



Brussels, 20 November 2020
(OR. en)

13031/20

Interinstitutional File:
2020/0102(COD)

SAN 412
PHARM 57
MI 500
CADREFIN 382
COVID-19 38
IA 87
CODEC 1164

NOTE

From:	General Secretariat of the Council
To:	Delegations
No. prev. doc.:	11056/20 SAN 323 PHARM 41 MI 356 CADREFIN 264 IA 55 CODEC 856
No. Cion doc.:	8595/20 SAN 184 PHARM 17 MI 157 CADREFIN 114 IA 32 CODEC 464
Subject:	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”)

This is a document comparing the text of the Commission Proposal, amendments voted by the European Parliament on 13 November 2020 and changes to the Proposal approved by the Permanent Representatives Committee on 21 October 2020 (document 11056/20).

This document contains

in Annex A explanations of the content of the tables;

in Annexes B, C, D, E and F the Commission text, the amendments voted by the European Parliament and the Coreper text, together with comments.

Explanation of the table layout¹

Item	Article/ Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
1 item is unchanged compared to the previous document		Plain text in this column is text from the Commission proposal.	Plain text in this column is text from the Commission proposal that the European Parliament proposes to maintain.	Plain text in this column is text from the Commission proposal that Coreper wishes to maintain.	<i>This column contains comments, compromise proposals and tentatively agreed text.</i>

¹ For the sake of readability this document does not contain footnotes. The footnotes will be reintroduced in the consolidated compromise text at the end of the negotiation process.

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1* Item numbering followed by asterisk means that the contents of the item has been changed compared to an earlier version of the document.		<i>Text in bold italics in this column is text from the Commission proposal that the EP proposes to delete.</i>	<i>Text in bold italics in this column is text that the EP proposes to add to the Commission proposal.</i>	<i>Text in bold italics</i> in this column is text that Coreper has agreed to add. Text in strike through in this column is text that Coreper has agreed to delete.	

Citations and Recitals

This Annex contains the Citations and Recitals in the Proposal 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”). For explanations of layout and fonts see Annex A.

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
1	Citations	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(5) thereof, Having regard to the proposal from the European Commission, After transmission of the draft legislative act to the national parliaments, Having regard to the opinion of the European Economic and Social Committee, Having regard to the opinion of the Committee of the Regions,	No EP amendment	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(5) thereof, Having regard to the proposal from the European Commission, After transmission of the draft legislative act to the national parliaments, Having regard to the opinion of the European Economic and Social Committee, Having regard to the opinion of the Committee of the Regions,	<i>No changes proposed.</i>

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
1 continued		Acting in accordance with the ordinary legislative procedure, Whereas:		Acting in accordance with the ordinary legislative procedure, Whereas:	
2	Recital 1	(1) According to Article 3(1) of the Treaty on the European Union, amongst the aims of the Union is to promote the well- being of its peoples.		(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.	
3	Recital 1a (new)		Amendment 1 <i>(1a) According to Article 8 of the Treaty on the Functioning of the European Union, in all its activities, the Union shall aim to eliminate inequalities, and to promote equality, between men and women, establishing the principle of gender mainstreaming.</i>		

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
4	Recital 2	(2) In accordance with Articles 9 and 168 of the Treaty on the Functioning of the European Union (TFEU) and Article 35 of the Charter of Fundamental Rights of the European Union (the Charter), a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities.	Amendment 2 (2) In accordance with Articles 9, 114 , 168 and 191 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.	(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.	
5	Recital 3	(3) Article 168 TFEU provides that the Union is to complement and support national health policies, encourage cooperation between Member States and promote the coordination between their programmes, in full respect of the responsibilities of the Member States for the definition of their health policies and the organisation and delivery of health services and medical care.	Amendment 3 (3) Article 168 TFEU provides that the Union is to complement and support national health policies, encourage cooperation between Member States, particularly in border regions , and promote the coordination between their programmes, in full respect of the responsibilities of each Member State to define their own health policy and to organise, deliver and manage health services and medical care.	(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.	

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6	Recital 4	(4) Continued actions have been taken in particular under the previous programmes of Union action in the field of public health to meet the requirements set out in Article 168 TFEU.		(4) Continued actions <i>provided for by Decisions No 1786/2002/EC 2002 and No 1350/2007/EC of the European Parliament and of the Council and Regulation (EU) No 282/2014 of the European Parliament and of the Council</i> have been taken in particular under the previous programmes of Union action in the field of public health to meet the requirements set out in Article 168 TFEU.	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
7	Recital 5	(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.	Amendment 4 (5) On 11 March 2020 the World Health Organization (WHO), <i>due to an exponential increase of cases,</i> declared <i>COVID-19 (the disease resulting from the novel coronavirus SARS-CoV-2), and associated respiratory disease</i> outbreak a global pandemic. <i>The COVID-19 pandemic and more specifically the moderate to severe cases of the disease that need intermediate and intensive medical care pushed several health systems to breaking point within and outside of the Union,</i> caused an unprecedented worldwide health crisis with severe socio-economic consequences and human suffering, <i>particularly affecting people with chronic conditions, causing both premature death and chronic conditions, and hitting the most vulnerable, patients, women, children, carers and the elderly the hardest. The severity of the crisis demonstrates also the importance of Union action and of adequately responding to threats deriving</i>	(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.	

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7 continued			<i>from infectious diseases, and in general of strengthening the Union's actions to complement national policies in the field of public health.</i>		
8	Recital 5a (new)		Amendment 5 <i>(5a) Health care workers, which have been essential during the COVID-19 crisis, are predominantly women, and have been exposed to greater health risks during the crisis.</i>		
9	Recital 5b (new)		Amendment 6 <i>(5b) Taking into account that the effects of diseases can be different between men and women, as it seems clear with Covid 19, which has a higher mortality rate in men, the Programme should study the causes of diseases' behaviour in order to advance as regards pathology, treatment and cures.</i>		

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10	Recital 6	(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity⁸. 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 <i>in order to</i> 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.	Amendment 7 (6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity⁸. 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, <i>in particular between neighbouring border regions, as well as between authorities and relevant stakeholders. This cooperation should</i> improve the <i>preparedness</i>, prevention and control of the spread of severe human <i>infections and</i> diseases across borders, <i>to develop and make available products for the prevention and treatment of diseases</i>, to combat other serious cross-border threats to health, and to safeguard <i>and improve</i> the health and well-being of <i>all</i> people in the Union. <i>Preparedness is the key to improving resilience to future threats, and Member States, given their responsibility for the</i>	(6) While Member States are responsible for their health policies, they are expected to <i>should</i> protect public health in a spirit of European solidarity 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.	

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10 continued			<i>provision of healthcare, should carry out stress tests on their healthcare systems to identify weaknesses and verify that they are prepared for a possible future health crisis.</i>		

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11	Recital 6a (new)		Amendment 8 <i>(6a) While the Union's action in the field of health is limited, the Union should follow a coherent public health strategy in order to respond to existing epidemics taking into consideration regional and national specificities and have the capacity to face future worrying realities and health threats, such as pandemics and cross-border threats, including antimicrobial resistance, environmental health and the health impacts of the climate change. The Union should support Member States in reducing health inequalities and in achieving universal health coverage, including provision of sexual and reproductive health services, addressing healthcare associated infections, addressing the challenges of vulnerable groups, such as children, infant and maternal care, an ageing population, of chronic diseases, and disease prevention, in promoting a healthy lifestyle, prevention services and preparing</i>		

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11 continued			<i>their health systems for emerging technologies in order to fully benefit from the digital revolution while seeking synergies with other relevant Union programmes such as Horizon Europe, Digital Europe, the Connecting Europe Facility programme or the Union's Space Programme.</i>		
12	Recital 7	(7) It is therefore appropriate to establish a new Programme for the Union's action in the field of health, called EU4Health Programme ('the Programme') for the period 2021 - 2027. In line with the goals of the Union action and its competences in the area of public health the Programme should place emphasis on actions in relation to which there are advantages and efficiency gains from collaboration and cooperation at Union level and actions with an impact on the internal market.	Amendment 9 (7) It is therefore appropriate to establish a new Programme for the Union's action in the field of public health, called EU4Health Programme ('the Programme') for the period 2021 -2027. In line with the goals of the Union action and its competences in the area of public health the Programme should place emphasis on actions in relation to which there are advantages and efficiency gains from collaboration at Union level as well as from cross-border cooperation at regional level and actions with an impact on the internal market. A holistic approach is needed to improve health outcomes, and EU policy-makers should ensure that the principle of 'health in all policies' is applied in all policy-making.	(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.	

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13	Recital 7a (new)			<i>(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.</i>	

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

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16	Recital 10	(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats.	Amendment 10 (10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level, as well as between neighbouring regions to address different aspects of such threats.	(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.	<i>Council split this recital into (10) and (10a).</i>
17	Recital 10 (continued)	With a view to strengthen the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council ¹⁰ and other relevant mechanisms and structures established at Union level. This could include strategic stockpiling of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes.	With a view to strengthen the capability in the Union to prepare for, respond to and manage any future health crises , the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council ¹⁰ and other relevant mechanisms and structures established at Union level. This could include capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes, health information, and platforms to share best practices.	(10a) With a view to strengthen the capability in the Union to prevent , prepare for, respond to and manage health crisis 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 Council and other relevant mechanisms and structures established at Union level. This could include strategic stockpiling of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes.	<i>Council split this recital into (10) and (10a).</i>

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17 continued	Recital 10 (continued)	In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” approach . It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.	In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” and “Health in all policies” approaches . It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.	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.	

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18	Recital 11	(11) <i>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.</i> The Commission has adopted a proposal ¹¹ on Health Technology Assessment (HTA) to support cooperation on health technology assessment at Union level.	Amendment 11 (11) In the <i>context of public</i> health <i>crises,</i> Health Technology Assessment (<i>HTA)</i> and clinical trials can contribute to the rapid development, <i>identification and availability</i> of medical countermeasures. The Commission has adopted a proposal ¹¹ on Health Technology Assessment (HTA) to support cooperation on health technology assessment at Union level. <i>The Programme should provide support to facilitate such actions.</i>	(11) As in the time of health crisis emergency health technology assessment as well as clinical trials can contribute to the rapid development of medical countermeasures the Programme should provide support to facilitate such actions. The Commission has adopted a proposal on Health Technology Assessment (HTA) to support cooperation on health technology assessment at Union level.	

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19	Recital 12	(12) With a view to protect people in vulnerable situations, including those suffering from mental illnesses and chronic diseases, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups.	Amendment 12 (12) With a view to protect people in vulnerable situations, including those suffering from mental illnesses, <i>living with or most affected by communicable or non-communicable diseases</i> and chronic diseases, <i>such as obesity, cancer, diabetes, cardiovascular disease and neurological disorders</i> , the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups. <i>With a view to guaranteeing continued high standards of essential healthcare services, including prevention, the Programme should, in particular in times of crisis and pandemics, encourage a transition to accessible and affordable telemedicine, at-home administration of medication and implementation of preventative and self-care plans, where possible and appropriate, while ensuring that access to healthcare and prevention services is provided to chronic patients and patients at risk.</i>	(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 <i>and prevent</i> the collateral impacts of health crises on people belonging to such vulnerable groups <i>and improve mental health.</i>	

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20	Recital 13	(13) The COVID-19 crisis has highlighted many challenges in ensuring the supply of medicines, medical devices as well as personal protective equipment needed in the Union during the pandemics. The Programme therefore should provide support to actions which <i>foster</i> the production, procurement and management of crisis relevant products ensuring complementarity with other Union instruments.	Amendment 13 (13) The COVID-19 crisis has highlighted many challenges <i>including the Union's dependency on third countries</i> in ensuring the supply of <i>chemical raw and starting materials, active pharmaceutical ingredients</i> , medicines, medical devices as well as personal protective equipment needed in the Union during the pandemics. The Programme therefore should provide support to actions which <i>will increase the security of production, procurement, management and distribution of medicinal products and medical devices in the Union and reduce dependency on third countries by encouraging the diversification of supply chains, fostering the production in the Union and joint</i> procurement and management of crisis relevant products ensuring complementarity with other Union instruments, <i>to mitigate the risk of shortages, especially in periods of health crises</i> .	(13) The COVID-19 crisis has highlighted many challenges in ensuring the supply of medicines <i>medicinal products</i> , medical devices as well as <i>and</i> personal protective equipment needed in the Union during <i>health crises in particular</i> pandemics. The Programme therefore should provide support to actions which foster the production, procurement and management of crisis relevant products <i>within the Union</i> , ensuring complementarity with other Union instruments.	

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

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22	Recital 14 a (new)		Amendment 15 <i>(14a) The establishment of a communication portal for the public would allow the Union to share validated information, send alerts to European citizens and fight against disinformation. It could include a wide range of information, prevention campaigns and youth education programs. This portal could also be used to promote, in cooperation with the European Centre for Disease Control ('ECDC'), strong immunization coverage at European level.</i>		
23	Recital 15	(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	(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, sustainability and resilience. In the context of such transformation and reforms, the Programme should promote, in synergy with,	(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	

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23 continued		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 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 <i>primordial, primary, secondary, tertiary and quaternary</i> disease prevention and health promotion, to provide new <i>outcome -based</i> care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs <i>enhancing citizens' levels of health literacy and digital health literacy</i> , and ensure an efficient public health workforce equipped with the right skills, including digital skills, <i>regularly updated in the light of scientific and technological progress, as provided for in Directive 2005/36 /EC of the European Parliament and of the Council The synergy between the European Health Programme and the Digital Europe Programme should contribute to</i>	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.	

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23 continued		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 2006¹² the Programme should support actions ensuring the universality and inclusivity of	<i>the implementation and expansion of e-health, reducing unnecessary travel and unmet healthcare needs.</i> The development of a European health data space <i>and of a European electronic health record</i> would provide health care systems, researchers and public authorities with means to improve the <i>accessibility, affordability, availability and quality of healthcare, increasing the amount of data available to patients and health workers, and thereby improving the quality of healthcare and the patient's freedom of movement around the Union.</i> 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 2006¹² the Programme should support actions ensuring the universality and inclusivity of	The development of a European health data space would provide health care systems, researchers and public authorities with means to improve the availability and quality of healthcare. Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006 the Programme should support actions ensuring the universality and inclusivity of	

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23 continued		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.	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. <i>The Programme should support access to and sharing of personal health data, without prejudice to the application of GDPR and increase the digital skills of patients.</i>	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.	
24	Recital 15a (new) (EP)		Amendment 17 <i>(15 a) Gender and sex sensitivity and knowledge need to be improved in the education of health care professionals, the research, diagnosis, treatment and impact of medicines and therapeutics to better understand and treat both sexes.</i>		
24a	Recital 15a (new) (Council)			<i>(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.</i>	

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25	Recital 15 b (new)		Amendment 18 <i>(15 b) Under Article 153 TFEU, the Union is to support and complement the activities of Member States concerning improvement of the working environment, and protection of workers' health, safety and working conditions. It is important to take account of the large amount of time that workers spend in their workplaces and the potential health risk they could be exposed to, such as health hazard substances and carcinogens and to repeated movements, leading to a high burden as regards incapacity and number of work days lost, which in turn has consequences for the individual, family and society. The Programme should also reflect the importance of occupational health and its impact on health workers and societies. The Commission should work with Member States to create new legislation to improve workers' health conditions, improve their</i>		

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25 continued			<i>working conditions, the balance between work and life, promote wellbeing and better mental health, prevent early-retirement due to ill health and poor health management.</i>		
26	Recital 15 c (new)		Amendment 19 <i>(15c) The programme should facilitate the revision of the EU-OSHA's mandate to promote healthy and safe workplaces across the Union and to support the Agency's activities and analysis regarding occupational safety and health. The Commission should propose a new Union strategic framework on occupational safety and health for the period 2021 – 2027 and continue updating Directive 2004/37/EC of the European Parliament and of the Council. The programme should also support actions to facilitate people's return to the workplace after long-term sick leave and to better include people who are chronically sick or have a disability in the workforce.</i>		

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
27	Recital 16	(16) Keeping people healthy and active longer and empowering them to take an active role in managing their health will have positive effects on health, health inequalities, quality of life, productivity, competitiveness and inclusiveness, while reducing pressures on national budgets. The Commission has committed to help Member States to reach the sustainable development targets set in the 'UN 2030 Agenda for Sustainable Development' in particular Sustainable Development Goal 3 "Ensure healthy lives and promote well-being for all at all ages". ¹³	Amendment 20 (16) <i>Health is an investment and the Programme should have this concept at its core.</i> Keeping people healthy and active longer and empowering them to take an active role in managing their health, <i>by improving their health literacy,</i> will have positive effects on health, health inequalities, <i>health inequities,</i> quality of life, productivity, competitiveness and inclusiveness, while reducing pressures on national <i>health systems and</i> budgets. <i>The Programme should also support action to reduce inequalities in the provision of healthcare, in rural and remote areas including in the outermost regions, for the purposes of achieving inclusive growth.</i> The Commission has committed to help Member States to reach the sustainable development targets set in the 'UN 2030 Agenda for Sustainable Development' in particular Sustainable Development Goal 3 "Ensure healthy lives and promote well-being for all at all ages". ¹³	(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".	

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27 continued		The Programme therefore should contribute to the actions taken towards reaching <i>these</i> goals.	The Programme therefore should contribute to the actions taken towards reaching <i>the SDGs</i> goals, <i>and consequently improve the social determinants of health and enhance the health of the Union's citizens.</i>	The Programme therefore should contribute to the actions taken towards reaching these goals.	
28	Recital 17	(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental <i>and behavioural factors</i> . Such non-communicable diseases as cardiovascular diseases, cancer, chronic respiratory diseases, <i>and</i> diabetes, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts. To decrease the impact of non-communicable diseases on individuals and	Amendment 21 (17) Non-communicable diseases are a result of a combination of genetic <i>and health determinants</i> (physiological, <i>behavioural</i> , and environmental) Such non-communicable diseases, as cardiovascular diseases, cancer, <i>obesity</i> , chronic respiratory diseases, diabetes, <i>mental health illness and neurological disorders</i> represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, <i>while non-communicable diseases were responsible for 87% of Disability-Adjusted Life Years (DALYs) in the Union in 2017</i> ,resulting in considerable <i>affective</i> , social and economic impacts. To decrease the impact of non-communicable diseases on individuals and	(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and behavioural factors. Such non <i>Non-communicable diseases such as cardiovascular diseases, cancer, mental illnesses, neurological disorders</i> , chronic respiratory diseases and diabetes, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, <i>and resulting in cause</i> considerable social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society	

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28 continued		society in the Union and reach goal 3 of the Sustainable Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors and policy fields , combined with efforts to strengthen health systems.	society in the Union and reach goal 3 of the Sustainable Development Goals, particularly but not exclusively Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on health promotion and prevention across sectors, specialties and policy-fields, taking into account the interrelated nature of most non-communicable diseases , combined with efforts to strengthen health systems and the supply of appropriate medicines., on strengthening the implementation of the WHO Framework Convention on Tobacco Control is crucial to achieving an effective, sustainable reduction in preventable non-communicable diseases. The Program should support actions aimed at integrating mental health into all areas, including in the workspace and in schools, and promote actions to combat depression and suicide and to implement integrative mental health care.	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.	

