

## I

(Legislative acts)

## REGULATIONS

**REGULATION (EU) 2021/522 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL****of 24 March 2021****establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014****(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 <sup>(1)</sup>,

Having regard to the opinion of the Committee of the Regions <sup>(2)</sup>,

Acting in accordance with the ordinary legislative procedure <sup>(3)</sup>,

Whereas:

- (1) According to Article 3(1) of the Treaty on European Union (TEU), among the aims of the Union is the promotion of the well-being of its peoples.
- (2) According to 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, 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 Member States for the definition of their health policies and for the organisation, management and delivery of health services and medical care.

<sup>(1)</sup> OJ C 429, 11.12.2020, p. 251.

<sup>(2)</sup> OJ C 440, 18.12.2020, p. 131.

<sup>(3)</sup> Position of the European Parliament of 9 March 2021 (not yet published in the Official Journal) and decision of the Council of 17 March 2021.

- (4) Actions have been taken in particular under the previous programmes of Union action in the field of public health, namely those provided for by Decisions No 1786/2002/EC <sup>(4)</sup> and No 1350/2007/EC <sup>(5)</sup> of the European Parliament and of the Council and by Regulation (EU) No 282/2014 of the European Parliament and of the Council <sup>(6)</sup>, to meet the requirements set out in Article 168 TFEU.
- (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, which particularly affect people with chronic conditions. In addition, staff in health care settings, who have been essential during the COVID-19 crisis, have been exposed to great health risks.
- (6) While Member States are responsible for their health policies, they should protect public health in a spirit of European solidarity, as called for in the communication of the Commission of 13 March 2020 on coordinated economic response to the COVID-19 outbreak. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for further action at Union level to support cooperation and coordination among the Member States. That cooperation should improve preparedness for, and the prevention and control of, the spread of severe human infections and diseases across borders in order to combat other serious cross-border threats to health and to safeguard and improve the health and well-being of all people in the Union. Preparedness is the key to improving resilience to future threats. In that regard, Member States should be given the possibility of carrying out stress tests on a voluntary basis to improve preparedness and increase resilience.
- (7) It is therefore appropriate to establish a new and reinforced programme for Union action in the field of health, called the 'EU4Health Programme' (the 'Programme'), for the period 2021-2027. In line with the goals of the Union's action and the Union's competences in the area of public health, the Programme should emphasise actions in relation to which there are advantages and efficiency gains from collaboration and cooperation at Union level, and actions that have an impact on the internal market.
- (8) The Programme should be a means of promoting actions in areas where there is a Union added value that can be demonstrated. Such actions should include, inter alia, strengthening the exchange of best practices between Member States, supporting networks for the sharing of knowledge or for mutual learning, addressing cross-border threats to health so as to reduce the risks of such threats and to mitigate their consequences, addressing certain issues relating to the internal market in relation to which the Union can achieve Union-wide high-quality solutions, thereby unlocking the potential of innovation in health, and improving efficiency by avoiding the duplication of activities and optimising the use of financial resources. The Programme should also support capacity-building actions to strengthen strategic planning, access to multisource financing and the capacity to invest in and implement actions of the Programme. In that respect, the Programme should provide country-specific tailor-made assistance to the Member States, or groups of Member States, with the greatest needs.
- (9) This Regulation lays down a financial envelope for the Programme which is to constitute the prime reference amount, within the meaning of point 18 of the Interinstitutional Agreement of 16 December 2020 between the European Parliament, the Council of the European Union and the European Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management, as well as on new own resources, including a roadmap towards the introduction of new own resources <sup>(7)</sup>, for the European Parliament and the Council during the annual budgetary procedure. This financial envelope comprises an amount of EUR 500 000 000 in 2018 prices in line with the joint declaration by the European Parliament, Council and Commission on the reinforcement of specific programmes and adaptation of basic acts of 22 December 2020 <sup>(8)</sup>.

<sup>(4)</sup> 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).

<sup>(5)</sup> 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).

<sup>(6)</sup> 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).

<sup>(7)</sup> OJ L 433L, 22.12.2020, p. 28.

<sup>(8)</sup> OJ C 444I, 22.12.2020, p. 1.

- (10) In order for the Programme to be balanced and focused, minimum and maximum shares of the overall budget should be laid down in this Regulation, for certain areas of action, with a view to providing guidance for the allocation of resources in relation to the implementation of the Programme.
- (11) Due to the serious nature of cross-border threats to health, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthening the capability in the Union to prepare for, respond to and manage any future health crises, the Programme should provide support to actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council <sup>(9)</sup> and other relevant mechanisms and structures referred to in the communication of the Commission of 11 November 2020 entitled 'Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats', including actions directed at strengthening preparedness planning and response capacity at national and Union level, at reinforcing the role of the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA), and at establishing a health emergency preparedness and response authority. Such actions could include building capacity for responding to health crises, preventive measures related to vaccination and immunisation, strengthened surveillance programmes, provision of health information, and platforms to share best practices. In this context, the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness and surveillance, and the management capacity and response capacity of actors at Union and Member State levels, including contingency planning and preparedness exercises, in keeping with the 'One Health' and 'Health in All Policies' approaches. The Programme should facilitate the setting up of an integrated cross-cutting risk communication framework for all phases of a health crisis, namely prevention, preparedness and response.
- (12) With a view to strengthening capabilities in the Union to prevent, prepare for, respond to and manage health crises, the Programme should provide support to actions taken in the framework of the mechanisms and structures established under relevant Union legislation. That support could include capacity building in health crisis response, including contingency planning and preparedness, preventive measures such as those related to vaccination and immunisation, strengthened surveillance programmes and improved coordination and cooperation.
- (13) In the context of public health crises, clinical trials and health technology assessment (HTA) can contribute to speeding up the development and identification of effective medical countermeasures. It should therefore be possible for the Programme to provide support to facilitate actions in those fields.
- (14) With a view to protecting people in vulnerable situations, including those suffering from mental illness and those living with or most affected by communicable or non-communicable diseases and chronic diseases, the Programme should also promote actions which address and prevent the collateral impact of health crises on people belonging to such vulnerable groups and actions which improve mental health.
- (15) The COVID-19 crisis has highlighted many challenges, including the dependence of the Union on third countries in ensuring the supply of raw materials, active pharmaceutical ingredients, medicinal products, medical devices and personal protective equipment needed in the Union during health crises, in particular pandemics. The Programme should therefore provide support to actions that foster the production, procurement and management of crisis-relevant products within the Union to mitigate the risk of shortages, while ensuring complementarity with other Union instruments.
- (16) 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 improve the interoperability of Member States' health systems through cooperation and the exchange of best practices and also by increasing the number of joint actions. Those actions should ensure that Member States are able to respond to health emergencies, including by undertaking contingency planning, preparedness exercises and the upskilling of the healthcare and public health workforce as well as the establishment, in accordance with national strategies, of mechanisms for the efficient monitoring and needs-driven distribution or allocation of goods and services needed in times of crisis.

