necessary.

3. The performance reporting system shall ensure that data for monitoring programme implementation and results are collected efficiently, effectively, and in a timely manner. To that end, proportionate reporting requirements shall be imposed on recipients of Union funds and, where relevant, on Member States.

*Article 20*

***Evaluation***

1. Evaluations shall be carried out in a sufficiently timely manner to feed into the decision-making process.

2. The interim evaluation of the Programme shall be performed once there is sufficient information available about their implementation, but not later than four years after the start of the implementation.

3. At the end of the implementation period, but no later than four years after the end of the period specified in Article 1, a final evaluation shall be carried out by the Commission.

4. The Commission shall communicate the conclusions of the evaluations accompanied by its observations, to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

*Article 21*

***Audits***

Audits on the use of the Union contribution carried out by persons or entities, including ~~by~~ others than those mandated by the Union Institutions or bodies, shall form the basis of the overall assurance pursuant to Article 127 of Regulation (EU, *Euratom*) 2018/1046.

*Article 22*

***Protection of the financial interests of the Union***

Where a third country participates in the Programme by a decision under an international agreement, the third country shall grant the necessary rights and access required for the authorizing officer responsible, the European Anti-Fraud Office (OLAF), the European Court of Auditors to comprehensively exert their respective competences. In the case of OLAF, such rights shall include the right to carry out investigations, including on-the-spot checks and inspections, provided for in Regulation (EU, *Euratom*) No 883/2013 concerning investigations conducted by the European Anti- Fraud Office (OLAF).

*Article 23*

***Committee procedure***

1. The Commission shall be assisted by a EU4Health Programme Committee. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

*Article 24*

***Exercise of the delegation***

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 19(2) shall be conferred on the Commission until 31 December 2028.

3. The delegation of power referred to in Article 19(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal* of the European

Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 19(2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

# CHAPTER VI

# TRANSITIONAL AND FINAL PROVISIONS

*Article 24*

***Information, communication and publicity***

1. The recipients of Union funding shall acknowledge the origin and ensure the visibility of the Union funding (in particular when promoting the actions and their results), by providing coherent, effective and targeted information to multiple audiences, including the media and the public.

2. The Commission shall implement information and communication actions related to the Programme, and its actions and results. Financial resources allocated to the Programme shall also contribute to the corporate communication of the political priorities of the Union, as far as they are related to the objectives referred to in Articles 3 and 4.

*Article 25*

***Repeal***

Regulation (EU) No 282/2014 is repealed with effect from 1 January 2021, without prejudice to Article 26 of this Regulation.

*Article 26*

***Transitional provisions***

1. This Regulation shall not affect the continuation or modification of the actions concerned, until their closure, under Regulation (EU) No 282/2014, which shall continue to apply to the actions concerned until their closure.

2. The financial envelope for the Programme may also cover technical and administrative assistance expenses necessary to ensure the transition between the

Programme and the measures adopted under its predecessor, the third Programme for the Union's action in the field of health (2014-2020).

*Article 27*

***Entry into force***

This Regulation shall enter into force on the twentieth day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2021.This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the European Parliament*
*The President*

*For the Council*
*The President*

# LEGISLATIVE FINANCIAL STATEMENT

## 1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

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# LEGISLATIVE FINANCIAL STATEMENT

## 1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

### 1.1. Title of the proposal/initiative

EU4Health Programme

### 1.2. Policy area(s) concerned

Heading 5: Resilience, Security and Defence

### 1.3. Nature of the proposal/initiative

☐ The proposal/initiative relates to **a new action**

☐ The proposal/initiative relates to **a new action following a pilot project/preparatory action**[29]

☐ The proposal/initiative relates to **the extension of an existing action**

☑ The proposal/initiative relates to **an action redirected towards a new action**

### 1.4. Objective(s)

*1.4.1. The Commission's multiannual strategic objective(s) targeted by the proposal/initiative*

The EU4Health Programme would seek to contribute to the following main strategic objectives below, in keeping with the "One Health" approach where relevant:

a) protect people in the Union from serious cross-border threats to health

b) improve the availability in the Union of medicines, medical devices and other crisis relevant products, contribute to their affordability, and support innovation;

c) strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, sustained implementation of best practice and data sharing, to increase the general level of public health.

*1.4.2. Specific objective(s)*

Specific objective No 1:

Strengthen the capability of the Union for prevention, preparedness and response to serious cross-border threats to health, and the management of health crises, including through coordination, provision and deployment of emergency health care capacity, data gathering and surveillance;

Specific objective No 2:

Ensure the availability in the Union of reserves or stockpiles of crisis-relevant products, and a reserve of medical, healthcare and support staff to be mobilised in case of a crisis;

[29] As referred to in Article 54(2)(a) or (b) of the Financial Regulation.

Specific objective No 3:

Support actions to ensure appropriate availability, accessibility and affordability of crisis relevant products and other necessary health supplies;

Specific objective No 4:

Strengthen the effectiveness, accessibility, sustainability and resilience of health systems, including by supporting digital transformation, the uptake of digital tools and services, systemic reforms, implementation of new care models and universal health coverage, and address inequalities in health;

Specific objective No 5:

Support actions aimed at strengthening health systems' ability to foster disease prevention and health promotion, patient rights and cross-border healthcare, and promote the excellence of medical and healthcare professionals;

Specific objective No 6:

Support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer;

Specific objective No 7:

Foster and support the prudent and efficient use of medicines, and in particular of antimicrobials, and more environmentally friendly production and disposal of medicines and medical devices;

Specific objective No 8:

Support the development, implementation and enforcement of Union health legislation and provide high-quality, comparable and reliable data to underpin policy making and monitoring, and promote the use of health impact assessments of relevant policies;

Specific objective No 9:

Support integrated work among Member States and in particular their health systems, including the implementation of high-impact prevention practices, and scaling up networking through the European Reference Networks, and other transnational networks;

Specific objective No 10:

Support the Union's contribution to international and global health initiatives.