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29	Recital 18	(18) <i>The Programme</i> therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of	Amendment 22 (18) <i>Health promotion and health prevention are vastly more cost-efficient than treatment, both in terms of money and of quality-adjusted life years, therefore the Programme</i> should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing <i>determinants of health, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, an unhealthy food environment, and the consumption of illicit drugs and psychoactive substances. To achieve the best health status possible, the Programme should tackle all health determinants. Health promotion, health protection and disease prevention throughout the lifetime of an individual should be at the core of the programme by addressing health and mental</i> risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of	(18) The Programme therefore should <i>therefore support</i> contribute to <i>health promotion and</i> disease prevention <i>and improve mental health</i> throughout the lifetime of an individual and to health promotion by addressing health risk factors, such as <i>obesity, unhealthy diets, physical inactivity</i> , the use of tobacco and related products and exposure to their emissions , the harmful use of	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
29 continued		alcohol, and the consumption of <i>illicit</i> drugs. The Programme should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits <i>and</i> 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 <i>therefore</i> contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.	alcohol, and the consumption of drugs <i>and other addictive behaviours</i> . The Programme should also contribute to the reduction of drugs-related health damage, <i>obesity and</i> unhealthy dietary habits, physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. <i>The Programme therefore should contribute to a high level of human health protection and prevention, throughout the entire lifetime of an individual, including through the promotion of physical activity, nutritional care and promotion of health education. The Programme should also strengthen and support the implementation of the Union's health-related legislation, including in the area of environmental health, and foster the 'Health in All Policies' approach. The Programme should also</i> contribute to the objectives of the European Green	alcohol, and the consumption of illicit drugs, <i>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'</i> . 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.	

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29 continued			Deal, the Farm to Fork Strategy and the Biodiversity Strategy <i>and the Chemicals strategy for sustainability</i> .		
30	Recital 18a (new)		Amendment 23 <i>(18a) The Programme should continue supporting actions in the area of reducing and preventing alcohol related harm in the perspective of a revised Union alcohol strategy. Protecting children from alcohol should be one of the Programme's priorities.</i>		
31	Recital 18 b (new)		Amendment 24 <i>(18b) The burden of chronic diseases is still significant in the Union. Chronic diseases develop slowly, are long-lasting and often incurable. Chronic diseases are, in many cases, associated with more than one comorbidity, which makes them even more difficult to treat and manage. They have caused great human suffering and also placed an enormous burden on health systems. However, many chronic diseases, such as cardiovascular</i>		

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31 continued			<i>diseases and type 2 diabetes, could be prevented by healthy lifestyle choices, while other illnesses, for instance neurological diseases, can be managed to slow the onset if detected early, or helping patients feel their best and remain active for longer. The Union and the Member States can therefore greatly reduce the burden of Member States by working together to achieve a better and more effective management of diseases, and the Programme should support actions in this area. The Programme should support the development of specific European preventive and disease management guidelines in the area of both communicable and non-communicable diseases, such as cardiovascular diseases, neurodegenerative diseases, respiratory diseases and diabetes.</i>		

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32	Recital 19	(19) Cancer is the second leading cause of mortality in the Member States after cardiovascular diseases. It is also one of non-communicable diseases that share common risk factors and the prevention and control of which would benefit the majority of citizens. In 2020 the Commission announced the	Amendment 25 (19) Cancer is the second leading cause of mortality in the Member States after cardiovascular diseases. <i>Cancer is caused by many factors and therefore requires a new prevention paradigm that addresses individual health determinants (genetic, lifestyle) and wider (populations) determinants related to occupational, environmental and social exposure factors.</i> It is also one of non-communicable diseases that share common risk factors <i>with others</i> and the prevention and control of which would benefit the majority of citizens. <i>Poor nutrition, physical inactivity, obesity, tobacco and alcohol are risk factors common to other chronic diseases, such as cardiovascular diseases, and therefore cancer prevention programmes should be implemented within the context of an integrated chronic disease prevention programme.</i> In 2020 the Commission announced the	(19) Cancer is the second leading cause of mortality in the Member States after cardiovascular diseases. It is also one of <i>the</i> 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	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
32 continued		‘Europe’s Beating Cancer Plan’ which would cover <i>the entire cycle</i> of the disease <i>starting from</i> prevention <i>and early</i> diagnosis <i>to</i> treatment <i>and</i> quality of life <i>of patients and survivors</i> . The measures should benefit from the Programme and from Horizon Europe’s Mission on Cancer.	‘Europe’s Beating Cancer Plan’ which would cover <i>every key stage</i> of the disease: prevention, diagnosis, treatment, <i>life as a cancer survivor, reinsertion and palliative care and pain management. The programme should promote actions to complement the 'Europe's Beating Cancer Plan' and thus improve cancer patients'</i> quality of life. The measures should benefit from the Programme and from Horizon Europe’s Mission on Cancer <i>in particular by initiatives which support the mid- and long- term goals of the Plan, and address cancer’s common risk factors and synergies with other major non-communicable diseases.</i>	‘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 <i>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.</i>	
33	Recital 19a (new)			<i>(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.</i>	

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34	Recital 20	(20) The Programme will work in synergy and complementarity with other EU policies, programmes and funds such as actions implemented under the Digital Europe Programme, Horizon Europe, rescEU reserve under the Union Civil Protection Mechanism, Emergency Support Instrument, European Social Fund+ (ESF+, including as regards synergies on better protecting the health and safety of millions of workers in the EU), including the Employment and Social Innovation Strand (EaSI), the InvestEU fund, Single Market Programme, European Regional Development Fund (ERDF), Recovery and Resilience Facility including the Reform Delivery Tool, Erasmus, European Solidarity Corps, Support to mitigate Unemployment Risks in an Emergency (SURE), and EU external action instruments, such as the Neighbourhood,	Amendment 26 (20) The Programme will work in synergy and complementarity with other EU policies, programmes and funds such as actions implemented under the Digital Europe Programme, Horizon Europe, rescEU reserve under the Union Civil Protection Mechanism, Emergency Support Instrument, European Social Fund+ (ESF+, including as regards synergies on better protecting the health and safety of millions of workers in the EU), including the Employment and Social Innovation Strand (EaSI), the InvestEU fund, Single Market Programme, European Regional Development Fund (ERDF), including Interreg , Recovery and Resilience Facility including the Reform Delivery Tool, Erasmus, European Solidarity Corps, Support to mitigate Unemployment Risks in an Emergency (SURE), and EU external action instruments, such as the Neighbourhood,	(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,	

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34 continued		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+.	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, <i>avoiding any overlap or duplication of financing</i> , 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+.	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+. <i>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.</i>	
34a	Recital 20a (new) (Council)			<i>(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.</i>	

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35	Recital 20 a (new) (EP)		Amendment 249 <i>(20a) The Programme should contribute to the establishment of a reserve of health crisis relevant products, such as essential medicines, vaccines and medical devices, in synergy and complementarity with rescEU, the Emergency Support Instrument, the Resilience Instrument and with other Union policies, programmes and funds.</i>		

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36	Recital 21	(21) In accordance with Article 114 TFEU, a high level of health protection should be ensured in the legislation adopted by the Union for the establishment and the functioning of the internal market. On the basis of Article 114 TFEU and point (c) of Article 168(4) TFEU, a considerable body of Union acquis was developed which guarantees the high standards of quality and safety for medicinal products and medical devices. Given the rising healthcare demand, Member States' healthcare systems face challenges in the availability and affordability of medicines and medical devices. To ensure a better public health protection as well as the safety and empowerment of patients in the Union, it is essential that patients and health systems have access to high quality healthcare products and can fully benefit from them.	Amendment 27 (21) In accordance with Article 114 TFEU, a high level of health protection should be ensured in the legislation adopted by the Union for the establishment and the functioning of the internal market. On the basis of Article 114 TFEU and point (c) of Article 168(4) TFEU, a considerable body of Union acquis was developed which guarantees the high standards of quality and safety for medicinal products and medical devices. Given the rising healthcare demand, Member States' healthcare systems face challenges in the availability and affordability of medicines and medical devices. To ensure a better public health protection as well as the safety and empowerment of patients in the Union, it is essential that patients and health systems have access to <i>sustainable, efficient, equitable, affordable and</i> high quality healthcare products, <i>including in a cross-border context</i> , and can fully benefit from them, <i>based on transparent, consistent, patient-oriented medical information</i> .	(21) In accordance with Article 114 TFEU, a high level of health protection should be ensured in the legislation adopted by the Union for the establishment and the functioning of the internal market. On the basis of Article 114 TFEU and point (c) of Article 168(4) TFEU, a considerable body of Union acquis was developed which guarantees the high standards of quality and safety for medicinal products and medical devices. Given the rising healthcare demand, Member States' healthcare systems face challenges in the availability and affordability of medicines and medical devices. To ensure a better public health protection as well as the safety and empowerment of patients in the Union, it is essential that patients and health systems have access to high quality healthcare products and can fully benefit from them.	

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37	Recital 22	(22) The Programme should therefore support actions to monitor shortages of medicines, medical devices and other healthcare products and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet medical needs, the Programme should provide support to clinical trials so as to speed up the development, authorisation and access to innovative and effective medicines,	Amendment 28 (22) The Programme should support the development of a European monitoring, reporting and notification system for shortages of medicines, medical devices, vaccines, diagnostic tools, and other healthcare products, to avoid fragmentation of the single market and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries. The Programme should, therefore encourage the production of medicinal products and medical devices within the Union. In particular, in order to address unmet medical needs, the Programme should provide support to clinical and real world evidence generation to enable the development, authorisation, evaluation of and access to effective medicines, including generics and biosimilars, medical devices, and treatment, promote research and the development of new medicinal products, with	(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 ,	

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37 continued		promote incentives to <i>develop such medicinal products as</i> antimicrobials and foster the <i>digital</i> transformation of healthcare products and platforms for monitoring and collecting information on medicines.	<i>particular attention to be given to antimicrobials and vaccines to tackle AMR and vaccine-preventable diseases</i> , promote incentives to <i>boost the production capacity for</i> antimicrobials, <i>personalized treatment and vaccination</i> , and foster the <i>digital</i> transformation of healthcare products and platforms for monitoring and collecting information on medicines. <i>The Programme should also strengthen decision-making on medicines by enabling access to and analysis of real-world healthcare data by regulators and health technology assessments ('HTA'), bodies. The Programme should also help to ensure best use of research results and facilitate the uptake, scaling-up and deployment of health innovation in healthcare systems and clinical practice.</i>	promote incentives to develop such medicinal products, <i>in particular as</i> antimicrobials, and foster the digital <i>digital</i> transformation of healthcare products <i>systems</i> and platforms for monitoring and collecting information on medicines <i>medicinal products</i> .	

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38	Recital 22 a (new)		Amendment 29 <i>(22 a) A harmonised definition should be laid down at Union level for the terms ‘shortage’, ‘tension’, ‘supply disruptions’, ‘stock-out’ and ‘overstocking’. The Commission should work towards developing such harmonised definitions in close cooperation with the Member States and all the relevant stakeholders, including patient organisations. Moreover, the Commission should, in particular, reinforce the definition of ‘shortage’ proposed by the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) joint Task Force in 2019.</i>		
39	Recital 23	(23) As the optimal use of medicines and antimicrobials in particular yields benefits for individuals and health systems, the Programme should promote their prudent and efficient use. In	(23) As the optimal use of medicines and antimicrobials in particular yields benefits for individuals and health systems, the Programme should promote their prudent and efficient use. In	(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	

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39 continued		line with the European One Health Action Plan against Antimicrobial Resistance ¹⁴ , adopted in June 2017 following the request from Member States, and given <i>the experience with the bacterial secondary infections related to COVID 19</i> , 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.	line with the European One Health Action Plan against Antimicrobial Resistance ¹⁴ , adopted in June 2017 following the request from Member States, and given <i>that infections and sepsis caused by antibiotic-resistant bacteria are responsible for a high number of deaths in the Union</i> , it is essential that the Programme supports actions aimed at the prudent use of antimicrobials in humans, animals and crops, <i>and actions including the use of non-antibiotic integrative treatments</i> , in the framework of an integrated policy on patient safety and prevention of medical errors. <i>The Programme should support the monitoring and surveillance programmes on the usage of antimicrobials and AMR, and the support to the implementation of local, regional and national plans to fight against AMR, supported by evidence-based strategies and the sharing of good practices within the Union.</i>	<i>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)’, 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’</i> , 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.	

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40	Recital 24	(24) Since <i>environmental</i> pollution caused by human and veterinary pharmaceutical substances is an emerging environmental problem that can impact on public health, the Programme should foster measures to strengthen the assessment and appropriate management of environmental risks associated with the production, use and disposal of medicinal products, in line with the European Union Strategic Approach to Pharmaceuticals in the Environment ¹⁵ .	Amendment 31 (24) Since <i>the</i> pollution caused by human and veterinary pharmaceutical substances is an emerging environmental problem that can impact on public health, the Programme should foster measures to strengthen the assessment and appropriate management of environmental risks associated with the production, use and disposal of medicinal products, in line with the European Union Strategic Approach to Pharmaceuticals in the Environment ¹⁵ .	(24) Since environmental pollution caused by human and veterinary pharmaceutical substances is an emerging environmental problem that can impact on public health, the Programme should foster measures to strengthen the assessment and appropriate management of environmental risks associated with the production, use and disposal of medicinal products, in line with the European Union Strategic Approach to Pharmaceuticals in the Environment.	
41	Recital 25	(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	Amendment 32 (25) The Union health legislation has an immediate impact on public health <i>and safety</i> , 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	(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	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
41 continued		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.	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, <i>in conjunction with key partners such as EMA and ECDC</i> , provide high quality, <i>unbiased</i> , comparable and reliable data, <i>including real-world healthcare data collected locally across Europe, through a well-defined homogeneous methodology</i> , to underpin policymaking and monitoring, <i>set targets and develop tools to measure progress</i> .	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.	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
42	Recital 26	(26) Cross-border cooperation in the provision of healthcare to patients moving between Member States, collaboration on health technology assessments (HTA), and European Reference Networks (ERNs) are examples of areas where integrated work among Member States has shown to have strong added value and great potential to increase the efficiency of health systems and thus health in general. The Programme should therefore <i>support activities to enable</i> such integrated and coordinated work, <i>which also serves</i> to foster the implementation of high-impact practices that are aimed at distributing in the most effective way the available resources to the <i>concerned</i> population and areas so as to maximise their impact.	Amendment 33 (26) Cross-border cooperation in the provision of healthcare to patients moving between Member States <i>or living in border regions</i> , collaboration on health technology assessments (HTA), and European Reference Networks (ERNs) are examples of areas where integrated work among Member States has shown to have strong added value and great potential to increase the efficiency of health systems and thus health in general. The Programme should therefore <i>be aimed at ensuring that</i> such integrated and coordinated work <i>is developed and implemented to its full potential in areas such as HTA and ERNs. That work would serve</i> to foster the implementation of high-impact practices that are aimed at distributing in the most effective way the available resources to the <i>relevant groups of the</i> population and areas so as to maximise their impact.	(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 <i>between</i> Member States has <i>been</i> shown to have strong added value and great potential to increase the efficiency of health systems and thus <i>to improve public</i> health in general. <i>Collaboration on health technology assessments (HTA) is another area that has the potential to bring added value to Member States.</i> The Programme should therefore support activities to <i>that</i> enable integrated and <i>sustained</i> coordinated work, which also serves to foster the implementation of <i>best</i> 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.	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
43	Recital 26 a (new)		Amendment 34 <i>(26 a) Solidarity and unity are principles of the Union and the programme should ensure that the Union has a coherent approach to combating cross-border health-threats. In order to respond to public health threats, the Programme should under Article 168 TFEU support the creation of a European Health Response Mechanism, coordinated by the ECDC and led by the Commissioner for Health and the Commissioner for Crisis Management, fully articulated with the other EU health agencies. This Mechanism with its own medical resources under a strengthened Union Civil Protection Mechanism should be prepared with a pandemic emergency plan, in order to have a coordinated response and the capacity to rapidly scale up the response to future health crises, based on standardised information.</i>		

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
44	Recital 27	(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council ¹⁶ are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources.	Amendment 35 (27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council ¹⁶ are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. <i>ERNs are a ground-breaking platform that represents a unique opportunity and which, based on the innovative use and sharing of knowledge and health data across borders, aims to improve diagnosis and care for people living with a rare or complex disease. The Programme should, therefore, provide adequate funding to support the coordination and collaborative activities of both existing and future ERNs through grants or other instruments that are fit for purpose. It should increase upscale current funding to ensure that ERNs fulfil the</i>	(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council, 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.	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
44 continued		As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider <i>the extension of ERNs beyond rare diseases to</i>	<i>objectives set out in their mission.</i> As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should <i>also</i> contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider <i>reinforcing ERNs, supporting the creation of new ERNs to cover infectious diseases, complex pregnancies and rare and complex mental health diseases. The reinforcement of ERNs can play a key role in supporting the adoption of a common newly developed screening framework at Union level, starting from disease selection criteria and mechanisms, with the aim of overcoming existing inequalities in terms of screening coverage across Member States. The Programme should also consider the development of excellence networks in the field of</i>	As the Networks the <i>ERNs</i> 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 <i>strengthening and</i> upscaling of networking through <i>and between</i> the ERNs, and other transnational networks with an <i>that have EU Union added value by supporting the coordination of activities between Member States.</i> It should consider the extension of ERNs beyond rare diseases to	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
44 continued		communicable and non-communicable diseases <i>such as</i> cancer.	communicable and non-communicable diseases, <i>including</i> cancer <i>and paediatric cancer, cardiovascular disease, chronic respiratory disease, diabetes, mental health conditions, neurodegenerative diseases and other major chronic diseases, and in the field of health crisis management.</i>	communicable and non-communicable diseases such as cancer.	
45	Recital 27 a (new)		Amendment 36 <i>(27 a) The ERNs face significant challenges as regards ensuring they are financially sustainable and are able to operate effectively within and across national healthcare systems, as highlighted by the European Court of Auditors, in their “Special report no 07/2019: EU actions for cross-border healthcare”.</i>		

