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Subject: 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”)
- Mandate for negotiation with the European Parliament

I. INTRODUCTION

1. On 28 May 2020, the Commission adopted its 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”)¹ and transmitted it to the Council and to the European Parliament.
2. The legal basis for this Proposal is Article 168(5) of the Treaty on the Functioning of the European Union (“TFEU”). The ordinary legislative procedure is applicable.

¹ 8595/20

3. The draft Regulation lays down the general and specific objectives of the EU4Health Programme, its budget for the period from 1 January 2021 to 31 December 2027, the forms of Union funding of the Programme and the rules for providing such funding. It also sets out an indicative list of eligible actions. The aim of the Regulation is to improve public health in the Union. It puts special emphasis on protecting people from serious cross-border threats to health, notably by addressing shortcomings identified during the COVID-19 crisis. As a result of the guidance provided by the European Council at its meeting on 17-21 July 2020², the budget of the EU4Health Programme amounts to EUR 1.9 billion, which makes it about four times bigger than its predecessor the third Health Programme³.
4. Member States' national parliaments were consulted on the compliance of the proposed provisions with the principle of subsidiarity. None of the national parliaments objected to the proposal⁴.
5. The European Economic and Social Committee was consulted and issued its opinion on the Proposal⁵ on 18 September 2020, whilst the Committee of the Regions adopted its opinion at its 12-14 October 2020 Plenary session⁶.
6. The European Parliament has appointed MEP Cristian-Silviu BUȘOI (EPP, RO) as Rapporteur on the Programme. On 14 October 2020, the EP Committee on the Environment, Public Health and Food Safety adopted its report on the Programme. The Parliament is expected to vote on this report at the latest at its part-session on 11-13 November 2020.

² 10/20

³ Regulation (EU) No 282/2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020). OJ L 86, 21.3.2014, p. 1.

⁴ <http://www.ipex.eu/>

⁵ SOC/656, <https://dmsearch.eesc.europa.eu/search/opinion>

⁶ CDR 2917/2020, <https://dmsearch.cor.europa.eu/search/opinion>

7. The proposal is part of the Multiannual Financial Framework (MFF) 2021-2027. At its meeting on 17-21 July 2020, the European Council invited the Council to take up negotiations with the European Parliament with a view to ensuring finalisation of work on all legal acts in accordance with the relevant legal basis as a matter of exceptional urgency. The Presidency therefore considers that negotiations with the European Parliament should start as soon as possible.

II. PREPARATION OF THE NEGOTIATION MANDATE

8. On 12 June 2020, Ministers of Health - meeting in an informal videoconference⁷ replacing the June EPSCO Council - held a first exchange of views⁸ on the Commission proposal to provide political guidance for the examination at technical level.
9. The Working Party on Public Health met on eleven occasions⁹ under the Croatian and German Presidencies.
10. In the light of interventions made by delegations in those meetings and taking into account written contributions received from delegations¹⁰, the Presidency prepared the compromise text set out in the Annex to this document.
11. Certain parts of the Presidency compromise text, some of which reflect the political guidance on the MFF from the meeting of the European Council on 17-21 July, are of a horizontal nature and have thus not been subject to discussion by the Working Party on Public Health. Instead, those provisions have been aligned with the horizontal MFF provisions and the political guidance.

⁷ Prepared in Coreper on 3 and 10 June, Agenda set out in WK 5582/2020 REV 2.

⁸ Based on Presidency questions set out in document WK 5824/2020.

⁹ The Working Party met on 17 June, 1, 13, 23, 27 and 30 July 2020. In addition its members met in informal videoconferences on 2 June, 9 and 20 July, 17 September and 7 October 2020.

¹⁰ Including the written contributions sent in as follow-up to the informal videoconference of the Working Party on 7 October set out in WK 10971/2020. The Council legal service suggested a redrafting of Article 10, which is reflected in the compromise text.

III. FUTURE STEPS

12. Provided it receives a mandate from the Permanent Representatives Committee, the Presidency intends to enter into negotiations as soon as the European Parliament is ready.
13. The Presidency will report back to the Committee and seek further guidance as the negotiations evolve.

IV. CONCLUSION

14. In the light of the above, the Permanent Representatives Committee is invited to:
 - (a) mandate¹¹ the Presidency to enter into negotiations with the European Parliament aiming to reach an agreement at first reading on the Proposal for a Regulation 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”) using the text set out in the Annex as the Council starting point; and to
 - (b) instruct the Working Party on Public Health to assist the Presidency as necessary during the negotiations.

¹¹ In accordance with the new approach on legislative transparency endorsed by the Permanent Representatives Committee on 14 July 2020 (doc. 9493/20), and in full consistency with Regulation (EC) No 1049/2001 and the Council's Rules of Procedure, the agreed mandate will be made public..

Text conventions in the annex

New text added by the Presidency is set out in *bold italics*.

Text deleted from the Commission proposal is set out in ~~strikethrough~~.

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 Committee¹²,

Having regard to the opinion of the Committee of the Regions¹³,

Acting in accordance with the ordinary legislative procedure¹⁴,

Whereas:

- (1) According to Article 3(1) of the Treaty on the European Union, amongst the aims of the Union is ~~the to promote~~ **promotion of** the well-being of its peoples.
- (2) ~~In accordance~~ **According to** with Articles 9 and 168 of the Treaty on the Functioning of the European Union (TFEU) and Article 35 of the Charter of Fundamental Rights of the European Union (the Charter), a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities.

¹² OJ C [...], [...], p. [...].

¹³ OJ C [...], [...], p. [...].

¹⁴ 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*~~in~~ fully respecting of the responsibilities of the Member States for the definition of their health policies and *for* the organisation and delivery of health services and medical care.
- (4) Continued actions *provided for by Decisions No 1786/2002/EC 2002*¹⁵ and *No 1350/2007/EC*¹⁶ of the European Parliament and of the Council and *Regulation (EU) No 282/2014 of the European Parliament and of the Council*¹⁷ 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 TFEU¹⁸.
- (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.

