Council of the European Union

Brussels, 25 November 2020
(OR. en)

12892/20

Interinstitutional File: 2020/0108(COD)

CODEC 1143	EDUC 408
ECOFIN 1069	EF 297
CADREFIN 374	TELECOM 218
COMPET 570	IA 89
RECH 455	FSTR 176
ENER 440	CULT 70
TRANS 530	AUDIO 47
ENV 724	PE 82

INFORMATION NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing the InvestEU Programme - Outcome of the European Parliament's proceedings (Brussels, 11 to 13 November 2020)

I. INTRODUCTION

The co-rapporteurs, José Manuel FERNANDES (EPP, PT) and Irene TINAGLI (S&D, IT), presented a report consisting of 1 amendment (amendment 1) to the abovementioned proposal for a Regulation on behalf of the the Committee on Budgets

In addition, the S&D Group tabled 1 amendment (amendment 2), the GUE/NGL Group tabled 6 amendments (amendment 3, 4, 5, 6, 7, 8), the ECR Group tabled 6 amendments (amendment 9, 10, 11, 12, 13, 14), and the Greens/EFA Group tabled 22 amendments (amendment 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36)

II. VOTE

When it voted on 13 November 2020, the plenary adopted one amendment (amendment 1) to the proposal for a Regulation. No other amendments were adopted. The amendments adopted are set out in the annex.

At the end of the vote, the proposal was referred back to the Committee, pursuant to Rule 59(4) of the European Parliament's Rules of Procedure, thereby not bringing the Parliament's first reading to a close and opening the negotiations with the Council.

ANNEX
(13.11.2020)

Programme for the Union's action in the field of health for the period 2021-2027 ("EU4Health Programme") ***I

Amendments adopted by the European Parliament on 13 November 2020 on the proposal for a regulation of the European Parliament and of the Council on the establishment of a Programme for the Union's action in the field of health –for the period 2021-2027 and repealing Regulation (EU) No 282/2014 ("EU4Health Programme") (COM(2020)0405 – C9-0152/2020 – 2020/0102(COD))[1]

(Ordinary legislative procedure: first reading)

[1] The matter was referred back for interinstitutional negotiations to the committee responsible, pursuant to Rule 59(4), fourth subparagraph (A9-0196/2020).

Amendment 1

Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission	*Amendment*
	(1 a) 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.

Amendment 2

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(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.	(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.

Amendment 3

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(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.	(3) Article168 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.

Amendment 4

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(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.	(5) On 11 March 2020 the World Health Organization (WHO)***, due to an exponential increase of cases,*** declared ***COVID-19 (the disease resulting from*** the novel coronavirus ***SARS-CoV-2*****), and associated respiratory disease** outbreak a global pandemic. ***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, and*** caused an unprecedented worldwide health crisis with severe socio-economic consequences and human suffering***, 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 from infectious diseases, and in general of strengthening the Union's actions to complement national policies in the field of public health.

Amendment 5

Proposal for a regulation
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5 a) 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.

Amendment 6

Proposal for a regulation
Recital 5 b (new)

Text proposed by the Commission	*Amendment*
	(5 b) 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.

Amendment 7

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity[8] . Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States ***in order to*** improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.	(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity[8] . Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States***, in particular between neighbouring border regions, as well as between authorities and relevant stakeholders. This cooperation should*** improve the ***preparedness,*** prevention and control of the spread of severe human ***infections and*** diseases across borders***, to develop and make available products for the prevention and treatment of diseases***, to combat other serious cross-border threats to health***,*** and to safeguard ***and improve*** the health and well-being of ***all*** people in the Union. ***Preparedness is the key to improving resilience to future threats, and Member States, given their responsibility for the 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.***
[8] Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.	[8] Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

Amendment 8

Proposal for a regulation
Recital 6 a (new)

Text proposed by the Commission	*Amendment*
	(6 a) 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 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.