<sup>(9)</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

- (17) The provision of information to individuals plays an important role in preventing and responding to diseases. The Programme should therefore support communication activities addressed to the general public or to specific groups of people or professionals, in order to promote disease prevention and healthy lifestyles, to counter misinformation and disinformation as regards the prevention, cause and treatment of diseases, to address vaccine hesitancy and to support efforts to strengthen altruistic behaviour, such as organ and blood donations, in a manner that complements national campaigns on those matters.
- (18) In synergy with other Union programmes, such as the Digital Europe programme established by a Regulation of the European Parliament and of the Council establishing the Digital Europe programme and repealing Decision (EU) 2015/2240, Horizon Europe - the Framework Programme for Research and Innovation established by a Regulation of the European Parliament and of the Council establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 ('Horizon Europe'), the European Regional Development Fund ('ERDF') established by a Regulation of the European Parliament and of the Council on the European Regional Development Fund and on the Cohesion Fund, the European Social Fund Plus (ESF+) established by a Regulation of the European Parliament and of the Council on the European Social Fund Plus (ESF+), the InvestEU Programme established by Regulation (EU) 2021/523 of the European Parliament and of the Council <sup>(10)</sup>, and the Recovery and Resilience Facility established by Regulation (EU) 2021/241 of the European Parliament and of the Council <sup>(11)</sup>, actions that advance the digital transformation of health services and increase the interoperability of such services, including the development of a European health data space, could be supported under the Programme.
- (19) Health is an investment, and the Programme should have this concept at its core. Keeping people healthy and active longer and empowering them to take an active role in managing their health by improving their health literacy will have positive effects on health, health inequalities and inequities, access to sexual and reproductive healthcare, quality of life, workers' health, productivity, competitiveness and inclusiveness, while reducing pressures on national healthcare systems and national budgets. The Programme should also support actions to reduce inequalities in the provision of healthcare, in particular in rural and remote areas, including in the outermost regions, for the purposes of achieving inclusive growth. The Commission has committed to helping Member States to reach the sustainable development targets set in the UN resolution of 25 September 2015 entitled 'Transforming our world: the 2030 Agenda for Sustainable Development'(the 'UN 2030 Agenda'), in particular Sustainable Development Goal 3 'Ensure healthy lives and promote well-being for all at all ages'. The Programme should therefore contribute to the actions towards reaching those targets.
- (20) Non-communicable diseases are often the result of a combination of genetic, physiological, environmental and behavioural factors. Non-communicable diseases such as cardiovascular disease, cancer, mental illness, neurological disorders, chronic respiratory disease and diabetes represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, and cause a considerable social and economic impact. To decrease the impact of non-communicable diseases on individuals and society in the Union and to reach Goal 3 of the UN 2030 Agenda Sustainable Development Goals, in particular but not exclusively Target 3.4 of that Goal, namely to reduce premature mortality from non-communicable diseases by one third by 2030, it is essential to provide an integrated response that focuses on health promotion and disease prevention across relevant sectors.
- (21) The Programme therefore should support health promotion and disease prevention and improve mental health throughout the lifetime of an individual by addressing health risk factors, and health determinants, which would also contribute to the attainment of Goal 3 of the UN 2030 Agenda Sustainable Development Goals. The Programme should also therefore contribute to the objectives set out in the Commission communication of 11 December 2019 entitled 'The European Green Deal' (the 'European Green Deal').

<sup>(10)</sup> Regulation (EU) 2021/523 of the European Parliament and of the Council of 24 March 2021 establishing the InvestEU Programme and amending Regulation (EU) 2015/1017 (see page 30 of this Official Journal).

<sup>(11)</sup> Regulation (EU) 2021/241 of the European Parliament and of the Council of 12 February 2021 establishing the Recovery and Resilience Facility (OJ L 57, 18.2.2021, p. 17).

- (22) The Programme should continue to support actions in the area of reducing and preventing alcohol-related harm, with particular emphasis on protecting the young.
- (23) The burden of chronic diseases is significant in the Union. It is well acknowledged that prevention and early detection are important in that regard. The Programme should support actions in those areas and should support the development of specific Union preventive and disease management guidelines and therefore aim to reduce the burden of Member States by working together to achieve better and more effective management of chronic diseases. Demographic changes, in particular the ageing of society, challenge the sustainability of health systems. Age-related diseases and disorders, such as dementia, and age-related disabilities, necessitate specific attention.
- (24) Cancer is the second leading cause of mortality in the Member States after cardiovascular disease. It is also one of the non-communicable diseases that share common risk factors and the prevention and control of which would benefit the majority of citizens. Poor nutrition, physical inactivity, obesity, tobacco use and harmful use of alcohol are risk factors common to other chronic diseases, such as cardiovascular disease, and therefore cancer prevention programmes should be implemented within the context of an integrated approach to preventing chronic diseases. Relevant measures in the 'Europe's Beating Cancer Plan' set out in the communication of the Commission of 3 February 2021 should benefit from the Programme and from Horizon Europe's mission on cancer, and should contribute to fostering an integrated approach that covers prevention, screening, early diagnosis, monitoring, treatment and care, as well as improving the quality of life of patients and survivors.
- (25) It should be possible to support studies on the influence of gender on the characteristics of diseases in order to contribute to improving knowledge and education in that area, thereby improving prevention, diagnosis, monitoring and treatment.
- (26) The Programme should work in synergy with and in a manner that complements other Union policies, programmes and funds, such as the Digital Europe Programme, Horizon Europe, the rescEU reserve under the Union Civil Protection Mechanism established by Decision (EU) 2019/420 of the European Parliament and of the Council <sup>(12)</sup> (the 'rescEU reserve'), the Emergency Support Instrument established by Council Regulation (EU) 2016/369 <sup>(13)</sup>, the ESF+, of which the Employment and Social Innovation strand forms part, including as regards synergies in relation to better protecting the health and safety of millions of workers in the Union, the InvestEU Programme, the Single Market Programme established by a Regulation of the European Parliament and of the Council establishing a programme for the internal market, competitiveness of enterprises, including small and medium-sized enterprises, the area of plants, animals, food and feed, and European statistics (Single Market Programme) and repealing Regulations (EU) No 99/2013, (EU) No 1287/2013, (EU) No 254/2014 and (EU) No 652/2014, the ERDF, the Recovery and Resilience Facility, Erasmus+ established by a Regulation of the European Parliament and of the Council establishing Erasmus+: the Union Programme for education and training, youth and sport and repealing Regulation (EU) No 1288/2013, the European Solidarity Corps Programme established by a Regulation of the European Parliament and of the Council establishing the European Solidarity Corps Programme and repealing Regulations (EU) 2018/1475 and (EU) No 375/2014,

and external action instruments of the Union, such as the Neighbourhood, Development and International Cooperation Instrument established by a Regulation of the European Parliament and of the Council establishing the Neighbourhood, Development and International Cooperation Instrument – Global Europe, amending and repealing Decision No 466/2014/EU of the European Parliament and of the Council and repealing Regulation (EU) 2017/1601 of the European Parliament and of the Council and Council Regulation (EC, Euratom) No 480/2009, and the Instrument for Pre-accession Assistance III established by a Regulation of the European Parliament and of the Council establishing the Instrument for Pre-accession Assistance (IPA III). Where appropriate, common rules should be established with a view to ensuring that there is consistency and complementarity between Union policies, programmes and funds, while ensuring that the specificities of those policies are respected, and with a view to aligning with the strategic requirements of those policies, programmes and funds, such as the

<sup>(12)</sup> Decision (EU) 2019/420 of the European Parliament and of the Council of 13 March 2019 amending Decision No 1313/2013/EU on a Union Civil Protection Mechanism (OJ L 77I, 20.3.2019, p. 1).

<sup>(13)</sup> Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union (OJ L 70, 16.3.2016, p. 1).

enabling conditions under the ERDF and ESF+. The Commission and the Member States should ensure that such synergies and complementarities are duly taken into consideration when drafting the annual work programmes as provided for in this Regulation.

- (27) The Commission should consult the Member States through a 'EU4Health Steering Group' to be established by this Regulation on the priorities and strategic orientations of the Programme, in order to ensure that there is consistency and complementarity between the Programme and other policies, instruments and actions of the Union, as well as on the implementation of the Programme.
- (28) The Programme should contribute to the establishment of a reserve of essential crisis-relevant products, in synergy and complementarity with the rescEU reserve, with the emergency support established under Regulation (EU) 2016/369, with the Recovery and Resilience Facility and with other Union policies, programmes and funds, complementing national stockpiles at Union level where needed.
- (29) Given rising healthcare demand, Member States' healthcare systems face challenges regarding the availability and affordability of medicinal products. To ensure that there is better public health protection, as well as that patients in the Union are safe and empowered, it is essential that patients and health systems have access to sustainable, efficient, equitable, affordable and high-quality medicinal products, including in the cross-border context, and that they can fully benefit from those medicinal products on the basis of transparent, consistent, and patient-oriented medical information.
- (30) Given rising healthcare demand, inter alia, the Programme should support the development of a Union system for the monitoring, reporting and notification of shortages of medicinal products and medical devices in order to avoid fragmentation of the internal market and to ensure greater availability and affordability of those medicinal products and medical devices while limiting the extent to which their supply chains depend on third countries. The Programme should therefore encourage the production of medicinal products and medical devices within the Union. In particular, in order to address unmet medical needs, the Programme should provide support to the generation of clinical and real-world evidence to enable the development of, authorisation of, evaluation of and access to effective medicinal products, including generics and biosimilars, to medical devices and to treatment, should promote research and development with respect to new medicinal products, with particular attention to be given to antimicrobials and vaccines to tackle antimicrobial resistance and vaccine-preventable diseases, respectively, should promote incentives to boost the production capacity for antimicrobials, personalised treatment and vaccination, and should foster the digital transformation of healthcare products and platforms for monitoring and collecting information on medicinal products. The Programme should also strengthen decision-making regarding medicinal products by enabling access to and the analysis of real-world healthcare data. The Programme should also help to ensure that the best use is made of research results and facilitate the uptake, scaling-up and deployment of health innovations in healthcare systems and clinical practice.
- (31) As the optimal delivery and use of medicinal products, and of antimicrobials in particular, yield benefits for individuals and health systems, the Programme should promote their prudent and efficient use in accordance with the One Health approach, with the 'European One Health Action Plan against Antimicrobial Resistance (AMR)' set out in the communication of the Commission of 29 June 2017, and with the 'European Union Strategic Approach to Pharmaceuticals in the Environment' set out in the communication of the Commission of 11 March 2019. The Programme should also foster measures to strengthen the assessment and appropriate management of environmental risks associated with the production, use and disposal of medicinal products.
- (32) Union health legislation has an immediate impact on public health, on the lives of people, on the efficiency and resilience of health systems and on the proper functioning of the internal market. The regulatory framework for medical products and technologies, including medicinal products, medical devices and substances of human origin, and the regulatory frameworks for tobacco, patients' rights in cross-border healthcare and serious cross-border threats to health, are essential to the protection of health in the Union. The Programme therefore should support

the development, implementation and enforcement of Union health legislation and, in conjunction with relevant bodies such as EMA and ECDC, should provide high-quality, comparable and reliable data, including real-world healthcare data, to support policymaking and monitoring, set targets and develop tools to measure progress.

