

Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on the establishment of a Programme for the Union's action in the field of health –for the
period 2021-2027 and repealing Regulation (EU) No 282/2014 (“EU4Health Programme”)
(Text with EEA relevance)

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 Committee¹,
Having regard to the opinion of the Committee of the Regions²,
Acting in accordance with the ordinary legislative procedure³,

Whereas:

- (1) According to Article 3(1) of the Treaty on the European Union, amongst 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 (the Charter), a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities.

¹ OJ C [...], [...], p. [...].

² OJ C [...], [...], p. [...].

³ Position of the European Parliament of and decision of the Council of

- (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, while fully respecting 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.
- (4) Continued actions provided for by Decisions No 1786/2002/EC⁴ and No 1350/2007/EC⁵ of the European Parliament and of the Council and Regulation (EU) No 282/2014 of the European Parliament and of the Council⁶ have been taken in particular under the previous programmes of Union action in the field of public health to meet the requirements set out in Article 168 TFEU.
- (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, particularly affecting people with chronic conditions.
- (5a) Staff in health care settings have been essential during the COVID-19 crisis and have been exposed to great health risks.
- (5b) It should be possible to support studies on the influence of gender on the characteristics of diseases in order to contribute to improve knowledge and education in this area, thereby strengthening prevention, diagnoses, monitoring and treatment.

⁴ 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).

⁵ 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 (2008-2013).

⁶ 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).

- (6) While Member States are responsible for their health policies, they should protect public health in a spirit of European solidarity⁷. 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. This cooperation should improve the preparedness, prevention and control of the spread of severe human infections and diseases across borders, 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. Member States should be given the possibility to carry 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 the Union's action in the field of health, called EU4Health Programme ('the Programme') for the period 2021 - 2027. In line with the goals of the Union action and its competences in the area of public health the Programme should place emphasis on actions in relation to which there are advantages and efficiency gains from collaboration and cooperation at Union level and actions with an impact on the internal market.
- (7a) The Programme should be a means of promoting actions in areas where there is a Union added value that can be demonstrated. Such actions include, inter alia, strengthening the exchange of best practices between Member States, supporting networks for knowledge sharing or mutual learning, addressing cross-border threats to health to reduce their risks and mitigate their consequences, addressing certain issues relating to the internal market where the Union can achieve Union-wide high-quality solutions, unlocking the potential of innovation in health, and improving efficiency by avoiding 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 support to Member States, or groups of Member States, with the highest needs.

⁷ Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak COM(2020)112 final of 13.03.2020.

- (8) 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 between the European Parliament, the Council and the Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management for the European Parliament and the Council during the annual budgetary procedure⁸. This financial envelope comprises an amount of EUR 500 000 000 in 2018 prices in line with the joint declaration of the European Parliament, Council and Commission on the reinforcement of specific programmes and adaptation of basic acts of [date]⁹.
- (8a) In order for the Programme to be balanced and focused, minimum and maximum shares of the overall budget should be laid down in this act, for certain areas of action, with a view to providing guidance for the allocation of resources in relation to the implementation of the Programme.

⁸ [reference to be added]

⁹ [reference to be added]

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage any future health crises, the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council¹⁰ and other relevant the mechanisms and structures outlined in the Communication “Building a European Health Union: Reinforcing the EU’s resilience for cross-border health threats”, including those directed at strengthening preparedness planning and response capability at national and European level, at reinforcing the role of the ECDC and the EMA, and at establishing a Health Emergency Preparedness and Response Authority. This could include capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes, health information, and platforms to share best practices. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union and Member States level, including contingency planning and preparedness exercises, in keeping with the “One Health” and “Health in all policies” approaches. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis, *i.e.* prevention, preparedness and response.

(10a) With a view to strengthen the capability in the Union to prevent, prepare for, respond to and manage health crises, the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under relevant EU legislation. This could include capacity building in crisis response, including contingency planning and preparedness, preventive measures such as those related to vaccination and immunisation, and strengthened surveillance programmes and improved coordination and cooperation.

¹⁰ Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2010, p. 1)

- (11) In the context of public health crises, clinical trials and Health Technology Assessment (HTA) can contribute to speed up development and identification of effective medical countermeasures. It should therefore be possible to provide support to facilitate actions in these fields through the Programme.
- (12) With a view to protect people in vulnerable situations, including those suffering from mental illnesses, 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 impacts of health crises on people belonging to such vulnerable groups and improve mental health.
- (13) The COVID-19 crisis has highlighted many challenges, including the Union's dependency 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 therefore should provide support to actions which foster the production, procurement and management of crisis relevant products within the Union, ensuring complementarity with other Union instruments, to mitigate the risk of shortages.
- (14) In order to minimise the public health consequences of serious cross-border threats to health, it should be possible for actions supported under the Programme to improve the interoperability of Member States' health systems through cooperation and exchange of best practices also via an increased number of joint actions. Those actions should ensure that Member States are able to respond to health emergencies, which includes undertaking contingency planning, preparedness exercises and the upskilling of healthcare and public health workforce as well as the establishment, according to national strategies, of mechanisms for the efficient monitoring and needs-driven distribution or allocation of goods and services needed in times of crisis.