¹⁵ *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).*

¹⁶ *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).*

¹⁷ *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).*

¹⁸ ~~Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008) (OJ L 271, 9.10.2002, p.1); Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-13) (OJ L 301, 20.11.2007, p. 3); Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's *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 ~~are expected to~~ **should** protect public health in a spirit of European solidarity¹⁹. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further ~~firm~~ action at Union level to support cooperation and coordination among the Member States in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.
- (7) It is ~~therefore~~ appropriate to establish a new **and reinforced** Programme for the Union's action in the field of health, called **the 'EU4Health Programme' (hereinafter referred to as 'the Programme')** for the period **from 1 January 2021 - to 31 December 2027**. In line with the goals of ~~the~~ Union action and ~~its~~ **the Union's** 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.**

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

- (8) This Regulation should lay down a financial envelope for the Programme ~~for the Union's action in the field of health~~ which is to constitute the prime reference amount, within the meaning of point 16 of the Proposal for an Interinstitutional Agreement between the European Parliament, the Council and the Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management as adopted by ~~the said~~ **those** Institutions²⁰.
- (9) ~~In accordance with Regulation {reference to the European Union Recovery Instrument} and within the limits of resources allocated therein, recovery and resilience measures under the Programme should be carried out to address the unprecedented impact of the COVID-19 crisis. Such additional resources should be used in such a way as to ensure compliance with the time limits provided for in Regulation {reference to the European Union Recovery Instrument}.~~
- (10) ~~The~~ **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 *the serious nature of cross-border threats to health such as pandemics.***

²⁰ COM/2018/323 final.

- (10a) With a view to strengthen the capability in the Union to **prevent**, prepare for, respond to and manage health ~~erisis~~ **crises**, the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under **relevant EU legislation** ~~Decision No 1082/2013/EU of the European Parliament and of the Council²¹ and other relevant mechanisms and structures established at Union level.~~ This could include ~~strategie stockpiling of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes.~~ In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local levels, including contingency planning and preparedness, **preventive measures such as those related to vaccination and immunisation, and strengthened surveillance programmes and improved coordination and cooperation.** ~~exercises, in keeping with the “One Health” approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis—prevention, preparedness and response.~~
- (11) ~~As in the time of health crisis emergency health technology assessment as well as clinical trials can contribute to the rapid development of medical countermeasures the Programme should provide support to facilitate such actions. The Commission has adopted a proposal²² on Health Technology Assessment (HTA) to support cooperation on health technology assessment at Union level.~~
- (12) With a view to protect people in vulnerable situations, including those suffering from ~~mental illnesses and~~ chronic diseases, the Programme should also promote actions which address **and prevent** the collateral impacts of health crises on people belonging to such vulnerable groups **and improve mental health.**

²¹ ~~Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p.1).~~

²² Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU, COM(2018) 51 final of 31.01. 2018.

- (13) The COVID-19 crisis has highlighted many challenges in ensuring the supply of ~~medicines~~ **medicinal products**, medical devices ~~as well as~~ **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.
- (14) In order to minimise the public health consequences of serious cross-border threats to health, it should be possible for actions supported under the Programme to ~~cover coordination of the activities which strengthen~~ **improve** the interoperability ~~and coherence~~ of Member States' health-systems through ~~benchmarking~~, cooperation and exchange of best practices. **Those actions should** ~~and ensure~~ **that Member States are able** ~~their capability~~ to respond to health emergencies, ~~that~~ **which** includes **undertaking** contingency planning, preparedness exercises and the upskilling of health-care and public health staff **workforce** ~~and 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.

(15) Experience from the COVID-19 crisis has indicated that there is a general need for the support to structural transformation of and systemic reforms of health systems across the Union to improve their effectiveness, accessibility and resilience. In the context of such transformation and reforms, the Programme should promote, in synergy with the Digital Europe Programme, actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide new care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs and ensure an efficient public health workforce equipped with the right skills, including digital skills. The development of a European health data space would provide health care systems, researchers and public authorities with means to improve the availability and quality of healthcare. Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006²³ the Programme should support actions ensuring the universality and inclusivity of health care, meaning that no-one is barred access to health care, and those ensuring that patients' rights, including on the privacy of their data, are duly respected.

(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.

²³ Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p.1).

(16) Keeping people healthy and active longer and empowering them to take an active role in managing their health will have positive effects on health, health inequalities, quality of life, productivity, competitiveness and inclusiveness, while reducing pressures on national budgets. The Commission has committed to help Member States to reach the sustainable development targets set in the 'UN 2030 Agenda for Sustainable Development' in particular Sustainable Development Goal 3 "Ensure healthy lives and promote well-being for all at all ages".²⁴ The Programme therefore should contribute to the actions taken towards reaching these goals.

²⁴ 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 a result of a combination of genetic, physiological, environmental and behavioural factors. Such non-~~**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 resulting in cause* considerable social and economic impacts. ~~To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, It is key~~ ***essential*** to provide an integrated response focusing on prevention across sectors and policy fields, ~~combined with efforts to strengthen health systems.~~**
- (18) The Programme therefore should ~~therefore support~~ ***contribute to health promotion and disease prevention and improve mental health*** throughout the lifetime of an individual and ~~to health promotion~~ by addressing health risk factors, such as ***obesity, unhealthy diets, physical inactivity***, the use of tobacco and related products ~~and exposure to their emissions~~, the harmful use of alcohol, and the consumption of illicit drugs, ***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’²⁵.*** The Programme ~~should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits and physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also therefore contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.~~

²⁵ 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. ~~In 2020 the Commission announced the ‘Europe’s Beating Cancer Plan’ which would cover the entire cycle of the disease starting from prevention and early diagnosis to treatment and quality of life of patients and survivors. The *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.~~

(19a) 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.

(20) The Programme ~~will~~ **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, ~~Support to mitigate Unemployment Risks in an Emergency (SURE)~~, and EU external action instruments, such as the Neighbourhood, Development and International Cooperation Instrument and the Instrument for Pre-accession Assistance III. Where appropriate, common rules will be established in view of ensuring consistency and complementarity between funds, while making sure that specificities of these policies are respected, and in view of aligning with the strategic requirements of these policies, programmes and funds, such as the enabling conditions under ERDF and ESF+. ***The Commission should in cooperation with Member States, ensure to establish 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.