*1.4.3. Expected result(s) and impact*

*Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.*

Specific objective No 1:

Strengthen the capability of the Union for prevention, preparedness and response to serious cross-border threats to health, and the management of health crises, including through coordination, provision and deployment of emergency health care capacity, data gathering and surveillance

Expected result(s) and impact:

Improved emergency response capacities, better prevention, early detection, response, planning and readiness in all MS.

All of Member States reporting full compliance with the International Health Regulations, through annual reporting to WHO.

Specific objective No 2:

Ensure the availability in the Union of reserves or stockpiles of crisis-relevant products, and a reserve of medical, healthcare and support staff to be mobilised in case of a crisis.

Expected result(s) and impact:

Better crisis management capacities and availability of medical countermeasures and supplies, as well as treatment capacities to be used during disease outbreaks and crises.

Improved access to medicines for EU patients and health systems, in terms of quality, quantity and price affordability, environmental friendliness.

Ensure supply of affordable medicines and reduce shortages across the EU, faciliate clinical trials and ensure safe and effective medicines and vaccines.

Specific objective No 3:

Support actions to ensure appropriate availability, accessibility and affordability of crisis relevant products and other necessary health supplies.

Expected result(s) and impact:

Optimal utilisation of health care capacities during health crises, avoiding geographical/regional imbalances improving resilience of overall healthcare offer and capacity of the system to absorb sudden pics of health care demand during health crises.

Specific objective No 4:

Strengthen the effectiveness, accessibility, sustainability and resilience of health systems, including by supporting digital transformation, the uptake of digital tools and services, systemic reforms, implementation of new care models and universal health coverage, and address inequalities in health.

Expected result(s) and impact:

Effective, accessible, sustainable and resilient health systems, reduced health inequalities within and across MSs.

Better knowledge, improved skills and support to clinitians by using computer-based tools, AI and more efficient analysis of data. Increase the use of telehealth in Member States.

Specific objective No 5:

Support actions aimed at strengthening health systems' ability to foster disease prevention and health promotion, patient rights and cross-border healthcare, and promote the excellence of medical and healthcare professionals.

Expected result(s) and impact:

Support Member States with knowledge transfer useful for the national reform processes for more effective, accessible and resilient health systems and better health promotion and disease prevention, thus increasing healthy life years.

Specific objective No 6:

Support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer.

Expected result(s) and impact:

The actions will contribute to reaching the targets set by the World Health Organisation on non-communicable diseases, the Sustainable Development Goals (SDG), the Framework Convention on Tobacco Control and its Protocol on Illicit Trade in Tobacco Products and the recommendations of the future EU cancer plan.

Specific objective No 7:

Foster and support the prudent and efficient use of medicines, and in particular of antimicrobials, and more environmentally friendly production and disposal of medicines and medical devices.

Expected result(s) and impact:

More prudent use of antimicrobials through a One Health approach through the development of EU databases using modern technologies to guide the prescription of antimicrobials.

Increased awareness and understanding of the burden of antimicrobial resistance (AMR) on health systems and society at large, conducive to more targeted, innovative policy measures.

Contribution better implementation of existing guidelines, for better diagnosis and decreasing level of antimicrobial resistance.

Reduce environmental footprint.

Specific objective No 8:

Support the development, implementation and enforcement of Union health legislation and provide high-quality, comparable and reliable data to underpin policy making and monitoring, and promote the use of health impact assessments of relevant policies.

Expected result(s) and impact:

This objective will help Member States to ensure healthy lives and promote well-being for all at all ages (SDG 3).

Patients' Rights to be fully reflected in the implementation of cross-border healthcare legislation. Optimisation and possibly improvement of the framework on substances of human origin.

Enhanced degree of Implementation of the EU legislation in the field of health and health-related products (medicinal products, medical devices etc.).

Specific objective No 9:

Support integrated work among Member States and in particular their health systems, including the implementation of high-impact prevention practices, and scaling up networking through the European Reference Networks (ERN), and other transnational networks.

Expected result(s) and impact:

Increase the number of patients to be diagnosed and treated by ERN networks.

Better outcomes of treatments and improvement of knowledge on rare diseases.

Increase the number clinical assessments jointly carried out by Health Technology Assessment bodies.

Increased exchange of best practices between Member States.

Specific objective No 10:

Support the Union's contribution to international and global health initiatives.

Expected result(s) and impact:

Strengthen the role of the EU and its Member States in global health by investing in cooperation with relevant international and multilateral organisations such as the United Nations and its specialised agencies, in particular the WHO, and help Member States to reach their sustainable development goals (SDG).

*1.4.4. Indicators of results and impact*

*Specify the indicators for monitoring implementation of the proposal/initiative.*

General objectives:

I. Protect people in the Union from serious cross-border threats to health.

*Indicator 1:* Quality and completeness of EU and MS preparedness and response planning for serious cross border threats to health.

II. Improve the availability in the Union of medicines, medical devices and other crisis relevant products, contribute to their affordability, and support innovation.

*Indicator 2:* Access to centrally authorised medicines, e.g. number of orphan authorisations, Advanced Therapy Medicinal Products, Paediatric Use Medicinal Products or vaccines, for unmet needs.

III. Strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, sustained implementation of best practice and data sharing, to increase the general level of public health.

*Indicator 3:* Number of actions and best practices directly contributing to the SDG 3.4/Member.

*Indicator 4:* Implementation of best practices by EU Member States.

## 1.5. Grounds for the proposal/initiative

*1.5.1. Requirement(s) to be met in the short or long term*

The current COVID-19 crisis has shown that health must be given higher priority in the future financial framework. The Programme will reflect the lessons learned from the crisis, as well as provide support for the challenges ahead.