- (14a) The provision of information to individuals plays an important role in the prevention and response to diseases. The programme should therefore support communication activities addressed to the general public or specific groups of citizens or professionals, to promote disease prevention and healthy lifestyle, to counter misinformation and disinformation as regards to prevention, cause and treatment of diseases, to address vaccine hesitancy and to support efforts to strengthen altruist behaviour, such as organ and blood donations, in complementarity with national campaigns on those matters.
- (15a) In synergy with other Union programmes, such as the Digital Europe Programme, Horizon Europe, the European Regional Development Fund, the European Social Fund+, InvestEU and the Recovery and Resilience Facility, actions which advance digital transformation of health services and increase their interoperability, including the development of a European health data space, could be supported under the Programme.
- (16) 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 health systems and budgets. The Programme should also support action 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 help Member States to reach the sustainable development targets set in the 'UN 2030 Agenda for Sustainable Development' in particular Sustainable Development Goal 3 "Ensure healthy lives and promote well-being for all at all ages"¹¹. The Programme therefore should contribute to the actions taken towards reaching these goals.

¹¹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Next steps for a sustainable European future European action for sustainability COM (2016) 739 final of 22.11.2016.

- (17) Non-communicable diseases are often a combination of genetic, physiological, environmental and behavioural factors. Non-communicable diseases, such as cardiovascular diseases, cancer, mental illnesses, neurological disorders, chronic respiratory diseases and diabetes, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, and cause considerable social and economic impact. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, particularly but not exclusively Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on health promotion and disease prevention across sectors.
- (18) The Programme should therefore 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 the Sustainable Development Goal 3 “Ensure healthy lives and promote well-being for all at all ages” of the 'UN 2030 Agenda for Sustainable Development'¹². The Programme should also therefore contribute to the objectives of the European Green Deal.
- (18a) The Programme should continue to support actions in the area of reducing and preventing alcohol-related harm, with particular emphasis on protecting the young.
- (18b) The burden of chronic diseases is significant in the Union. It is well acknowledged that prevention and early detection are important. The Programme should support actions in this area and should support the development of specific European preventive and disease management guidelines in the Union and therefore aiming at reducing the burden of Member States by working together to achieve a better and more effective management of chronic diseases. Demographic changes, in particular the ageing society, challenge the sustainability of health systems. Moreover, age-related diseases and disorders, such as dementia, and age-related disabilities, call for specific attention.

¹² Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Next steps for a sustainable European future. European action for sustainability COM (2016) 739 final of 22.11.2016.

- (19) Cancer is the second leading cause of mortality in the Member States after cardiovascular diseases. 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 and harmful use of alcohol are risk factors common to other chronic diseases, such as cardiovascular diseases, and therefore cancer prevention programmes should be implemented within the context of an integrated chronic disease prevention approach. Relevant measures in the announced ‘Europe’s Beating Cancer Plan’ should benefit from the Programme and from Horizon Europe’s Mission on Cancer, and contribute to foster 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.
- (20) The Programme should work in synergy and complementarity with other EU policies, programmes and funds such as actions implemented under the Digital Europe Programme, Horizon Europe, rescEU reserve under the Union Civil Protection Mechanism, Emergency Support Instrument, European Social Fund+ (ESF+, including as regards synergies on better protecting the health and safety of millions of workers in the EU), including the Employment and Social Innovation Strand (EaSI), the InvestEU fund, the Single Market Programme, the European Regional Development Fund (ERDF), the Recovery and Resilience Facility including the Reform Delivery Tool, Erasmus, the European Solidarity Corps, and EU external action instruments, such as the Neighbourhood, Development and International Cooperation Instrument and the Instrument for Pre-accession Assistance III. Where appropriate, common rules will be established in view of ensuring consistency and complementarity between funds, while making sure that specificities of these policies are respected, and in view of aligning with the strategic requirements of these policies, programmes and funds, such as the enabling conditions under ERDF and ESF+. The Commission and the Member States should ensure such synergies and complementarities when drafting the annual work programmes as set out in this Regulation.
- (20a) The Commission should consult the Member States in the EU4Health Steering Group on the priorities and strategic orientations, in order to ensure the consistency and complementarity between the Programme and other policies, instruments and actions of the Union, as well as on the Programme's implementation.

- (20aa) The Programme should contribute to the establishment of a reserve of essential crisis relevant products, in synergy and complementarity with rescEU, the Emergency Support Instrument, the Resilience Instrument and with other Union policies, programmes and funds, complementing national stockpiling on Union level where needed.
- (21) Given the rising healthcare demand, Member States' healthcare systems face challenges in the availability and affordability of medicinal products. To ensure a better public health protection, as well as the safety and empowerment of patients in the Union, it is essential that patients and health systems have access to sustainable, efficient, equitable, affordable and high quality medicinal products, including in a cross-border context, and can fully benefit from them, based on transparent, consistent, patient-oriented medical information.
- (22) With regard, inter alia, to the rising healthcare demand, the Programme should support the development of a European monitoring, reporting and notification system for shortages of medicinal products and medical devices, to avoid fragmentation of the single market and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains 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 clinical and real world evidence generation to enable the development, authorisation, evaluation of and access to effective medicinal products, including generics and biosimilars, and medical devices, and treatment, promote research and the development of new medicinal products, with particular attention to be given to antimicrobials and vaccines to tackle AMR and vaccine-preventable diseases, promote incentives to boost the production capacity for antimicrobials, personalised treatment and vaccination, and foster the digital transformation of healthcare products and platforms for monitoring and collecting information on medicinal products. The Programme should also strengthen decision-making on medicinal products by enabling access to and analysis of real-world healthcare data. The Programme should also help to ensure best use of research results and facilitate the uptake, scaling-up and deployment of health innovation in healthcare systems and clinical practice.