- (33) European Reference Networks (ERNs), which were established pursuant to Directive 2011/24/EU of the European Parliament and of the Council <sup>(14)</sup>, are virtual networks of healthcare providers across Europe. They aim to facilitate discussion regarding complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. As ERNs 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 ERNs and other transnational networks.
- (34) ERNs and cross-border cooperation in the provision of healthcare to patients moving between Member States are examples of areas where integrated work between Member States has been shown to have strong added value and great potential to increase the efficiency of health systems and thus to improve public health in general. Collaboration as regards HTA is another area that is bringing added value to Member States. The Programme should therefore support activities that enable integrated and sustained coordinated work, thereby also serving to foster the implementation of best practices that are aimed at distributing the available resources to the population and areas concerned in the most effective way so as to maximise their impact.
- (35) Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council <sup>(15)</sup> (the 'Financial Regulation') applies to this Programme. The Financial Regulation lays down rules on the implementation of the Union budget, including the rules on grants, prizes, procurement, indirect management, financial instruments, budgetary guarantees, financial assistance and the reimbursement of external experts.
- (36) 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 concerned and to deliver results, taking into account, in particular, the costs of controls, the administrative burden, and the expected risk of non-compliance. That choice should include consideration of the use of lump sums, flat-rate financing and unit costs, as well as the use of financing that is not linked to costs as envisaged in Article 125(1) of the Financial Regulation. Technical and financial reporting requirements for the beneficiaries should be such as to ensure that there is compliance with applicable financial provisions while minimising the administrative burden.
- (37) 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 and other Union programmes, including those under shared-management. To maximise those synergies, and avoid duplications, appropriate mechanisms should be provided for, including cumulative funding in an action from the Programme 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 of declaring the same cost or expenditure on a pro-rata basis under the Programme and another Union programme, in order to ensure that there is detailed and transparent reporting.
- (38) Given the specific nature of the objectives and actions covered by the Programme, the respective competent authorities of the Member States will be best placed, in some cases, to implement actions related to the Programme. Those authorities, designated by the Member States, should therefore be considered to be identified beneficiaries for

<sup>(14)</sup> Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

<sup>(15)</sup> 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, (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).

the purpose of Article 195 of the Financial Regulation and grants should therefore be awarded to those authorities without the prior publication of calls for proposals. Investments under the Programme should be implemented in close cooperation with Member States.

- (39) Under Article 193(2) of the Financial Regulation, a grant may be awarded for an action, which has already begun, provided that the applicant can demonstrate the need to start the action prior to the signature of the grant agreement. However, costs incurred prior to the date of submission of the grant application are not eligible costs, except in duly justified exceptional cases. In order to avoid any disruption to Union support which could be prejudicial to the Union's interests, it should be possible to provide for the eligibility of activities and costs from the beginning of the 2021 financial year in the financing decision, for a limited period at the beginning of the multiannual financial framework 2021-2027, and only in duly justified cases, even if those activities were implemented and those costs were incurred before the grant application was submitted.
- (40) ERNs are approved by the Board of Member States of the ERNs, following the approval procedure set out in Commission Implementing Decision 2014/287/EU<sup>(16)</sup>. ERNs should therefore be considered to be identified beneficiaries for the purpose of Article 195 of the Financial Regulation, and the grants to ERNs should therefore be awarded without prior publication of calls for proposals. Direct grants should also be awarded to other entities that have been designated in accordance with Union rules, for example reference laboratories and centres, centres of excellence and transnational networks.
- (41) Given the commonly agreed values of solidarity in relation to equitable and universal coverage of quality health services as a basis for the Union's policies in this area and the fact that the Union has a central role to play in accelerating progress, coordination and cooperation in tackling global health challenges as set out in the Council conclusions of 10 May 2010 on the EU role in Global Health, and as expressed in the UN 2030 Agenda Sustainable Development Goals, the Programme should reinforce the Union's support for international and global health initiatives, in particular for initiatives by the WHO, with a view to improving health, addressing health inequalities and strengthening protection against global health threats.
- (42) 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 the World Bank, as well as with the Council of Europe and the Organisation for Economic Co-operation and Development (OECD), when implementing the Programme. In order to increase impact, synergies should also be sought with the national organisations of Member States that are active in global health. In accordance with Council Decision 2013/755/EU<sup>(17)</sup>, persons and entities established in Overseas Countries and Territories (OCTs) should be eligible for funding under the Programme, subject to the rules and objectives of the Programme and to possible arrangements applicable to the Member State to which the relevant OCTs are linked.
- (43) The implementation of the Programme should be supported by extensive outreach activities to ensure that the views and needs of civil society are duly represented and taken into account. To this end, the Commission should seek feedback on the Programme's priorities and strategic orientations and on the needs to be addressed through its actions from relevant stakeholders once a year, including from representatives of civil society and patients' associations, academics and organisations of healthcare professionals. Each year, before the end of the preparatory work for the work programmes, the Commission should also inform the European Parliament about the progress regarding such preparatory work and on the outcome of its outreach activities towards stakeholders.

<sup>(16)</sup> 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).

<sup>(17)</sup> 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).

- (44) Third countries which are members of the European Economic Area (EEA) are able to participate in Union programmes in the framework of the cooperation established under the Agreement on the European Economic Area <sup>(18)</sup>, which provides for the implementation of such programmes on the basis of a decision adopted under that agreement. A specific provision should be introduced in this Regulation requiring third countries that participate in the Programme to grant the necessary rights and access required for the authorising officer responsible, the European Anti-Fraud Office (OLAF) and the Court of Auditors to comprehensively exercise their respective competences.
- (45) Cooperation with third countries should be strengthened as regards the exchange of knowledge and best practices in order to improve health systems' preparedness and response capacity.
- (46) In accordance with the Financial Regulation, Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council <sup>(19)</sup> and Council Regulations (EC, Euratom) No 2988/95 <sup>(20)</sup>, (Euratom, EC) No 2185/96 <sup>(21)</sup> and (EU) 2017/1939 <sup>(22)</sup>, 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, OLAF 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 Regulation (EU) 2017/1939, to investigate and prosecute criminal offences affecting the financial interests of the Union, as provided for in Directive (EU) 2017/1371 of the European Parliament and of the Council <sup>(23)</sup>.
- (47) 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 pursuant to Regulation (EU) 2017/1939, the EPPO, and ensure that any third parties involved in the implementation of Union funds grant equivalent rights.
- (48) Horizontal financial rules adopted by the European Parliament and the Council on the basis of Article 322 TFEU apply to this Regulation. Those 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, financial instruments, budgetary guarantees, financial assistance and the reimbursement of external experts and provide for checks on the responsibility of financial actors. Rules adopted on the basis of Article 322 TFEU also include a general regime of conditionality for the protection of the Union budget.
- (49) Reflecting the importance of tackling climate change in line with the Union's commitments to implement the Paris Agreement adopted under the United Nations Framework Convention on Climate Change and the UN Agenda 2030 Sustainable Development Goals, the Programme should contribute to mainstreaming climate action in the Union's policies and to the achievement of an overall target of at least 30 % of the total amount of the Union budget and the European Union Recovery Instrument, established by Council Regulation (EU) 2020/2094 <sup>(24)</sup>, expenditures, supporting climate objectives. The Programme should support activities that would respect the climate and

<sup>(18)</sup> OJ L 1, 3.1.1994, p. 3.

<sup>(19)</sup> 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).

<sup>(20)</sup> 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).