Experience from the crisis has demonstrated that the EU must do more to get health systems ready to provide state of the art services medicines and medical products and technologies (medical devices and substances of human origin) and to be prepared to cope with epidemics and other unforeseeable crisis or challenges. It has also shown that the structural challenges that pre-existed the crisis in terms of effectiveness, accessibility and resilience of health systems have been exacerbated by the crisis and that the need to address them, through long term transformation and investments, is even more crucial.

It has demonstrated the need to have a future-proof and crisis-proof system to ensure timely access to safe, quality and efficacious medicines under all circumstances and to address shortages and dependency on imports of medicines and active pharmaceutical ingredients due to manufacturing outside the EU. Also stregthened cooperation and coordination between regulatory authorities in case of emerging health threats is needed.

Experience with the crisis has also demonstrated the need for focussing on a healthy population at the first place. Therefore, good health promotion and disease prevention activities must be an integral part of functioning health systems. Prevention is much more cost effective than care, especially in an ageing population.

The Programme should also contribute to the recovery strategy by supporting the long term resilience of health systems across Europe to address structural challenges such as the ageing of the population, reaching the right balance between needed innovation and the cost of the new technologies and new treatments, the changing nature of care delivery, the obstacles to universal health coverage, multisectoral approaches to develop policies that contribute to wellbeing and the health of the population.

*1.5.2. Added value of Union involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this point 'added value of Union involvement' is the value resulting from Union intervention which is additional to the value that would have been otherwise created by Member States alone.*

Reasons for action at European level (ex-ante):

The current COVID pandemic has revealed the importance of preparedness and responses capacities of the Member States to swiftly react to health emergencies which requires an engagement across borders.

Expected generated Union added value (ex-post):

A strong, legally sound and financially well equipped framework for EU health crisis preparedness and response, able to cope with cross-border health threats, including those from outside the EU, where EU intervention can add tangible value. The social and economic activity in the EU should be secured in all times. Improving health systems in the Member States will have positive effects on overall health, health inequalities, while reducing pressures on national budgets.

From a post-crisis recovery perspective, the Programme will make an important contribution to ensuring that the EU will be better prepared to face future health threats affecting the whole or large parts of its territory.

The programme will support Member States in reaching the SDG health target with its subtargets, so that internal health policies are in line with international commitments. The work on health determinants, disease prevention and health promotion is an important component of this work and the most cost-effective investment in health.

The EU4Health Programme will build on ongoing work, such as the European Reference Networks for rare diseases and crisis preparedness and management, to ensure sufficient critical mass and economy of scale.

The EU4Health programme will support the implementation and development of Health legislation under Articles 114 and 168 of the Treaty on the Functioning of the European Union (TFEU), to set measures to ensure the functioning of the internal market and ensure high standards of quality and safety of medicinal and medical products, and to support, coordinate or supplement the actions of EU Member States for the protection and improvement of human health.

*1.5.3. Compatibility and possible synergy with other appropriate instruments*

The EU4Health programme will work in synergy and complementarity with other EU policies and funds such as actions implemented under the Digital Europe Programme, Horizon Europe, rescEU reserve under the Union Civil Protection Mechanism, Emergency Support Instrument, European Social Fund + (ESF+, including as regards synergies on better protecting the health and safety of millions of workers in the EU), including the Employment and Social Innovation Strand (EaSI), the InvestEU fund, Single Market Programme, European Regional Development Fund (ERDF), Recovery and Resilience Facility including the Reform Delivery Tool, Erasmus, European Solidarity Corps, Support to mitigate Unemployment Risks in an Emergency (SURE), and EU external action instruments, such as the Neighbourhood, Development and International Cooperation Instrument and the Instrument for Pre-accession Assistance III. Where appropriate, common

rules will be established in view of ensuring consistency and complementarity between funds, while making sure that specificities of these policies are respected, and in view of aligning with the strategic requirements of these policies, programmes and funds, such as the enabling conditions under ERDF and ESF+.

## 1.6. Duration and financial impact

☑ Proposal/initiative of **limited duration**

– ☑ in effect from 01/01/2021 to 31/12/2027

– ☑ Financial impact from 2021 to 2027 for commitment appropriations and from 2021 to 2030 for payment appropriations.

☐ Proposal/initiative of **unlimited duration**

– Implementation with a start-up period from YYYY to YYYY,

– followed by full-scale operation.

## 1.7. Management mode(s) planned[30]

☑ **Direct management** by the Commission

– ☑ by its departments, including by its staff in the Union delegations;

– ☑ by the executive agencies

☐ **Shared management** with the Member States

☑ **Indirect management** by entrusting budget implementation tasks to:

– ☐ third countries or the bodies they have designated;

– ☑ international organisations and their agencies (to be specified);

– ☐the EIB and the European Investment Fund;

– ☑ Union bodies referred to in Articles 70 and 71 of the Financial Regulation;

– ☐ public law bodies;

– ☐ bodies governed by private law with a public service mission to the extent that they provide adequate financial guarantees;

– ☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that provide adequate financial guarantees;

– ☐ persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU, and identified in the relevant basic act.

Comments

The Commission may decide to delegate part of the implementation of the EU4Health programme to an executive agency.

Moreover it may entrust its decentralised Agencies (EMA, ECDC, EFSA, ECHA) with tasks aiming to achieve the objectives under the EU4Health programme 2021-2027.

Indirect management with international organisations:

For the implementation of the EU4Health programme 2021-2027, cooperation with international organisations like UN agencies, notably the WHO, Council of Europe, OECD,

[30] Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: https://myintracomm.ec.europa.eu/budgweb/EN/man/budgmanag/Pages/budgmanag.aspx

or any other relevant International Organisations will be continued, extended or pursued, for example by paying assessed contributions to FCTC/Illicit Trade Protocol, etc.