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
46	Recital 28	(28) Regulation (EU, <i>Euratom</i>) 2018/1046 of the European Parliament and of the Council (the ‘Financial Regulation’) applies to this Programme. It lays down rules on the implementation of the Union budget, including the rules on grants, prizes, procurement, indirect implementation, financial assistance, financial instruments and budgetary guarantees.		(28) Regulation (EU, <i>Euratom</i>) 2018/1046 of the European Parliament and of the Council (the ‘Financial Regulation’) applies to this Programme. It <i>The Financial Regulation</i> lays down rules on the implementation of the Union budget, including the rules on grants, prizes, procurement, indirect implementation <i>management, budgetary guarantees</i> , financial assistance <i>and the reimbursement of external experts</i> , financial instruments and budgetary guarantees .	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
47	Recital 29	(29) The types of financing and the methods of implementation under this Regulation should be chosen on the basis of their ability to achieve the specific objectives of the actions and to deliver results, taking into account, in particular, the costs of controls, the administrative burden, and the expected risk of non-compliance. This should include consideration of the use of lump sums, flat rates and unit costs, as well as financing not linked to costs as envisaged in Article 125(1) of the Financial Regulation.		(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.	
48	Recital (30)	(30) In order to optimise the added value and impact from investments funded wholly or in part through the budget of the Union, synergies should be sought in particular between the Programme for the Union's action in the field of health and other Union programmes, including those under shared-management.	Amendment 37 (30) In order to optimise the added value and impact from investments funded wholly or in part through the budget of the Union, synergies should be sought in particular between the Programme for the Union's action in the field of health and other Union programmes, including those under shared-management, in particular the Interreg programme, which already	(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.	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
48 continued		To maximise those synergies, key enabling mechanisms should be ensured, including cumulative funding in an action from the Programme for the Union's action in the field of health and another Union programme, as long as such cumulative funding does not exceed the total eligible costs of the action. For that purpose, this Regulation should set out appropriate rules, in particular on the possibility to declare the same cost or expenditure on a pro-rata basis to Programme for the Union's action in the field of health and another Union programme.	<i>addresses cross-border cooperation in the field of health and helps to facilitate the cross-border mobility of patients and health professionals, and to develop access to high quality healthcare through the use of common equipment, shared services and joint facilities in cross-border areas.</i> To maximise those synergies, <i>and avoid duplications</i>, key enabling mechanisms should be ensured, including cumulative funding in an action from the Programme for the Union's action in the field of health and another Union programme, as long as such cumulative funding does not exceed the total eligible costs of the action. For that purpose, this Regulation should set out appropriate rules, in particular on the possibility to declare the same cost or expenditure on a pro-rata basis to Programme for the Union's action in the field of health and another Union programme, <i>guaranteeing detailed and transparent reporting.</i>	To maximise those synergies, key enabling mechanisms should be ensured <i>provided for</i>, 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 <i>this</i> Programme for the Union's action in the field of health and another Union programme.	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
49	Recital 31	(31) Given the specific nature of the objectives and actions covered by the Programme, the respective competent authorities of the Member States are best placed in some cases to implement the related activities. Those authorities, designated by the Member States themselves, should therefore be considered to be identified beneficiaries for the purpose of Article 195 of the Financial Regulation and the grants be awarded to such authorities without prior publication of calls for proposals.	Amendment 38 (31) Given the specific nature of the objectives and actions covered by the Programme, the respective competent authorities of the Member States are best placed in some cases to implement the related activities. Those authorities, designated by the Member States themselves, should therefore be considered to be identified beneficiaries for the purpose of Article 195 of the Financial Regulation and the grants be awarded to such authorities without prior publication of calls for proposals. <i>Investments from the Programme should be implemented in close cooperation with Member States especially in areas falling under national competences.</i>	(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 <i>related activities related to the Programme.</i> Those authorities, designated by the Member States themselves, should therefore be considered to be <i>as</i> identified beneficiaries for the purpose of Article 195 of the Financial Regulation and the grants <i>should therefore</i> be awarded to such authorities without prior publication of calls for proposals.	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
50	Recital 31 a (new)		Amendment 39 <i>(31 a) In order to ensure that each of these objectives is implemented at Union level, the Commission should increase the budget and should submit a proposal to strengthen the mandates of the ECDC and of EMA, which are already pursuing some of the EU4Health objectives at their level, and should have a greater role in the implementation of the Programme.</i>		

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
51	Recital 32	(32) The ERNs are approved as Networks by the Board of Member States of the European Reference Networks, following the approval procedure set out in Commission Implementing Decision 2014/287/EU of 10 March 2014. Those networks, should therefore be considered to be identified beneficiaries for the purpose of Article 195 of the Financial Regulation and the grants to the ERNs be awarded without prior publication of calls for proposals. Direct grants should also be awarded to other entities designated in accordance with Union rules (for example reference laboratories and centres, centres of excellence and transnational networks).		(32) The ERNs are approved as Networks by the Board of Member States of the European Reference Networks, following the approval procedure set out in Commission Implementing Decision 2014/287/EU of 10 March 2014. 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).	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
52	Recital 33	(33) Given the common agreed values of solidarity towards equitable and universal coverage of quality health services as a basis for the Union's policies in this area and that the Union has a central role to play in accelerating progress on global health challenges ¹⁹ , the Programme should support the Union's contribution to international and global health initiatives with a view to improve health, address inequalities and increase protection against global health threats.	Amendment 40 (33) Given the common agreed values of solidarity towards <i>accessible</i> , equitable and universal coverage of quality health services, <i>including in a cross-border context</i> , as a basis for the Union's policies in this area and that the Union has a central role to play in accelerating progress on global health challenges ¹⁹ , the Programme should support the Union's contribution to international and global health initiatives with a view to improve health, address inequalities and increase protection against global health threats.	(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, <i>coordination and cooperation in tackling</i> global health challenges, <i>as expressed in the sustainable development goals</i> , the Programme should support the Union's contribution to international and global health <i>organizations, in particular the World Health Organization (WHO)</i> , with a view to improve health, address <i>health</i> inequalities and <i>strengthen</i> protection against global health threats.	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
53	Recital 34	(34) In order to maximise the effectiveness and efficiency of actions at Union and international level, cooperation should be developed with relevant international organisations such as the United Nations and its specialised agencies, in particular the WHO, the World Bank, as well as with the Council of Europe and the Organisation for Economic Co-operation and Development (OECD) to implement the Programme. Pursuant to Article 94 of Council Decision 2013/755/EU²⁰, 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.	Amendment 41 (34) In order to maximise the effectiveness and efficiency of actions at Union and international level, cooperation should be developed <i>with the Member States and</i> with relevant international organisations such as the United Nations and its specialised agencies, in particular the WHO, the World Bank, as well as with the Council of Europe and the Organisation for Economic Co-operation and Development (OECD) to implement the Programme. Pursuant to Article 94 of Council Decision 2013/755/EU²⁰, 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.	(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, <i>and</i> the World Bank, as well as with the Council of Europe and the Organisation for Economic Co-operation and Development (OECD) <i>in implementing</i> the Programme. <i>Synergies should also be sought with the national organisations of Member States active in global health to increase impact.</i> Pursuant to Article 94 of Council Decision 2013/755/EU, 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.	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
54	Recital 34 a (new)		Amendment 42 <i>(34 a) The programme should guarantee that there is strong involvement of civil society, in particular patients' associations, and academics, in particular healthcare professionals' societies, to ensure a balanced representation and participation in achieving public health goals. European health organisations should contribute to the implementation and the evaluation of the programme.</i>		
55	Recital 34b (new)		Amendment 43 <i>(34b) To achieve a coherent implementation of the actions included in the Programme, a EU4Health Steering Group should be established.</i>		

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
56	Recital 35	(35) Third countries which are members of the European Economic Area (EEA) may participate in Union programmes in the framework of the cooperation established under the EEA agreement, which provides for the implementation of the programmes by a decision under that agreement. A specific provision should be introduced in this Regulation to grant the necessary rights for and access to the authorising officer responsible, the European Anti-Fraud Office (OLAF) as well as the European Court of Auditors (ECA) to comprehensively exert their respective competences.		(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 , 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.	
57	Recital 36	(36) Cooperation with third countries should be strengthened on the exchange of knowledge and best practices in health systems preparedness and response.		(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.	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
58	Recital 37	(37) In accordance with the Financial Regulation, Regulation (EU, <i>Euratom</i>) No 883/2013 of the European Parliament and of the Council, Council Regulation (EC, <i>Euratom</i>) No 2988/95, Council Regulation (<i>Euratom</i> , EC) No 2185/96 and Council Regulation (EU) 2017/1939, 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 (<i>Euratom</i> , EC) No 2185/96 and (EU, <i>Euratom</i>) No 883/2013, the European Anti-Fraud Office has the power to carry out administrative investigations, including on-the-spot checks and inspections with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the		(37) In accordance with the Financial Regulation, Regulation (EU, <i>Euratom</i>) No 883/2013 of the European Parliament and of the Council, Council Regulations (EC, <i>Euratom</i>) No 2988/95, Council Regulation (Euratom, EC) No 2185/96 and Council Regulation (EU) 2017/1939, 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 (<i>Euratom</i> , EC) No 2185/96 and (EU, <i>Euratom</i>) 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	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
58 continued		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 Council.		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 Council.	
59	Recital 38	(38) In accordance with the Financial Regulation, any person or entity receiving Union funds is to fully cooperate in the protection of the financial interests of the Union, grant the necessary rights and access to the Commission, OLAF, the Court of Auditors and in respect of those Member States participating in enhanced cooperation, the EPPO pursuant to Regulation (EU) 2017/1939, and ensure that any third parties involved in the implementation of Union funds grant equivalent rights.		(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.	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
60	Recital 39	(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.		(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 <i>other conditionalities to protect the budget.</i>	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
61	Recital 39 a (new)		Amendment 44 <i>(39a) According to the WHO, climate change affects the social and environmental determinants of health, including clean air, safe drinking water, sufficient food and secure shelter, and that 250 000 additional deaths, from malnutrition, malaria, diarrhoea and heat stress, are expected every year between 2030 and 2050, with extreme high air temperatures contributing directly to deaths particularly amongst the elderly and vulnerable individuals. Through flood, heatwaves, drought and fires, climate change has a considerable impact on human health, including under nutrition, cardiovascular and respiratory diseases, and vector-borne infections.</i>		

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
62	Recital 40	(40) Reflecting the importance of tackling climate change in line with the Union's commitments to implement the Paris Agreement and the United Nations Sustainable Development Goals, this Programme will contribute to mainstream climate action in the Union's policies and to the achievement of an overall target of 25 % of the EU budget expenditures supporting climate objectives. Relevant actions will be identified during the Programme's preparation and implementation, and reassessed in the context of its mid-term evaluation.	Amendment 45 (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 % 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.	(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.	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
63	Recital 40 a (new)		Amendment 46 <i>(40 a) Recognising the importance of achieving gender equality, this Programme should contribute to mainstream gender equality in the Union's policies. It should use gender mainstreaming and gender budgeting tools to ensure that health crises are responded to in a gender- sensitive and transformative manner and that women's and girls' specific health needs are addressed during and in the aftermath of a health crisis.</i>		
64	Recital 41	(41) The policy objectives of this Programme may be also addressed through financial instruments and budgetary guarantees under the InvestEU Fund. Financial support should be used to address market failures or sub-optimal investment situations, in a proportionate manner and actions should not duplicate or crowd out private financing or distort competition in the internal market. In general, actions should have a clear European added value.		(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.	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
65	Recital 42	(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.		(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. <i>Strong involvement of Member States in the governance and implementation of the programme should be ensured.</i>	
66	Recital 43	(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 <i>can</i> also be taken to support Member States' efforts in the pursuit of a high level of protection of public health, to improve the availability	Amendment 47 (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 <i>should</i> also be taken to support Member States' efforts in the pursuit of a high level of protection of public health, to improve the availability,	(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	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
66 continued		and affordability in the Union of medicines, medical devices and other crisis relevant products, to support innovation and to support integrated and coordinated work and implementation of best practices among Member States, and to address inequalities in access to health throughout the EU in a manner that creates efficiency gains and value-added impacts that could not be generated by action taken 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.	<i>sustainability, acceptability, accessibility, safety</i> and affordability in the Union of medicines, medical devices and other <i>health</i> crisis relevant products <i>and services</i> , to support innovation and to support integrated and coordinated work and implementation of best practices among Member States <i>and among their regions</i> , and to address inequalities <i>and inequities</i> 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.	and affordability in the Union of medicines <i>medicinal products</i> , 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.	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
67	Recital 44	(44) In order to allow for possible adjustments necessary to achieve the Programme's objectives, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the review, amendment and addition of the indicators set out in Annex II to this Regulation When exercising these delegated powers, it is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. 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.		(44) In order to allow for possible adjustments necessary to achieve the Programme's objectives, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the review, amendment and addition of the indicators set out in Annex II to this Regulation When exercising these delegated powers, it is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. 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.	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
68	Recital 44a (new)			<i>(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.</i>	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
69	Recital 45	(45) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt rules on technical and administrative arrangements necessary for the implementation of the actions of the Programme and 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.		(45) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt <i>implementing acts establishing annual work programmes in line with the criteria set out in this Regulation, approving eligible actions, setting indicators for the evaluation of the programme and establishing</i> 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. <i>The examination procedure should be used for the adoption of those implementing acts given that they relate to a programme with substantial implications.</i>	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
70				<i>(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.</i>	
71	Recital 46	(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.		(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.	

Item	Citation / Recital Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
72	Recital 47	(47) It is appropriate to ensure a smooth transition without interruption between the previous programme in the field of health (2014-2020) and the Programme, and to align the duration of the Programme with Regulation (new MFF). Therefore, the Programme should apply from 1 January 2021.		(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 <i>its</i> duration of the Programme with <i>that of the Multiannual Financial Framework laid down in Regulation {reference to the new MFF}</i> . Therefore, the Programme should apply from 1 January 2021.	
73		HAVE ADOPTED THIS REGULATION:		HAVE ADOPTED THIS REGULATION:	

Articles

This Annex contains the Articles in the Proposal 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”). For explanations of layout and fonts see Annex A.

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
74	Chapter I	CHAPTER I GENERAL PROVISIONS		CHAPTER I GENERAL PROVISIONS	
75	Article 1	<i>Article 1</i> Subject matter This Regulation establishes the EU4Health Programme ("the Programme"). It lays down the objectives of the Programme, its budget for the period from 1 January 2021 to 31 December 2027, the forms of Union funding of the Programme and the rules for providing such funding.		<i>Article 1</i> 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.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
76	Article 2 Article 2 paragraph (1) Article 2 paragraph (2)	<i>Article 2</i> Definitions For the purposes of this Regulation, the following definitions shall apply: (1) ‘associated country’ means a third country which is party to an agreement with the Union allowing for its participation in the Programme, in accordance with Article 7; (2) ‘blending operation’ means actions supported by the Union budget, including within blending facilities pursuant to Article 2(6) of Regulation (EU, <i>Euratom</i>) 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;		<i>Article 2</i> 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, <i>Euratom</i>) 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;	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
77	Article 2 paragraph (3)	(3) ‘health crisis’ means any crisis or serious incident arising from a threat of human, animal, plant, food <i>or environment</i> origin, having a health dimension and which requires urgent action by authorities;	Amendment 49 (3) ‘health crisis’ means any crisis or serious incident arising from a threat of human, animal, plant, food, <i>chemical, biological, radiological, nuclear, environmental or unknown</i> origin, having a health dimension and which requires urgent action by authorities;	(3) ‘health crisis’ means any crisis or serious incident arising from a threat of human, animal, plant, food or environment origin, having a <i>public</i> health dimension and which requires urgent action by authorities;	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
78	Article 2 paragraph (4)	(4) ‘crisis relevant products’ means products and substances necessary, in the context of a health crisis, to prevent, diagnose or treat a disease and its consequences, included but not limited to: medicinal products - including vaccines - and their intermediates, active pharmaceutical ingredients and raw materials; medical devices; hospital and medical equipment (such as ventilators, protective clothing and equipment, diagnostic materials and tools); personal protective equipment; disinfectants and their intermediary products and raw materials necessary for their production);	Amendment 50 (4) ‘crisis relevant products’ means products, tools and substances necessary, in the context of a health crisis, to prevent, diagnose or treat a disease and its consequences, and for the monitoring and the epidemiological surveillance of diseases and infections, including but not limited to: medicinal products - including vaccines - and their intermediates, active pharmaceutical ingredients and raw materials; medical devices; hospital and medical equipment (such as ventilators, protective clothing and equipment, diagnostic materials and tools); personal protective equipment; disinfectants and their intermediary products and raw materials necessary for their production);	(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);	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
79	Article 2 paragraph (5)	(5) ‘One Health approach’ means an approach which recognises <i>that</i> human <i>and</i> animal <i>health are interconnected</i> , that diseases may be transmitted from <i>humans to animals and vice versa</i> and must therefore be tackled in <i>both, and that the environment links humans and animals</i> ;	Amendment 48 (5) ‘One Health approach’ means an approach which recognises <i>the interconnection between the</i> human, animal <i>and environmental spheres</i> , that diseases may be transmitted from <i>one pillar to another</i> and must therefore be tackled in <i>a holistic approach</i> ;	(5) ‘One Health approach’ means an approach which recognises that human <i>health, and</i> animal health <i>and the environment</i> 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 ;	
80	Article 2 paragraph (6) Article 2 paragraph (7)	(6) ‘European Reference Networks’ means the networks referred to in Article 12 of Directive 2011/24; (7) ‘legal entity’ means any natural or legal person created and recognised as such under national law, Union law or international law, which has a legal personality and which may, acting in its own name, exercise rights and be subject to obligations, or an entity without a legal personality in accordance with Article 197(2)(c) of the Financial Regulation;		(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 <i>as referred to in</i> Article 197(2)(c) of the Financial Regulation (<i>EU, Euratom 2018/1046</i>);	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
80 continued	Article 2 paragraph (8)	(8) ‘third country’ means a country that is not member of the European Union;		(8) ‘third country’ means a country that is not a Member State of the European Union;	
81	Article 2 point (9)	(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;	Amendment 51 (9) ‘serious cross-border threat to health’ means a life-threatening or otherwise serious hazard to health of biological, chemical, radiological, nuclear, 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;	(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;	
82	Article 2 – paragraph 1 – point 9 a (new)		Amendment 52 <i>(9a) ‘Health in all policies’ means an approach to the development, implementation and review of public policies, regardless of the sector, whereby the health implications of decisions are taken into account, and which seeks to achieve synergies, and to avoid harmful health impacts being caused by such policies, in order to improve the health of the population and health equity;</i>		