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

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

- (23) As the optimal *delivery and* use of medicines *medicinal products*, and *of* antimicrobials in particular, yield benefits for individuals and health systems, the Programme should promote their prudent and efficient use. ~~In~~ *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 26 June 2016 entitled ‘A European One Health Action Plan against Antimicrobial Resistance (AMR)’²⁶, 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’²⁷, adopted in June 2017 following the request from Member States, and given the experience with the bacterial secondary infections related to COVID-19, it is essential that the Programme supports actions aimed at the prudent use of antimicrobials in humans, animals and crops, in the framework of an integrated policy on patient safety and prevention of medical errors.*
- (24) ~~Since environmental pollution caused by human and veterinary pharmaceutical substances is an emerging environmental problem that can impact on public health, the Programme should foster measures to strengthen the assessment and appropriate management of environmental risks associated with the production, use and disposal of medicinal products, in line with the European Union Strategic Approach to Pharmaceuticals in the Environment²⁸.~~

²⁶ ~~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.~~

²⁷ ~~**COM(2019)128 final of 11.03.2019.**~~

²⁸ ~~Communication of the Commission to the European Parliament, the Council and the European economic and Social Committee ‘European Union Strategic Approach to Pharmaceuticals in the Environment’; COM(2019)128 final of 11.03.2019.~~

- (25) The Union health legislation has an immediate impact on public health, the lives of citizens, the efficiency and resilience of the health systems and the good functioning of the internal market. The regulatory framework for medical products and technologies (medicinal products, medical devices and substances of human origin), as well as for tobacco legislation, patients' rights in cross-border healthcare and serious cross-border threats to health is essential to health protection in the Union. The Programme therefore should support the development, implementation and enforcement of Union health legislation and provide high quality, comparable and reliable data to underpin policymaking and monitoring.
- (26) Cross-border cooperation in the provision of healthcare to patients moving between Member States, ~~collaboration on health technology assessments (HTA)~~, and European Reference Networks (ERNs) are examples of areas where integrated work ~~among~~ *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 has the potential to bring added value to Member States.* The Programme should therefore support activities ~~to~~ *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 Council²⁹, 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 ERNs can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions, and can be focal points for medical training, and research and dissemination of information, the Programme should contribute to the~~ *strengthening and* upscaling of networking through *and between* the ERNs, and other transnational networks ~~with an~~ *that have EU Union added value by supporting the coordination of activities between Member States.* ~~It should consider the extension of ERNs beyond rare diseases to communicable and non-communicable diseases such as cancer.~~

²⁹ 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).

- (28) Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council³⁰ (the ‘Financial Regulation’) applies to this Programme. ~~It~~ ***The Financial Regulation*** lays down rules on the implementation of the Union budget, including the rules on grants, prizes, procurement, indirect ~~implementation~~ ***management, budgetary guarantees***, financial assistance ***and the reimbursement of external experts***, ~~financial instruments and budgetary guarantees.~~
- (29) The types of financing and the methods of implementation under this Regulation should be chosen on the basis of their ability to achieve the specific objectives of the actions and to deliver results, taking into account, in particular, the costs of controls, the administrative burden, and the expected risk of non-compliance. This should include consideration of the use of lump sums, flat-rates ***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.
- (30) In order to optimise the added value and impact ~~from~~ ***of*** investments ***that are*** funded ~~wholly~~ ***fully*** or in part through the budget of the Union, synergies should be sought in particular between the Programme ~~for the Union's action in the field of health~~ and other Union programmes, including those under shared-management. To maximise those synergies, key enabling mechanisms should be ~~ensured~~ ***provided for***, including cumulative funding in an action from the Programme ~~for the Union's action in the field of health~~ and another Union programmes, 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 ***this*** Programme ~~for the Union's action in the field of health~~ and another Union programme.

³⁰ 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).

- (31) Given the specific nature of the objectives and actions covered by the Programme, the respective competent authorities of the Member States are best placed in some cases to implement ~~the related~~ activities **related to the Programme**. Those authorities, designated by the Member States themselves, should therefore be considered ~~to be~~ **as** 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.
- (32) The ERNs are approved ~~as Networks~~ by the Board of Member States of the European Reference Networks, following the approval procedure set out in Commission Implementing Decision 2014/287/EU of 10 March 2014³¹. ~~Those networks,~~ **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 challenges³², **as expressed in the sustainable development goals**, the Programme should support the Union's contribution to international and global health **organizations, in particular the World Health Organization (WHO)**, with a view to improve health, address **health** inequalities and **strengthen** protection against global health threats.

³¹ 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).

³² Council conclusions on the EU role in Global Health, 3011th Foreign Affairs Council meeting, Brussels, 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 its specialised agencies, in particular the WHO,~~ **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 ~~Article 94 of~~ Council Decision 2013/755/EU³³, persons and entities established in Overseas Countries and Territories (OCTs) are eligible for funding subject to the rules and objectives of the Programme and possible arrangements applicable to the Member State to which the relevant OCTs are linked.
- (35) Third countries which are members of the European Economic Area (EEA) ***are able to*** ~~may~~ participate in Union programmes in the framework of the cooperation established under the ~~EEA Agreement~~ ***on the European Economic Area***³⁴, which provides for the implementation of ~~the~~ ***such*** programmes ~~by~~ ***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 ~~for~~ and access ***required for*** ~~to~~ the authorising officer responsible, the European Anti-Fraud Office (OLAF) ~~as well as~~ ***and*** the European Court of Auditors (ECA) to comprehensively ~~exert~~ ***exercise*** their respective competences.
- (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.

³³ 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).

³⁴ ***OJ L 1, 3.1.1994, p. 3.***

(37) In accordance with the Financial Regulation, Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council³⁵, Council Regulation (EC, Euratom) No 2988/95³⁶, ~~Council Regulation (Euratom, EC) No 2185/96³⁷ and Council Regulation (EU) 2017/1939³⁸~~, the financial interests of the Union are to be protected by means of proportionate measures including measures relating to the prevention, detection, correction and investigation of irregularities, including fraud, to the recovery of funds lost, wrongly paid or incorrectly used and, where appropriate, to the imposition of administrative penalties. In particular, in accordance with Regulations (Euratom, EC) No 2185/96 and (EU, Euratom) No 883/2013, ~~the European Anti-Fraud Office~~ **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 Council³⁹.

³⁵ 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).

³⁶ 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).

³⁷ 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).

³⁸ 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).

³⁹ 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).

- (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, ~~the EPPO~~ pursuant to Regulation (EU) 2017/1939 **the EPPO**, and ensure that any third parties involved in the implementation of Union funds grant equivalent rights.
- (39) Horizontal financial rules adopted by the European Parliament and the Council on the basis of Article 322 TFEU apply to this Regulation. These rules are laid down in the Financial Regulation and determine in particular the procedure for establishing and implementing the budget through grants, procurement, prizes, indirect implementation, and provide for checks on the responsibility of financial actors. Rules adopted on the basis of Article 322 TFEU also concern ~~the protection of the Union's budget in case of generalised deficiencies as regards the rule of law in the Member States, as the respect for the rule of law is an essential precondition for sound financial management and effective EU funding~~ **other conditionalities to protect the 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 ~~30~~ **25** % of the EU budget expenditures supporting climate objectives. Relevant actions will be identified during the Programme's preparation and implementation, and reassessed in the context of its mid-term evaluation.
- (41) The policy objectives of ~~this~~ **the** Programme may ~~be~~ also **be** addressed through financial instruments and budgetary guarantees under the InvestEU Fund. Financial support should be used to address market failures ~~or~~ **and** sub-optimal investment situations, in a proportionate manner. ~~and actions~~ **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 ~~clear European~~ **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 and affordability in the Union of ~~medicines~~ ***medicinal products***, medical devices and other crisis relevant products, to support innovation and to support integrated and coordinated work and implementation of best practices among Member States, and to address inequalities in access to health throughout the EU in a manner that creates efficiency gains and value-added impacts that could not be generated by action taken 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 2016⁴⁰. 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.~~

⁴⁰ 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 line accordance with the criteria set out in this Regulation, approving eligible actions, setting indicators for the evaluation of the programme and establishing*** rules on technical and administrative arrangements necessary for the implementation of the actions of the Programme and on uniform templates for the collection of data necessary to monitor the implementation of the Programme. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of European Parliament and of the Council.⁴¹ ***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.