## 2. MANAGEMENT MEASURES

### 2.1. Monitoring and reporting rules

*Specify frequency and conditions.*

Performance frameworks will be developed building on the relevant practices of the previous Health programme 2014-2020 to ensure that data is collected efficiently, effectively and timely.

### 2.2. Management and control system(s)

*2.2.1. Justification of the management mode(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed*

The EU4Health programme will be implemented through direct and indirect management, using the implementation modes offered by the Financial Regulation, mainly being grants and procurement. Direct management allows to establish grant agreements/contracts with beneficiaries/contractors directly engaged in activities that serve Union policies. The Commission ensures direct monitoring over the outcome of the actions financed. The payment modalities of the actions funded will be adapted to the risks pertaining to the financial transactions.

In order to ensure the effectiveness, efficiency and economy of the Commission controls, the control strategy will be oriented towards a balance of ex-ante and ex-post checks and focus on three key stages of grant/contract implementation, in accordance with the Financial Regulation:

– Selection of proposals/tenders that fit the policy objectives of the programme;

– Operational, monitoring and ex-ante controls that cover project implementation, public procurement, pre-financing, interim and final payments, management of guarantees;

– Ex-post controls at the beneficiaries/contractors' sites will also be carried out on a sample of transactions. The selection of these transactions will combine a risk assessment and a random selection.

*2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them*

The implementation of the EU4Health programme focuses on the attribution of public procurement contracts as well as a number of grants for specific activities and organisations.

The public procurement contracts will mainly be concluded in areas such as procurement of medicines, vaccines, potential new treatements, surveys, studies, collection of data, benchmark exercises, monitoring and assessment activities, information campaigns, IT and communication services, etc. The contractors are mainly consultancy firms and other private companies; institutes and laboratories might also be main contractors.

Grants will mainly be awarded for support activities to non-governmental organisations, respective competent authorities of the Member States, European Reference Networks, health organisations, national agencies, etc. The period of execution of the subsidised projects and activities varies from one to three years mostly.

The main risks are the following:

• Risk of not fully achievening the objectives of the programme due to insufficient uptake or quality/delays in the implementation of the selected projects or contracts;

• Risk of inefficient or non-economic use of funds awarded, both for grants (complexity of funding rules) and for procurement (limited number of economic providers with the required specialist knowledge entailing insufficient possibilities to compare price offers in some sectors);

• Reputational risk for the Commission, if fraud or criminal activities are discovered; only partial assurance can be drawn from the third parties' internal control systems due to the rather large number of heterogeneous contractors and beneficiaries, each operating their own control system.

The Commission put in place internal procedures that aim at covering the risks identified above. The internal procedures are in full compliance with the Financial Regulation and include anti-fraud measures and cost-benefit considerations. Within this framework, the Commission continues to explore possibilities to enhance the management and to realise efficiency gains. Main features of the control framework are the following:

**Controls before and during the implementation of the projects:**

• An appropriate project management system will be put in place focussing on the contributions of projects and contracts to the policy objectives, ensuring a systematic involvement of all actors, establishing a regular project management reporting complemented by on-site-visits on a case by case basis, including risk reports to senior management, as well as maintaining appropriate budgetary flexibility.

• Model grant agreements and service contracts used are developed within the Commission. They provide for a number of control provisions such as audit certificates, financial guarantees, on-site audits as well as inspections by OLAF. The rules governing the eligibility of costs are being simplified, for example, by using unit costs, lump sums, contributions not linked to costs and other possibilities offered by the Financial Regulation. This will reduce the cost of controls and put the focus on checks and controls in high risk areas.

• All staff sign up to the code of good administrative behaviour. Staff who are involved in the selection procedure or in the management of the grant agreements/contracts (also) sign a declaration of absence of a conflict of interest. Staff is regularly trained and uses networks to exchange best practices.

• Technical implementation of a project is checked at regular intervals at the desk on the basis of technical progress reports of the contractors and beneficiaries; in addition contractors'/beneficiaries' meetings and on-site-visits are foreseen on a case by case basis.

**Controls at the end of the project:** Ex-post audits are performed on a sample of transactions to verify on-the-spot the eligibility of cost claims. The aim of these controls is to prevent, detect and correct material errors related to the legality and regularity of financial transactions. With a view to achieving a high control impact, the selection of beneficiaries to be audited foresees to combine a risk based selection with a random sampling, and to pay attention to operational aspects whenever possible during the on-site audit.

*2.2.3. Estimation and justification of the cost-effectiveness of the controls (ratio of "control costs ÷ value of the related funds managed"), and assessment of the expected levels of risk of error (at payment & at closure)*

The yearly costs of the suggested level of controls under the third Health programme 2014-2020 represented approximately 4 to 7% of the yearly budget of the operational expenditure. This is justified by the diversity of transactions to be controlled. Indeed, in the area of health, direct management involves the attribution of numerous contracts and grants for actions of very small to very large sizes, and the payment of numerous operating grants to non-governmental organisations. The risk related to these activities concerns the capacity of (especially) smaller organisations to effectively control expenditure.

The Commission considers that the average costs of controls is likely to decrease in view of the extended scope and increased budget of the new EU4Health programme.

Under the third Health Programme 2014-2020, on a 5 years basis, the error rate for the on-the-spot audits of grants under direct management was 1.8% while for procurement contracts it was below 1%. This level of error is considered acceptable, as it is under the materiality level of 2%.

The proposed changes for the programme will not affect the way the appropriations are currently managed. The existing control system proved to be able to prevent and/or to detect errors and/or irregularities, and in case of errors or irregularities, to correct them. It will be adapted to include the new actions and to ensure that residual error rates (after correction) remain below the threshold of 2%.