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
83	Article 2 – paragraph 1 - point 9 b (new)		Amendment 53 <i>(9b) “Health determinants” means a range of factors, such as behaviour- related, biological , socio-economic and environmental factors, that influence the health status of a person;</i>		
84	Article 2 – point 10	(10) ‘emergency support’ means a needs-based emergency response, complementing the response of the affected Member States aimed at preserving life, preventing and alleviating human suffering, and maintaining human dignity wherever the need arises as a result of serious cross-border threats to health referred to in Article 3 (1).		(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) .	
85	Article 3	<i>Article 3</i> General objectives		<i>Article 3</i> General objectives	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
85 continued	Article 3 – introductory part	The Programme shall pursue the following general objectives, in keeping with the “One Health” approach where relevant:	Amendment 54 The Programme shall pursue the following general objectives, in keeping with the “ <i>Health in all policies</i> ” approach where applicable , and with the “One Health” approach :	The Programme shall <i>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</i> pursue the following general objectives, in keeping with <i>following</i> the “One Health” approach where relevant:	
86	Article 3 –point 1	<i>(1) protect people</i> in the Union <i>from serious cross-border threats</i> to health;	Amendment 55 <i>(1) improve and foster health</i> in the Union, <i>by supporting health promotion and disease prevention, reducing health inequalities and ensuring equal and full access</i> to health;	(1) <i>protecting</i> people in the Union from serious cross-border threats to health <i>and strengthening the responsiveness of health systems to cope with those threats</i> ;	
87	Article 3 –point 1 a (new)		Amendment 56 <i>(1a) protect people in the Union from any serious cross-border threats to health; support the development and implementation of better preparedness and coordination within and between Member States as regards health emergencies</i> ;		

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
88	Article 3 –point 2	(2) improve the availability <i>in the Union of medicines, medical devices and other crisis relevant products, contribute to their</i> affordability, and support innovation;	Amendment 57 (2) <i>supporting existing and future Union legislation and policies, in order to, inter alia, restore pharmaceutical independence and address shortages,</i> improve the availability, <i>accessibility and affordability of health care and services in the Union,</i> and support <i>research and innovation as well as development in health and healthcare without duplicating efforts under other programmes, including Horizon Europe;</i>	(2) improving the availability, <i>accessibility and affordability in the Union of medicines, medical devices and other health products as well as</i> crisis relevant products, contribute to their affordability in the Union ; and supporting innovation <i>regarding such products;</i>	
89	Article 3 –point 3	(3) strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, sustained implementation of best <i>practice and</i> data sharing, to increase the general level of public health.	Amendment 58 (3) strengthen health systems and <i>their sustainability, as well as</i> the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, <i>including at national, regional and local level, by</i> sustained implementation of best <i>practices, and by sharing of comparable and interoperable</i> data, <i>with the aim</i> of increasing the general level of public health, <i>health literacy and make health systems more resilient and responsive.</i>	(3) strengthening health systems <i>by improving their resilience and green sustainability, through:</i> and the healthcare workforce, including by digital transformation and by increased	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
89 continued				- 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;	
90	Article 3 – point 4			(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.	
91	Article 4 Article 4 – introductory part	<i>Article 4</i> Specific objectives The general objectives referred to in Article 3 shall be pursued through the following specific objectives, in keeping with the ‘One Health’ approach where relevant:	Amendment 59 The general objectives referred to in Article 3 shall be pursued through the following specific objectives, in keeping with the “Health in all policies” approach where applicable , and with the “One Health” approach:	<i>Article 4</i> 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:	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
92	Article 4 –point 1	(1) strengthen the capability of the Union for prevention, preparedness and response to serious cross-border threats to health, and the management of health crises, including through coordination, provision and deployment of emergency health care capacity, data gathering and surveillance;	Amendment 226 (1) strengthen the capability of the Union for prevention, preparedness and <i>rapid</i> response to serious cross-border threats to health, and the management of health crises, including through coordination, provision and deployment of emergency health care capacity, data gathering and surveillance, <i>the coordination of stress testing of national healthcare systems and the development of quality healthcare standards</i> ;	(1) strengthening the capability of the Union for prevention, preparedness and response to serious cross-border threats to health <i>in accordance with relevant EU legislation</i> and <i>improving</i> the management of health crises, including <i>particularly</i> through <i>the</i> coordination, provision and deployment of emergency health- <i>care healthcare</i> capacity, <i>supporting</i> to data gathering, <i>information exchange</i> and surveillance;	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
93	Article 4 –point 2	(2) <i>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;</i>	Amendment 250 (2) <i>In synergy with other Union instruments, programmes and funds, support actions to allow medical, healthcare and support staff to be mobilised in case of a crisis, such as staff of the European Medical Corps, including by improving the staff's training and updating their knowledge, and support action to contribute to the availability in the Union, during a crisis, of health crisis relevant products such as essential medicines, vaccines and medical devices;</i>	(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;	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
94	Article 4 –point 3	(3) <i>support actions</i> to ensure <i>appropriate</i> availability, accessibility and affordability of <i>crisis relevant</i> products and other necessary health supplies;	Amendment 62 (3) <i>strengthen the European Medicines Market</i> , to ensure <i>in a sustainable manner the</i> availability, accessibility and affordability of <i>medicinal</i> products, <i>e-health solutions, medical devices</i> and other necessary health <i>related</i> supplies <i>and crisis relevant medical products</i> ;	(3) supporting actions to ensure appropriate <i>enhance the</i> availability, accessibility and affordability of <i>health products as well as</i> crisis relevant products, and other necessary health supplies, <i>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</i> ;	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
95	Article 4 –point 4	(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;	Amendment 222 (4) strengthen the effectiveness, accessibility, sustainability and resilience of health systems, including by supporting digital transformation, including the creation and implementation of a European Health Data Space , systemic reforms, implementation of new care models, enhance the equal and timely access to quality, sustainable affordable, person-centred, outcome-based healthcare and related care services, the achievement of universal health coverage, encompassing access to sexual and reproductive health and rights, and reduce inequalities and inequities in health;	(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;	
96	Article 4 –point 4a (new)		Amendment 64 (4a) strengthen the Union’s innovation to ensure the development and uptake of the next generation of medicines, vaccines and medical devices to meet increasing healthcare challenges and expectations that arise;	(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;	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
97	Article 4 –point 5	(5) support actions aimed at strengthening health system's ability to foster disease prevention and health promotion, patient rights and cross-border healthcare, and promote the excellence of medical and healthcare professionals;	Amendment 65 (5) support actions aimed at strengthening health system's ability to foster disease prevention, screening and early diagnosis, and implement health promotion, address health determinants, improve health literacy, patient rights and safety and cross-border healthcare;	(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;	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
98	Article 4 –point 6	(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer;	Amendment 245 (6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, <i>the early diagnosis of neurodegenerative disorders and other brain diseases</i> , and notably of cancer;	(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer;	
99	Article 4 –point 6 a (new)		Amendment 66 <i>(6a) strengthen the Union fight against cancer in synergy with the Europe’s Beating Cancer Plan, including by supporting actions for the surveillance, prevention, early diagnosis and treatment and care of cancer, including paediatric cancer, and by supporting the establishment of the European Cancer Institute;</i>		
100	Article 4 –point 6 b (new)		Amendment 67 <i>(6b) strengthen the fight against communicable diseases and health threats;</i>		

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
101	Article 4 –point 6 c (new)		Amendment 68 <i>(6c) address vaccine hesitancy, and support action for the elimination of vaccine preventable diseases, including cancers;</i>		
102	Article 4 –point 7	(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;	Amendment 69 (7) foster and support the informed , prudent and efficient use of medicines, and in particular of antimicrobials, the development of medicines that are intrinsically less harmful for the environment , more environmentally friendly production of medicines and environmentally sound disposal of medicinal products and medical devices;	(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;	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
103	Article 4 –point 8	(8) support the development, implementation and enforcement of Union health legislation and provide high-quality, comparable and reliable data to underpin policy making and monitoring, and promote the use of health impact assessments of relevant policies;	Amendment 70 (8) support the development, implementation and enforcement and, when necessary, the revision, of Union health legislation, and provide high-quality, comparable, and reliable, data to underpin policy making and monitoring, support the delivery of care and respond to unmet medical needs, and promote the use of health impact assessments of other relevant Union policies;	(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;	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
104	Article 4 –point 9	(9) support integrated work among Member States, and in particular their health systems, including the implementation of high-impact prevention practices, and scaling up networking through the European Reference Networks and other transnational networks;	Amendment 246 and 71 (9) support integrated work among Member States, and in particular their health systems, including the implementation of high-impact prevention practices, support the identification of health technologies that are required to undergo a Union assessment, and strengthening and scaling up networking through the ERNs, develop and implement excellence networks for high prevalence communicable and non-communicable diseases and other transnational networks, including the Orphanet network, in full synergy with Horizon Europe and its Missions and Partnerships, and aim to increase the coverage of patients and the response to diseases , and health problems, in greater numbers;	(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;	
105	Article 4 –point 10	(10) support the Union’s contribution to international and global health initiatives.	Amendment 223 (10) support the Union’s contribution to international and global health commitments and initiatives, including access to sexual and reproductive health and rights.	(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.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
106	Article 5 Article 5 – paragraph 1	<i>Article 5</i> <i>Budget</i> 1. The financial envelope for the implementation of the Programme for the period 2021-27 shall be EUR 1 946 614 000 in current prices.	Amendment 73 1. The financial envelope for the implementation of the Programme for the period 2021-27 shall be EUR 10 398 000 000 in current prices (EUR 9 370 000 000 in constant prices).	<i>Article 5</i> <i>Budget</i> 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.	
107	Article 5 – paragraph 2	2. The amount referred to in paragraph 1 may be used for technical and administrative assistance for the implementation of the Programme, such as preparatory, monitoring, control, audit and evaluation activities including corporate information technology systems.	Amendment 74 2. The amount referred to in paragraph 1 may be also used for technical and administrative assistance for the implementation of the Programme, such as preparatory, monitoring, control, audit and evaluation activities including corporate information technology systems. The administrative expenses related to indirect actions shall not exceed 5% of the total amount under the Programme.	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.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
108	Article 5 – paragraph 3 Article 5 – paragraph 4 Article 5 – paragraph 5 Article 5 – paragraph 6	3. Appropriations deriving from activities under point (c) of Article 10 of this Regulation, shall constitute assigned revenue within the meaning of point (a) of paragraph 3 and paragraph 5 of Article 21 of Regulation (EU, <i>Euratom</i>) 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, <i>Euratom</i>) 2018/1046, expenditure for actions resulting from projects included in the first work programme may be eligible as from 1 January 2021. 6. If necessary, appropriations may be entered in the budget beyond 2027 to cover the expenses provided for in paragraph (2) to enable the management of actions not completed by 31 December 2027.		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, <i>Euratom</i>) 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, <i>Euratom</i>) 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.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
109	Article 6	<i>Article 6</i> <i>Resources from the European Union Recovery Instrument Measures referred to in Article 2 of Regulation [European Union Recovery Instrument] shall be implemented under the Programme through an amount of up to EUR 8 451 000 000 in current prices referred to in point (iii) of Article 3(2)(a) of that Regulation, subject to its Article 5(4) and (8). These amounts shall constitute external assigned revenue in accordance with Article 21(5) of Regulation (EU, Euratom) 2018/1046.</i>	Amendment 75 deleted	<i>Article 6</i> <i>Resources from the European Union Recovery Instrument</i> 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.	
110	Article 7 Article 7 – paragraph 1 – point 1	<i>Article 7</i> <i>Third countries associated to the Programme</i> The Programme shall be open to the following associated countries: (1) European Free Trade Association (EFTA) members which are members of the European Economic Area (EEA), in accordance with the conditions laid down in the Agreement on the European Economic Area;		<i>Article 7</i> <i>Third countries associated to the Programme</i> 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;	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
111	Article 7 – paragraph 1 – point 1 a (new)		Amendment 76 <i>(1 a) The contributions of all associated countries shall be included in the relevant parts of the Programme. The Commission shall report to the Council and the Parliament during the annual budgetary procedure the total budget of each part of the Programme, identifying each of the associated countries, individual contributions and their financial balance.</i>		
112	Article 7 – paragraph 1 – point 2	(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;		(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;	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
112 continued	Article 7 – paragraph 1 – point 3 Article 7 – paragraph 1 – point 4 Article 7 – paragraph 1 – point 4 i	(3) Countries covered by the European Neighbourhood Policy, in accordance with the general principles and general terms and conditions for the participation of those countries in Union programmes established in the respective framework agreements and association council decisions, or similar agreements, and in accordance with the specific conditions laid down in agreements between the Union and those countries; (4) Third countries, in accordance with the conditions laid down in a specific agreement covering the participation of the third country to any programme, provided that the agreement: (i) ensures a fair balance as regards the contributions and benefits of the third country participating in the Union programmes;		(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;	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
112 continued	Article 7 – paragraph 1 – point 4 ii Article 7 – paragraph 1 – point 4 iii Article 7 – paragraph 1 – point 4 iv	(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, <i>Euratom</i> 2018/1046); (iii) does not confer to the third country a decisional power; (iv) guarantees the rights of the Union to ensure sound financial management and to protect its financial interests.		(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, <i>Euratom</i> 2018/1046); (iii) does not confer to the third country a decisional power <i>in respect of the programme</i> ; (iv) guarantees the rights of the Union to ensure sound financial management and to protect its financial interests.	
113	Chapter II	Chapter II FUNDING		Chapter II FUNDING	
114	Article 8	<i>Article 8</i> <i>Implementation and forms of Union funding</i>		<i>Article 8</i> <i>Implementation and forms of Union funding</i>	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
114 continued	Article 8 – paragraph 1	1. The Programme shall be implemented in direct management in accordance with Regulation (EU, Euratom) 2018/1046 or in indirect management with the bodies referred to in Article 62(1) (c) of Regulation (EU, Euratom) 2018/1046.	Amendment 77 1. The Programme shall be implemented in direct management in accordance with Regulation (EU, Euratom) 2018/1046 or in indirect management with the bodies referred to in Article 62(1) (c) of Regulation (EU, Euratom) 2018/1046, to ensure there is no overlap or duplication with other funding programmes at the Union level.	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.	
115	Article 8 – paragraph 2	2. The Programme may provide funding in any of the forms laid down in Regulation (EU, Euratom) 2018/1046, in particular grants, prizes and procurement.	Amendment 78 2. The Programme may provide funding in any of the forms laid down in Regulation (EU, Euratom) 2018/1046, in particular grants, prizes and procurement. The Commission shall seek to achieve effective and balanced geographical coverage across the Union, including by supporting Member States to increase the quality of the projects through capacity building.	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.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
116	Article 8 – paragraph 3 Article 8 – paragraph 4	3. Contributions to a mutual insurance mechanism may cover the risk associated with the recovery of funds due by recipients and may be considered as sufficient guarantee under Regulation (EU, <i>Euratom</i>) 2018/1046. The Commission shall set up specific rules for the operation of the mechanism. 4. Where the Commission implements emergency support operations through non-governmental organisations, the criteria concerning financial and operational capacity shall be deemed to be satisfied where there is a framework partnership agreement in force between that organisation and the Commission pursuant to Regulation (EC) No 1257/96.		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, <i>Euratom</i>) 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.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
117	Article 8 – paragraph 4 a (new)		Amendment 79 <i>4 a. The Commission shall facilitate the consistent implementation of the Programme while seeking maximal administrative simplification. The Commission and the Member States shall, commensurate to their respective responsibilities, foster synergies and ensure effective coordination between the Programme and the other Union programmes and funds.</i> <i>For that purpose, they shall:</i> <i>(a) ensure that there is complementarity, synergy, coherence and consistency among different instruments at Union, national and, where appropriate, regional levels, in particular in relation to measures financed by Union funds, both in the planning phase and during implementation;</i> <i>(b) optimise coordination mechanisms to avoid duplication of effort;</i>		

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
117 continued			Amendment 79 continued <i>(c) ensure that close cooperation exists between those responsible for implementation at Union, national and, where appropriate, regional levels to deliver coherent and streamlined support actions under the instrument.</i>		
118	Article 8 – paragraph 4 b (new)		Amendment 80 <i>4b. The Commission shall develop cooperation with relevant international organisations such as the United Nations and its specialised agencies, in particular the World Health Organisation (WHO), as well as with the Council of Europe and the Organisation for Economic Co-operation and Development (OECD) when implementing the Programme, in order to maximise the effectiveness and efficiency of actions at Union and international level.</i>		

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
119	Article 8 – paragraph 4 c (new)		<i>Amendment 81</i> <i>4c. The Commission shall consult the health authorities of the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases or in other relevant Commission expert groups as well as stakeholders, in particular professional bodies in the health sector and NGOs active in the field, at all stages of the implementation of the Programme .</i>		
120	Article 9 Article 9 – paragraph 1	<i>Article 9</i> <i>Grants</i> 1. Grants under the Programme shall be awarded and managed in accordance with Title VIII of Regulation (EU, Euratom) 2018/1046.		<i>Article 9</i> <i>Grants</i> 1. Grants under the Programme shall be awarded and managed in accordance with Title VIII of Regulation (EU, Euratom) 2018/1046.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
120 continued	Article 9 – paragraph 1 2	2. Grants may be used in combination with financing from the European Investment Bank or national promotional banks or other development and public financial institutions as well as from private-sector finance institutions and private-sector investors, including through public private partnerships.		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 <i>in combination with financing</i> from private-sector finance institutions and <i>public or</i> private-sector investors, including through <i>public-public or</i> public-private partnerships.	
121	Article 9 – paragraph 3 Article 9 – paragraph 3a			3. <i>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:</i> (a) <i>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</i>	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
121 continued	Article 9 – paragraph 3b			<i>(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.</i>	
122	Article 9 – paragraph 4			<i>4. In the case of the direct grants referred to in Article 14(6) and (6a), the eligible costs may be up to 100%.</i>	
123	Article 9 – paragraph 5			<i>5. Applications for projects shall include different legal entities from at least three different States participating in the Programme.</i>	
124	Article 9 a (new) Article 9 a (new) – paragraph 1		Amendment 82 <i>Article 9a Award criteria</i> <i>The award criteria shall be defined in the work programmes referred to in Article 18 and in the calls for proposals taking into account, to the extent applicable, the following elements:</i> <i>(a) consistency with the specific objectives provided for in Article 4;</i>		