- (23) 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 and in line with the European One Health Action Plan against Antimicrobial Resistance set out in the communication of the Commission of 29 June 2017 entitled ‘A European One Health Action Plan against Antimicrobial Resistance (AMR)’¹³, and the European Union Strategic Approach to Pharmaceuticals in the Environment set out in the communication of the Commission of 11 March 2019 entitled ‘European Union Strategic Approach to Pharmaceuticals in the Environment’¹⁴ and foster measures to strengthen the assessment and appropriate management of environmental risks associated with the production, use and disposal of medicinal products.
- (25) The Union health legislation has an immediate impact on public health, the lives of citizens, the efficiency and resilience of the health systems and the good functioning of the internal market. The regulatory framework for medical products and technologies (medicinal products, medical devices and substances of human origin), as well as for tobacco legislation, patients’ rights in cross-border healthcare and serious cross-border threats to health is essential to health protection in the Union. The Programme therefore should support the development, implementation and enforcement of Union health legislation and, in conjunction with relevant bodies such as EMA and ECDC, provide high quality, comparable and reliable data, including real-world healthcare data, to underpin policymaking and monitoring, set targets and develop tools to measure progress.

¹³ Communication from the Commission to the Council and the European Parliament ‘A European One Health Action Plan against Antimicrobial Resistance (AMR)’ COM(2017)0339 final of 29.6.2017.

¹⁴ Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee ‘European Union Strategic Approach to Pharmaceuticals in the Environment’ COM(2019)128 final of 11.03.2019.

- (26) Cross-border cooperation in the provision of healthcare to patients moving between Member States and European Reference Networks (ERNs) 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 on Health Technology Assessments (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, which also serves to foster the implementation of best practices that are aimed at distributing in the most effective way the available resources to the concerned population and areas so as to maximise their impact.
- (27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council¹⁵ are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should contribute to the upscaling of networking through the ERNs, and other transnational networks.
- (28) Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council¹⁶ (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, budgetary guarantees, financial assistance and the reimbursement of external experts.

¹⁵ 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).

¹⁶ 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).

- (29) The types of financing and the methods of implementation under this Regulation should be chosen on the basis of their ability to achieve the specific objectives of the actions and to deliver results, taking into account, in particular, the costs of controls, the administrative burden, and the expected risk of non-compliance. This should include consideration of the use of lump sums, flat-rates 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 ensure compliance with applicable financial provisions while minimising administrative burden.
- (30) In order to optimise the added value and impact from investments funded wholly or in part through the budget of the Union, synergies should be sought in particular between the Programme for the Union's action in the field of health and other Union programmes, including those under shared-management. To maximise those synergies, and avoid duplications, key enabling mechanisms should be ensured, including cumulative funding in an action from the Programme for the Union's action in the field of health and another Union programme, as long as such cumulative funding does not exceed the total eligible costs of the action. For that purpose, this Regulation should set out appropriate rules, in particular on the possibility to declare the same cost or expenditure on a *pro-rata* basis to Programme for the Union's action in the field of health and another Union programme, guaranteeing detailed and transparent reporting.
- (31) Given the specific nature of the objectives and actions covered by the Programme, the respective competent authorities of the Member States are best placed in some cases to implement activities related to the Programme. Those authorities, designated by the Member States themselves, should therefore be considered to be identified beneficiaries for the purpose of Article 195 of the Financial Regulation and the grants should therefore be awarded to such authorities without prior publication of calls for proposals. Investments from the Programme should be implemented in close cooperation with Member States.

- (31aa) In accordance with Article 193(2) of Regulation (EU, Euratom) No 2018/1046, a grant may be awarded for an action, which has already begun, provided that the applicant can demonstrate the need for starting the action prior to signature of the grant agreement. However, the costs incurred prior to the date of submission of the grant application are not eligible, except in duly justified exceptional cases. In order to avoid any disruption in Union support which could be prejudicial to Union's interests, it should be possible to provide in the financing decision, during a limited period of time at the beginning of the multi-annual financial framework 2021-2027, and only in duly justified cases, for eligibility of activities and costs from the beginning of the 2021 financial year, even if they were implemented and incurred before the grant application was submitted.
- (32) The ERNs are approved by the Board of Member States of the European Reference Networks, following the approval procedure set out in Commission Implementing Decision 2014/287/EU of 10 March 2014¹⁷. ERNs should therefore be considered to be identified beneficiaries for the purpose of Article 195 of the Financial Regulation, and the grants to the 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).
- (33) Given the common agreed values of solidarity towards equitable and universal coverage of quality health services as a basis for the Union's policies in this area and that the Union has a central role to play in accelerating progress, coordination and cooperation in tackling global health challenges¹⁸, as expressed in the sustainable development goals, the Programme should reinforce the Union's support to international and global health initiatives, in particular by the World Health Organization (WHO), with a view to improve health, address health inequalities and strengthen protection against global health threats.

¹⁷ 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).

¹⁸ Council conclusions on the EU role in Global Health, 3011th Foreign Affairs Council meeting, 10 May 2010.