## 2.3. Measures to prevent fraud and irregularities

*Specify existing or envisaged prevention and protection measures, e.g. from the Anti-Fraud Strategy.*

As for its activities in direct and indirect management, the Commission shall take appropriate measures ensuring that the financial interests of the European Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportional and deterrent penalties. To this effect, the Commission adopted an anti-fraud strategy, latest update of April 2019 (COM(2019) 176), covering notably the following preventive, detective and corrective measures:

The Commission or its representatives and the Court of Auditors shall have the power of audit, on the basis of documents and on-the-spot, over all grant beneficiaries, contractors and subcontractors who have received Union funds. OLAF shall be authorised to carry out on-the-spot checks and inspections on economic operators concerned directly or indirectly by such funding.

The Commission also implements a series of measures such as:

- decisions, agreements and contracts resulting from the implementation of the programme will expressly entitle the Commission, including OLAF, and the Court of Auditors to conduct audits, on-the-spot checks and inspections and to recover amounts unduly paid and, where appropriate, impose administrative sanctions;

- during the evaluation phase of a call for proposals/tender, the applicants and tenderers are checked against the published exclusion criteria based on declarations and the Early Detection and Exclusion System (EDES);

- the rules governing the eligibility of costs will be simplified in accordance with the provisions of the Financial Regulation;

- regular training on issues related to fraud and irregularities is given to all staff involved in contract management as well as to auditors and controllers who verify the beneficiaries' declarations on the spot.

## 3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

### 3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- New budget lines requested

*In order of multiannual financial framework headings and budget lines.*

| Heading multiannual financial framework | Budget line | Type of expenditure | Contribution | | | |
|---|---|---|---|---|---|---|
| | **Heading 5:** Resilience, Security and Defence | Diff./Non-diff. | from EFTA countries | from candidate countries | from third countries | within the meaning of Article 21(2)(b) of the Financial Regulation |
| 2 | New Budget line: 14 01 xx EU4Health Programme – Support expenditure | on-diff. | Yes | Yes | Yes | No |
| 2 | New Budget line: 14 04 01 EU4Health Programme | Diff. | Yes | Yes | Yes | No |

## 3.2. Estimated impact on expenditure

### *3.2.1. Summary of estimated impact on expenditure*

EUR million (to three decimal places)

| **Heading of multiannual financial framework** | **5** | Resilience, Security and Defence |
|---|---|---|

| DG: SANTE | | | **2021** | **2022** | **2023** | **2024** | **2025** | **2026** | **2027** | ***Post 2027*** | **TOTAL** |
|---|---|---|---|---|---|---|---|---|---|---|---|
| • Operational appropriations | | | | | | | | | | | |
| 14 04 01 – annual budgetary procedures | Commitments | (1) | 20,163 | 30,849 | 52,444 | 85,588 | 491,064 | 578,800 | 590,376 | | **1.849,284** |
| | Payments | (2) | 4,056 | 12,928 | 24,360 | 42,368 | 140,831 | 303,186 | 411,044 | 910,511 | **1.849,284** |
| • Appropriations of an administrative nature financed from the envelope of specific programmes[31] | | | | | | | | | | | |
| 14 01 xx - support | Commitments = Payments | (3) | 1,061 | 1,624 | 2,760 | 4,505 | 25,845 | 30,463 | 31,072 | | **97,330** |
| **TOTAL appropriations from budgetary procedures for the envelope of the programme** | Commitments | =1+1 a +3 | 21,224 | 32,473 | 55,204 | 90,093 | 516,909 | 609,263 | 621,448 | | **1.946,614** |
| | Payments | =2+2 a +3 | 5,117 | 14,552 | 27,120 | 46,873 | 166,676 | 333,649 | 442,116 | 910,511 | **1.946,614** |

The programme might be (partially) delegated to an executive agency, subject to the outcome of a cost-benefit analysis. Following this, the related administrative appropriations for programme implementation in the Commission and the executive agencies will be adapted accordingly.

In addition to the financial envelope defined in Article 5 of the proposed 'EU4Health programme Regulation', EUR 8 451 000 000 (in current prices) will be available as external assigned revenues, within the meaning of Article 21(5) of the Financial Regulation stemming from the borrowing operations of the Union as set out in Regulation (EU) XXX/XX (EURI regulation).

[31] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research. This amount includes the potential contribution to an executive agency.

Out of this up to EUR 433 560 000 may be dedicated to administrative expenditure, including external staff costs.

In line with the provisions of the EURI Regulation, the legal commitments covered by external assigned revenue stemming from borrowing shall be entered into by 31 December 2024.

The indicative breakdown of the expenditure for external assigned revenue is as follows (in current prices):

| EU4Health programme | | | **2021** | **2022** | **2023** | **2024** | **2025** | **2026** | **2027** | ***Post 2027*** | **TOTAL** |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 14 04 01 – external assigned revenues | Commitments | (1) | 1.108,630 | 2.467,470 | 2.622,280 | 1.819,060 | 0 | 0 | 0 | 0 | **8.017,440** |
| | Payments | (2) | 138,205 | 712,667 | 1.440,778 | 1.794,434 | 1.524,367 | 838,302 | 475,867 | 1.092,820 | **8.017,440** |
| 14 01 xx – support line external assigned revenues | Commitments = Payments | (3) | 58,370 | 59,530 | 60,720 | 61,940 | 63,000 | 64,000 | 66,000 | | **433,560** |
| Total external assigned revenues | Commitments | =1+3 | **1.167,000** | **2.527,000** | **2.683,000** | **1.881,000** | **63,000** | **64,000** | **66,000** | | **8.451,000** |
| | Payments | =2+3 | **196,575** | **772,197** | **1.501,498** | **1.856,374** | **1.587,367** | **902,302** | **541,867** | **1.092,820** | **8.451,000** |

| **Heading of multiannual financial framework** | **7** | ‘Administrative expenditure’ |
|---|---|---|