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
124 continued			<i>(b) contribution to the accessibility and affordability of the health system;</i> <i>(c) cross-border dimension;</i> <i>(d) contribution to digital transformation;</i> <i>(e) social impact (benefits and costs);</i> <i>(f) consistency with the provisions of Annex 1;</i> <i>(g) contribution to the prevention of diseases and notably of cancer;</i> <i>(h) contribution to access to medicine;</i> <i>(i) maturity of the action in the project development;</i> <i>(j) soundness of the implementation plan proposed.</i>		

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
125	Article 10 Article 10 – paragraph 1	<i>Article 10</i> Procurement 1. Emergency support under this Regulation may be granted in any of the following forms: (a) joint procurement with the Member States as referred to in Article 165 (2) of Regulation (EU, <i>Euratom</i>) 2018/1046 whereby Member States may acquire, rent or lease fully the capacities jointly procured; (b) procurement by the Commission on behalf of the Member States based on an agreement between the Commission and the Member States;		<i>Article 10</i> 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 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, <i>Euratom</i>) 2018/1046 whereby Member States may acquire, rent or lease fully the capacities capacities jointly procured capacities; (b) procurement by the Commission on behalf of the Member States based on the basis of or based on the basis of an agreement between the Commission and the Member States;	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
125 continued		(c) procurement by the Commission as wholesaler by buying, stocking and reselling or donating supplies and services, including rentals, to Member States or partner organisations selected by the Commission.		(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.	
126	Article 10 – paragraph 2	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.		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.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
127	Article 10 – paragraph 3	3. In the event of procurement procedures as referred to in points (b) and (c) of paragraph 1, the Commission shall follow the rules set out in Regulation (EU, <i>Euratom</i>) 2018/1046 for its own procurement.		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, <i>Euratom</i>) 2018/1046 for its own procurement, applying as necessary the derogations set out below.	
128	Article 10 – paragraph 4			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.	
129	Article 10 – paragraph 5			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.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
130	Article 10 – paragraph 6			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.	
131	Article 11	<i>Article 11</i> Blending operations Blending operations under the Programme shall be implemented in accordance with the [InvestEU regulation] and Title X of the Financial Regulation.		<i>Article 11</i> 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.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
132	Article 12	<i>Article 12</i> <i>Cumulative funding</i> An action that has received a contribution from the Programme may also receive a contribution from any other Union programme, including under shared management, provided that the contributions do not cover the same costs. The rules of each contributing Union programme shall apply to its respective contribution to the action. The cumulative funding shall not exceed the total eligible costs of the action and the support from the different Union programmes may be calculated on a pro-rata basis in accordance with the documents setting out the conditions for support.		<i>Article 12</i> <i>Cumulative funding</i> 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 <i>for an action</i> 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.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
133	Article 12 – paragraph 3 a (new)		Amendment 83 <i>A reliable and efficient mechanism shall be created in order to avoid any duplication of funding and to ensure synergies between the different Union programmes and policies that are pursuing health objectives. All data on funding operations and actions financed under different Union programmes and funds shall be centralised under this mechanism. It shall follow the principles of transparency and accountability and shall allow better monitoring and evaluation of actions pursuing health objectives.</i>		
134	Chapter III	CHAPTER III ACTIONS		CHAPTER III ACTIONS	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
135	Article 13	<i>Article 13</i> Eligible actions Only actions implementing the objectives referred to in Articles 3 and 4, including those set out in Annex I, shall be eligible for funding.		<i>Article 13</i> 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.	
136	Article 14 Article 14 – paragraph 1 Article 14 – paragraph 1 – point a	<i>Article 14</i> Eligible entities 1. In addition to the criteria set out in Article 197 of Regulation (EU, <i>Euratom</i>) 2018/1046, the following criteria shall apply: (a) legal entities established in any of the following countries: (i) a Member State or an overseas country or territory linked to it; (ii) a third country associated to the Programme; (iii) a third country listed in the work programme under the conditions specified in paragraph 2 and 3;		<i>Article 14</i> 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, <i>Euratom</i>) 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	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
137	Article 14 – paragraph 1 – point b Article 14 – paragraph 2	(b) any legal entity created under Union law or any international organisation; 2. Legal entities established in a third country which is not an associated country are exceptionally eligible to participate where this is necessary for the achievement of the objectives of a given action.	Amendment 84 (b) any legal entity created under Union law or any <i>relevant</i> international organisation <i>such as public authorities, public sector bodies, health establishments, research institutes, universities and higher education establishments, patient associations</i> ;	(b) <i>be</i> created <i>directly</i> under Union or international <i>law</i> . 2. Legal entities <i>that are</i> established in a third country which is not an associated <i>to the Programme</i> country are <i>may in exceptional cases be</i> exceptionally eligible to participate where this <i>such participation</i> is necessary for the achievement of the objectives of a given action. <i>The assessment of that necessity shall be duly reflected in the funding decision.</i>	
138	Article 14 – paragraph 3	3. Legal entities established in a third country which is not associated to the Programme should <i>in principle</i> bear the cost of their participation.	Amendment 85 3. Legal entities established in a third country which is not associated to the Programme should bear the cost of their participation.	3. Legal entities <i>that are</i> established in a third country which is not associated to the Programme should in principle <i>shall</i> bear the cost of their participation.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
139	Article 14 – paragraph 4	4. Natural persons are not eligible.		4. Natural persons are not eligible <i>for funding under the Programme.</i>	
140	Article 14 – paragraph 5	5. Under the Programme, direct grants may be awarded without a call for proposals to fund actions having a clear Union added value co-financed by the competent authorities that are responsible for health in the Member States or in the third countries associated to the Programme, relevant international health organisations or by public sector bodies and non-governmental bodies, acting individually or as a network, mandated by those competent authorities.	Amendment 86 5. Under the Programme, direct grants may be awarded without a call for proposals to fund actions if such grants are duly justified, if they have a clear Union added value co-financed by the local, regional or national competent authorities that are responsible for health in the Member States or in the third countries associated to the Programme, relevant international health organisations or by Interreg programmes , public sector bodies and non-governmental bodies, acting individually or as a network, mandated by those competent authorities.	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.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
141	Article 14 – paragraph 6	6. Under the Programme, direct grants <i>may</i> be awarded without a call for proposals to European Reference Networks . Direct grants may also be awarded to other transnational networks set out in accordance with EU rules .	Amendment 87 6. Under the Programme, direct grants <i>shall</i> be awarded without a call for proposals to ERNs with a simplified financial and technical reporting system . Direct grants may also be awarded to other transnational networks, including to Interreg programmes , set out in accordance with Union law .	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 .	
142	Article 14 – paragraph 6 a (new)		Amendment 88 <i>6a. Adequate funding shall be ensured to consolidate and expand the ERN model of cross-border healthcare by securing the provision of a range of clinical services through different channels, including online second opinions and specialist advice for patients on treatment and management and “online out-patient” clinics.</i>	<i>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.</i>	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
143	Article 14 – paragraph 7	7. Under the Programme, grants may be awarded without a call for proposals to fund the functioning of non-governmental bodies where financial support is necessary for the pursuit of one or more of the specific objectives of the Programme as long as those bodies fulfil all the following criteria: (i) they are non-governmental, non-profit-making and independent of industry, commercial and business or other conflicting interests; (ii) they work in the public health area, pursue at least one of the specific objectives of the Programme and play an effective role at Union level; (iii) they are active at Union level and in at least half of the Member States, and have a balanced geographical coverage of the Union.		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; <i>The analysis of the fulfilment of those criteria shall be duly reflected in the funding decision.</i>	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
144	Article 15 Article 15 – paragraph 1 Article 15 – paragraph 1 – point a Article 15 – paragraph 1 – point b	<i>Article 15</i> <i>Eligible costs</i> 1. In addition to the criteria set out in Article 186 of Regulation (EU, <i>Euratom</i>) 2018/1046, and in accordance with point (a) of the second subparagraph of Article 193 of that Regulation, costs incurred prior to the date of submission of the grant application shall be eligible: (a) for actions which implement the objective referred to in point (1) of Article 3; (b) for actions implementing other objectives, in duly justified exceptional cases, provided that those costs are directly linked to the implementation of the supported actions and activities.		<i>Article 15</i> <i>Eligible costs</i> 1. In addition to the criteria set out in Article 186 of Regulation (EU, <i>Euratom</i>) 2018/1046; and in accordance with point (a) of the second subparagraph of Article 193 of that Regulation, Subject to the criteria set out in Article 186 of Regulation (EU, <i>Euratom</i>) 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.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
144 continued	Article 15 – paragraph 2 Article 15 – paragraph 3	2. The costs under point (a) of paragraph 1 of this Article, related to measures aiming to address suspected occurrence of a disease that could trigger a cross-border health threat, shall be eligible from the date of notification of the suspected occurrence of the disease to the Commission, provided that that occurrence or presence is subsequently confirmed. 3. In exceptional cases, during a crisis caused by a serious cross-border health threat as defined in Article 3(g) of Decision 1082/2013/EU, costs incurred by entities established in non-associated countries may be considered exceptionally eligible if they are duly justified for reasons of countering the spread of the risk for the protection of the health of people in the Union.		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.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
145	Chapter IV	CHAPTER IV GOVERNANCE		CHAPTER IV GOVERNANCE	
146	Article 16 Article 16 – paragraph 1 Article 16 – paragraph 2	<i>Article 16</i> <i>Joint policy implementation</i>		<i>Article 16</i> <i>Joint policy implementation</i> 1. A EU4Health Steering Group is hereby established. 2. The Members of the EU4Health Steering Group are the Commission and the Member States. Each Member State shall appoint one member and one alternate to the EU4Health Steering Group. The Commission shall provide the secretariat of the EU4Health Steering Group.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
147	Article 16 – paragraph 3 Article 16 – paragraph 3 – point a	The Commission shall consult the health authorities of the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases on the work plans established for the Programme and its priorities and strategic orientations and its implementation.	Amendment 89 The Commission shall consult the health authorities of the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases on the <i>annual</i> work plans established for the Programme and its priorities and strategic orientations and its implementation <i>and on possible synergies with Member States' own resources to ensure long-term effectiveness and sustainability of actions.</i>	3. The Commission shall: (a) consult the health authorities of the Member States in the <i>EU4Health</i> 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 <i>on the Commission's preparatory work for the work programmes referred to in Article 16a(1);</i>	
148	Article 16 – paragraph 3 – point b and paragraph 1b (new)		Amendment 90 <i>The Commission shall consult the EU4Health Steering Group on the annual work plans established for the Programme and on the Programme's priorities, strategic orientations and implementation, and on possible synergies with European funds to ensure the long-term effectiveness and sustainability of actions.</i>	(b) <i>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.</i>	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
149	Article 16 – paragraph 1b (new)		Amendment 91 <i>The Commission shall also consult relevant Union decentralised agencies and stakeholders, such as representatives of civil society organisations, in particular patients’ organisations, on the annual work plans established for the Programme and the Programme’s priorities, strategic orientations and implementation.</i>		
150	Article 16 – paragraph 1c (new)		Amendment 92 <i>The Commission shall adopt the annual work plans by means of delegated acts. Those delegated acts shall be adopted in accordance with Article 24 of this Regulation.</i>		

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
151	Article 16 – paragraph 4 Article 16 – paragraph 4 – point a Article 16 – paragraph 4 – point b Article 16 – paragraph 4 – point c			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.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
152			Amendment 93 <i>Article 16a</i> <i>Establishment of EU4Health Steering Group</i> <i>1. The Commission shall establish a EU4Health Steering Group ('the Steering Group').</i> <i>2. The Steering Group shall:</i> <i>(i) provide input, in the form of a comprehensive strategy and steering, and contribute to the annual work plans for the Programme;</i> <i>(ii) elaborate a blueprint for steering coordination, cooperation and synergies between the Programme and other Programmes in which a health dimension is integrated;</i> <i>(iii) provide value-oriented health actions, sustainability, better health solutions, foster access to health and reduce health inequalities, promote engagement by patients and society.</i>		

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
152 continued			Amendment 93 continued 3. <i>The Steering Group shall be an independent stakeholder group, composed of actors in the field of public health, such as representatives of the European Parliament, independent health experts and patient representatives.</i> 4. <i>The Steering Group shall be composed of 20 high-level individuals respecting the principle of geographical and gender balance, drawn from various disciplines and activities referred to in paragraph 3.</i> 5. <i>The members of the Steering Board shall be appointed by the Commission in consultation with the Parliament, following an open call for nominations or for expression of interest.</i> <i>The members shall be appointed for the period referred to in Article 1(2). The Commission shall also appoint a Chair from among its members.</i>		

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
152 continued			Amendment 93 continued 6. <i>The Steering Group shall meet at least three times a year, which allows regular and transparent exchanges of views.</i> <i>The blueprint for steering coordination, cooperation and synergies shall facilitate ensuring visibility and coordination of all the existing financial mechanisms relevant to health, and shall help to steer coordination and cooperation.</i> <i>The Commission may consult the Steering Group on matters other than those referred to in paragraph 2.</i>		
153	Article 17	<i>Article 17</i> <i>Implementation of the Programme</i>		<i>Article 16a</i> <i>Implementation of the Programme</i> <i>1. The Commission shall implement the Programme by establishing annual work programmes in accordance with Regulation (EU, Euratom) 2018/1046.</i>	<i>[Comment : Art. 16a in CRP mandate corresponds to Art. 17 in COM and EP texts]</i>

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
154	Article 17 – paragraph 2	The Commission may, by means of implementing acts, lay down rules on:		2. The Commission may shall adopt, by means of implementing acts, lay down rules on: (a) <i>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.</i> (b) <i>decisions approving eligible actions with cost of EUR 20 000 000 or more.</i> (c) <i>decisions approving eligible actions falling under the cases referred to in Article 8(3) and (4).</i> (d) <i>decisions approving eligible actions by:</i> (i) <i>entities from a third country associated to the Programme;</i> (ii) <i>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);</i>	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
154 continued	Article 17 – paragraph 2 continued	(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).		<i>(iii) any legal entity created directly under Union or international law.</i> <i>(e) rules establishing:</i> <i>(i) the technical and administrative arrangements necessary for the implementation of the actions of the Programme;</i> <i>(ii) uniform templates for the collection of data necessary to monitor the implementation of the Programme.</i> Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 23(2).	
155	Article 16b			<u>Article 16b</u> <u>Data Protection</u> <i>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.</i>	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
156	Chapter V	CHAPTER V PROGRAMMING, MONITORING, EVALUATION AND CONTROL		CHAPTER V PROGRAMMING, MONITORING, EVALUATION AND CONTROL	
157	Article 18	<i>Article 18</i> <i>Work programme</i> 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.	Amendment 94 The Programme shall be implemented by <i>annual</i> 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.	<i>Article 18</i> <i>Work programme</i> 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.	
157a	Article 18 – paragraph 1a (new)		Amendment 95 <i>The work programmes shall be informed by a gender impact assessment.</i>		

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
158	Article 19 Article 19 – paragraph 1	<i>Article 19</i> Monitoring and reporting 1. Indicators to report on progress of the Programme towards the achievement of the general and specific objectives set out in Articles 3 and 4 are set out in Annex II.	Amendment 96 1. Indicators, including programme- and action-specific indicators , to report on progress of the Programme towards the achievement of the general and specific objectives set out in Articles 3 and 4 are set out in Annex II.	<i>Article 19</i> 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).	
159	Article 19 – paragraph 1 a (new)		Amendment 97 1a. The Commission shall monitor continuously the management and implementation of the Programme. In order to enhance transparency, the constantly updated data on the management and implementation shall be made publicly available in an accessible manner on the Commission's website. In particular, data for projects funded shall be included in the same database. Those data shall include:		

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
159 continued			<i>(a) information on the types of financing and the types of beneficiaries, that allows for a transparent tracking of the financial allocations; a detailed overview of the synergies with other Union programmes, including the activities implemented by Union agencies, that allows for a proper analysis of the complementarity between different activities to be carried out.</i> <i>(b) the levels of expenditure disaggregated at project level in order to allow for specific analysis, including per intervention area as defined in Article 13 and Annex I.</i>		
160	Article 19 – paragraph 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.	Amendment 98 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, <i>including programme- and action-specific ones</i>, where considered necessary.	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.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
161	Article 19 – paragraph 2 a (new)		Amendment 99 <i>2 a. Indicators shall be collected, where relevant, dissagregated by gender.</i>		
162	Article 19 – paragraph 3	3. The performance reporting system shall ensure that data for monitoring programme implementation and results are collected efficiently, effectively, and in a timely manner. To that end, proportionate reporting requirements shall be imposed on recipients of Union funds and, where relevant, on Member States.	3. The performance reporting system shall ensure that data for monitoring programme implementation and results are collected efficiently, effectively, and in a timely manner <i>without increasing the administrative burden for beneficiaries.</i> To that end, proportionate reporting requirements shall be imposed on recipients of Union funds and, where relevant, on Member States.	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, <i>the Commission shall adopt implementing acts establishing</i> proportionate reporting requirements shall be imposed on recipients of Union funds and, where relevant, on Member States.	
163	Article 20 Article 20 – paragraph 1	<i>Article 20</i> <i>Evaluation</i> 1. Evaluations shall be carried out in a sufficiently timely manner to feed into the decision-making process.		<i>Article 20</i> <i>Evaluation</i> 1. Evaluations <i>in accordance with Article 34 (3) of Regulation (EU, Euratom) 2018/1046</i> shall be carried out <i>by the Commission</i> in a sufficiently timely manner to feed into the decision-making process.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
164	Article 20 – paragraph 2 Article 20 – paragraph 3	2. The interim evaluation of the Programme shall be performed once there is sufficient information available about their implementation, but not later than four years after the start of the implementation. 3. At the end of the implementation period, but no later than four years after the end of the period specified in Article 1, a final evaluation shall be carried out by the Commission.		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.	
165	Article 20 – paragraph 4	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.	Amendment 101 4. The Commission shall <i>publish, communicate and present</i> the conclusions of <i>both the interim and final</i> evaluations accompanied by its observations, to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.	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.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
166	Article 21 Article 21 – paragraph 1	<i>Article 21</i> Audits Audits on the use of the Union contribution carried out by persons or entities, including by others than those mandated by the Union Institutions or bodies, shall form the basis of the overall assurance pursuant to Article 127 of Regulation (EU, Euratom) 2018/1046.		<i>Article 21</i> 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.	
167	Article 21 – paragraph 1 a (new)		Amendment 102 <i>The audit system for the Programme shall ensure an appropriate balance between trust and control, taking into account administrative and other costs of controls at all levels, especially for beneficiaries. Audit rules shall be clear, consistent and coherent throughout the Programme.</i>		