- (34) In order to maximise the effectiveness and efficiency of actions at Union and international level, cooperation should be developed with relevant international organisations such as the United Nations and the World Bank, as well as with the Council of Europe and the Organisation for Economic Co-operation and Development (OECD) in implementing the Programme. Synergies should also be sought with the national organisations of Member States active in global health to increase impact. Pursuant to Council Decision 2013/755/EU¹⁹, persons and entities established in Overseas Countries and Territories (OCTs) are eligible for funding subject to the rules and objectives of the Programme and possible arrangements applicable to the Member State to which the relevant OCTs are linked.
- (34a) 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 once a year seek feedback from relevant stakeholders, including representatives of civil society and patients' associations, academics, healthcare professionals' societies, on the programme's priorities and strategic orientations and on the needs to be addressed through its actions. Each year, the Commission should also, before the end of the preparatory work for the work programmes, inform the European Parliament on progress of such preparatory work and on the outcome of its outreach activities towards stakeholders.
- (35) 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 Area²⁰, 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 European Court of Auditors (ECA) to comprehensively exercise their respective competences.

¹⁹ 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).

²⁰ OJ L 1, 3.1.1994, p. 3.

- (36) 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.
- (37) In accordance with the Financial Regulation, Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council²¹, Council Regulations (EC, Euratom) No 2988/95²², (Euratom, EC) No 2185/96²³ and (EU) 2017/1939²⁴, 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 Council 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 Council²⁵.
- (38) In accordance with the Financial Regulation, any person or entity receiving Union funds is to fully cooperate in the protection of the financial interests of the Union, grant the necessary rights and access to the Commission, OLAF, the European 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.

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

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

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

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

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

- (39) Horizontal financial rules adopted by the European Parliament and the Council on the basis of Article 322 TFEU apply to this Regulation. These rules are laid down in the Financial Regulation and determine in particular the procedure for establishing and implementing the budget through grants, procurement, prizes, indirect implementation, and provide for checks on the responsibility of financial actors. Rules adopted on the basis of Article 322 TFEU also include a general regime of conditionality for the protection of the Union budget.
- (40) Reflecting the importance of tackling climate change in line with the Union's commitments to implement the Paris Agreement and the United Nations Sustainable Development Goals, this Programme will contribute to mainstream climate action in the Union's policies and to the achievement of an overall target of at least 30 % of the total amount of the Union budget and the EU Recovery Instrument expenditures, supporting climate objectives. The instrument should support activities that would respect the climate and environmental standards and priorities of the Union and the “do no harm” principle of the European Green Deal. Relevant actions will be identified during the Programme's preparation and implementation, and reassessed in the context of its mid-term evaluation.
- (40a) According to Article 8 of the Treaty on the Functioning of the European Union, 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 these objectives should be taken into account and promoted throughout the assessment, preparation, implementation and monitoring of the programme.
- (41) The policy objectives of the Programme may also be addressed through financial instruments and budgetary guarantees under the InvestEU Fund. 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 a Union added value.

- (42) The implementation of the Programme should be such that the responsibilities of the Member States, for the definition of their health policy and for the organisation and delivery of health services and medical care, are respected. Strong involvement of Member States in the governance and implementation of the programme should be ensured.
- (43) Given the nature and potential scale of cross-border threats to human health, the objective of protecting people in the Union from such threats and to increase crisis prevention and preparedness cannot be sufficiently achieved by the Member States acting alone. In accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union, action at Union level can also be taken to support Member States' efforts in the pursuit of a high level of protection of public health, to improve the availability, sustainability, acceptability, accessibility, safety and affordability in the Union of medicinal products, medical devices and health crisis relevant products and services, to support innovation and to support integrated and coordinated work and implementation of best practices among Member States and to address inequalities and inequities in access to health throughout the EU in a manner that creates efficiency gains and value-added impacts that could not be generated by action taken at national level, while respecting the Member States' competence and responsibility in the areas covered by the Programme. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (44) In order to allow for possible adjustments necessary to achieve the Programme's objectives, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the review, amendment and addition of the indicators set out in Annex II to this Regulation. When exercising these delegated powers, it is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016²⁶. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council are to receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

²⁶ OJ L 123, 12.5.2016, p. 13.

- (44a) Member States 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) and, where relevant, in the dissemination of its results and the available information on its impact in their respective countries. It is appropriate to support such activities under the Programme with the aim of continuing those important activities.
- (45) 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 Council²⁷. The examination procedure should be used for the adoption of those implementing acts given that they relate to a programme with substantial implications.
- (45a) 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 longer period 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.
- (46) As the third Programme for the Union's action in the field of health (2014-2020), established by Regulation (EU) No 282/2014, comes to an end, that Regulation becomes obsolete and should be repealed.

²⁷

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

(47) In order to ensure continuity in providing support in the field of health and to allow implementation as of the beginning of the multi-annual financial framework 2021-2027, it is necessary to provide for the application of this Regulation from the beginning of the 2021 financial year.

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 (MFF) 2021 to 2027. The duration of the Programme is aligned with the duration of the MFF.