⁴¹ 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) It is appropriate to ensure a smooth transition without interruption between the previous programme in the field of health (2014-2020) and the Programme, and to align ~~the~~ *its* duration of the Programme with *that of the Multiannual Financial Framework laid down in Regulation {reference to the new MFF}*. Therefore, the Programme should apply from ~~1 January 2021~~.

HAVE ADOPTED THIS REGULATION:

CHAPTER I GENERAL PROVISIONS

Article 1

Subject matter

This Regulation establishes the EU4Health Programme ("the Programme") *for the period from 1 January 2021 to 31 December 2027*.

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

Article 2
Definitions

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

- (1) ‘associated country’ means a third country which is party to an agreement with the Union allowing for its participation in the Programme, in accordance with Article 7;
- (2) ‘blending operation’ means actions supported by the Union budget, including within blending facilities pursuant to Article 2(6) of Regulation (EU, Euratom) No 2018/1046, combining non-repayable forms of support and/or financial instruments from the Union budget with repayable forms of support from development or other public finance institutions, as well as from commercial finance institutions and investors;
- (3) ‘health crisis’ means any crisis or serious incident arising from a threat of human, animal, plant, food or environment origin, having a **public** health dimension and which requires urgent action by authorities;
- (4) ‘crisis relevant products’ means products and substances necessary, in the context of a health crisis, to prevent, diagnose or treat a disease and its consequences, ~~included~~ **including** but not limited to: medicinal products- ~~including~~, **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) ‘One Health approach’ means an approach which recognises that human **health**, ~~and~~ animal health **and the environment** are interconnected, that diseases may be transmitted from humans to animals and vice versa and must therefore be tackled in both, ~~and that the environment links humans and animals~~;
- (6) ‘European Reference Networks’ means the networks referred to in Article 12 of Directive 2011/24;

- (7) ‘legal entity’ means any natural or legal person created and recognised as such under national law, Union law or international law, which has a legal personality and which may, acting in its own name, exercise rights and be subject to obligations, or an entity without a legal personality ~~in accordance with~~ **as referred to in** Article 197(2)(c) of the ~~Financial 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;
- (10) ‘emergency support’ means a needs-based emergency response, **which complementing 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 (1) of** Article 3-~~(1)~~.

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. It shall** pursue the following general objectives, ~~in keeping with~~ **following** the “One Health” approach where relevant:

- (1) **protecting** people in the Union from serious cross-border threats to health **and strengthening the responsiveness of health systems to cope with those threats**;
- (2) **improving** the availability, **accessibility and affordability** ~~in the Union of medicines, medical devices and other~~ **health products as well as** crisis relevant products; ~~contribute to their affordability~~ **in the Union** ; and **supporting** innovation **regarding such products**;

(3) strengthening health systems **by improving their resilience and green sustainability, through:**

~~and the healthcare workforce, including by digital transformation and by increased~~

- **supporting** integrated and coordinated work ~~among~~ **between** the Member States; ;
- ~~sustained~~ **promoting the** implementation of best practices data sharing, ~~to increase the general level of public health. ;~~
- **reinforcing the healthcare workforce;**
- **tackling the implications of demographic challenges, and**
- **advancing digital transformation;**

(4) **promoting disease prevention, health promotion and fostering healthy lifestyles in order to reduce the burden of communicable and non-communicable diseases and reduce health inequalities.**

Article 4

Specific objectives

The general objectives referred to in Article 3 shall **have a Union added value and** be pursued through the following specific objectives, ~~in keeping with the “One Health” approach where relevant:~~

- (1) strengthening **the** capability of the Union for prevention, preparedness and response to serious cross-border threats to health **in accordance with relevant EU legislation** and **improving** the management of health crises, ~~including~~ **particularly** through **the** coordination, provision and deployment of emergency ~~health-care~~ **healthcare** capacity, **supporting** ~~to~~ data gathering, **information exchange** and surveillance;
- (2) ~~ensure the availability in the Union of reserves or stockpiles of crisis relevant products, and a reserve of medical, healthcare and support staff to be mobilised in case of a crisis;~~

- (3) supporting **actions to ensure appropriate *enhance the*** availability, accessibility and affordability of ***health products as well as*** crisis relevant products, ~~and other necessary health supplies, 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, as well as the environmental-friendly production and disposal of medicinal products and medical devices;~~
- (4) ~~strengthen the effectiveness, accessibility, sustainability and resilience of health systems, including by supporting digital transformation, the uptake of digital tools and services, systemic reforms, implementation of new care models and universal health coverage, and address inequalities in health;~~
- (4a) *strengthening the use and re-use of health data 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;***
- (5) supporting **actions aimed at strengthening health system's ability to foster *for*** disease prevention, health promotion ***and reduction of health damage due to illicit drug use and addiction, actions to address inequalities in health, patient rights and patient safety, quality of care*** and cross-border healthcare, and ~~promote the excellence of medical and healthcare professionals~~ ***actions for the improvement of the surveillance, diagnosis and treatment of communicable and non-communicable diseases, notably cancer, as well as actions to improve mental health, with special attention to new care models and the challenges of long term care, thereby buttressing in order to strengthen the resilience of the health systems in the Union;***
- (6) ~~support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer;~~
- (7) ~~foster and support the prudent and efficient use of medicines, and in particular of antimicrobials, and more environmentally friendly production and disposal of medicines and medical devices;~~

- (8) supporting the development, implementation and enforcement of Union health legislation and ~~provide high-quality, comparable and~~ **supporting the provision of valid, reliable and comparable high-quality monitoring** data to underpin policy for evidence-based decision-making and monitoring, and ~~promote~~ **promoting** the use of health impact assessments of relevant policies;
- (9) supporting integrated **and coordinated** work among Member States, and in particular ~~their~~ health systems, including the implementation of high-impact prevention practices, and scaling up networking through the European Reference Networks and other transnational networks;
- (10) supporting **global health initiatives by increasing** the Union's contribution to international **organisations, in particular the World Health Organization (WHO), and global health initiatives and foster cooperation with third countries.**