EUR million (to three decimal places)

| | **2021** | **2022** | **2023** | **2024** | **2025** | **2026** | **2027** | **TOTAL** |
|---|---|---|---|---|---|---|---|---|

| DG SANTE | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| • Human resources | | 1,500 | 1,500 | 1,500 | 1,500 | 1,500 | 1,500 | 1,500 | **10,500** |
| • Other administrative expenditure | | | | | | | | | |
| **TOTAL appropriations under HEADING 7 – DG SANTE** | Appropriations | **1,500** | **1,500** | **1,500** | **1,500** | **1,500** | **1,500** | **1,500** | **10,500** |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **TOTAL appropriations under HEADING 7** of the multiannual financial framework | (Total commitments = Total payments) | **1,500** | **1,500** | **1,500** | **1,500** | **1,500** | **1,500** | **1,500** | **10,500** |

EUR million (to three decimal places)

| | | **2021** | **2022** | **2023** | **2024** | **2025** | **2026** | **2027** | ***Post 2027*** | **TOTAL** |
|---|---|---|---|---|---|---|---|---|---|---|
| **TOTAL appropriations under HEADINGS** of the multiannual financial framework **– from budgetary procedures** | Commitments | 22,724 | 33,973 | 56,704 | 91,593 | 518,409 | 610,763 | 622,948 | 0 | **1.957,114** |
| | Payments | 6,617 | 16,052 | 28,620 | 48,373 | 168,176 | 335,149 | 443,616 | 910,511 | **1.957,114** |
| | | | | | | | | | | |

*3.2.2. Estimated impact on appropriations of an administrative nature*

3.2.2.1. Summary

– ☐ The proposal/initiative does not require the use of appropriations of an administrative nature

– ☑ The proposal/initiative requires the use of appropriations of an administrative nature, as explained below:

EUR million (to three decimal places)

| | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | TOTAL |
|---|---|---|---|---|---|---|---|---|
| **HEADING 7 of the multiannual financial framework** | | | | | | | | |
| Human resources | **1,500** | **1,500** | **1,500** | **1,500** | **1,500** | **1,500** | **1,500** | **10,500** |
| Other administrative expenditure (missions, meetings) | | | | | | | | |
| **Subtotal HEADING 7 of the multiannual financial framework** | **1,500** | **1,500** | **1,500** | **1,500** | **1,500** | **1,500** | **1,500** | **10,500** |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Outside HEADING 7[32] of the multiannual financial framework** | | | | | | | | |
| Human resources[33] | 4,000 | 4,000 | 4,000 | 4,000 | 4,000 | 4,000 | 4,000 | **28,000** |
| Other expenditure of an administrative nature | 1,061 | 1,624 | 2,760 | 4,505 | 25,845 | 30,463 | 31,072 | **97,330** |
| **Subtotal outside HEADING 7 of the multiannual financial framework** | 5,061 | 5,624 | 7,760 | 8,505 | 29,845 | 34,463 | 35,072 | **125,330** |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **TOTAL** | **6,561** | **7,124** | **8,260** | **10,005** | **31,345** | **35,963** | **36,572** | **135,830** |

The appropriations required for human resources and other expenditure of an administrative nature will be met by appropriations from the DG that are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

32 Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

33 Assigned revenue.

Disclaimer: This represents the estimated resources for DG SANTE for the implementation of the EU4Health Programme. It does not cover the resources needed for any delegations of actions to the decentralised agencies under DG SANTE's remit (EMA, ECDC, EFSA, ECHA).

3.2.2.2. Estimated requirements of human resources

– ☐ The proposal/initiative does not require the use of human resources.

– ☑ The proposal/initiative requires the use of human resources, as explained below:

*Estimate to be expressed in full time equivalent units*

| | | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 |
|---|---|---|---|---|---|---|---|---|
| **• Establishment plan posts (officials and temporary staff)** | | | | | | | | |
| Headquarters and Commission's Representation Offices | | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| Delegations | | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Research | | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **• External staff (in Full Time Equivalent unit: FTE)[34]** | | | | | | | | |
| Financed from HEADING 7 of the multiannual financial framework | - at Headquarters | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |
| | - in Delegations | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |
| Financed from the envelope of the programme [35] | - at Headquarters | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |
| | - in Delegations | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |
| Research | | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |
| Other (assigned revenue) | | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| **TOTAL** | | **60** | **60** | **60** | **60** | **60** | **60** | **60** |

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Disclaimer: This represents the estimated resources for DG SANTE for the implementation of the EU4Health Programme. It does not cover the resources needed for any delegations of actions to the decentralised agencies under DG SANTE's remit (EMA, ECDC, EFSA, ECHA).

34 AC= Contract Staff; AL = Local Staff; END= Seconded National Expert; INT = agency staff; JED= Junior Experts in Delegations.

35 Sub-ceiling for external staff covered by operational appropriations (former 'BA' lines).

Description of tasks to be carried out:

| | |
|---|---|
| Officials and temporary staff | Policy development and strategy, programme management and governance, finance, legal, procurement, audit or coordination |
| External staff | Administrative and financial support tasks |

*3.2.3. Third-party contributions*

– ☐ The proposal/initiative does not provide for co-financing by third parties.

– ☑ The proposal/initiative provides for the co-financing estimated below:

Appropriations in EUR million (to three decimal places)

| | **2021** | **2022** | **2023** | **2024** | **2025** | **2026** | **2027** | Total |
|---|---|---|---|---|---|---|---|---|
| EEA/EFTA | p.m. | p.m. | p.m. | p.m. | p.m. | p.m. | p.m. | p.m. |
| Candidates countries | p.m. | p.m. | p.m. | p.m. | p.m. | p.m. | p.m. | p.m. |
| Third countries, including neighbouring countries | p.m. | p.m. | p.m. | p.m. | p.m. | p.m. | p.m. | p.m. |
| TOTAL appropriations co-financed | p.m. | p.m. | p.m. | p.m. | p.m. | p.m. | p.m. | p.m. |

### 3.3. Estimated impact on revenue

– ☑ The proposal/initiative has no financial impact on revenue.