It 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 allowing for its participation in the Programme, in accordance with Article 7;
- (2) ‘blending operation’ means actions supported by the Union budget, including within blending facilities pursuant to Article 2(6) of Regulation (EU, Euratom) No 2018/1046, combining non-repayable forms of support and/or financial instruments from the Union budget with repayable forms of support from development or other public finance institutions, as well as from commercial finance institutions and investors;
- (3) ‘health crisis’ means any crisis or serious incident arising from a threat of human, animal, plant, food, chemical, biological or environmental or unknown origin, having a public health dimension and which requires urgent action by authorities;

- (4) 'crisis relevant products' means products, tools and substances necessary, in the context of a health crisis, to prevent, diagnose or treat a disease and its consequences, and 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; 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 raw materials necessary for their production;
- (5) The 'One Health approach' is a multi-sectoral 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 these three dimensions;
- (6) 'European Reference Networks' means the networks referred to in Article 12 of Directive 2011/24;
- (7) 'legal entity' means any natural or legal person created and recognised as such under national law, Union law or international law, which has a legal personality and which may, acting in its own name, exercise rights and be subject to obligations, or an entity without legal personality as referred to in Article 197(2)(c) of Regulation (EU, Euratom 2018/1046);
- (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;

- (9a) ‘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;
- (9b) ‘health determinants’ means a range of factors, such as behaviour-related, biological, socio-economic and environmental factors, that influence the health status of a person;
- (10) ‘emergency support’ means a needs-based emergency response, which complements the response of the affected Member States and which 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 referred to in point (2) of Article 3.

Article 3

General objectives

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

- (1) improving and fostering health in the Union, by supporting health promotion and disease prevention, by reducing health inequalities, by fostering healthy lifestyles and by promoting access to healthcare, to reduce the burden of communicable and non-communicable diseases;
- (1a) 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 to cope with those threats;
- (2) improving the availability, accessibility and affordability of medicinal products and medical devices as well as crisis relevant products, in the Union, and supporting innovation regarding such products;

- (3) strengthening health systems by improving their resilience and resource efficiency, in particular through:
- supporting integrated and coordinated work between Member States;
 - promoting the implementation of best practices data sharing;
 - reinforcing the healthcare workforce;
 - tackling the implications of demographic challenges; and
 - 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:

- (1) supporting actions for disease prevention, health promotion and addressing health determinants, including by reduction of health damage due to illicit drug use and addiction, actions to address inequalities in health, improve health literacy, improve patient rights and patient safety, quality of care and cross-border healthcare, and actions for the improvement of the surveillance, diagnosis and treatment of communicable and non-communicable diseases, notably cancer and paediatric cancer in synergy with other relevant Union actions, as well as actions to improve mental health, with special attention to new care models and the challenges of long term care, in order to strengthen the resilience of the health systems in the Union;
- (2) strengthening the capability of the Union for prevention, preparedness and rapid response to serious cross-border threats to health in accordance with relevant EU legislation and improving the management of health crises, particularly through the coordination, provision and deployment of emergency healthcare capacity, supporting to data gathering, information exchange, surveillance and the coordination of voluntary stress testing of national healthcare systems and the development of quality healthcare standards at national level;

- (3) supporting actions to enhance the availability, accessibility and affordability of medicinal products and medical devices as well as crisis relevant products, by encouraging sustainable production and supply chains as well as innovation in the Union, while supporting the prudent and efficient use of medicinal products, in particular of antimicrobials, and support the development of medicinal products that are less harmful for the environment, as well as the environmental-friendly production and disposal of medicinal products and medical devices;
- (4) in synergy with other Union instruments, programmes and funds, without prejudice to Member State competences, in close cooperation with relevant Union bodies, support actions complementing national stockpiling of essential crisis relevant products at Union level, where needed;
- (5) 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 case of a health crisis;
- (6) strengthening the use and re-use of health data for the provision of healthcare and for research and innovation, advance 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;
- (7) enhancing access to quality, patient-centred, outcome-based healthcare and related care services, with the aim to achieve universal health coverage;
- (8) supporting the development, implementation and enforcement and, when 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;

- (9) supporting integrated work among Member States, and in particular their health systems, including the implementation of high-impact prevention practices, support work on HTA, and strengthen and scale up networking through the ERNs and other transnational networks, also outside the area of rare diseases, to increase the coverage of patients and the response to low prevalence and complex communicable and non-communicable diseases;
- (10) supporting global commitments and health initiatives by reinforcing the Union's support to actions by international organisations, in particular the World Health Organization (WHO), and foster 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.
 - 1a. As a result of the Programme specific adjustment provided for in Article 5 of Council Regulation (EU, Euratom) [20XX/XXXX (the MFF regulation)] the amount referred to in paragraph 1 shall be increased by an additional allocation of EUR 2 900 000 000 in 2018 prices as specified in Annex II to that Regulation.
2. The amount referred to in paragraph 1 and paragraph 1a may be also 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.
 - 2a. The distribution of the amounts referred to in paragraph 1 and 1a shall comply with the following:
 - (a) A minimum of 20% of the amounts shall be reserved for health promotion and disease prevention measures referred to in point 1 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, referred to in point 4 of Article 4.
 - (c) A maximum of 12.5% of the amounts shall be reserved for supporting global commitments and health initiatives referred to in point 10 of Article 4.
 - (d) A maximum of 8% of the amounts shall be reserved for covering administrative expenses referred to in paragraph 2.
3. Appropriations related to activities under point (c) of Article 10(1) of this Regulation, shall constitute assigned revenue within the meaning of point (a) of paragraph 3 and paragraph 5 of Article 21 of Regulation (EU, Euratom) 2018/1046.
 4. The budgetary commitments extending over more than one financial year, may be broken down over several years into annual instalments.
 5. In accordance with point (a) of the second subparagraph of Article 193(2) of Regulation (EU, Euratom) No 2018/1046, in duly justified cases specified in the financing decision and for a limited period, activities supported under this Regulation and the underlying costs may be considered eligible as of 1 January 2021, even if they were implemented and incurred before the grant application was submitted.
 6. If necessary, appropriations may be entered in the budget beyond 31 December 2027 to cover the expenses referred to in paragraph 2 to enable the management of actions not completed by 31 December 2027.