<sup>(21)</sup> 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).

<sup>(22)</sup> 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).

<sup>(23)</sup> 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).

<sup>(24)</sup> Council Regulation (EU) 2020/2094 of 14 December 2020 establishing a European Union Recovery Instrument to support the recovery in the aftermath of the COVID-19 crisis (OJ L 433I, 22.12.2020, p. 23).

environmental standards and priorities of the Union and the 'do no harm' principle of the European Green Deal. Relevant actions should be identified during the Programme's preparation and implementation, and reassessed in the context of its interim evaluation.

- (50) According to Article 8 TFEU, in all its activities, the Union shall aim to eliminate inequalities and to promote equality between men and women. Gender equality, as well as rights and equal opportunities for all, and the mainstreaming of those objectives should be taken into account and promoted throughout the assessment, preparation, implementation and monitoring of the Programme.
- (51) It should be possible for the policy objectives of the Programme to also be addressed through financial instruments and budgetary guarantees under the InvestEU Fund provided for by the InvestEU Programme. Financial support should be used to address market failures and sub-optimal investment situations, in a proportionate manner. Actions funded by the Programme should not duplicate or crowd out private financing or distort competition in the internal market. In general, actions should have Union added value.
- (52) The implementation of the Programme should be such that the responsibilities of the Member States for the definition of their health policies and for the organisation and delivery of health services and medical care are respected. Strong involvement of Member States in the governance and implementation of the Programme should be ensured.
- (53) Given the nature and potential scale of cross-border threats to health, the objectives of protecting people in the Union from such threats and increasing health 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 TEU, 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, sustainability, acceptability, accessibility, safety and affordability in the Union of medicinal products, medical devices and crisis-relevant products and services, to support innovation, to support integrated and coordinated work and the implementation of best practices among Member States, and to address inequalities and inequities in access to healthcare throughout the Union in a manner that creates efficiency gains and value-added impacts that could not be generated by action taken 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.
- (54) In order to allow possible adjustments necessary to achieve the Programme's objectives to be made, 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. It is of particular importance that the Commission carry 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 of 13 April 2016 on Better Law-Making <sup>(25)</sup>. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council 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.
- (55) Member States and participating countries have designated National Focal Points to assist the Commission in the promotion of the third Programme for the Union's action in the field of health (2014-2020) established by Regulation (EU) No 282/2014, and, where relevant, in the dissemination of its results and the information available on its impact in the Member States and participating countries. Given the importance of such activities, it is appropriate to support such activities under the Programme in order to continue them.

<sup>(25)</sup> OJ L 123, 12.5.2016, p. 1.

- (56) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt implementing acts establishing annual work programmes in accordance with the criteria set out in this Regulation, approving certain eligible actions and establishing rules on technical and administrative arrangements necessary for the implementation of the actions of the Programme 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 <sup>(26)</sup>. The examination procedure should be used for the adoption of those implementing acts given that they relate to a programme with substantial implications.
- (57) The value and impact of the Programme should be regularly and closely monitored and evaluated. The evaluation should focus on the goals of the Programme and take into account the fact that the achievement of the Programme's objectives could require a period that is longer than the length of the Programme. To that end, an interim evaluation report should be drawn up, as well as an evaluation report at the end of the Programme, in order to assess the implementation of the priorities of the Programme.
- (58) As the third Programme for the Union's action in the field of health (2014-2020) has come to an end, Regulation (EU) No 282/2014 has become obsolete and should be repealed.
- (59) In order to ensure continuity in providing support in the field of health and to allow implementation to start from the beginning of the multiannual financial framework 2021-2027, this Regulation should enter into force as a matter of urgency and should apply, with retroactive effect, from 1 January 2021,

HAVE ADOPTED THIS REGULATION:

## CHAPTER I

### GENERAL PROVISIONS

#### *Article 1*

#### **Subject matter**

This Regulation establishes the EU4Health Programme (the 'Programme') for the period of the multiannual financial framework 2021 to 2027. The duration of the Programme is aligned with the duration of the multiannual financial framework.

This Regulation also lays down the objectives of the Programme, the budget for the period from 2021 to 2027, the forms of Union funding and the rules for providing such funding.

#### *Article 2*

#### **Definitions**

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

- (1) 'associated country' means a third country which is party to an agreement with the Union that allows for its participation in the Programme, in accordance with Article 6;
- (2) 'blending operations' means actions supported by the Union budget, including within blending facilities pursuant to point (6) of Article 2 of the Financial Regulation, combining non-repayable forms of support, and/or financial instruments from the Union budget with repayable forms of support from development institutions or other public finance institutions, as well as from commercial finance institutions and commercial investors;

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<sup>(26)</sup> 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).

- (3) 'health crisis' means a crisis or serious incident arising from a threat of human, animal, plant, food, biological, chemical, environmental or unknown origin, which has a public health dimension and which requires urgent action by authorities;
- (4) 'crisis-relevant products' means products, tools and substances that are necessary, in the context of a health crisis, for the prevention, diagnosis or treatment of a disease and its consequences, or for the monitoring and the epidemiological surveillance of diseases and infections, including, but not limited to, medicinal products, such as vaccines and their intermediates, active pharmaceutical ingredients and raw materials, as well as medical devices and hospital and medical equipment, such as ventilators, protective clothing and equipment, diagnostic materials and tools, personal protective equipment, disinfectants and their intermediary products, and the raw materials necessary for their production;
- (5) 'One Health approach' means a multisectoral approach which recognises that human health is connected to animal health and to the environment, and that actions to tackle threats to health must take into account those three dimensions;
- (6) 'European Reference Networks (ERNs)' means the networks referred to in Article 12 of Directive 2011/24/EU;
- (7) 'legal entity' means a natural person, or a legal person created and recognised as such under national, Union or international law which has legal personality and which can, acting in its own name, exercise rights and be subject to obligations, or an entity without legal personality as referred to in point (c) of Article 197(2) of the Financial Regulation;
- (8) 'third country' means a country that is not a Member State 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) 'Health in All Policies' means an approach to the development, implementation and review of public policies, regardless of the sector, whereby the health implications of decisions are taken into account, and which seeks to achieve synergies and to avoid harmful health impacts being caused by such policies, in order to improve the health of the population and health equity;
- (11) 'health determinants' means a range of factors that influence the health status of a person, such as behaviour-related, biological, socio-economic and environmental factors;
- (12) 'emergency support' means a needs-based emergency response that complements the response of the affected Member States and is 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.

### Article 3

#### General objectives

The Programme shall have a Union added value and complement the policies of the Member States, in order to improve human health throughout the Union and to ensure a high level of protection of human health in all Union policies and activities. It shall pursue the following general objectives in keeping with the One Health approach, where applicable:

- (a) improving and fostering health in the Union to reduce the burden of communicable and non-communicable diseases, by supporting health promotion and disease prevention, by reducing health inequalities, by fostering healthy lifestyles and by promoting access to healthcare;
- (b) protecting people in the Union from serious cross-border threats to health and strengthening the responsiveness of health systems and coordination among the Member States in order to cope with serious cross-border threats to health;
- (c) improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, and supporting innovation regarding such products;

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

#### Article 4

### Specific objectives

The general objectives referred to in Article 3 shall be pursued through the following specific objectives, ensuring a high level of human health protection in all Union policies and activities in keeping with the One Health approach, where applicable:

- (a) in synergy with other relevant Union actions, supporting actions for disease prevention, for health promotion and for addressing health determinants, including through the reduction of damage to health resulting from illicit drug use and addiction, supporting actions to address inequalities in health, to improve health literacy, to improve patient rights, patient safety, quality of care and cross-border healthcare, and supporting actions for the improvement of the surveillance, diagnosis and treatment of communicable and non-communicable diseases, in particular cancer and paediatric cancer, as well as supporting actions to improve mental health, with special attention given to new care models and the challenges of long term care, in order to strengthen the resilience of the health systems in the Union;
- (b) strengthening the capability of the Union for prevention of, preparedness for, and rapid response to, serious cross-border threats to health in accordance with relevant Union legislation, and improving the management of health crises, particularly through the coordination, provision and deployment of emergency healthcare capacity, supporting data gathering, information exchange, surveillance, the coordination of voluntary stress testing of national healthcare systems, and the development of quality healthcare standards at national level;
- (c) supporting actions to enhance the availability, accessibility and affordability of medicinal products, medical devices and crisis-relevant products by encouraging sustainable production and supply chains and innovation in the Union, while supporting the prudent and efficient use of medicinal products, in particular antimicrobials, and actions to support the development of medicinal products that are less harmful for the environment, as well as the environmentally friendly production and disposal of medicinal products and medical devices;
- (d) in synergy with other Union instruments, programmes and funds, without prejudice to Member State competences, and in close cooperation with relevant Union bodies, supporting actions complementing national stockpiling of essential crisis-relevant products, at Union level, where needed;
- (e) in synergy with other Union instruments, programmes and funds, without prejudice to Member State competences and in close cooperation with the ECDC, establishing a structure and training resources for a reserve of medical, healthcare and support staff allocated voluntarily by Member States for its mobilisation in the event of a health crisis;
- (f) strengthening the use and re-use of health data for the provision of healthcare and for research and innovation, promoting the uptake of digital tools and services, as well as the digital transformation of healthcare systems, including by supporting the creation of a European health data space;
- (g) enhancing access to quality, patient-centred, outcome-based healthcare and related care services, with the aim of achieving universal health coverage;
- (h) supporting the development, implementation and enforcement and, where necessary, the revision of Union health legislation and supporting the provision of valid, reliable and comparable high-quality data for evidence-based decision-making and monitoring, and promoting the use of health impact assessments of other relevant Union policies;