Article 5

Budget

1. The financial envelope for the implementation of the Programme for the period **from 1 January 2021 to 31 December 2027** shall be EUR ~~1 946 614 000~~ **1 882 000 000** in current prices.
2. The amount referred to in paragraph 1 may **also** be used for technical and administrative assistance for the implementation of the Programme, such as preparatory, monitoring, control, audit and evaluation activities including corporate information technology systems.
3. Appropriations ~~deriving from~~ **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. Without prejudice to the Regulation (EU, Euratom) 2018/1046, expenditure for actions resulting from projects included in the first work programme may be eligible *for funding* as from 1 January 2021.
6. If necessary, appropriations may be entered in the budget beyond **31 December** 2027 to cover the expenses ~~provided~~ *referred to* ~~for~~ in paragraph (2) to enable the management of actions not completed by 31 December 2027.

Article 6

Resources from the European Union Recovery Instrument

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

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

Article 7

Third countries associated to the Programme

The Programme shall be open to the following associated countries:

- (1) European Free Trade Association (EFTA) members ~~which~~ **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) Acceding countries, candidate countries and potential candidates, in accordance with the general principles and general terms and conditions for the participation of those countries in Union programmes established in the respective framework agreements and Association Council decisions, or similar agreements, and in accordance with the specific conditions laid down in agreements between the Union and those countries;
- (3) Countries covered by the European Neighbourhood Policy, in accordance with the general principles and general terms and conditions for the participation of those countries in Union programmes established in the respective framework agreements and association council decisions, or similar agreements, and in accordance with the specific conditions laid down in agreements between the Union and those countries;
- (4) Third countries, in accordance with the conditions laid down in a specific agreement covering the participation of the third country to any **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)-(e) of ***that*** Regulation ~~(EU, Euratom) 2018/1046~~.
2. The Programme may provide funding in any of the forms laid down in Regulation (EU, Euratom) 2018/1046, in particular ***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 ~~set up~~ ***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 ~~where~~ ***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, or 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%.***
5. ***Applications for projects shall include different legal entities from at least three different States participating in the Programme.***

Article 10

Procurement in health emergency situations

1. ~~Emergency support~~ ***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 ~~be granted in~~ ***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 ~~capacities~~ jointly procured ***capacities***;
 - (b) procurement by the Commission on behalf of the Member States ~~based on the basis of~~ ***on*** 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, ~~to~~ ***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 ~~follow the rules set out in~~ ***comply with*** Regulation (EU, Euratom) 2018/1046 for its own procurement, ***applying as necessary the derogations set out below***.
4. ***By way of derogation from Article 1(6) of Decision 1313/2013/EU, all the capabilities of the Union Civil Protection Mechanism may be used in the context of the procurement and delivery of medical countermeasures under the above procedures.***

5. *By way of derogation from Article 172(1) of Regulation 2018/1046, the contracting authorities shall be entitled to request the delivery of goods or services as from the date of sending the draft contracts resulting from the procurement carried out in accordance with this Article.*

6. *By way of derogation from point 30 of Annex I of Regulation 2018/1046, and for the purposes of awarding the contracts, the authorizing officer may merge the content of the evaluation report and the award decision into a single document and sign it. The electronic signature referred to in point 30(1) of Annex I of Regulation 2018/1046 may be substituted by a confirmation from the members through a secured email or simply scanned signature.*

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

The procedure referred to in Article 16a(2) shall be applied for the approval of funding of eligible actions.

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) ***be*** created ***directly*** under Union or international ***law***.;
2. Legal entities ***that are*** established in a third country which is not ~~an~~ associated ***to the Programme*** ~~country are~~ ***may in exceptional cases be*** ~~exceptionally~~ eligible to participate where ~~this~~ ***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 ~~should in principle~~ ***shall*** bear the cost of their participation.
4. Natural persons are not eligible ***for funding under the Programme.***

5. Under the Programme, direct grants may be awarded without a call for proposals to fund actions ~~having~~ **which have** a Union added value **that is explicitly provided for in the annual work programmes and that are** co-financed by the competent authorities ~~that are~~ 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 may be awarded without a call for proposals to European Reference Networks ~~– Direct grants may also be awarded~~ **and** to other transnational networks **established under Union law set out in accordance with EU rules to fund actions which have a Union added value that is explicitly provided for in the annual work programmes.**
- 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** ~~pursuit~~ 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. ~~In addition~~ **Subject** to the criteria set out in Article 186 of Regulation (EU, Euratom) 2018/1046, and ~~in accordance with~~ point (a) of the second subparagraph of Article 193 of that Regulation, costs incurred prior to the date of submission of the grant application shall be eligible **for funding for actions**:
 - (a) ~~for actions which~~ implementing **the** objective referred to in point (1) of Article 3 **of this Regulation; or**
 - (b) ~~for actions~~ implementing other objectives, in duly justified exceptional cases, provided that those costs are directly linked to the implementation of the supported actions and activities.
2. The costs under point (a) of paragraph 1 of this Article, ~~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 ~~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 ~~exceptionally~~ eligible if ~~they~~ **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 ~~its~~ the secretariat of the EU4Health Steering Group.*
3. The Commission shall:
 - (a) *consult ~~the health authorities of the Member States in the EU4Health Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases on the work plans established for the Programme and its priorities and strategic orientations and its implementation~~ 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 political orientations of the Programme and its implementation.*
4. *The Steering Group shall:*
 - (a) *work towards ensuring consistency and complementarity between the Programme and other policies, instruments and actions of the Union, including those relevant to the Union agencies;*
 - (b) *follow up the implementation of the Programme and propose any necessary adjustments based on evaluations;*
 - (c) *adopt its rules of procedure, which shall contain provisions to ensure that the group will meet where appropriate physically at least three times a year, thus allowing for a regular and transparent exchange of views among Member States.*

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, the actions to be undertaken, including the indicative allocation of financial resources for each action. The programmes shall also set out, where applicable, the overall amount reserved for blending operations.*
 - (b) *decisions approving eligible actions with cost of EUR 20 000 000 or more.*
 - (c) *decisions approving eligible actions falling under the cases referred to in Article 8(3) and (4).*
 - (d) *decisions approving eligible actions by:*
 - (i) *entities from a third country associated to the Programme;*
 - (ii) *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);*
 - (iii) *any legal entity created directly under Union or international law.*
 - (e) *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.