Amendment 9

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(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.	(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.***

Amendment 10

Proposal for a regulation
Recital 10

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

stockpiling of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the "One Health" ***approach***. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.	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***. 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.
[10] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).	[10] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

Amendment 11

Proposal for a regulation
Recital 11

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

facilitate such actions.

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

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

Amendment 12

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(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.	(12) With a view to protect people in vulnerable situations, including those suffering from mental illnesses***, living with or most affected by communicable or non-communicable diseases*** and chronic diseases***, such as obesity, cancer, diabetes, cardiovascular disease and neurological disorders***, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups. ***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.***

Amendment 13

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) The COVID-19 crisis has highlighted many challenges in ensuring the supply of medicines, medical devices as well as personal protective equipment needed in the Union during the pandemics. The Programme therefore should provide support to actions which ***foster*** the production**,** procurement and management of crisis relevant products ensuring complementarity with other Union instruments.	(13) The COVID-19 crisis has highlighted many challenges ***including the Union's dependency on third countries*** in ensuring the supply of ***chemical raw and starting materials, active pharmaceutical ingredients,*** 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 ***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*** procurement and management of crisis relevant products ensuring complementarity with other Union instruments***, to mitigate the risk of shortages, especially in periods of health crises***.

Amendment 14

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(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	(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.	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***.

Amendment 15

Proposal for a regulation
Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 16

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) Experience from the COVID-19 crisis has indicated that there is a general need for the support to structural transformation of and systemic reforms of health systems across the Union to improve their effectiveness, accessibility and resilience. In the context of such transformation and reforms, the Programme should promote, in synergy with the Digital Europe Programme, actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide new care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs and ensure an efficient public health workforce equipped with the right skills, including digital skills. The development of a European health data space would provide health care systems, researchers and public authorities with means to improve the availability and quality of healthcare. Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006[12] the Programme should support actions ensuring the universality and inclusivity of health care, meaning that no-one is barred access to health care, and those ensuring that patients' rights, including on the privacy of their data, are duly respected.	(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 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 ***primordial, primary, secondary, tertiary and quaternary*** disease prevention and health promotion, to provide new ***outcome-based*** care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs ***enhancing citizens' levels of health literacy and digital health literacy,*** and ensure an efficient public health workforce equipped with the right skills, including digital skills***, 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*** [11a] ***. The synergy between the European Health Programme and the Digital Europe Programme should contribute to the implementation and expansion of e-health, reducing unnecessary travel and unmet healthcare needs***. The development of a European health data space ***and of a European electronic health record*** would provide health care systems, researchers and public authorities with means to improve the ***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***.

	Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006[12] the Programme should support actions ensuring the universality and inclusivity of health care, meaning that no-one is barred access to health care, and those ensuring that patients' rights, including on the privacy of their data, are duly respected. ***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.***
[12] Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).	***[11a] Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ L 255, 30.9.2005, p. 22).*** [12] Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

Amendment 17

Proposal for a regulation
Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 18

Proposal for a regulation
Recital 15 b (new)

Text proposed by the Commission	*Amendment*
	(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 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.

Amendment 19

Proposal for a regulation
Recital 15 c (new)

Text proposed by the Commission	*Amendment*
	(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 [12a]. 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.

[12a] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50).

Amendment 20

Proposal for a regulation
Recital 16

Text proposed by the Commission	*Amendment*
(16) Keeping people healthy and active longer and empowering them to take an active role in managing their health will have positive effects on health, health inequalities, quality of life, productivity, competitiveness and inclusiveness, while reducing pressures on national budgets. The Commission has committed to help Member States to reach the sustainable development targets set in the 'UN 2030 Agenda for Sustainable Development' in particular Sustainable Development Goal 3 "Ensure healthy lives and promote well-being for all at all ages".[13] The Programme	(16) ***Health is an investment and the Programme should have this concept at its core.*** Keeping people healthy and active longer and empowering them to take an active role in managing their health***, by improving their health literacy,*** will have positive effects on health, health inequalities***, health inequities***, quality of life, productivity, competitiveness and inclusiveness, while reducing pressures on national ***health systems and*** budgets***. The Programme should also support action to reduce inequalities in the provision of healthcare, in rural and remote areas***