– ☐ The proposal/initiative has the following financial impact:

  – ☐ on own resources

  – ☐ on miscellaneous revenue

For miscellaneous ‘assigned’ revenue, specify the budget expenditure line(s) affected.

| |
|---|
| |

Specify the method for calculating the impact on revenue.

| |
|---|
| |

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COMMISSION

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ANNEXES 1 to 2

**ANNEXES**

**to the**

**Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on the establishment of a Programme for the Union's action in the field of health –for the period 2021-2027 and repealing Regulation (EU) No 282/2014 ("EU4Health Programme")**

## ANNEX I

## LIST OF POSSIBLE ELIGIBLE ACTIONS PROVIDED FOR IN ARTICLE 13

(a) **Investment in**:

(i) Precursory projects for high added-value up-scalable initiatives;

(ii) Critical health infrastructure relevant in the context of health crises, tools, structures, processes, production and laboratory capacity, including tools for surveillance, modelling, forecast, prevention and management of outbreaks.

(b) Transfer, adaptation and roll-out of **best practices** and innovative solutions with established Union level added-value between Member States, and country-specific tailor made support to countries, or groups of countries, with the highest needs, through the funding of specific projects including twinning, expert advice and peer support.

(c) Support **analytical activities and expert advice**, in particular:

(i) Surveys, studies, collection of data and statistics, methodologies, classifications, microsimulations, indicators, knowledge brokering and benchmark exercises;

(ii) The establishment and operation of a health intelligence and knowledge infrastructure;

(iii) Expert groups and panels providing advice, data and information to support health policy development and implementation;

(iv) Studies and analysis, and scientific advice to support policymaking, and support to the scientific committees on "Consumer Safety" and on "Health, Environmental and Emerging Risks".

(d) **Development and implementation of Union health legislation and action**, in particular through support to:

(i) Implementation, enforcement, monitoring of Union health legislation and action; and technical support to the implementation of legal requirements;

(ii) Cross-border collaboration and partnerships, including in cross-border regions, with a view to transferring and upscaling innovative solutions;

(iii) Cross-sectoral collaboration and coordination;

(iv) Development and operation of databases and digital tools and their interoperability, including where appropriate with other sensing technologies, such as space-based;

(v) Auditing and assessment work in accordance with Union legislation;

(vi) Collaboration between the Union institutions, its Agencies, and international organisations and networks, and the Union’s contribution to global initiatives;

(vii) Stakeholder consultation activities;

(viii) Networking by non-governmental organisations and their involvement in projects covered by the Programme;

(ix) Collaboration with third countries on the areas covered by the Programme;

(x) National contact points providing guidance, information and assistance related the implementation of Union health legislation and of the Programme;

(xi) Stakeholders in view of transnational cooperation.

(e) **Structural stockpile and crisis preparation**:

(i) Establishment and support of a mechanism to develop, procure and manage crisis relevant products;

(ii) Establishment and management of EU reserves and stockpiles of crisis relevant products in complementarity with other Union instruments;

(iii) Establishment and support of mechanisms for the efficient monitoring and allocation of available care facilities (such as hospital beds and places in ICUs), for the distribution or allocation of goods and services needed in the case of a health crisis, and to ensure the supply and safe use of medicines, investigational medicines and medical devices;

(iv) Procurement of goods and services necessary for the prevention and management of health crises and action to secure access to those essential goods and services;

(v) Establishment and operation of a Union reserve of medical and healthcare staff and experts and of a mechanism to deploy such staff and experts as necessary to prevent or respond to a health crisis throughout the Union; establishment and operation of a Union Health Emergency team to provide expert advice and technical assistance on request by the Commission in the case of a health crisis;

(f) P**reparedness, prevention and response to cross-border health threats**:

(i) Actions to foster Union-wide and cross-sectoral health crisis prevention, preparedness, management and response capacity of actors at Union, national, regional and local level, including contingency planning and preparedness exercises and the upskilling of medical, healthcare and public health staff;

(ii) Setting up an integrated cross cutting risk communication framework covering all phases of a health crisis - prevention, preparedness and response;

(iii) Support and/or procure emergency production of medical countermeasures, including essential chemicals and active substances, and the financing of cooperation on emergency health technology assessments and clinical trials;

(iv) Preventive actions to protect vulnerable groups from health threats and actions to adjust the response to and management of crisis to the needs of those vulnerable groups;

(v) Actions to address the collateral health consequences of a health crisis, in particular those on mental health, on patients suffering from chronic diseases and other vulnerable groups;

(vi) Actions to strengthen surge capacity, research, development, laboratory capacity, production and deployment of crisis-relevant niche products;

(vii) Establishment and operation of a mechanism for cross-sectorial One-Health coordination.

(viii) Actions to support investigation, risk assessment and risk management work on the link between animal health, environmental factors, and human diseases, including during health crises.