Article 7

Third countries associated to the Programme

The Programme shall be open to the following associated countries:

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

- (2) Accessing countries, candidate countries and potential candidates, in accordance with the general principles and general terms and conditions for the participation of those countries in Union programmes established in the respective framework agreements and Association Council decisions, or similar agreements, and in accordance with the specific conditions laid down in agreements between the Union and those countries;
- (3) Countries covered by the European Neighbourhood Policy, in accordance with the general principles and general terms and conditions for the participation of those countries in Union programmes established in the respective framework agreements and association council decisions, or similar agreements, and in accordance with the specific conditions laid down in agreements between the Union and those countries;
- (4) Third countries, in accordance with the conditions laid down in a specific agreement covering the participation of the third country to any 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 programmes;
 - (ii) lays down the conditions of participation in the programmes, including the calculation of financial contributions to individual programmes and their administrative costs.
These contributions shall constitute assigned revenues in accordance with Article 21(5) of Regulation (EU, Euratom 2018/1046);
 - (iii) does not confer to the third country a decisional power in respect of the programme;
 - (iv) guarantees the rights of the Union to ensure sound financial management and to protect its financial interests.

Chapter II

FUNDING

Article 8

Implementation and forms of Union funding

1. The Programme shall be implemented in direct management in accordance with Regulation (EU, Euratom) 2018/1046 or in indirect management with the bodies referred to in point (c) of Article 62(1) of that Regulation.
2. The Programme may provide funding in any of the forms laid down in Regulation (EU, Euratom) 2018/1046, 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 Regulation (EU, Euratom) 2018/1046. The Commission shall lay down specific rules for the operation of the mechanism.
4. Where the Commission implements emergency support operations through non-governmental organisations, the criteria concerning financial and operational capacity shall be deemed to be satisfied if there is a framework partnership agreement in force between that organisation and the Commission pursuant to Regulation (EC) No 1257/96.

Article 9

Grants

1. Grants under the Programme shall be awarded and managed in accordance with Title VIII of Regulation (EU, Euratom) 2018/1046.
2. Grants may be used in combination with financing from the European Investment Bank, national promotional banks or other development and public financial institutions, as well as in combination with financing from private-sector finance institutions and public 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. For the actions having a clear Union added value exceptional utility is achieved, *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, out 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 14(6) and (6a), the eligible costs may be up to 100%.

Article 10

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 a situation of public health emergency has been recognised under Article 12 of Decision No 1082/2013/EU, 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 Regulation (EU, Euratom) 2018/1046 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 a procurement procedure as referred to in point (b) of paragraph 1, the ensuing contracts shall be concluded by either of the following:
 - (a) by the Commission whereby the services or goods are to be rendered or delivered to Member States or to partner organisations selected by the Commission;
 - (b) by the participant Member States whereby they are to directly acquire, rent or lease the capacities procured for them by the Commission.

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

Article 11

Blending operations

Blending operations under the Programme shall be implemented in accordance with the {reference to the InvestEU Regulation} and Title X of Regulation (EU, Euratom) 2018/1046.

Article 12

Cumulative funding

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

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

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

Chapter III

ACTIONS

Article 13

Eligible actions

Only actions 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 14

Eligible entities

1. In order to be eligible for funding, legal entities shall, in addition to the criteria set out in Article 197 of Regulation (EU, Euratom) 2018/1046:
 - (a) be established in any of the following countries:
 - (i) a Member State or an overseas country or territory linked to it;
 - (ii) a third country associated to the Programme; or
 - (iii) a third country listed in the work programme under the conditions specified in paragraph 2 and 3; or
 - (b) any legal entity created under Union law or any 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 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 are not 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 responsible for health in the Member States or in the third countries associated to the Programme, by relevant international health organisations by public sector bodies and non-governmental bodies, acting individually or as a network, that are mandated by those competent authorities.
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.
- 6a. Under the Programme, direct grants may be awarded without a call for proposals to fund actions of the World Health Organization where financial support is necessary for the implementation of one or more of the specific objectives of the Programme which have a Union added value that is explicitly provided for in the annual work programmes.
7. Under the Programme, grants may be awarded without a call for proposals to fund the functioning of non-governmental bodies where financial support is necessary for the implementation of one or more of the specific objectives of the Programme which have a Union added value that is explicitly provided for in the annual work programmes, as long as those bodies fulfil all the following criteria:
 - (i) they are non-governmental, non-profit-making and independent of industry, commercial and business or other conflicting interests;
 - (ii) they work in the public health area, pursue at least one of the specific objectives of the Programme and play an effective role at Union level;
 - (iii) they are active at Union level and in at least half of the Member States, and have a balanced geographical coverage of the Union.