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
168	Article 21 – paragraph 1 b (new)		Amendment 103 <i>The audit strategy for the Programme shall be based on the financial audit of a representative sample of expenditure across the Programme as a whole. The representative sample shall be complemented by a selection based on an assessment of the risks related to expenditure. Actions that receive joint funding from different Union programmes shall be audited only once, covering all programmes involved and their respective applicable rules.</i>		

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
169	Article 21 – paragraph 1 c (new)		Amendment 104 <i>The Commission or the funding body may rely on combined system reviews at beneficiary level. Such combined reviews shall be optional for certain types of beneficiaries and shall consist in a systems and process audit, complemented by an audit of transactions, carried out by a competent independent auditor qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC. They may be used by the Commission or funding body to verify overall assurance on the sound financial management of expenditure and for reconsideration of the level of ex-post audits and certificates on financial statements.</i>		
170	Article 21 – paragraph 1 d (new)		Amendment 105 <i>Audits may be carried out up to two years after the payment of the balance.</i>		

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
171	Article 21 – paragraph 1 e (new)		Amendment 106 <i>The Commission shall publish audit guidelines with the aim of ensuring that there is reliable and uniform application and interpretation of the audit procedures and rules throughout the duration of the programme.</i>		

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
172	Article 22 Article 22 – paragraph 1	<i>Article 22</i> <i>Protection of the financial interests of the Union</i> Where a third country participates in the Programme by a decision under an international agreement, the third country shall grant the necessary rights and access required for the authorizing officer responsible, the European Anti-Fraud Office (OLAF), the European Court of Auditors to comprehensively exert their respective competences. In the case of OLAF, such rights shall include the right to carry out investigations, including on-the-spot checks and inspections, provided for in Regulation (EU, <i>Euratom</i>) No 883/2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF).		<i>Article 22</i> <i>Protection of the financial interests of the Union</i> Where a third country participates in the Programme by <i>means of</i> a decision under <i>adopted pursuant to</i> an international agreement <i>or by virtue on the basis of any other legal instrument</i>, the third country shall grant the necessary rights and access required for the authorizing <i>authorising</i> officer responsible, the European Anti-Fraud Office (OLAF), and the European Court of Auditors (ECA) to comprehensively exert <i>exercise</i> 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, <i>as</i> provided for in Regulation (EU, <i>Euratom</i>) No 883/2013 <i>concerning investigations conducted by the European Anti-Fraud Office (OLAF).</i>	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
173	Article 23 Article 23 – paragraph 1 Article 23 – paragraph 2	<i>Article 23</i> Committee procedure 1. The Commission shall be assisted by a EU4Health Programme Committee. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011. 2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.		<i>Article 23</i> 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. <i>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.</i>	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
174	Article 23a			<i>Article 23a</i> <i>Consistency and complementarity with other policies, instruments and actions</i> <i>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.</i>	
175	Article 24 Article 24 – paragraph 1	<i>Article 24</i> <i>Exercise of the delegation</i> 1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.		<i>Article 24</i> <i>Exercise of the delegation</i> 1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
176	Article 24 – paragraph 2	2. The power to adopt delegated acts referred to in Article 19(2) shall be conferred on the Commission <i>until 31 December 2028.</i>	Amendment 107 2. The power to adopt delegated acts referred to in Article 19(2) shall be conferred on the Commission <i>for a period of three years from [date of entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the three-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.</i>	2. The power to adopt delegated acts referred to in Article 19(2) shall be conferred on the Commission until 31 December 2028.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
177	Article 24 – paragraph 3 Article 24 – paragraph 4 Article 24 – paragraph 5	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 <i>Official Journal</i> 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.		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 <i>Official Journal of the European Union</i> 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.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
177 continued	Article 24 – paragraph 6	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.		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.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
178	Chapter VI	CHAPTER VI TRANSITIONAL AND FINAL PROVISIONS		CHAPTER VI TRANSITIONAL AND FINAL PROVISIONS	
179	Article 24a Article 24a – paragraph 1 Article 24a – paragraph 2	<i>Article 24</i> Information, communication and publicity 1. The recipients of Union funding shall acknowledge the origin and ensure the visibility of the Union funding (in particular when promoting the actions and their results), by providing coherent, effective and targeted information to multiple audiences, including the media and the public. 2. The Commission shall implement information and communication actions related to the Programme, and its actions and results.		<i>Article 24a</i> 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.	<i>Numbered 24a since there were two Articles 24 in the Commission proposal.</i>

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
179 continued	Article 24a – paragraph 3	Financial resources allocated to the Programme shall also contribute to the corporate communication of the political priorities of the Union, as far as they are related to the objectives referred to in Articles 3 and 4.		3. Financial resources allocated to the Programme shall also contribute to the corporate communication of the political priorities of the Union, as <i>insofar as they those priorities</i> are related to the objectives referred to in Articles 3 and 4.	
180	Article 25	<i>Article 25</i> <i>Repeal</i> Regulation (EU) No 282/2014 is repealed with effect from 1 January 2021, without prejudice to Article 26 of this Regulation.		<i>Article 25</i> <i>Repeal</i> Regulation (EU) No 282/2014 is repealed with effect from 1 January 2021, without prejudice to Article 26 of this Regulation.	
181	Article 26 Article 26 – paragraph 1	<i>Article 26</i> <i>Transitional provisions</i> 1. This Regulation shall not affect the continuation or modification of the actions concerned, until their closure, under Regulation (EU) No 282/2014, which shall continue to apply to the actions concerned until their closure.		<i>Article 26</i> <i>Transitional provisions</i> 1. This Regulation shall not affect the continuation or modification of the actions concerned , <i>initiated pursuant to</i> until their closure, under Regulation (EU) No 282/2014, which shall continue to apply to the those actions concerned until their closure.	

Item	Article Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
181 continued	Article 26 – paragraph 2	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).		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 .	
182	Article 27	<i>Article 27</i> Entry into force This Regulation shall enter into force on the twentieth day following its publication in the <i>Official Journal of the European Union</i>. It shall apply from 1 January 2021. This Regulation shall be binding in its entirety and directly applicable in all Member States.		<i>Article 27</i> Entry into force This Regulation shall enter into force on the twentieth day following its publication in the <i>Official Journal of the European Union</i>. It shall apply from 1 January 2021. This Regulation shall be binding in its entirety and directly applicable in all Member States.	

Annex I

This Annex contains Annex I to the Proposal 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”). For explanations of layout and fonts see Annex A. In the Council column, the actions in Annex I of the text approved by Coreper that correspond to the actions proposed by the Commission or the Parliament are set out in the same order as in the Commission proposal in order to facilitate comparison of the Commission, Parliament and Council texts. A consolidated version of the Annex I as approved by Coreper is set out in Annex E.

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
183		ANNEX I		ANNEX I	
184		LIST OF POSSIBLE ELIGIBLE ACTIONS PROVIDED FOR IN ARTICLE 13		LIST OF POSSIBLE ELIGIBLE ACTIONS PROVIDED FOR IN ARTICLE 13	
185				<i>1. Actions meeting the objective laid down in Article 4(1)</i>	<i>Council section heading in Annex I</i>
186				<i>2. Actions meeting the objective laid down in Article 4(3)</i>	<i>Council section heading in Annex I</i>

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
187				3. <i>Actions meeting the objective laid down in Article 4(4a)</i>	<i>Council section heading in Annex I</i>
188				4. <i>Actions meeting the objective laid down in Article 4(5)</i>	<i>Council section heading in Annex I</i>
189				5. <i>Actions meeting the objective laid down in Article 4(8), in particular through</i>	<i>Council section heading in Annex I</i>
190				6. <i>Actions meeting the objective laid down in Article 4(9)</i>	<i>Council section heading in Annex I</i>
191				7. <i>Actions meeting the objective laid down in Article 4(10)</i>	<i>Council section heading in Annex I</i>
192	(a)	(a) Investment in:		(a) Investment in:	
193	(a)(i)	(i) Precursory projects for high added-value up-scalable initiatives;		(i) Precursory projects for high added-value up-scalable initiatives;	
194	(a)(ii)	(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.	Amendment 108 (ii) Coordinated action relevant in the context of health crises, tools, mechanisms , structures, processes, production and laboratory capacity, including tools for surveillance, modelling, forecast, prevention and management of outbreaks.	1(a) Strengthening the critical health infrastructure relevant in the context of to cope with health crises; by supporting the setup of tools for surveillance, modelling, forecast, prevention and management of outbreaks;	<i>Moved to become I(a) and amended</i>

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
195	(b)	(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.	Amendment 109 (b) Transfer, adaptation and roll-out of best practices and innovative solutions with established Union level added-value between Member States or regions , and country-specific tailor made support to regions or countries, or groups of regions or countries, with the highest needs, through the funding of specific projects including twinning, expert advice and peer support.	6(c) Supporting the transfer, adaptation and roll-out of best practices and innovative solutions with established Union level added-value between 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;	<i>Moved to become 6(c) and slightly amended.</i>
196	(c)	(c) Support analytical activities and expert advice , in particular:		(e) Support analytical activities and expert advice, in particular:	
197	(c)(i)	(i) Surveys, studies, collection of data and statistics, methodologies, classifications, microsimulations, indicators, knowledge brokering and benchmark exercises;	Amendment 110 (i) Surveys, studies, collection of comparable data and statistics, where relevant including disaggregated data by gender and age methodologies, classifications, microsimulations, pilot studies , indicators, knowledge brokering and benchmark exercises;	4(b) Supporting the implementation and advancement of surveys, studies, collection of data and statistics, methodologies, classifications, microsimulations, and health indicators, and fostering knowledge brokering and benchmarking exercises;	<i>Moved to become 4(b) and amended.</i>

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
198	(c)(ii)	(ii) The establishment and operation of a health intelligence and knowledge infrastructure;		5(a) Supporting the establishment and operation of a health intelligence and knowledge infrastructure;	<i>Moved to become 5(a) and amended.</i>
199	(c)(iii)	(iii) Expert groups and panels providing advice, data and information to support health policy development and implementation;	Amendment 111 (iii) Expert groups and panels, <i>including representatives of relevant stakeholders where applicable</i> , providing advice, <i>evaluation</i> , data and information to support health policy development and implementation, <i>including follow-up evaluations of the implementation of health policies</i> ;	5(f) Supporting the establishment of expert groups and panels providing advice, data and information to support health policy development and implementation;	<i>Moved to become 5(f) and slightly amended.</i>
200	(c)(iv)	(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".	Amendment 112 (iv) Studies and analysis, <i>systematic health impact assessment of other Union policy actions</i> and scientific advice to support <i>evidence-based</i> policymaking, and support to the scientific committees on "Consumer Safety" and on "Health, Environmental and Emerging Risks", <i>as well as the expert group on "Health Systems Performance Assessment"</i> .	5(e) Supporting the development of scientific studies and analysis, and scientific advice to support <i>underpin evidence-based public health measures and</i> policymaking, and support to the scientific committees on "Consumer Safety" and on "Health, Environmental and Emerging Risks" .	<i>Moved to become 5(e) and amended.</i>

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
201	(d)	(d) Development and implementation of Union health legislation and action , in particular through support to:	Amendment 113 (d) Development, implementation, <i>and evaluation</i> , of Union health legislation and action, in particular through support to:	(d) Development and implementation of Union health legislation and action, in particular through support to:	
202	(d)(i)	(i) Implementation, enforcement, monitoring of Union health legislation and action; and technical support to the implementation of legal requirements;	Amendment 114 (i) Implementation, enforcement, monitoring of Union health legislation and action, <i>including promotion of health</i> ; and technical support to the <i>full</i> implementation of legal <i>and operational</i> requirements <i>throughout Member States</i> ;	5(b) Implementation, enforcement, monitoring of Union health legislation and action; and Supporting technical and administrative assistance support, including development, maintenance and management of digital tools and databases needed for to the implementation of legal requirements Union health legislation;	<i>Moved to become 5(b) and amended.</i>
203	(d)(ii)	(ii) Cross-border collaboration and partnerships, including in cross-border regions, with a view to transferring and upscaling innovative solutions;		6(d) Supporting cross-border collaboration and partnerships, including in cross-border regions, with a view to transferring and upscaling innovative solutions;	<i>Moved to become 6(d) and slightly amended.</i>
204	(d)(iii)	(iii) Cross-sectoral collaboration and coordination;		6(e) Strengthening cross-sectoral collaboration and coordination <i>where appropriate</i> ;	<i>Moved to become 6(e) and amended.</i>

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
205	(d)(iv)	(iv) Development and operation of databases and digital tools and their interoperability, including where appropriate with other sensing technologies, such as space-based;	Amendment 115 (iv) Development, operation and maintenance of databases and digital tools and their interoperability, including already established projects , where appropriate with other sensing technologies, such as space-based and artificial intelligence ;	3(e) Supporting the development and operation of digital databases and digital tools and their interoperability, including where appropriate with other technologies, such as space-based artificial intelligence ;	<i>Moved to become 3(e) and amended.</i>
206	(d)(v)	(v) Auditing and assessment work in accordance with Union legislation;	Amendment 116 (v) Auditing, assessment and inspection work in accordance with Union legislation;	(v) Auditing and assessment work in accordance with Union legislation;	
207	(d)(vi)	(vi) Collaboration between the Union institutions, its Agencies, and international organisations and networks, and the Union's contribution to global initiatives;		7(b) Supporting collaboration between the Union institutions, its Agencies, and international organisations and networks, and the Union's contribution to global initiatives;	<i>Moved to become 7(b) and slightly amended.</i>
208	(d)(vii)	(vii) Stakeholder consultation activities;		(vii) Stakeholder consultation activities;	
209	(d)(viii)	(viii) Networking by non-governmental organisations and their involvement in projects covered by the Programme;		(viii) Networking by non-governmental organisations and their involvement in projects covered by the Programme;	

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
210	(d)(ix)	(ix) Collaboration with third countries on the areas covered by the Programme;		7(c) Supporting collaboration with third countries on the areas covered by the Programme;	<i>Moved to become 7(c) and slightly amended.</i>
211	(d)(x)	(x) National contact points providing guidance, information and assistance related the implementation of Union health legislation and of the Programme;	Amendment 117 (x) National contact points providing guidance, information and assistance related to the promotion and implementation of Union health legislation and of the Programme;	5(g) Supporting national focal contact points in providing guidance, information and assistance related to the implementation of Union health legislation and of the Programme.	<i>Moved to become 5(g) and amended.</i>
212	(d)(xi)	(xi) Stakeholders in view of transnational cooperation.	Amendment 118 (xi) Stakeholders in view of transnational and regional cooperation.	(xi) Stakeholders in view of transnational cooperation.	
213	(e) (e)(i)	(e) Structural stockpile and crisis preparation: (i) Establishment and support of a mechanism to develop, procure and manage crisis relevant products;	Amendment 119 <i>Deleted</i> <i>Deleted</i>	(e) Structural stockpile and crisis preparation: (i) Establishment and support of a mechanism to develop, procure and manage crisis relevant products;	

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
213 continued	(e)(ii) (e)(iii)	(ii) <i>Establishment and management of EU reserves and stockpiles of crisis relevant products in complementarity with other Union instruments;</i> (iii) <i>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;</i>	Amendment 119 continued <i>Deleted</i> <i>Deleted</i>	(ii) <i>Establishment and management of EU reserves and stockpiles of crisis relevant products in complementarity with other Union instruments;</i> (iii) <i>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;</i>	
214	(e)(iv)	(iv) <i>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;</i>	Amendment 119 continued <i>Deleted</i>	2(a) Supporting actions for the procurement and supply of goods and services necessary for the prevention and management of health products and crisis erises relevant products and action to secure access to those essential goods and services contribute to their affordability;	<i>Moved to become 2(a) and amended.</i>

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
215	(e)(v)	(v) <i>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;</i>	Amendment 119 continued <i>Deleted</i>	(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;	

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
216	(f)	(f) Preparedness, prevention and response to cross-border health threats:		(f) Preparedness, prevention and response to cross-border health threats:	
217	(f)(i)	(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;	Amendment 227 (i) Actions to foster Union-wide and cross-sectoral health crisis prevention, preparedness, management and the response capacity of actors at Union, national, regional and local level, including stress tests , contingency planning and preparedness exercises, development of quality healthcare standards and the upskilling of medical, healthcare and public health staff;	1(b) Supporting actions to foster Union-wide and cross-sectoral health crisis prevention, preparedness, management and response capacity of actors at Union, and national, regional and local level, including contingency planning, and preparedness exercises, and the upskilling of medical, healthcare and public health staff mechanisms for the efficient coordination of preparedness and response and coordination of those actions at Union level;	<i>Moved to become 1(b) and amended.</i>
218	(f)(ia)		Amendment 121 (ia) Establishment of a European Health Response Mechanism (EHRM) to respond to all types of health treats and crises and to strengthen operational coordination at European level, coordinated by ECDC with the assistance of relevant agencies ;		