(g) **Strengthen national health systems**:

(i) Support knowledge transfer actions and Union level cooperation to assist national reform processes towards improved effectiveness, accessibility, sustainability and resilience, in particular to address the challenges identified by the European Semester and to strengthen primary care, reinforce the integration of care and aim at universal health coverage and equal access to healthcare;

(ii) Training programmes for medical and healthcare staff, and programmes for temporary exchanges of staff;

(iii) Support to improve the geographical distribution of healthcare workforce and avoidance of 'medical deserts';

(iv) Support the establishment and coordination of Union Reference Laboratories and Centres, and of Centres of excellence;

(v) Audit of Member States preparedness and response arrangements (such as crisis management, antimicrobial resistance, vaccination);

(vi) Support upwards convergence of national systems' performance through indicator development, analysis and knowledge brokering and the organisation of stress tests of national healthcare systems;

(vii) Support capacity building for investing in and implementing health system reforms (strategic planning and access to multi-source financing);

(viii) Support capacity building of national systems for the implementation of legislation on substances of human origin, and for the promotion of the sustainable and safe supply of such substances through networking activities;

(ix) Support the establishment and implementation of programmes assisting Member States and their action to improve health promotion and disease prevention (for communicable and non-communicable diseases);

(x) Support Member States' actions to put in place healthy and safe urban, work and school environments, to enable healthy life choices and promote healthy diets taking into account the needs of vulnerable groups;

(xi) Support the functioning of the European Reference Networks and the establishment and operation of new transnational networks set out in accordance with Union health legislation, and support Member States' actions to coordinate the activities of these networks with the operation of national health systems;

(xii) Support for Member States to strengthen the administrative capacity of their healthcare systems through benchmarking, cooperation and exchange of best practices.

(xiii) Support an Union framework and the respective interoperable digital tools for cooperation among Member States and in networks, including those needed to enable Member States to deliver joint clinical assessments and joint scientific consultations to exchange outcomes of HTA cooperation.

(h) **Actions on cancer**:

(i) Support Member States and NGOs in the promotion and implemention of the recommendations of the European Code against Cancer;

(ii) Support the stablishement of quality assurance schemes for cancer centres;

(iii) Support prevention programmes on the main cancer risk factors;

(iv) Actions to support secondary prevention of cancer, such as early detection and diagnosis through screening;

(v) Actions supporting access to cancer services and to innovative medicines for cancer;

(vi) Actions supporting the continuity of care (integrated care approaches for prevention, diagnosis, treatment and follow-up care);

(vii) Actions supporting quality in cancer prevention and care including diagnosis and treatment;

(viii) Actions supporting the quality of life of cancer survivors and care givers;

(ix) Support to the implementation of the Union's tobacco control policy and legislation;

(x) Establishment and support of a mechanisms for cross-specialty capacity building and continuous education in the area of cancer care.

(i) **Actions on medicines, vaccines and medical devices:**

(i) Support to initiatives to improve vaccination coverage rates in the Member States;

(ii) Support actions to fight vaccine hesitancy;

(iii) Support clinical trials to speed up the development, authorisation and access to innovative, safe and effective medicines and vaccines;

(iv) Support action to ensure greater availability in the Union of medicines and medical devices and contribute to their affordability for patients and health systems;

(v) Support action to encourage the develoment of innovative products and of less commercially interesting products such as antimicrobials;

(vi) Support action to monitor shortages of medicines and medical devices occurring in hospitals and community pharmacies, to address such shortages, and to increase security of supplies;

(vii) Support actions to encourage the development of innovative medicines and medical devices less harmful for the environment and promote greener manufacturing;

(viii) Action to strengthen the environmental risk assessment of pharmaceuticals;

(ix) Action to promote the prudent use and disposal of antimicrobials;

(x) Support action to foster international regulatory covergence on medicines and medical devices.

(j) **Digital transformation** of health**:**

(i) Support for the deployment, operation and maintenance of mature interoperable digital service infrastructures and data quality assurance processes for data exchange, access, use and reuse; support for cross border

networking, including through the use of electronic health records, registries and other databases;

(ii) Support to the digital transformation of health care and health systems including through benchmarking and capacity building for the uptake of innovative tools and technologies; digital upskilling of health care professsionals;

(iii) Support the deployment and interoperability of digital tools and infrastructures within and between Member States and with Union Institutions and bodies; develop appropriate governance structures and sustainable, interoperable Union health information systems, as part of the European Health Data Space and strengthen citizens' access to and control over their health data;

(iv) Support optimal use of telemedicine/telehealth, including through satellite communication for remote areas, foster digitally-driven organisational innovation in healthcare facilities and promote digital tools supporting citizen empowerment and person-centred care.

(k) **Communication and outreach to stakeholders and citizens**, in particular:

(i) Communication adressed to citizens in the context of risk management and crisis preparedness.

(ii) Communication addressed to citizens and stakeholders to promote Union action in the areas mentioned in this Annex.

(iii) Communication to promote disease prevention and healthy lifestyles, in cooperation with all concerned actors at international, Union and national level.

## ANNEX II

## INDICATORS FOR THE EVALUATION OF THE PROGRAMME

A Programme Indicators

I. Quality and completeness of EU and MS preparedness and response planning for serious cross border threats to health

II. Access to centrally authorised medicines, e.g. number of orphan authorisations, Advanced Therapy Medicinal Products, Paediatric Use Medicinal Products or vaccines, for unmet needs

III. Number of actions and best practices directly contributing to the SDG 3.4/Member State

IV. Implementation of best practices by EU Member States

B The following indicators will also be used to monitor the implementation of the Programme:

1. Number of Member States with improved preparedness and response planning
2. Vaccines, medicines, medical devices and other countermeasures during crises [made available by type and by MS]
3. Number of vaccine doses distributed
4. Number of entities benefiting of medicines and medical devices
5. EU Laboratory capacity index (EULabCap)
6. Age-standardised five-year net survival of cervical, breast and colorectal cancer
7. Ratio of Cancer Registries (CRs) and number of Member States (MSs) reporting information on cervical, breast, and colorectal cancer stage at diagnosis
8. Smoking prevalence
9. Number of shortages of medicines in the single point of contact network
10. Access to centrally authorised medicines for unmet needs
11. Number of audits conducted in the EU and in third countries to ensure good manufacturing practices and good clinical practices (Union control)
12. Deaths attributable to antimicrobial resistant infections
13. Number of hospital units involved in ERN and of patients diagnosed and treated by the members of ERN networks
14. Number of Health Technology Assessment reports jointly carried out