The analysis of the fulfilment of those criteria shall be duly reflected in the funding decision.

Article 15

Eligible costs

1. Subject to Article 186 of Regulation (EU, Euratom) 2018/1046, and point (a) of the second subparagraph of Article 193 of that Regulation, costs incurred prior to the date of submission of the grant application shall be eligible for funding for actions:
 - (a) implementing the objective referred to in point (1a) of Article 3 of this Regulation; or
 - (b) implementing other objectives, in duly justified exceptional cases, provided that those costs are directly linked to the implementation of the supported actions and activities.
2. The costs under point (a) of paragraph 1 of this Article, that related to measures aiming to address suspected occurrences of a disease that could trigger a cross-border health threat, shall be eligible from the date of notification of the suspected occurrence of the disease to the Commission, provided that the occurrence or presence of the disease is subsequently confirmed.
3. In exceptional cases, during a crisis caused by a serious cross-border health threat as defined in Article 3(g) of Decision 1082/2013/EU, costs incurred by entities established in non-associated countries may be considered eligible if those costs are duly justified for reasons of countering the spread of the risk for the protection of the health of people in the Union.

**CHAPTER IV
GOVERNANCE**

Article 16

Joint policy implementation

1. A EU4Health Steering Group is hereby established.
2. The Members of the EU4Health Steering Group are the Commission and the Member States. Each Member State shall appoint one member and one alternate to the EU4Health Steering Group. The Commission shall provide the secretariat of the EU4Health Steering Group.

3. The Commission shall:
 - (a) consult the EU4Health Steering Group on the Commission's preparatory work for the work programmes referred to in Article 16a(1);
 - (b) each year, at least 6 months in advance of the presentation to the EU4Health Programme Committee of the draft work programme referred to in Article 16a(1), consult the Steering Group on the priorities and strategic orientations of the annual work programme.

4. The Steering Group shall:
 - (a) work towards ensuring consistency and complementarity between the Member States' health policies as well as 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 where appropriate physically at least three times a year, thus allowing for a regular and transparent exchange of views among Member States.

Article 16aa

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 annual work programme's priorities and strategic orientations;
 - (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 in Article 23.

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. Every year the Commission shall present to the European Parliament, prior to the last meeting of the Steering Group, referred to in Article 16, the outcome of the proceedings of the EU4Health Steering Group and the consultation of stakeholders referred to in paragraphs 1 and 2.

Article 16a

Implementation of the Programme

1. The Commission shall implement the Programme by establishing annual work programmes in accordance with Regulation (EU, Euratom) 2018/1046.
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 the cases referred to in Article 8(3) and (4);
 - (iv) eligible actions by legal entities created under Union or international law;
 - (v) eligible actions by legal entities from a third country not associated to the Programme but listed in the work programme under the conditions specified in Article 14 (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.

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

Article 16b

Data Protection

In managing and implementing the Programme, the Commission and the Member States shall ensure compliance with all relevant legal provisions regarding personal data protection and, where appropriate, the introduction of mechanisms to ensure the confidentiality and safety of such data.

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 set out in Articles 3 and 4 are set out in Annex II.
2. The Commission is empowered to adopt delegated acts in accordance with Article 24 concerning amendments to Annex II to amend and supplement the indicators where considered necessary.
3. The performance reporting system shall ensure that data for monitoring programme implementation and results are collected efficiently, effectively, and in a timely manner. To that end, the Commission shall adopt implementing acts establishing proportionate reporting requirements imposed on recipients of Union funds and, where relevant, on Member States.

Article 20

Evaluation

1. Evaluations in accordance with Article 34 (3) of Regulation (EU, Euratom) 2018/1046 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 four years after the date of application of this Regulation. The interim evaluation shall be the basis for adjusting the implementation of the Programme as appropriate.
3. The Commission shall present an evaluation at the end of the Programme and no later than four years after the end of the period specified in Article 1.
4. The Commission shall publish, 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 the Union contribution that are carried out by persons or entities, including 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 Regulation (EU, Euratom) 2018/1046.

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 ECA 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~~ the 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 23a

Consistency and complementarity with other policies, instruments and actions

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

Article 24

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 19(2) shall be conferred on the Commission until 31 December 2028.

3. The delegation of power referred to in Article 19(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 19(2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

CHAPTER VI
TRANSITIONAL AND FINAL PROVISIONS

Article 24a

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 25

Repeal

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

Article 26

Transitional provisions

1. This Regulation shall not affect the continuation or modification of the actions, 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 Programme and the measures adopted under Regulation (EU) No 282/2014.