Article 17
Implementation of the Programme

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

- (a) technical and administrative arrangements necessary for the implementation of the actions of the Programme;
- (b) uniform templates for the collection of data necessary to monitor the implementation of the Programme.

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

CHAPTER V

PROGRAMMING, MONITORING, EVALUATION AND CONTROL

Article 18

Work programme

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

Article 19

Monitoring and reporting

1. Indicators to ***monitor the implementation and*** report on ***the*** progress of the Programme towards the achievement of ~~the~~ ***its*** general and specific objectives set out in Articles 3 and 4 ~~are set out in Annex II~~ ***shall be adopted by the Commission by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 23(2).***
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 ~~shall be~~ 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 ~~adoption~~ date of application of this Regulation. The interim evaluation shall be the basis for adjusting the implementation of the Programme as appropriate ~~performed once there is sufficient information available about their implementation, but not later than four years after the start of the implementation.~~
3. ~~At~~ ***The Commission shall present an evaluation at*** the end of the ***Programme and implementation period,*** but no later than four years after the end of the period specified in Article 1, ~~a final evaluation shall be carried out by the Commission.~~
4. The Commission shall communicate the conclusions of the evaluations accompanied by its observations, to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

Article 21

Audits

Audits ~~on~~ **of** the use of the Union contribution **that are** carried out by persons or entities, including by ~~others~~ **persons or entities other** than those mandated by the Union Institutions or bodies, shall form the basis of the overall assurance ~~pursuant~~ **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 ~~under adopted~~ **pursuant to** an international agreement **or by virtue on the basis of any other legal instrument**, the third country shall grant the necessary rights and access required for the ~~authorizing~~ **authorising** officer responsible, ~~the European Anti-Fraud Office (OLAF), and the European Court of Auditors (ECA)~~ to comprehensively ~~exert~~ **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 ~~concerning investigations conducted by the European Anti-Fraud Office (OLAF).~~

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, ~~and its~~ ***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, as ***insofar as they 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 ~~concerned~~, ***initiated pursuant to*** ~~until their closure, under Regulation (EU) No 282/2014, which shall continue to apply to the~~ ***those*** ~~actions concerned until their closure.~~
2. The financial envelope for the Programme may also cover technical and administrative assistance expenses necessary to ensure the transition between the Programme and the measures adopted under its predecessor, ~~the third Programme for the Union's action in the field of health (2014-2020)~~ ***Regulation (EU) No 282/2014.***

Article 27
Entry into force

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

It shall apply from 1 January 2021.

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX I

LIST OF POSSIBLE ELIGIBLE ACTIONS PROVIDED FOR IN ARTICLE 13

(a) **Investment in:**

- (i) ~~Precursory projects for high added value up-scalable initiatives;~~
- (ii) ~~Critical health infrastructure relevant in the context of health crises, tools, structures, processes, production and laboratory capacity, including tools for surveillance, modelling, forecast, prevention and management of outbreaks.~~

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

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

- (i) ~~Surveys, studies, collection of data and statistics, methodologies, classifications, microsimulations, indicators, knowledge brokering and benchmark exercises;~~
- (ii) ~~The establishment and operation of a health intelligence and knowledge infrastructure;~~
- (iii) ~~Expert groups and panels providing advice, data and information to support health policy development and implementation;~~
- (iv) ~~Studies and analysis, and scientific advice to support policymaking, and support to the scientific committees on "Consumer Safety" and on "Health, Environmental and Emerging Risks".~~

- (d) ~~Development and implementation of Union health legislation and action~~, in particular through support to:
- (i) ~~Implementation, enforcement, monitoring of Union health legislation and action; and technical support to the implementation of legal requirements;~~
 - (ii) ~~Cross-border collaboration and partnerships, including in cross-border regions, with a view to transferring and upscaling innovative solutions;~~
 - (iii) ~~Cross-sectoral collaboration and coordination;~~
 - (iv) ~~Development and operation of databases and digital tools and their interoperability, including where appropriate with other sensing technologies, such as space-based;~~
 - (v) ~~Auditing and assessment work in accordance with Union legislation;~~
 - (vi) ~~Collaboration between the Union institutions, its Agencies, and international organisations and networks, and the Union's contribution to global initiatives;~~
 - (vii) ~~Stakeholder consultation activities;~~
 - (viii) ~~Networking by non-governmental organisations and their involvement in projects covered by the Programme;~~
 - (ix) ~~Collaboration with third countries on the areas covered by the Programme;~~
 - (x) ~~National contact points providing guidance, information and assistance related the implementation of Union health legislation and of the Programme;~~
 - (xi) ~~Stakeholders in view of transnational cooperation.~~
- (e) ~~Structural stockpile and crisis preparation:~~
- (i) ~~Establishment and support of a mechanism to develop, procure and manage crisis relevant products;~~
 - (ii) ~~Establishment and management of EU reserves and stockpiles of crisis relevant products in complementarity with other Union instruments;~~

- (iii) Establishment and support of mechanisms for the efficient monitoring and allocation of available care facilities (such as hospital beds and places in ICUs), for the distribution or allocation of goods and services needed in the case of a health crisis, and to ensure the supply and safe use of medicines, investigational medicines and medical devices;
- (iv) Procurement of goods and services necessary for the prevention and management of health crises and action to secure access to those essential goods and services;
- (v) Establishment and operation of a Union reserve of medical and healthcare staff and experts and of a mechanism to deploy such staff and experts as necessary to prevent or respond to a health crisis throughout the Union; establishment and operation of a Union Health Emergency team to provide expert advice and technical assistance on request by the Commission in the case of a health crisis;

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

- (i) Actions to foster Union-wide and cross-sectoral health crisis prevention, preparedness, management and response capacity of actors at Union, national, regional and local level, including contingency planning and preparedness exercises and the upskilling of medical, healthcare and public health staff;
- (ii) Setting up an integrated cross-cutting risk communication framework covering all phases of a health crisis – prevention, preparedness and response;
- (iii) Support and/or procure emergency production of medical countermeasures, including essential chemicals and active substances, and the financing of cooperation on emergency health technology assessments and clinical trials;
- (iv) Preventive actions to protect vulnerable groups from health threats and actions to adjust the response to and management of crisis to the needs of those vulnerable groups;
- (v) Actions to address the collateral health consequences of a health crisis, in particular those on mental health, on patients suffering from chronic diseases and other vulnerable groups;