- (i) supporting integrated work among Member States, and in particular their health systems, including the implementation of high-impact prevention practices, supporting work on HTA, and strengthening and scaling up networking through ERNs and other transnational networks, including in relation to diseases other than rare diseases, to increase the coverage of patients and improve the response to low prevalence and complex communicable and non-communicable diseases;
- (j) supporting global commitments and health initiatives by reinforcing the Union's support for actions by international organisations, in particular actions by the WHO, and fostering cooperation with third countries.

#### Article 5

#### **Budget**

1. The financial envelope for the implementation of the Programme for the period 2021 - 2027 shall be EUR 2 446 000 000 in current prices.
2. As a result of the Programme-specific adjustment provided for in Article 5 of Council Regulation (EU, Euratom) 2020/2093 <sup>(27)</sup>, the amount referred to in paragraph 1 of this Article shall be increased by an additional allocation of EUR 2 900 000 000 in 2018 prices as specified in Annex II to that Regulation.
3. The amounts referred to in paragraphs 1 and 2 may also 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.
4. The distribution of the amounts referred to in paragraphs 1 and 2 shall comply with the following:
  - (a) a minimum of 20 % of the amounts shall be reserved for health promotion and disease prevention actions as referred to in point (a) of Article 4;
  - (b) a maximum of 12,5 % of the amounts shall be reserved for procurement complementing national stockpiling of essential crisis-relevant products at Union level as referred to in point (d) of Article 4;
  - (c) a maximum of 12,5 % of the amounts shall be reserved for supporting global commitments and health initiatives as referred to in point (j) of Article 4;
  - (d) a maximum of 8 % of the amounts shall be reserved for covering administrative expenses as referred to in paragraph 3.
5. Appropriations related to activities under point (c) of Article 9(1) of this Regulation, shall constitute assigned revenue within the meaning of point (a) of paragraph 3, and paragraph 5, of Article 21 of the Financial Regulation.
6. Budgetary commitments extending over more than one financial year may be broken down over several years into annual instalments.
7. In accordance with point (a) of the second subparagraph of Article 193(2) of the Financial Regulation, for a limited period in duly justified cases specified in the financing decision, activities supported under this Regulation and their underlying costs may be considered eligible as of 1 January 2021, even if those activities were implemented and those costs were incurred before the grant application was submitted.
8. If necessary, appropriations may be entered in the budget beyond 31 December 2027 to cover the expenses referred to in paragraph 3 to enable the management of actions not completed by 31 December 2027.

<sup>(27)</sup> Council Regulation (EU, Euratom) 2020/2093 of 17 December 2020 laying down the multiannual financial framework for the years 2021 to 2027 (OJ L 433I, 22.12.2020, p. 11).

*Article 6***Third countries associated to the Programme**

1. The Programme shall be open to the participation of the following third countries:
  - (a) members of the European Free Trade Association which are members of the European Economic Area, in accordance with the conditions laid down in the Agreement on the European Economic Area;
  - (b) 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;
  - (c) European Neighbourhood Policy countries, 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 in similar agreements and in accordance with the specific conditions laid down in agreements between the Union and those countries;
  - (d) other third countries, in accordance with the conditions laid down in a specific agreement covering the participation of the third country in any Union programme, provided that the agreement:
    - (i) ensures a fair balance as regards the contributions and benefits of the third country participating in the Union programme;
    - (ii) lays down the conditions of participation in the Union programme, including the calculation of financial contributions to individual programmes, and their administrative costs;
    - (iii) does not confer on the third country a decision-making power in respect of the Union programme;
    - (iv) guarantees the rights of the Union to ensure sound financial management and to protect its financial interests.
2. The contributions referred to in point (d)(ii) of paragraph 1 shall constitute assigned revenue in accordance with Article 21(5) of the Financial Regulation.

## CHAPTER II

**FUNDING***Article 7***Implementation and forms of Union funding**

1. The Programme shall be implemented in direct management in accordance with the Financial Regulation or in indirect management with the bodies referred to in point (c) of Article 62(1) of that Regulation.
2. The Programme may provide funding in any of the forms laid down in the Financial Regulation, in particular in the form of 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 a sufficient guarantee under the Financial Regulation. The Commission shall lay down specific rules for the operation of the mechanism.

4. Where the Commission implements emergency support operations through a non-governmental organisation, the criteria concerning financial and operational capacity shall be deemed to be satisfied if there is a framework partnership agreement in force between that organisation and the Commission pursuant to Council Regulation (EC) No 1257/96 <sup>(28)</sup>.

#### Article 8

##### Grants

1. Grants under the Programme shall be awarded and managed in accordance with Title VIII of the Financial Regulation.
2. Grants may be used in combination with financing from the European Investment Bank, from national promotional banks or from other development or public financial institutions, as well as in combination with financing from private-sector finance institutions and from public-sector or private-sector investors, including through public-public or public-private partnerships.
3. Grants paid by the Union shall not exceed 60 % of eligible costs for an action relating to an objective of the Programme or for the functioning of a non-governmental body. In cases of exceptional utility, the contribution by the Union may be up to 80 % of eligible costs. Actions with a clear Union added value shall be considered to have exceptional utility, inter alia, where:
  - (a) at least 30 % of the budget of the proposed action is allocated to Member States whose GNI per inhabitant is less than 90 % of the Union average; or
  - (b) bodies from at least 14 participating Member States participate in the action, of which at least four are Member States whose GNI per inhabitant is less than 90 % of the Union average.
4. In the case of the direct grants referred to in Article 13(6) and (7), such grants may be up to 100 % of eligible costs.

#### Article 9

##### Procurement in health emergency situations

1. In cases where the emergence or development of a serious cross-border threat to health has been notified under Article 9 of Decision No 1082/2013/EU, or where a situation of public health emergency has been recognised under Article 12 of that Decision, procurement under this Regulation may take any of the following forms:
  - (a) joint procurement with the Member States as referred to in Article 165(2) of the Financial Regulation whereby Member States may acquire, rent or lease fully the jointly procured capacities;
  - (b) procurement by the Commission on behalf of the Member States on the basis of an agreement between the Commission and the Member States;
  - (c) procurement by the Commission acting as wholesaler by buying, stocking and reselling or donating supplies and services, including rentals, for the benefit of Member States or partner organisations selected by the Commission.
2. In the event of the procurement procedure referred to in point (b) of paragraph 1 being used, the ensuing contracts shall be concluded by either of the following:
  - (a) by the Commission, where the services or goods are to be provided or delivered to Member States or to partner organisations selected by the Commission;
  - (b) by the participant Member States, where they are to directly acquire, rent or lease the capacities procured for them by the Commission.

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<sup>(28)</sup> Council Regulation (EC) No 1257/96 of 20 June 1996 concerning humanitarian aid (OJ L 163, 2.7.1996, p. 1).

3. In the event of the procurement procedures referred to in points (b) and (c) of paragraph 1 being used, the Commission shall comply with the Financial Regulation for its own procurement.

#### *Article 10*

### **Blending operations**

Blending operations under the Programme shall be implemented in accordance with Regulation (EU) 2021/523 and Title X of the Financial Regulation.

#### *Article 11*

### **Cumulative funding**

1. An action that has received a contribution under the Programme may also receive a contribution from any other Union programme, including Funds under shared management, provided that the contributions do not cover the same costs.
2. The rules of the relevant Union programme shall apply to the corresponding contribution to the action.
3. The cumulative funding shall not exceed the total eligible costs of the action. 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 12*

### **Eligible actions**

Only actions that implement the objectives listed in Articles 3 and 4, in particular the actions set out in Annex I, shall be eligible for funding.