Article 27

Entry into force

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

It shall apply from 1 January 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament

The President

For the Council

The President

ANNEX I

LIST OF POSSIBLE ELIGIBLE ACTIONS PROVIDED FOR IN ARTICLE 13

1. **Actions meeting the objective laid down in Article 4(1)**
 - (a) Supporting the establishment and implementation of programmes assisting Member States and their actions to improve health promotion and disease prevention;
 - (b) Supporting the implementation and advancement 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 health damage 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; support the revision of the current edition of the European Code against Cancer;
 - (k) Action to support the implementation of cancer registries in all Member States;

- (l) Further the cooperation of relevant national bodies from participating Member States with a view to support the creation of a virtual European network of excellence in order to strengthen research on all types of cancer including paediatric cancer, 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 in cancer care including prevention, screening, early diagnosis, monitoring and treatment, supportive and palliative care, in an integrative and patient-centred approach and the establishment of quality assurance schemes for cancer centres or other centres treating cancer patients, including those treating paediatric cancer;
- (n) Support the establishment of quality assurance schemes for cancer centre 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 care givers, including provision of psychological support, pain management and health-related aspects of professional re-integration;
- (q) Strengthening collaboration on patient rights, patient safety and quality of care.
- (r) Support action regarding epidemiological surveillance, thus contributing to assessment of factors that affect or determine the health of citizens;
- (s) Supporting, in synergy with other programmes, actions to improve the geographical distribution of healthcare workforce and avoidance of ‘medical deserts’, without prejudice to Member States’ competences;
- (t) Supporting the development of guidelines for preventing and managing diseases in the area of both 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 addressed to citizens and stakeholders to promote Union action in the areas mentioned in this Annex;
- (y) Awareness-raising campaigns and communications activities for the general population as well as for targeted groups aimed at preventing and addressing vaccine hesitancy, misinformation and disinformation as regards to prevention, causes and treatment of diseases, in complement to national campaigns and communications activities on those matters;
- (z) Communication to citizens 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 Article 4(2)

- (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, preparedness, management and response capacity of actors at Union and national level, including voluntary stress tests, contingency planning, preparedness exercises, supporting the development of quality health standards at national level, mechanisms for the efficient coordination of preparedness and response and 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 - *i.e.* 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 crisis to the needs of those vulnerable groups, such as securing basic care for chronic and rare diseases patients;
- (e) Supporting actions to address the collateral health consequences of a health crisis, in particular the consequences for mental health, on and 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 and Centres, Centres of Excellence;
- (h) Auditing Member States' preparedness and response arrangements (such as crisis management, antimicrobial resistance, vaccination);
- (i) Communicating to citizens in the context of risk management and 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) Actions to support investigation, risk assessment and risk management work on the link between animal health, environmental factors, and human diseases, including during health crises.

3. Actions meeting the objective laid down in Article 4(3)

- (a) Supporting actions to strengthen the production, research, development, laboratory capacity, production 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 action 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 environmental-friendly production and disposal of medicinal products and medical devices and 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 APIs and medicinal products in the Union, including by diversifying supply chain production of active ingredients and generics within the Union to reduce the 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) Action 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 Article 4(4)

- (a) Monitoring of information of national stockpiling activities of 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 complementarity with 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 and contribute to their affordability, in complementarity to the Member States' stockpiling actions.

5. Actions meeting the objective laid down in Article 4(5)

- (a) 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 case of a health crisis, in close collaboration with the ECDC, in synergy with other EU 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 Article 4(6)

- (a) Supporting a Union framework and the respective interoperable digital tools for cooperation among Member States and in networks, including those needed for HTA cooperation;
- (b) Supporting the deployment, operation and maintenance of mature, secure and interoperable digital service infrastructures 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; 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 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 infrastructures 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, at-home administration of medication;
- (j) Supporting the establishment of interoperable Electronic Health Records, in line with 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 Article 4(7)

- (a) Actions promoting access to health services and related facilities and care for people with disabilities;
- (b) Support the strengthening of primary care, reinforcing the integration of care with a view to universal health coverage and equal access to good quality healthcare;
- (c) Support Member States' actions to promote access to sexual and reproductive healthcare and support integrated and intersectional approaches to prevention, diagnosis, treatment and care.

8. Actions meeting the objective laid down in Article 4(8)

- (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 technical support to the implementation of legal requirements;
- (c) Supporting studies and analysis, health impact assessment of other Union policy actions and 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 for the implementation of legislation on substances of human origin, and for the promotion of the sustainable and safe supply of such substances through networking activities;
- (j) Supporting Member States to strengthen the administrative capacity of their healthcare systems through cooperation and exchange of best practices;

- (k) 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;
- (l) Supporting capacity building for investing in and implementing health system reforms (strategic planning and access to multi-source financing).

9. Actions meeting the objective laid down in Article 4(9)

- (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 country-specific tailor made support, to Member States, or groups of Member States, with the highest 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 the European Reference Networks and the establishment and operation of new transnational networks set out in accordance with Union health legislation, and supporting Member States' actions to coordinate the activities of these networks with the operation of national health systems;
- (e) Supporting further the implementation of the ERNs in Member States and fostering their strengthening also by continuous assessment, monitoring, evaluation and improvement;
- (f) Supporting the creation of new ERNs, to cover rare complex and low prevalence diseases, where appropriate, for the collaboration of 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 Article 4(10)

- (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 between the Union institutions, its Agencies, and international organisations and networks, and the Union's contribution to global initiatives;
 - (c) Supporting collaboration with third countries on the areas covered by the Programme;
 - (d) Support action 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, e.g. number of existing and new orphan authorisations, Advanced Therapy Medicinal Products, Paediatric Use Medicinal Products 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, prevention and health inequalities
5. Number of Member States participating in the European Health Data Space (EHDS)
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 (as far as 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 (CRs) 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 diseases, 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 dependencies to third countries imports for the production of essential APIs and medicinal products in the EU
17. Number of audits conducted in the EU 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 ERN and of patients diagnosed and treated by the members of ERN networks
20. Number of Health Technology Assessment 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