- ~~(vi) Actions to strengthen surge capacity, research, development, laboratory capacity, production and deployment of crisis-relevant niche products;~~
- ~~(vii) Establishment and operation of a mechanism for cross-sectorial One-Health coordination.~~
- ~~(viii) Actions to support investigation, risk assessment and risk management work on the link between animal health, environmental factors, and human diseases, including during health crises.~~

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

- ~~(i) Support knowledge transfer actions and Union-level cooperation to assist national reform processes towards improved effectiveness, accessibility, sustainability and resilience, in particular to address the challenges identified by the European Semester and to strengthen primary care, reinforce the integration of care and aim at universal health coverage and equal access to healthcare;~~
- ~~(ii) Training programmes for medical and healthcare staff, and programmes for temporary exchanges of staff;~~
- ~~(iii) Support to improve the geographical distribution of healthcare workforce and avoidance of ‘medical deserts’;~~
- ~~(iv) Support the establishment and coordination of Union Reference Laboratories and Centres, and of Centres of excellence;~~
- ~~(v) Audit of Member States preparedness and response arrangements (such as crisis management, antimicrobial resistance, vaccination);~~
- ~~(vi) Support upwards convergence of national systems’ performance through indicator development, analysis and knowledge brokering and the organisation of stress tests of national healthcare systems;~~

- (vii) Support capacity building for investing in and implementing health system reforms (strategic planning and access to multi-source financing);
- (viii) Support capacity building of national systems for the implementation of legislation on substances of human origin, and for the promotion of the sustainable and safe supply of such substances through networking activities;
- (ix) Support the establishment and implementation of programmes assisting Member States and their action to improve health promotion and disease prevention (for communicable and non-communicable diseases);
- (x) Support Member States' actions to put in place healthy and safe urban, work and school environments, to enable healthy life choices and promote healthy diets taking into account the needs of vulnerable groups;
- (xi) Support the functioning of the European Reference Networks and the establishment and operation of new transnational networks set out in accordance with Union health legislation, and support Member States' actions to coordinate the activities of these networks with the operation of national health systems;
- (xii) Support for Member States to strengthen the administrative capacity of their healthcare systems through benchmarking, cooperation and exchange of best practices.
- (xiii) Support an Union framework and the respective interoperable digital tools for cooperation among Member States and in networks, including those needed to enable Member States to deliver joint clinical assessments and joint scientific consultations to exchange outcomes of HTA cooperation.

(h) **Actions on cancer:**

- (i) Support Member States and NGOs in the promotion and implementation of the recommendations of the European Code against Cancer;
- (ii) Support the establishment of quality assurance schemes for cancer centres;
- (iii) Support prevention programmes on the main cancer risk factors;

- (iv) ~~Actions to support secondary prevention of cancer, such as early detection and diagnosis through screening;~~
 - (v) ~~Actions supporting access to cancer services and to innovative medicines for cancer;~~
 - (vi) ~~Actions supporting the continuity of care (integrated care approaches for prevention, diagnosis, treatment and follow-up care);~~
 - (vii) ~~Actions supporting quality in cancer prevention and care including diagnosis and treatment;~~
 - (viii) ~~Actions supporting the quality of life of cancer survivors and care givers;~~
 - (ix) ~~Support to the implementation of the Union's tobacco control policy and legislation;~~
 - (x) ~~Establishment and support of a mechanisms for cross-specialty capacity building and continuous education in the area of cancer care.~~
- (i) **Actions on medicines, vaccines and medical devices:**
- (i) ~~Support to initiatives to improve vaccination coverage rates in the Member States;~~
 - (ii) ~~Support actions to fight vaccine hesitancy;~~
 - (iii) ~~Support clinical trials to speed up the development, authorisation and access to innovative, safe and effective medicines and vaccines;~~
 - (iv) ~~Support action to ensure greater availability in the Union of medicines and medical devices and contribute to their affordability for patients and health systems;~~
 - (v) ~~Support action to encourage the development *development* of innovative products and of less commercially interesting products such as antimicrobials;~~
 - (vi) ~~Support action to monitor shortages of medicines and medical devices occurring in hospitals and community pharmacies, to address such shortages, and to increase security of supplies;~~
 - (vii) ~~Support actions to encourage the development of innovative medicines and medical devices less harmful for the environment and promote greener manufacturing;~~
 - (viii) ~~Action to strengthen the environmental risk assessment of pharmaceuticals;~~
 - (ix) ~~Action to promote the prudent use and disposal of antimicrobials;~~
 - (x) ~~Support action to foster international regulatory convergence on medicines and medical devices.~~

- (j) **Digital transformation of health:**
- (i) Support for the deployment, operation and maintenance of mature interoperable digital service infrastructures and data quality assurance processes for data exchange, access, use and reuse; support for cross-border networking, including through the use of electronic health records, registries and other databases;
 - (ii) Support to the digital transformation of health care and health systems including through benchmarking and capacity building for the uptake of innovative tools and technologies; digital upskilling of health care professionals *professionals*;
 - (iii) Support the deployment and interoperability of digital tools and infrastructures within and between Member States and with Union Institutions and bodies; develop appropriate governance structures and sustainable, interoperable Union health information systems, as part of the European Health Data Space and strengthen citizens' access to and control over their health data;
 - (iv) Support optimal use of telemedicine/telehealth, including through satellite communication for remote areas, foster digitally driven organisational innovation in healthcare facilities and promote digital tools supporting citizen empowerment and person-centred care.
- (k) **Communication and outreach to stakeholders and citizens**, in particular:
- (i) Communication addressed *addressed* to citizens in the context of risk management and crisis preparedness.
 - (ii) Communication addressed to citizens and stakeholders to promote Union action in the areas mentioned in this Annex.
 - (iii) Communication to promote disease prevention and healthy lifestyles, in cooperation with all concerned actors at international, Union and national level.