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219	(f)(ib)		Amendment 251 <i>(ib) Contribute to the establishment of the reserve of health crisis relevant products in complementarity with rescEU, the Emergency Support Instrument, the Resilience Instrument and other Union instruments, programmes and funds, and ensure the availability of such products in times of crisis;</i>		
220	(f)(ii)	(ii) Setting up an integrated cross cutting risk communication framework covering all phases of a health crisis - prevention, preparedness and response;		1(c) Supporting actions for setting up an integrated cross cutting risk communication framework covering all phases of a health crisis - <i>i.e.</i> prevention, preparedness, and response and recovery;	<i>Moved to become 1(c) and amended.</i>
221	(f)(iii)	(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;	Amendment 122 <i>deleted</i>	(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;	

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
222	(f)(iv)	(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;	Amendment 123 (iv) Preventive actions to protect <i>all citizens, in particular</i> vulnerable groups from health threats and actions to adjust the response to and management of crisis to the needs of those vulnerable groups, <i>such as securing basic care for chronic disease patients in need of palliative care and pain management treatment</i> ;	<i>1(d) Supporting</i> preventive actions to protect vulnerable groups from health threats and actions to adjust <i>adapt</i> the response to and the management of crisis to the needs of those vulnerable groups;	<i>Moved to become 1(d) and slightly amended.</i>
223	(f)(iva)		Amendment 124 (iva) <i>Actions to support e-health, such as the transition to telemedicine, at-home administration of medication and implementation of preventative / self-care plans, where possible and appropriate;</i>		
224	(f)(ivb)		Amendment 125 (ivb) <i>Actions to support cross-border cooperation to ensure access to rapid treatment for all patients across the Union, particularly for those who suffer from a rare disease;</i>		

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
225	(f)(v)	(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 ;	Amendment 126 (v) Actions to address and manage the collateral health consequences of a health crisis, in particular those on mental health, on patients suffering from chronic diseases and other vulnerable situations, including people living with addiction, with HIV/AIDS, or suffering from tuberculosis ;	1(e) Supporting actions to address the collateral health consequences of a health crisis, in particular those on the consequences for mental health, on and patients suffering from cancer and from chronic diseases and other vulnerable groups;	<i>Moved to become 1(e) and amended.</i>
226	(f)(vi)	(vi) Actions to strengthen surge capacity, research, development, laboratory capacity, production and deployment of crisis-relevant niche products;		2(b) Supporting actions to strengthen surge capacity the production , research, development, laboratory capacity, production and deployment of health products and crisis relevant niche products within the Union ;	<i>Moved to become 2(b) and amended.</i>
227	(f)(vii)	(vii) Establishment and operation of a mechanism for cross-sectorial One-Health coordination;		7(d) Supporting the establishment and operation of a mechanism for cross-sectorial coordination following the One-Health approach .	<i>Moved to become 7(d) and amended.</i>

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
228	(f)(viii)	(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.		(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.	
229	(f)(viii a)		Amendment 127 <i>(viii a) Support action regarding epidemiological surveillance, focusing on national health entities, thus contributing to assessment of factors that affect or determine the health of citizens;</i>		
230	(f)(viii b)		Amendment 128 <i>(viii b) Actions to ensure that access to medicines is undisrupted, and that there is continuity of care and treatment, in particular for patients suffering from chronic conditions;</i>		

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
231	(g)	(g) Strengthen national health systems:	Amendment 129 (g) Strengthen national health systems, <i>promote and protect health and prevent diseases:</i>	(g) Strengthen national health systems:	
232	(g)(i)	(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	Amendment 130 (i) Support knowledge transfer actions and Union level cooperation to assist national reform processes towards improved effectiveness, accessibility, sustainability and resilience, <i>while linking available Union funding,</i> in particular to address the challenges identified by the European Semester <i>and Country Specific Recommendations on health,</i>	6(a) Supporting knowledge transfer actions and Union level cooperation to assist national reform processes towards improved effectiveness, accessibility, sustainability and resilience <i>of health systems,</i> in particular to address the challenges identified by the European Semester;	<i>The first part of section (g)(i) moved to become 6(a) and amended.</i>
233	(g)(i)	and to strengthen primary care, reinforce the integration of care and aim at universal health coverage and equal access to healthcare;	and to strengthen primary care, reinforce the integration of care, aim at universal health coverage and <i>reach</i> equal access to <i>good quality</i> healthcare;	6(f) and to <i>Support the strengthening of</i> primary care, reinforcing the integration of care and aim at <i>with a view to</i> universal health coverage and equal access to healthcare;	<i>The second part of section (g)(i) moved to become 6(f) and slightly amended.</i>

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234	(g)(ia)		Amendment 131 <i>(ia) Support implementing policies and actions to reduce health inequalities and inequities in relation to healthcare;</i>	<i>4(h) Supporting actions to address health inequalities;</i>	<i>No correspondence in Cion proposal, but in EP amendment 131</i>
235	(g)(ii)	(ii) Training programmes for medical and healthcare staff, and programmes for temporary exchanges of staff;	Amendment 132 (ii) <i>Support in synergy with other Programmes training, educational and mobility programmes for medical and healthcare staff, including online programmes, and programmes for temporary exchanges of staff, in particular with the aim of improving their curricula and digital skills;</i>	1(f) Training programmes for the upskilling of medical and healthcare and public health workforces staff, and programmes for temporary exchanges of staff;	<i>Moved to become 1(f) and amended.</i>

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
236	(g)(iii)	(iii) Support to improve the geographical distribution of healthcare workforce and avoidance of ‘medical deserts’;	Amendment 133 (iii) Support <i>in synergy with other Programmes</i> to improve the geographical distribution of <i>the</i> healthcare workforce, <i>while ensuring that such distribution of the workforce is also proportionate to the population of the area or region in question, and thus avoiding</i> ‘medical deserts’ <i>and promote and implement retention policies</i> ;	(iii) Support to improve the geographical distribution of healthcare workforce and avoidance of ‘medical deserts’;	
237	(g)(iv)	(iv) Support the establishment and coordination of Union Reference Laboratories and Centres, and of Centres of excellence;	Amendment 134 (iv) Support the establishment, coordination and deployment of Union Reference Laboratories and Centres, Centres of Excellence and EU disease-specific platforms for the exchange, comparison and benchmarking of best practices between Member States ;	I(g) Supporting the establishment and coordination of Union Reference Laboratories and Centres, and of Centres of excellence;	<i>Moved to become I(g) and amended.</i>

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
238	(g)(v)	(v) Audit of Member States preparedness and response arrangements (such as crisis management, antimicrobial resistance, vaccination);	Amendment 135 (v) Audit of Member States preparedness and response arrangements (such as crisis management, antimicrobial resistance, vaccination) and the implementation of their health promotion and disease prevention national strategies or programmes;	1(h) Auditing of Member States preparedness and response arrangements (such as crisis management, antimicrobial resistance, vaccination);	<i>Moved to become 1(h) and slightly amended.</i>
239	(g)(vi)	(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;		5(d) Supporting upwards convergence of national systems' performance through health indicator development, analysis and knowledge brokering and the organisation of stress tests of national healthcare systems;	<i>Moved to become 5(d) and amended</i>
240	(g)(vii)	(vii) Support capacity building for investing in and implementing health system reforms (strategic planning and access to multi-source financing);		6(b) Supporting capacity building for investing in and implementing health system reforms (strategic planning and access to multi-source financing);	<i>Moved to become 6(b) and slightly amended.</i>

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241	(g)(viii)	(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;		6(i) Supporting 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.	<i>Moved to become 6(i) and amended.</i>
242	(g)(viiiia)		Amendment 136 <i>(viiiia) Support a Union framework and the related interoperable digital tools to strengthen health technology assessment cooperation among Member States and in networks, including networks needed in order to enable Member States to deliver and exchange timely, reliable and high quality joint clinical assessments, and joint scientific consultations and other relevant activities to support decision-makers to exchange outcomes of cooperation regarding HTA;</i>		

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
243	(g)(ix)	(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);	Amendment 137 (ix) Support the establishment and implementation of <i>national and European</i> programmes, <i>including digital and evidence-based programmes</i> , assisting Member States and their action to improve health promotion, <i>health literacy</i> and disease prevention (for communicable and non-communicable diseases) <i>in health units and communities, and mitigate the main risk factors of chronic diseases</i> ;	<i>4(a)</i> Supporting the establishment and implementation of programmes assisting Member States and their actions to improve health promotion and disease prevention (for communicable and non-communicable diseases) ; <i>4(i)</i> Supporting actions to enhance health literacy;	<i>g(ix) moved to become 4(a) and amended.</i> <i>4(i) no correspondence in Cion proposal, but in EP Amendment 137</i>
244	(g)(ixa)		Amendment 138 <i>(ixa) Support the establishment and functioning of disease-specific Union platforms for the exchange, comparison and benchmarking of best practices between Member States, in the form of excellence networks in the field of communicable and non-communicable diseases, in particular in the area of chronic diseases</i> ;		

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245	(g)(ixb)		Amendment 139 <i>(ixb) Support the development of guidelines for preventing and managing diseases in the area of both communicable and non-communicable diseases;</i>		
246	(g)(x)	(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 <i>vulnerable groups</i> ;	(x) Support Member States' actions to put in place healthy and safe urban, work and school environments, to <i>promote mental health, health education</i> , enable healthy life choices and promote <i>regular physical activity</i> and healthy diets taking into account the needs of <i>people at every stage of their life with the aim of promoting life-long health</i> ;	4(c) Supporting Member States' actions to put in place healthy and safe urban, work and school environments, to enable healthy life choices and <i>to</i> promote healthy diets, taking into account the needs of vulnerable groups; 4(f) <i>Supporting actions to improve mental health;</i>	<i>g(x) moved to become 4(c) and slightly amended</i> <i>4(f) no correspondence in Cion proposal, but in EP amendment 140</i>
247	(g)(xa)		Amendment 141 <i>(xa) Support Member States actions to address health determinants, including reducing alcohol related harm and tobacco use;</i>		

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248	(g)(xb)		Amendment 142 <i>(xb) Support Member States' actions to ensure access to sexual and reproductive health services and related medicinal products, and support integrated and intersectional approaches to prevention, diagnosis, treatment and care;</i>		
249	(g)(xc)		Amendment 143 <i>(xc) Actions promoting care and support for victims of gender-based violence;</i>		
250	(g)(xd)		Amendment 144 <i>(xd) Actions promoting equal access to health services and related facilities and care for people with disabilities;</i>		

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251	(g)(xi)	(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;		6(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;	<i>Moved to become 6(g) and slightly amended.</i>
252	(g)(xia)		Amendment 145 <i>(xia) Support Member States in the revision of their rare disease national plans to put in place the necessary financial and organisational arrangements to integrate effectively the European Reference Networks system into the national health systems by also supporting the development and implementation of the set of policies, rules and procedures required to anchor the ERN system to the national level;</i>		

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253	(g)(xib)		Amendment 146 <i>(xib) Support the implementation of the ERNs' system for continuous assessment, monitoring, evaluation and quality improvement;</i>		
254	(g)(xic)		Amendment 147 <i>(xic) Earmark funding to create effective and permanent mechanisms for the collaboration of ERNs to address the multi-systemic needs arising from low prevalence diseases and rare diseases and to facilitate diagonal networking between different specialities and disciplines;</i>		

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255	(g)(xid)		Amendment 148 <i>(xid) Support Member States in strengthening their Centres of Expertise for rare diseases to increase the capacities of national health systems to diagnose, treat and manage such diseases, transnational cooperation on codification, information and knowledge in the field of rare diseases, in particular the Orphanet database;</i>		
256	(g)(xii)	(xii) Support for Member States to strengthen the administrative capacity of their healthcare systems through benchmarking, cooperation and exchange of best practices.		5(c) Supporting for Member States to strengthen the administrative capacity of their healthcare systems through benchmarking, cooperation and exchange of best practices;	<i>Moved to become 5(c) and amended</i>

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257	(g)(ii)		Amendment 149 <i>(xiia) Support cooperation and coordination between Member States for the creation of a European Network for Hospitals Excellence, improving the cross-border treatment for rare diseases and increasing access to treatment for all Union citizens;</i>		
258	(g)(xiii)	(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.		3(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; to exchange outcomes of HTA cooperation.	Moved to become 3(a) and amended.

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
259	(h)	(h) Actions on cancer:	Amendment 150 (h) Actions on cancer, <i>including paediatric cancer</i> ;	(h) Actions on cancer:	
260	(h)(i)	(i) Support Member States and NGOs in the promotion and implementation of the recommendations of the European Code against Cancer;	Amendment 151 (i) Support Member States, IARC and NGOs in the promotion and implementation of the recommendations of the European Code against Cancer; support the revision and continuous update of the current edition of the European Code against Cancer ;	4(j) Supporting Member States and NGOs in actions for the promotion and implementation of the recommendations of the European Code against Cancer;	Moved to become 4(j) and amended.
261	(h)(ia)		Amendment 152 (ia) <i>Support the establishment of a European Cancer Institute (ECI) as a platform for the implementation of the European Reference Cancer Networks, the collection of clinical data among centres from all participating countries across the Union and the prioritisation of academic and clinical research programmes of excellence in the area of cancer including paediatric cancer</i> ;		

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262	(h)(ii)	(ii) Support the establishment establishment of quality assurance schemes for cancer centres;			<i>Moved to become part of 4(k), see entry h(vii).</i>
263	(h)(iii)	(iii) Support prevention programmes on the main cancer risk factors;	Amendment 153 (iii) Support prevention programmes on the main cancer risk factors that are of demonstrated effectiveness and supported by established evidence ;		<i>Prevention part of 4(k), see entry h(vii).</i>
264	(h)(iv)	(iv) Actions to support secondary prevention of cancer, such as early detection and diagnosis through screening;		4(l) Supporting actions to support strengthen secondary prevention of cancer, such as early detection and diagnosis through screening;	<i>Moved to become 4(l) and slightly amended.</i>
265	(h)(iva)		Amendment 154 (iva) Action to support the implementation of cancer registries in all Member States ;		

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266	(h)(v)	(v) Actions supporting access to cancer services and to innovative medicines for cancer;	Amendment 155 (v) Actions supporting <i>implementing policies, national programmes and guidelines, in line with the Europe's Beating Cancer plan, to reduce inequalities and grant</i> access to cancer services, <i>supportive and palliative care</i> , and to innovative, <i>accessible and effective screening, treatments and</i> medicines for cancer <i>across all Member States, in full synergy with Horizon Europe and its missions and partnerships</i> ;	(v) Actions supporting access to cancer services and to innovative medicines for cancer;	
267	(h)(va)		Amendment 156 (va) <i>Actions supporting equal and timely access to new and innovative medicines and therapies, including for supportive and palliative care, for paediatric malignancies, across Europe, and foster the availability and affordability of such medicines and treatments in child-friendly doses and formulations</i> ;		

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268	(h)(vb)		Amendment 157 <i>(vb) Actions to address the unmet needs of children and adolescents with cancer, and of survivors of cancer, through dedicated programmes and plans that will enable the ERN, including those on paediatric cancer;</i>		
269	(h)(vi)	(vi) Actions supporting the continuity of care (integrated care approaches for prevention, diagnosis, treatment and follow-up care);		4(m) Supporting actions supporting to improve the continuity of care (integrated care approaches for prevention, diagnosis, treatment and follow-up care);	Moved to become 4(m) and slightly amended.
270	(h)(vii)	(vii) Actions supporting quality in cancer prevention and care including diagnosis and treatment;	Amendment 158 (vii) Actions supporting quality in cancer prevention and care including diagnosis and treatment, follow-up, and supportive and palliative care;	4(k) Supporting actions to improve the supporting quality in cancer prevention and 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;	Moved to become 4(k) and amended. In addition merged with Commission h(ii).

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
271	(h)(viii)	(viii) Actions supporting the quality of life of cancer survivors and care givers;	Amendment 159 (viii) Actions supporting the quality of life of cancer survivors and care givers, including provision of psychological support, pain management, and professional re-integration;	(viii) Actions supporting the quality of life of cancer survivors and care givers;	
272	(h)(ix)	(ix) Support to the implementation of the Union's tobacco control policy and legislation;	Amendment 160 (ix) Support to the implementation of the Union's tobacco control policy and legislation and other related legislation in the area of prevention and health promotion, including aimed at reducing alcohol related harm;	4(o) Supporting to the implementation and further development of the Union's tobacco control policy and legislation;	<i>Moved to become 4(o) and amended.</i>
273	(h)(x)	(x) Establishment and support of a mechanisms for cross-specialty capacity building and continuous education in the area of cancer care.	Amendment 161 (x) Establishment and support of a mechanisms for cross-specialty capacity building and continuous education of healthcare professionals and informal carers in the area of cancer care, screening and early diagnosis, in particular in the area of paediatric cancer, with the aim to improve the quality of care;	4(n) Establishment and supporting of a mechanisms for cross-specialty capacity building and continuous education, in particular in the area of cancer care;	<i>Moved to become 4(n) and amended.</i>

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
274	(h)(xa)		Amendment 162 <i>(x a) Actions to support an integrative, coordinated, multi-disciplinary and patient-centred approach concerning cancer patients and survivors;</i>		
275	(i)	(i) Actions on medicines, vaccines and medical devices:		(i) Actions on medicines, vaccines and medical devices:	
276	(i)(i)	(i) Support to initiatives to improve vaccination coverage rates in the Member States;		2(g) Supporting initiatives to improve vaccination coverage rates in the Member States;	<i>Moved to become 2(g) and slightly amended.</i>
277	(i)(ii)	(ii) Support actions to fight vaccine hesitancy;	Amendment 163 (ii) Support actions to fight vaccine hesitancy <i>and disinformation, and promote immunization throughout all stages of a person's lifetime;</i>	(ii) Support actions to fight vaccine hesitancy;	
278	(i)(ia)		Amendment 164 <i>(ia) Support tools and platforms to collect real-world evidence on the safety, effectiveness and impact of vaccines after use, without prejudice to the generation of robust evidence in the pre-approval phase;</i>		

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279	(i)(iib)		Amendment 165 <i>(iib) support action for the elimination of vaccine preventable diseases;</i>		
280	(i)(iii)	(iii) Support clinical trials to speed up the development, authorisation and access to innovative, safe and effective medicines and vaccines;	Amendment 166 (iii) Support clinical trials <i>and the use of real world data, including those involving increased coordination at Union level and with EMA</i> , to speed up the development, authorisation and access to innovative, safe and effective medicines and vaccines;	2(d) Supporting clinical trials to speed up the development, <i>market</i> authorisation and access to innovative, safe and effective medicines and vaccines;	<i>Moved to become 2(d) and amended-</i>