#### *Article 13*

### **Eligible legal entities**

1. In order to be eligible for funding, legal entities shall, in addition to the criteria set out in Article 197 of the Financial Regulation:
  - (a) be established in any of the following:
    - (i) a Member State or an overseas country or territory linked to it;
    - (ii) a third country associated to the Programme; or
    - (iii) a third country listed in the annual work programme established in accordance with Article 17 ('annual work programme') under the conditions specified in paragraphs 2 and 3; or
  - (b) be a legal entity created under Union law or an international organisation.
2. Legal entities that are established in a third country which is not associated to the Programme may in exceptional cases be eligible to participate in the Programme where such participation is necessary for the achievement of the objectives of a given action. The assessment of that necessity shall be duly reflected in the funding decision.
3. Legal entities that are established in a third country which is not associated to the Programme shall bear the cost of their participation.

4. Natural persons shall not be eligible for grants under the Programme.
5. Under the Programme, direct grants may be awarded without a call for proposals to fund actions, if such grants are duly justified, and if those actions have a Union added value that is explicitly provided for in the annual work programmes and are co-financed by the competent authorities that are responsible for health in the Member States or in third countries associated to the Programme, by relevant international health organisations, or by public sector bodies or non-governmental bodies that are mandated by those competent authorities, regardless of whether those bodies act individually or as a network.
6. Under the Programme, direct grants shall be awarded without a call for proposals to ERNs. Direct grants may also be awarded to other transnational networks set out in accordance with Union law.
7. Under the Programme, direct grants may be awarded without a call for proposals to fund actions of the WHO where financial support is necessary for the implementation of one or more of the specific objectives of the Programme that have a Union added value that is explicitly provided for in the annual work programmes.
8. 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 implementation of one or more of the specific objectives of the Programme that have a Union added value that is explicitly provided for in the annual work programmes, as long as those bodies fulfil all of the following criteria:
  - (a) they are non-profit-making and independent of industry, commercial and business or other conflicting interests;
  - (b) 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;
  - (c) they are active at Union level and in at least half of the Member States, with a balanced geographical coverage of the Union.

The Commission shall duly reflect the analysis of the fulfilment of those criteria in the funding decision.

#### Article 14

#### Eligible costs

1. Subject to Article 186 of the Financial Regulation, and point (a) of the second subparagraph of Article 193(2) of that Regulation, costs incurred prior to the date of submission of the grant application shall be eligible for funding with respect to actions:
  - (a) implementing the objective referred to in point (b) of Article 3 of this Regulation; or
  - (b) implementing objectives other than those referred to in point (a) of this paragraph, in duly justified exceptional cases, provided that those costs are directly linked to the implementation of the supported actions and activities.
2. Costs eligible under point (a) of paragraph 1 that relate to measures aiming to address suspected occurrences of a disease that could trigger a cross-border threat to health shall be eligible from the date of notification of the suspected occurrence of that disease to the Commission, provided that the occurrence or presence of that disease is subsequently confirmed.
3. In exceptional cases, during a health crisis caused by a serious cross-border threat to health as defined in point (g) of Article 3 of Decision No 1082/2013/EU, costs incurred by entities established in non-associated countries may be considered eligible if those costs are duly justified for reasons concerning countering the spread of the risk for the protection of the health of people in the Union.

## CHAPTER IV

## GOVERNANCE

*Article 15***Joint policy implementation**

1. A EU4Health Steering Group shall be established.
2. The Members of the EU4Health Steering Group shall be the Commission and the Member States. Each Member State shall appoint one member and one alternate member to the EU4Health Steering Group. The Commission shall provide the secretariat of the EU4Health Steering Group.
3. The Commission shall consult the EU4Health Steering Group:
  - (a) on the Commission's preparatory work for the annual work programmes;
  - (b) each year, at least 6 months in advance of the presentation of the draft of the annual work programme to the committee referred to in Article 23(1), on the priorities and strategic orientations of the annual work programme.
4. The EU4Health Steering Group shall:
  - (a) work towards ensuring that there is consistency and complementarity between the Member States' health policies as well as between the Programme and other policies, instruments and actions of the Union, including those relevant to the Union agencies;
  - (b) follow up the implementation of the Programme and propose any necessary adjustments based on evaluations;
  - (c) adopt its rules of procedure, which shall contain provisions to ensure that the group will meet at least three times a year, in person where appropriate, thus allowing for a regular and transparent exchange of views among Member States.

*Article 16***Stakeholder consultation and information of the European Parliament**

1. The Commission shall consult with relevant stakeholders, including representatives of civil society and patient organisations, to seek their views on:
  - (a) the priorities and strategic orientation of the annual work programme;
  - (b) the needs to be addressed through the annual work programme and the results achieved through it.
2. For the purposes of paragraph 1, the Commission shall organise the consultation and information of stakeholders at least once a year, in the six months preceding the presentation of the draft work programme to the committee referred to in Article 23(1).
3. The Commission may at any time seek the views of relevant decentralised agencies and of independent experts in the field of health on technical or scientific matters of relevance for the implementation of the Programme.
4. Each year, prior to the last meeting of the EU4Health Steering Group, the Commission shall present to the European Parliament the outcomes of the proceedings of the EU4Health Steering Group and the consultation of stakeholders referred to in paragraphs 1 and 2.

*Article 17***Implementation of the Programme**

1. The Commission shall implement the Programme by establishing annual work programmes in accordance with the Financial Regulation.

2. The Commission shall adopt, by means of implementing acts:
  - (a) the annual work programmes, which shall set out, in particular:
    - (i) the actions to be undertaken, including the indicative allocation of financial resources;
    - (ii) the overall amount reserved for blending operations;
    - (iii) eligible actions falling under Article 7(3) and (4);
    - (iv) eligible actions by legal entities referred to in point (b) of Article 13(1);
    - (v) eligible actions by legal entities from a third country not associated to the Programme but listed in the annual work programme under the conditions laid down in Article 13(2) and (3);
  - (b) decisions approving actions with a cost of EUR 20 000 000 or more;
  - (c) rules establishing:
    - (i) the technical and administrative arrangements necessary for the implementation of the actions of the Programme;
    - (ii) uniform templates for the collection of data necessary to monitor the implementation of the Programme.
3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 23(2).

#### *Article 18*

### **Data protection**

In managing and implementing the Programme, the Commission and the Member States shall ensure that there is compliance with all relevant legal provisions regarding personal data protection and, where appropriate, that mechanisms are introduced to ensure that such data remain confidential and safe.

#### CHAPTER V

### **MONITORING, EVALUATION AND CONTROL**

#### *Article 19*

### **Monitoring and reporting**

1. Indicators to report on progress of the Programme towards the achievement of the general and specific objectives listed in Articles 3 and 4 are set out in Annex II.
2. The Commission is empowered to adopt delegated acts in accordance with Article 25 to amend Annex II with regard to 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, the Commission shall adopt implementing acts establishing proportionate reporting requirements for recipients of Union funds and, where appropriate, for Member States.

#### *Article 20*

### **Evaluation**

1. Evaluations provided for in Article 34(3) of the Financial Regulation shall be carried out by the Commission in a sufficiently timely manner to feed into the decision-making process.

2. The Commission shall present an interim evaluation of the Programme no later than 31 December 2024. The interim evaluation shall be the basis for adjusting the implementation of the Programme as appropriate.
3. The Commission shall present a final evaluation at the end of the Programme and no later than four years after the end of the period referred to in Article 1.
4. The Commission shall publish and communicate the conclusions of both the interim and final evaluations accompanied by its observations, to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

#### Article 21

##### **Audits**

Audits of the use of Union contributions, including audits carried out by persons or entities other than those mandated by the Union institutions or bodies, shall form the basis of the overall assurance referred to in Article 127 of the Financial Regulation.

#### Article 22

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

Where a third country participates in the Programme by means of a decision adopted pursuant to an international agreement or on the basis of any other legal instrument, the third country shall grant the necessary rights and access required for the authorising officer responsible, OLAF, and the Court of Auditors to comprehensively exercise 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, as provided for in Regulation (EU, Euratom) No 883/2013.

#### 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.

Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

#### Article 24

##### **Consistency and complementarity with other Union policies, instruments and actions**

The Commission and the Member States shall ensure that there is overall consistency, synergy and complementarity between the Programme and other Union policies, instruments and actions, including those relevant to the Union agencies, including through their common work in the EU4Health Steering Group.