1. *Actions meeting the objective laid down in Article 4(1)*
 - (a) *Strengthening the critical health infrastructure to cope with health crises by supporting the setup of tools for surveillance, forecast 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 contingency planning, preparedness exercises, mechanisms for the efficient coordination of preparedness and response and coordination of the 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;*
 - (e) *Supporting actions to address the collateral health consequences of a health crisis, in particular the consequences for mental health and patients suffering from cancer and from chronic diseases;*
 - (f) *Training programmes for the upskilling of healthcare and public health workforces, and programmes for temporary exchanges of staff;*
 - (g) *Supporting the coordination of Union Reference Laboratories and Centres, and of 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.*

2. *Actions meeting the objective laid down in Article 4(3)*
 - (a) *Supporting actions for the procurement and supply of health products and crisis relevant products and contribute to their affordability;*
 - (b) *Supporting actions to strengthen the production, research, development and deployment of health products and crisis relevant products within the Union;*
 - (c) *Supporting actions to prevent shortages of medicinal products and medical devices as well as crisis relevant products to increase sustainability of supplies;*
 - (d) *Supporting clinical trials to speed up the development, market authorisation and access to innovative, safe and effective vaccines;*
 - (e) *Supporting actions to encourage the development of innovative products and of commercially unprofitable products such as antimicrobials;*
 - (f) *Supporting actions to improve environmental-friendly production and disposal of medicinal products and medical devices;*
 - (g) *Supporting initiatives to improve vaccination coverage rates in the Member States;*
 - (h) *Supporting actions to promote the prudent and efficient use of medicinal products, in particular of antimicrobials;*
 - (i) *Supporting actions to reduce the risk of healthcare-acquired infections.*

3. *Actions meeting the objective laid down in Article 4(4a)*
 - (a) *Supporting a Union framework and the respective interoperable digital tools for cooperation among Member States and in networks, including those needed to enable Member States to deliver joint clinical assessments and joint scientific consultations;*

- (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 and operation of digital databases and digital tools and their interoperability, including where appropriate with other technologies, such as artificial intelligence;*
 - (f) *Supporting actions to strengthen citizens' access to and control over their health data.*
 - (g) *Supporting preparatory activities and projects for the European Health Data Space;*
4. *Actions meeting the objective laid down in Article 4(5)*
- (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 and health indicators, and fostering knowledge-brokering and benchmarking exercises;*

- (c) *Supporting Member States' actions to put in place healthy and safe urban, work and school environments, to enable healthy life choices and to promote healthy diets, taking into account the needs of vulnerable groups;*
- (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 actions to address health inequalities;*
- (i) *Supporting actions to enhance health literacy;*
- (j) *Supporting actions for the promotion and implementation of the recommendations of the European Code against Cancer;*
- (k) *Supporting actions to improve the quality in cancer care including prevention, screening, early diagnosis, monitoring and treatment, and the establishment of quality assurance schemes for cancer centres or other centres treating cancer patients;*
- (l) *Supporting actions to strengthen secondary prevention of cancer, such as early detection and diagnosis through screening;*
- (m) *Supporting actions to improve the continuity of care (integrated care approaches for prevention, diagnosis, treatment and follow-up care);*
- (n) *Supporting mechanisms for cross-specialty capacity building and continuous education, in particular in the area of cancer care;*
- (o) *Supporting the implementation and further development of the Union's tobacco control policy and legislation;*
- (p) *Strengthening collaboration on patient rights, patient safety and quality of care.*

5. *Actions meeting the objective laid down in Article 4(8), in particular through*
- (a) *Supporting the establishment and operation of a health intelligence and knowledge infrastructure;*
 - (b) *Supporting technical and administrative assistance, including development, maintenance and management of digital tools and databases needed for implementation of Union health legislation;*
 - (c) *Supporting Member States to strengthen the administrative capacity of their healthcare systems through cooperation and exchange of best practices;*
 - (d) *Supporting upwards convergence of national systems' performance through health indicator development, analysis and knowledge brokering;*
 - (e) *Supporting the development of scientific studies and analysis to underpin evidence-based public health measures and policymaking.*
 - (f) *Supporting the establishment of expert groups and panels providing advice, data and information to support health policy development and implementation;*
 - (g) *Supporting national focal points in providing guidance, information and assistance related to the Programme.*
6. *Actions meeting the objective laid down in Article 4(9)*
- (a) *Supporting knowledge transfer actions and Union level cooperation to assist national reform processes towards improved effectiveness, accessibility, sustainability and resilience of health systems;*
 - (b) *Supporting capacity building for investing in and implementing health system reforms (strategic planning and access to multi-source financing);*
 - (c) *Supporting the transfer, adaptation and roll-out of best practices and innovative solutions with established Union level added-value across Member States, and country-specific tailor made support to countries, or groups of countries, with the highest needs, through the funding of specific projects including twinning, expert advice and peer support;*
 - (d) *Supporting cross-border collaboration and partnerships, including in cross-border regions, with a view to transferring and upscaling innovative solutions;*
 - (e) *Strengthening cross-sectoral collaboration and coordination where appropriate;*

- (f) Support the strengthening of primary care, reinforcing the integration of care with a view to universal health coverage and equal access to healthcare;*
- (g) 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;*
- (h) Fostering the system of European Reference Networks, especially for patients requiring highly specialised care as is the case for rare-diseases;*
- (i) 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.*

7. *Actions meeting the objective laid down in Article 4(10)*

- (a) Supporting the WHO as the directing and coordinating authority for Health within the United Nations. Enhancing the effort of the WHO in providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and training to health professionals and health policy makers, as well as monitoring and assessing health trends;*
- (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) Supporting the establishment and operation of a mechanism for cross-sectorial coordination following the One Health approach.*

ANNEX H

~~INDICATORS FOR THE EVALUATION OF THE PROGRAMME~~

A Programme Indicators

- I. ~~Quality and completeness of EU and MS preparedness and response planning for serious cross border threats to health~~
- II. ~~Access to centrally authorised medicines, e.g. number of orphan authorisations, Advanced Therapy Medicinal Products, Paediatric Use Medicinal Products or vaccines, for unmet needs~~
- III. ~~Number of actions and best practices directly contributing to the SDG 3.4/Member State~~
- IV. ~~Implementation of best practices by EU Member States~~

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

- 1. ~~Number of Member States with improved preparedness and response planning~~
- 2. ~~Vaccines, medicines, medical devices and other countermeasures during crises *{made available by type and by MS}*~~
- 3. ~~Number of vaccine doses distributed~~
- 4. ~~Number of entities benefiting of medicines and medical devices~~
- 5. ~~EU Laboratory capacity index (EULabCap)~~
- 6. ~~Age standardised five year net survival of cervical, breast and colorectal cancer~~
- 7. ~~Ratio of Cancer Registries (CRs) and number of Member States (MSs) reporting information on cervical, breast, and colorectal cancer stage at diagnosis~~
- 8. ~~Smoking prevalence~~

9. ~~Number of shortages of medicines in the single point of contact network~~
 10. ~~Access to centrally authorised medicines for unmet needs~~
 11. ~~Number of audits conducted in the EU and in third countries to ensure good manufacturing practices and good clinical practices (Union control)~~
 12. ~~Deaths attributable to antimicrobial resistant infections~~
 13. ~~Number of hospital units involved in ERN and of patients diagnosed and treated by the members of ERN networks~~
 14. ~~Number of Health Technology Assessment reports jointly carried out~~
-