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281	(i)(iiia)		Amendment 167 <i>(iiia) Support actions aimed at creating and developing a European digital mechanism for better reporting, notification and monitoring of potential shortages, in the form of a Union platform for shortages of medicines, vaccines and medical devices, based on one harmonised and interoperable data-collection model and national reporting systems for shortages, including the full implementation of an effective Union telematics infrastructure that will link data on medicines and supply chains;</i>		

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282	(i)(iiib)		Amendment 168 <i>(iiib) Support actions aimed at stimulating the increase in the production of essential APIs and medicinal products in the Union, including by diversifying supply chain production of active ingredients and generics within the Union to reduce the Member States' dependence on certain third countries;</i>		
283	(i)(iv)	(iv) Support action to ensure greater availability in the Union of <i>medicines</i> and medical devices and contribute to their affordability for patients and health systems;	Amendment 169 (iv) Support action to ensure greater availability in the Union of <i>medicinal products</i> and medical devices and contribute to their affordability for patients and health systems;	(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;	
284	(i)(v)	(v) Support action to encourage the <i>development</i> of innovative <i>products and of less commercially interesting products such as antimicrobials</i> ;	Amendment 170 (v) Support action to encourage the <i>discovery and development</i> of innovative <i>medicines and vaccines to meet rising healthcare challenges and patients' needs</i> ;	2(e) Supporting actions to encourage the development of innovative products and of less commercially interesting <i>unprofitable</i> products such as antimicrobials;	<i>Moved to become 2(e) and slightly amended.</i>

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285	(i)(va)		Amendment 171 <i>(va) Support actions to foster innovation in repurposing, reformulation and combining of off-patent medicines that deliver relevant improvements for patients, healthcare professionals and healthcare systems;</i>		
286	(i)(vb)		Amendment 172 <i>(vb) Action to address market failures with regard to antibiotics and encourage sustainable investments for the discovery and development of new antimicrobials, of medicines for rare diseases and of medicines to fight against communicable diseases, while ensuring equitable access;</i>		

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287	(i)(vi)	(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;	Amendment 173 (vi) Support action to monitor, <i>prevent, manage, report and notify</i> shortages of medicines and medical devices occurring in hospitals and community pharmacies, to <i>collect reported shortages in a centralized database, interoperable with databases that contained regulatory data on medicines</i> , to address such shortages, and to increase security of supplies;	2(c) Supporting actions to monitor shortages of medicines and medical devices occurring in hospitals and community pharmacies, to address <i>prevent</i> such shortages, and of medicinal products and medical devices as well as crisis relevant products to increase security <i>sustainability</i> of supplies;	<i>Moved to become 2 (c) and amended</i>
288	(i)(vii)	(vii) Support actions to encourage the development of innovative medicines and medical devices less harmful for the environment and promote greener manufacturing;		2(f) Supporting actions to <i>improve environmental-friendly production and disposal</i> encourage the development of innovative medicines <i>medicinal products</i> and medical devices less harmful for the environment and promote greener manufacturing;	<i>Moved to become 2(f) and amended.</i>
289	(i)(viii)	(viii) Action to strengthen the environmental risk assessment of pharmaceuticals;	Amendment 174 (viii) Action to strengthen the environmental risk assessment of pharmaceuticals <i>and medical devices</i> ;	(viii) Action to strengthen the environmental risk assessment of pharmaceuticals;	

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290	(i)(ix)	(ix) Action to promote the prudent use and disposal of antimicrobials;	Amendment 175 (ix) Action to promote the prudent use and disposal of medicines, especially antimicrobials and to reduce the overall use of medicines, action to support the surveillance of antimicrobial use and to support the fight against antimicrobial resistance (AMR);	2(h) Supporting actions to promote the prudent and efficient use and disposal of medicinal products, in particular of antimicrobials;	<i>Moved to become 2(h) and amended.</i>
291	(i)(x)	(x) Support action to foster international regulatory convergence on medicines and medical devices.	Amendment 176 (x) Support action to foster international regulatory convergence and reliance on medicinal products and medical devices, and to improve regulatory oversight by the Union.	(x) Support action to foster international regulatory convergence on medicines and medical devices.	

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292	(j)	(j) Digital transformation of health:		(j) Digital transformation of health:	
293	(j)(i)	(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;	Amendment 177 (i) Support for the deployment, operation and maintenance of mature interoperable digital service infrastructures and data security and quality assurance processes for data exchange, access, use and reuse; support for cross border networking, including through improvement and better use of electronic health records, registries and other databases;	3(b) Supporting for 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 for 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;	<i>Moved to become 3(b) and amended. Compare (j)(iii) as regards governance structure.</i>
294	(j)(ia)(new)		Amendment 178 (ia) Establish the European Electronic Health Record and support its implementation in the Member States in order to increase the use of e-health and improve the sustainability and resilience of healthcare systems;		

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295	(j)(ib)(new)		Amendment 179 <i>(ib) Support Member States to improve and further develop and implement ERN registries;</i>		
296	(j)(ii)	(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 <i>professionals</i> ;	Amendment 180 (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 <i>and strengthening the safe use and re-use of health data, in line with GDPR; support and implement</i> ; digital upskilling of health care <i>professionals and citizens, through enhanced education, training and (digital) health literacy measures</i> ;	3(c) Supporting to the digital transformation of healthcare and health systems including through benchmarking and capacity building for the uptake of innovative tools and technologies <i>such as artificial intelligence</i> ; digital upskilling of healthcare professionals;	<i>Moved to become 3(c) and amended.</i>

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
297	(j)(iii)	(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	Amendment 181 (iii) Support the deployment and interoperability of digital tools and infrastructures within and between Member States and with Union Institutions, agencies and bodies; develop appropriate governance structures and sustainable, interoperable Union health information systems, as part of the European Health Data Space	3(g) Supporting preparatory activities and projects for the European Health Data Space;	<i>Shortened and divided into 3(f) and 3(g). Compare j(i) as concerns governance structures.</i>
298	(j)(iii)	and strengthen citizens' access to and control over their health data;	and with a view to having safe and efficient deployment of AI in health care strengthening and facilitating citizens' access to and control over their health data; support uptake and broader implementation of current successful initiatives and projects on person-centred digital health and health data;	3(f) Supporting actions to strengthen citizens' access to and control over their health data.	

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299	(j)(iv)	(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.	Amendment 182 (iv) Support <i>access to and</i> 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; <i>promote involvement of patients and care professionals in the co-design and co-development of user-friendly, accessible, secure and efficient telemedicine/telehealth and other digital solutions.</i>	3(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 promote promoting digital tools to support supporting citizen empowerment and person patient -centred care;	<i>Moved to become 3(d) and amended.</i>
300	(k)	(k) Communication and outreach to stakeholders and citizens , in particular:		(k) Communication and outreach to stakeholders and citizens , in particular:	
301	(k)(i)	(i) Communication addressed to citizens in the context of risk management and crisis preparedness.		1(i) Communicating addressed to citizens in the context of risk management and crisis preparedness.	<i>Moved to become 1(i) and slightly amended</i>

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302	(k)(ii)	(ii) Communication addressed to citizens and stakeholders to promote Union action in the areas mentioned in this Annex.		(ii) Communication addressed to citizens and stakeholders to promote Union action in the areas mentioned in this Annex.	
303	(k)(iii)	(iii) Communication to promote disease prevention and healthy lifestyles, in cooperation with all concerned actors at international, Union and national level.	Amendment 183 (iii) Communication to promote health, healthy lifestyles and disease prevention , in cooperation with all concerned actors at international, Union, national and regional level;	(iii) Communication to promote disease prevention and healthy lifestyles, in cooperation with all concerned actors at international, Union and national level.	
304	(k)(iiia)(new)		Amendment 184 (iiia) Awareness-raising campaigns for the general population as well as for targeted groups and stakeholder-led projects, including prevention of and combating disinformation;		

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305	(k)(iiib)(new)		Amendment 185 <i>(iiib) Communication activities aimed at fighting against misinformation and disinformation, such as fake news, regarding medicines, vaccines, health products, causes and treatment of diseases;</i>		
306	(k)(iiic)(new)		Amendment 186 <i>(iiic) Communication to citizens on health risks and health determinants;</i>		
307	(k)(iiid)(new)		Amendment 187 <i>(iiid) Communication, information and awareness campaigns on blood components, organs, tissues and cells donation that alert the public to the importance of such donation, in terms of solidarity, health policy and therapeutical benefits.</i>		
308	2(i)(new)			<i>2(i) Supporting actions to reduce the risk of healthcare-acquired infections.</i>	<i>No corresponding action in Cion proposal.</i>

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309	4(d)(new)			<i>4(d) Supporting Member States in delivering effective responses to communicable diseases, and in the prevention, surveillance, diagnosis and treatment of such diseases;</i>	<i>No corresponding action in Cion proposal.</i>
310	4(e)(new)			<i>4(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;</i>	<i>No corresponding action in Cion proposal.</i>
311	4(g)(new)			<i>4(g) Supporting actions to complement measures of Member States in reducing health damage due to illicit drug use and addiction, including information and prevention;</i>	<i>No corresponding action in Cion proposal.</i>
312	4(p)(new)			<i>4(p) Strengthening collaboration on patient rights, patient safety and quality of care.</i>	<i>No corresponding action in Cion proposal.</i>
313	6(h)(new)			<i>6(h) Fostering the system of European Reference Networks, especially for patients requiring highly specialised care as is the case for rare-diseases;</i>	<i>No corresponding action in Cion proposal.</i>

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
314	7(a)(new)			<i>7(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;</i>	<i>No corresponding action in Cion proposal.</i>

Annex I

This Annex contains the consolidated text of Annex I to the Proposal 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”) as agreed by Coreper on 21 October 2020.

ANNEX I**LIST OF POSSIBLE ELIGIBLE ACTIONS PROVIDED FOR IN ARTICLE 13*****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 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 II

This Annex contains Annex II to the Proposal 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”). For explanations of layout and fonts see Annex A.

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
315				ANNEX II INDICATORS FOR THE EVALUATION OF THE PROGRAMME	
316				A Programme Indicators	
317	Annex II – part A – point I	I. Quality and completeness of EU and MS preparedness and response planning for serious cross border threats to health	Amendment 188 I. Quality and completeness of the preparedness and response planning of the Union and of Member States for serious cross border threats to health, <i>including resilience assessment indicators across the Union</i>	I. Quality and completeness of EU and MS preparedness and response planning for serious cross border threats to health	

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
318	Annex II – part A – point II	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	Amendment 189 II. Access to centrally authorised medicines <i>and medical devices</i> , e.g. number of <i>existing and new</i> orphan authorisations, Advanced Therapy Medicinal Products, Paediatric Use Medicinal Products or vaccines, for unmet needs	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	
319	Annex II – part A – point III	III. Number of actions and best practices directly contributing to <i>the SDG 3.4/Member State</i>	Amendment 190 III. Number of actions and best practices directly contributing to <i>achieve Universal Health Coverage / Member State</i>	III. Number of actions and best practices directly contributing to the SDG 3.4/Member State	
320	Annex II – part A – point IV	IV. Implementation of <i>best practices</i> by EU Member States	Amendment 191 IV. Implementation of <i>health programmes</i> by EU Member States, <i>that promote health, prevent diseases and address health inequalities</i>	IV. Implementation of best practices by EU Member States	
321	Annex II – part A – point IV a (new)		Amendment 192 <i>IV a. Implementation of the European Health Data Space (EHDS)</i>		
322	Annex II – part B	B The following indicators will also be used to monitor the implementation of the Programme:		B The following indicators will also be used to monitor the implementation of the Programme:	

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
323	Annex II – part B – point 1	1. Number of Member States with improved preparedness and response planning		1. Number of Member States with improved preparedness and response planning	
324	Annex II – part B – point 1 a (new)		Amendment 193 <i>1a. Number of new procedures for accelerated development and assessment of medicines for major public health needs, where relevant taking into account novel technologies</i>		
325	Annex II – part B – point 1 b (new)		Amendment 194 <i>1b. Number of Member States with adequate level of digital health infrastructure</i>		
326	Annex II – part B – point 1 c (new)		Amendment 195 <i>1c. Number of Member States that implemented the European Electronic Health Record</i>		
327	Annex II – part B – point 1 d (new)		Amendment 196 <i>1d. Proportion of Member States' population of citizens with access to their data on the EHDS, per Member State</i>		
328	Annex II – part B – point 2	2. Vaccines, medicines, medical devices and other countermeasures during crises {made available by type and by MS}		2. Vaccines, medicines, medical devices and other countermeasures during crises {made available by type and by MS}	

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
329	Annex II – part B – point 3	3. Number of vaccine doses <i>distributed</i>	Amendment 197 3. Number of vaccine doses <i>made available by type and by Member State</i>	3. Number of vaccine doses distributed	
330	Annex II – part B – point 3 a (new)		Amendment 198 <i>3a. Vaccination coverage, by age, and by vaccine-preventable-disease</i>		
331	Annex II – part B – point 4	4. Number of entities benefiting of medicines and medical devices		4. Number of entities benefiting of medicines and medical devices	
332	Annex II – part B – point 5	5. EU Laboratory capacity index (EULabCap)		5. EU Laboratory capacity index (EULabCap)	
333	Annex II – part B – point 6	6. Age-standardised five-year net survival of <i>cervical, breast and colorectal</i> cancer	Amendment 199 6. Age-standardised five-year net survival of cancer <i>by type, age, gender and Member State</i>	6. Age standardised five year net survival of cervical, breast and colorectal cancer	
334	Annex II – part B – point 6 a (new)		Amendment 200 <i>6a. Age-standardised five-year net survival rate for paediatric cancer by type, age, gender and Member State</i>		

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
335	Annex II – part B – point 6 b (new)		Amendment 201 <i>6b. Screening coverage for breast, cervical and colorectal cancer screening programmes, by type, age, gender and Member State</i>		
336	Annex II – part B – point 7	7. Ratio of Cancer Registries (CRs) and number of Member States (MSs) reporting information on <i>cervical, breast, and colorectal</i> cancer stage at diagnosis	Amendment 202 7. Ratio of Cancer Registries (CRs) and number of Member States (MSs) reporting information on cancer stage at diagnosis	7. Ratio of Cancer Registries (CRs) and number of Member States (MSs) reporting information on cervical, breast, and colorectal cancer stage at diagnosis	
337	Annex II – part B – point 7 a (new)		Amendment 203 <i>7a. Ratio of palliative care admissions and outcome result for cancer, and paediatric cancer, by type, age, gender and Member State</i>		
338	Annex II – part B – point 7 b (new)		Amendment 204 <i>7b. Ratio of Paediatric Cancer Registries (CRs) /Member State and number of Member States (MSs) reporting information on paediatric cancer stage at diagnosis</i>		

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
339	Annex II – part B – point 7 c (new)		Amendment 205 <i>7c. Prevalence of major chronic disease per Member State, by diseases, gender and age</i>		
340	Annex II – part B – point 7 d (new)		Amendment 206 <i>7d. Age-standardized NCD mortality rate (per 100 000 people), by disease</i>		
341	Annex II – part B – point 7 e (new)		Amendment 207 <i>7e. Percentage of HIV/AIDS, patients with access to adequate treatment, by Member State, gender and age</i>		
342	Annex II – part B – point 7 f (new)		Amendment 208 <i>7f. Proportion of tuberculosis patients with access to adequate treatment, by Member State, gender and age</i>		
343	Annex II – part B – point 8	8. Smoking prevalence	Amendment 209 8. <i>Age standardized prevalence of tobacco use, by gender</i>	8. Smoking prevalence	
344			Amendment 228 <i>8a. Age-standardised prevalence of harmful use of alcohol, by gender and age</i>		

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
345	Annex II – part B – point 9	9. Number of shortages of medicines in the <i>single point of contact network</i>	Amendment 210 9. Number of shortages of medicines in the <i>Member States</i>	9. Number of shortages of medicines in the single point of contact network	
346	Annex II – part B – point 9 a (new)		Amendment 211 <i>9a. Actions aimed at stimulating the production of essential APIs and medicinal products in the EU</i>		
347	Annex II – part B – point 10	10. Access to centrally authorised medicines for unmet needs		10. Access to centrally authorised medicines for unmet needs	
348	Annex II – part B – point 11	11. Number of audits conducted in the EU and in third countries to ensure good manufacturing practices and good clinical practices (Union control)		11. Number of audits conducted in the EU and in third countries to ensure good manufacturing practices and good clinical practices (Union control)	
349	Annex II – part B – point 12	12. Deaths attributable to antimicrobial resistant infections		12. Deaths attributable to antimicrobial resistant infections	
350	Annex II – part B – point 12 a (new)		Amendment 212 <i>12a. Antimicrobial use by ATC type and per Member States</i>		
351	Annex II – part B – point 12 b (new)		Amendment 213 <i>12b. Attributable mortality to Healthcare Associated Infections, by age, gender and Member State</i>		

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
352	Annex II – part B – point 12 c (new)		Amendment 214 <i>12c. Avoidable deaths attributed to cardiovascular disease, cancer, diabetes, DALYs attributable to the NCDs and QALYs, chronic respiratory disease, for persons aged less than 75 years, by gender and Member State</i>		
353	Annex II – part B – point 13	13. Number of <i>hospital</i> units involved in ERN and of patients diagnosed and treated by the members of ERN networks	13. Number of <i>health</i> units involved in ERN and of patients diagnosed and treated by the members of ERN networks	13. Number of hospital units involved in ERN and of patients diagnosed and treated by the members of ERN networks	
354	Annex II – part B – point 14			14. Number of Health Technology Assessment reports jointly carried out	
355	Annex II – part B – point 14 a (new)		Amendment 216 <i>14a. Number of health impact assessments of Union policies</i>		
356	Annex II – part B – point 14 b (new)		Amendment 217 <i>14b. Age-standardised obesity prevalence, by gender, age and Member State</i>		

Item	Section Number	Commission text (2020/0102 (COD))	EP amendments voted on 13 November 2020	Text approved by Coreper on 21 October 2020	Tentatively agreed text, compromise proposals and comments
357	Annex II – part B – point 14 c (new)		Amendment 218 <i>14c. Maternal mortality ratio, by age and by Member State</i>		
358	Annex II – part B – point 14 d (new)		Amendment 219 <i>14d. Infant mortality rate by Member State</i>		
359			Amendment 229 <i>14e. Age-standardized deaths attributable to environmental pollution (per 100 000 people), by gender and age</i>		