#### Article 25

##### **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 for a period of seven years from 26 March 2021.
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 of 13 April 2016 on Better Law-Making.
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 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 the Council.

## CHAPTER VI

### TRANSITIONAL AND FINAL PROVISIONS

#### *Article 26*

#### **Information, communication and publicity**

1. The recipients of Union funding shall acknowledge the origin of those funds and ensure the visibility of the Union funding, in particular when promoting the actions and their results, by providing coherent, effective and proportionate targeted information to multiple audiences, including the media and the public.
2. The Commission shall implement information and communication actions related to the Programme, to actions taken pursuant to the Programme and to the results obtained.
3. Financial resources allocated to the Programme shall also contribute to the corporate communication of the political priorities of the Union, insofar as those priorities are related to the objectives referred to in Articles 3 and 4.

#### *Article 27*

#### **Repeal**

Regulation (EU) No 282/2014 is repealed with effect from 1 January 2021, without prejudice to Article 28 of this Regulation.

#### *Article 28*

#### **Transitional provisions**

1. This Regulation shall not affect the continuation of or modification of actions initiated pursuant to Regulation (EU) No 282/2014 which shall continue to apply to those actions 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 measures adopted under Regulation (EU) No 282/2014 and the Programme.

*Article 29***Entry into force and application**

This Regulation shall enter into force on the day of 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, 24 March 2021.

*For the European Parliament*  
*The President*  
D. M. SASSOLI

*For the Council*  
*The President*  
A.P. ZACARIAS

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## ANNEX I

## LIST OF POSSIBLE ELIGIBLE ACTIONS PROVIDED FOR IN ARTICLE 12

## 1. Actions meeting the objective laid down in point (a) of Article 4

- (a) Supporting the establishment and implementation of programmes assisting Member States and supporting the actions of Member States to improve health promotion and disease prevention;
- (b) Supporting the implementation and further development of surveys, studies, collection of comparable data and statistics, where relevant including disaggregated data by gender and age, methodologies, classifications, microsimulations, pilot studies, indicators, knowledge brokering and benchmark exercises;
- (c) Supporting Member States' actions to put in place healthy and safe urban, work and school environments, to enable healthy life choices, to promote healthy diets and regular physical activity, taking into account the needs of vulnerable groups at every stage of their life, with the aim of promoting life-long health;
- (d) Supporting Member States in delivering effective responses to communicable diseases, and in the prevention, surveillance, diagnosis and treatment of such diseases;
- (e) Supporting Member States' actions in health promotion and disease prevention throughout the lifetime of an individual and by addressing health risk factors, such as obesity, unhealthy diets and physical inactivity;
- (f) Supporting actions to improve mental health;
- (g) Supporting actions to complement measures of Member States in reducing damage to health due to illicit drug use and addiction, including information and prevention;
- (h) Supporting implementing policies and actions to reduce health inequalities and inequities in relation to healthcare;
- (i) Supporting actions to enhance health literacy;
- (j) Supporting the promotion and implementation of the recommendations of the European Code against Cancer and supporting the revision of the current edition of that Code;
- (k) Actions to support the implementation of cancer registries in all Member States;
- (l) Furthering the cooperation among relevant national bodies of participating Member States with a view to supporting the creation of a virtual European network of excellence in order to strengthen research on all types of cancer, including paediatric cancer, and further the collection and exchange of clinical data and the translation of research findings into everyday care and treatment of cancer patients;
- (m) Supporting actions to improve the quality of cancer care, including as regards prevention, screening, early diagnosis, monitoring and treatment, supportive and palliative care, in an integrative and patient-centred approach and supporting the establishment of quality assurance schemes for cancer centres or other centres treating cancer patients, including those treating paediatric cancer;
- (n) Supporting the establishment of quality assurance schemes for cancer centres and centres treating cancer patients;
- (o) Supporting mechanisms for cross-specialty capacity building and continuous education, in particular in the area of cancer care;
- (p) Actions supporting the quality of life of cancer survivors and caregivers, including provision of psychological support, pain management and health-related aspects of professional reintegration;
- (q) Strengthening collaboration on patient rights, patient safety and quality of care;
- (r) Supporting actions regarding epidemiological surveillance, thus contributing to assessment of factors that affect or determine the health of people;

- (s) Supporting, in synergy with other programmes, actions to improve the geographical distribution of the healthcare workforce and actions for the avoidance of ‘medical deserts’, without prejudice to Member State competences;
- (t) Supporting the development of guidelines for preventing and managing communicable and non-communicable diseases, and of tools and networks for the exchange of best practices in that area;
- (u) Supporting Member States’ actions to address health determinants, including reducing alcohol-related harm and tobacco use;
- (v) Supporting tools and platforms to collect real-world evidence on the safety, effectiveness and impact of vaccines after use;
- (w) Supporting initiatives to improve vaccination coverage rates in the Member States;
- (x) Communication activities addressed to the public and stakeholders to promote Union action in the areas mentioned in this Annex;
- (y) Awareness-raising campaigns and communications activities for the general public as well as for targeted groups, aimed at preventing and addressing vaccine hesitancy, misinformation and disinformation as regards prevention, causes and treatment of diseases, in a manner that complements national campaigns and communications activities on those matters;
- (z) Communication activities addressed to the public on health risks and health determinants;
- (za) Supporting actions to reduce the risk of healthcare-acquired infections.

2. Actions meeting the objective laid down in point (b) of Article 4

- (a) Strengthening the critical health infrastructure to cope with health crises, by supporting the setup of tools for surveillance, forecast, prevention and management of outbreaks;
- (b) Supporting actions to foster Union-wide health crisis prevention and preparedness, and the management capacity and response capacity of actors at Union and national level, including voluntary stress tests, contingency planning and preparedness exercises; supporting the development of quality health standards at national level, mechanisms for the efficient coordination of preparedness and response, and the coordination of those actions at Union level;
- (c) Supporting actions for setting up an integrated cross-cutting risk communication framework covering all phases of a health crisis, namely prevention, preparedness, response and recovery;
- (d) Supporting preventive actions to protect vulnerable groups from health threats and actions to adapt the response to and the management of health crises to the needs of those vulnerable groups such as actions to secure basic care for patients with chronic or rare diseases;
- (e) Supporting actions to address the collateral health consequences of a health crisis, in particular the consequences for mental health, on patients suffering from cancer, from chronic diseases and other vulnerable situations, including people living with addiction, with HIV/AIDS, or suffering from hepatitis and tuberculosis;
- (f) Supporting, in synergy with other programmes, training and educational programmes for the upskilling of healthcare and public health workforces, and programmes for temporary exchanges of staff, in particular with the aim of improving their digital skills;
- (g) Supporting the establishment and coordination of Union Reference Laboratories, Union Reference Centres, and Centres of Excellence;
- (h) Auditing Member States’ preparedness and response arrangements, for example regarding health crisis management, antimicrobial resistance and vaccination;
- (i) Communicating to the public in the context of risk management and health crisis preparedness;

- (j) Supporting upwards convergence of national systems' performance through health indicator development, analysis and knowledge brokering and the organisation of voluntary stress tests of national healthcare systems;
  - (k) Supporting investigation, risk assessment and risk management work on the link between animal health, environmental factors, and human diseases, including during health crises.
3. Actions meeting the objective laid down in point (c) of Article 4
- (a) Supporting actions to strengthen laboratory capacity and the production, research, development, and deployment of health products and crisis-relevant niche products within the Union;
  - (b) Supporting actions and interoperable IT tools to monitor, prevent, manage, report and notify shortages of medicinal products and medical devices, while contributing to their affordability;
  - (c) Supporting, in synergy with other programmes, clinical trials to speed up the development, market authorisation and access to innovative, safe and effective medicinal products and vaccines;
  - (d) Supporting actions to encourage the development of innovative medicinal products and vaccines to meet rising healthcare challenges and patients' needs, and of less commercially profitable products such as antimicrobials;
  - (e) Supporting actions to improve the environmentally friendly production and disposal of medicinal products and medical devices and actions to support the development of medicinal products that are less harmful for the environment;
  - (f) Supporting actions to promote the prudent and efficient use of medicinal products, in particular of antimicrobials;
  - (g) Supporting actions aimed at stimulating the increase in the production of essential active pharmaceutical ingredients and medicinal products in the Union, including by diversifying supply chain production of active pharmaceutical ingredients and generics within the Union, to reduce Member States' dependence on certain third countries;
  - (h) Supporting actions to enhance the availability, accessibility and affordability of medicinal products and medical devices;
  - (i) Supporting actions to foster innovation in repurposing, reformulation and combining of off-patent medicinal products, in synergy with other programmes;
  - (j) Actions to strengthen the environmental risk assessment of medicinal products;
  - (k) Supporting the establishment and operation of a mechanism for cross-sectorial coordination following the One-Health approach.
4. Actions meeting the objective laid down in point (d) of Article 4
- (a) Monitoring of information on national stockpiling activities regarding essential crisis-relevant products to identify potential needs for additional stockpiling at Union level;
  - (b) Ensuring consistent management of stockpiling of essential crisis-relevant products at Union level, in a manner that complements other Union instruments, programmes and funds and in close coordination with relevant Union bodies;
  - (c) Supporting actions for the procurement and supply of essential crisis-relevant products, which contribute to their affordability, in a manner that complements Member States' stockpiling actions.
5. Actions meeting the objective laid down in point (e) of Article 4

Supporting actions for the preparatory work for mobilising and training at Union level a reserve of medical, healthcare and support staff to be mobilised in the event of a health crisis, in close collaboration with the ECDC, in synergy with other Union instruments, and in full respect of Member State competences; facilitating the exchange of best practices between existing national reserves of medical, healthcare and support staff.

6. Actions meeting the objective laid down in point (f) of Article 4
  - (a) Supporting a Union framework and the respective interoperable digital tools for cooperation among Member States and cooperation in networks, including those needed for HTA cooperation;
  - (b) Supporting the deployment, operation and maintenance of mature, secure and interoperable digital service infrastructure and data quality assurance processes for the exchange of, access to, and use and reuse of, data; supporting cross-border networking, including through the use and interoperability of electronic health records, registries and other databases; developing appropriate governance structures and interoperable health information systems;
  - (c) Supporting the digital transformation of healthcare and health systems, including through benchmarking and capacity building, for the uptake of innovative tools and technologies such as artificial intelligence, and supporting the digital upskilling of healthcare professionals;
  - (d) Supporting the optimal use of telemedicine and telehealth, including through satellite communication for remote areas, fostering digitally-driven organisational innovation in healthcare facilities and promoting digital tools to support citizen empowerment and patient-centred care;
  - (e) Supporting the development, operation and maintenance of databases and digital tools and their interoperability, including already established projects, where appropriate, with other sensing technologies, such as space-based technologies and artificial intelligence;
  - (f) Supporting actions to strengthen citizens' access to and control over their health data;
  - (g) Supporting the deployment and interoperability of digital tools and infrastructure within and between Member States and with Union institutions, agencies and bodies;
  - (h) Supporting preparatory activities and projects for the European health data space;
  - (i) Actions to support e-health, such as the transition to telemedicine and at-home administration of medication;
  - (j) Supporting the establishment of interoperable electronic health records, in line with the European Electronic Health Record Exchange format in order to increase the use of e-health and improve the sustainability and resilience of healthcare systems.
7. Actions meeting the objective laid down in point (g) of Article 4
  - (a) Actions promoting access to health services and related facilities and care for people with disabilities;
  - (b) Supporting the strengthening of primary care and reinforcing the integration of care, with a view to providing universal health coverage and equal access to good quality healthcare;
  - (c) Supporting Member States' actions to promote access to sexual and reproductive healthcare and supporting integrated and intersectional approaches to prevention, diagnosis, treatment and care.
8. Actions meeting the objective laid down in point (h) of Article 4
  - (a) Supporting the establishment and operation of a health intelligence and knowledge infrastructure;
  - (b) Supporting the implementation, enforcement, monitoring of Union health legislation and action; and providing technical support for the implementation of legal requirements;
  - (c) Supporting studies and analysis, health impact assessment of other Union policy actions and the provision of scientific advice to support evidence-based policymaking;
  - (d) Supporting expert groups and panels providing advice, data and information to support health policy development and implementation, including follow-up evaluations of the implementation of health policies;

- (e) Supporting national contact and focal points in providing guidance, information and assistance related to the promotion and implementation of Union health legislation and of the Programme;
  - (f) Auditing and assessment work in accordance with Union legislation, where appropriate;
  - (g) Supporting the implementation and further development of the Union's tobacco control policy and legislation;
  - (h) Supporting national systems as regards the implementation of legislation on substances of human origin, and as regards the promotion of the sustainable and safe supply of such substances through networking activities;
  - (i) Supporting Member States to strengthen the administrative capacity of their healthcare systems through cooperation and exchange of best practices;
  - (j) Supporting knowledge transfer actions and Union level cooperation to assist national reform processes towards improved effectiveness, accessibility, sustainability and resilience of health systems, while linking available Union funding;
  - (k) Supporting capacity building for investing in and implementing health system reforms, including strategic planning and access to multi-source financing.
9. Actions meeting the objective laid down in point (i) of Article 4
- (a) Supporting the transfer, adaptation and roll-out of best practices and innovative solutions with established Union level added-value between Member States, and in particular providing country-specific tailor-made assistance to the Member States, or groups of Member States, with the greatest needs, through the funding of specific projects including twinning, expert advice and peer support;
  - (b) Supporting cross-border collaboration and partnerships, including in cross-border regions, with a view to transferring and upscaling innovative solutions;
  - (c) Strengthening cross-sectoral collaboration and coordination;
  - (d) Supporting the functioning of ERNs and the establishment and operation of new transnational networks as provided for in Union health legislation, and supporting Member States' actions to coordinate the activities of such networks with the operation of national health systems;
  - (e) Supporting further the implementation of ERNs in Member States and fostering their strengthening, inter alia, by continuous assessment, monitoring, evaluation and improvement;
  - (f) Supporting the creation of new ERNs, to cover rare, complex and low prevalence diseases, where appropriate, and supporting collaboration among ERNs to address the multi-systemic needs arising from low prevalence diseases and rare diseases and to facilitate diagonal networking between different specialities and disciplines;
  - (g) Support Member States to improve and further develop and implement ERN registries;
  - (h) Stakeholder consultation activities.
10. Actions meeting the objective laid down in point (j) of Article 4
- (a) Supporting actions contributing to the objectives of the programme presented by the WHO, as the directing and coordinating authority for health within the United Nations;
  - (b) Supporting collaboration among Union institutions, Union agencies, and international organisations and networks, and supporting the Union's contribution to global initiatives;
  - (c) Supporting collaboration with third countries as regards the areas covered by the Programme;
  - (d) Supporting actions to foster international regulatory convergence on medicinal products and medical devices.
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## ANNEX II

## INDICATORS FOR THE EVALUATION OF THE PROGRAMME

## Programme indicators:

1. Preparedness and response planning of the Union and of Member States for serious cross-border threats to health
  2. Access to centrally authorised medicinal products, for example the number of existing and new orphan authorisations, advanced therapy medicinal products (ATMPs), medicinal products for paediatric use or vaccines, for unmet needs
  3. Number of actions contributing to the reduction of avoidable mortality in the area of non-communicable diseases and risk factors
  4. Number of Member States implementing best practices regarding health promotion, disease prevention and addressing health inequalities
  5. Number of Member States participating in the European health data space
  6. Number of Member States with improved preparedness and response planning
  7. Vaccination coverage by age for vaccine-preventable-diseases such as measles, flu, HPV and COVID-19
  8. EU Laboratory capacity index (EULabCap)
  9. Age-standardised five-year net survival rate for paediatric cancer by type, age, gender and Member State (to the extent available)
  10. Screening coverage for breast, cervical and colorectal cancer screening programmes, by type, target population, and Member State
  11. Percentage of population covered by Cancer Registries and number of Member States reporting information on cervical, breast, colorectal and paediatric cancer stage at diagnosis
  12. Number of actions addressing the prevalence of major chronic diseases per Member State, by disease, gender and age
  13. Number of actions addressing the age prevalence of tobacco use, if possible differentiated by gender
  14. Number of actions addressing the prevalence of harmful use of alcohol, if possible differentiated by gender and age
  15. Number of shortages of medicinal products in the Member States as reported through the single point of contact network
  16. Number of actions aimed at increasing the security and continuity of the global supply chains and addressing dependence on imports from third countries for the production of essential active pharmaceutical ingredients and medicinal products in the Union
  17. Number of audits conducted in the Union and in third countries to ensure good manufacturing practices and good clinical practices (Union control)
  18. Antimicrobial consumption for systemic use ATC (group J01) per Member State
  19. Number of healthcare units involved in ERNs and of patients diagnosed and treated by the members of ERNs
  20. Number of HTA reports jointly carried out
  21. Number of health impact assessments of Union policies
  22. Number of actions addressing the fight against communicable diseases
  23. Number of actions addressing environmental risk factors for health
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