therefore should contribute to the actions taken towards reaching ***these*** goals.	***including in the outermost regions, for the purposes of achieving inclusive growth***. The Commission has committed to help Member States to reach the sustainable development targets set in the 'UN 2030 Agenda for Sustainable Development' in particular Sustainable Development Goal 3 "Ensure healthy lives and promote well-being for all at all ages".[13] The Programme therefore should contribute to the actions taken towards reaching ***the SDGs*** goals***, and consequently improve the social determinants of health and enhance the health of the Union's citizens***.
[13] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Next steps for a sustainable European future. European action for sustainability COM (2016) 739 final of 22.11.2016.	[13] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Next steps for a sustainable European future. European action for sustainability COM (2016) 739 final of 22.11.2016.

Amendment 21

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) Non-communicable diseases are a result of a combination of genetic***,*** physiological, environmental ***and behavioural factors.*** Such non-communicable diseases as cardiovascular diseases, cancer, chronic respiratory diseases, ***and*** diabetes, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable	(17) Non-communicable diseases are a result of a combination of genetic ***and health determinants (***physiological, ***behavioural, and*** environmental***)*** Such non-communicable diseases***,*** as cardiovascular diseases, cancer, ***obesity,*** chronic respiratory diseases, diabetes, ***mental health illness and neurological disorders*** represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, ***while non-communicable diseases were responsible for 87% of Disability-Adjusted Life Years (DALYs) in the***

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.	***Union in 2017,***resulting in considerable ***affective,*** social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, ***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***, specialities 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.***

Amendment 22

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) ***The Programme*** therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of ***illicit*** drugs. The Programme should also contribute to the reduction of drugs-related health damage,	(18) ***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*** should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing ***determinants of*** health***, such as the use of tobacco and related products and exposure to their***

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.	***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*** risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of drugs ***and other addictive behaviours***. The Programme should also contribute to the reduction of drugs-related health damage, ***obesity and*** 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. ***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 contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy ***and the Chemicals strategy for sustainability***.

Amendment 23

Proposal for a regulation
Recital 18 a (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 24

Proposal for a regulation
Recital 18 b (new)

Text proposed by the Commission	*Amendment*
	(18 b) 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 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.

Amendment 25

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(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 'Europe's Beating Cancer Plan' which would cover ***the entire cycle*** of the disease ***starting from*** prevention ***and early*** diagnosis ***to*** treatment ***and*** quality of life ***of patients and survivors***. The measures should benefit from the Programme and from Horizon Europe's Mission on Cancer.	(19) Cancer is the second leading cause of mortality in the Member States after cardiovascular diseases. ***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.*** It is also one of non-communicable diseases that share common risk factors ***with others*** and the prevention and control of which would benefit the majority of citizens***. 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***. In 2020 the Commission announced the 'Europe's Beating Cancer Plan' which would cover ***every key stage*** of the disease***:*** prevention***,*** diagnosis***,*** treatment***, 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'*** quality of life. The measures should benefit from the Programme and

	from Horizon Europe's Mission on Cancer ***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***.

Amendment 26

Proposal for a regulation
Recital 20

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

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+.	***financing,*** 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+.

Amendment 249

Proposal for a regulation
Recital 20 a (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 27

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(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,	(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.	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 ***sustainable, efficient, equitable, affordable and*** high quality healthcare products***, including in a cross-border context,*** and can fully benefit from them***, based on transparent, consistent, patient-oriented medical information***.

Amendment 28

Proposal for a regulation
Recital 22

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

	antimicrobials and vaccines to tackle AMR and vaccine-preventable diseases, promote incentives to ***boost the production capacity for*** antimicrobials***, personalized treatment and vaccination,*** and foster the ***digital*** transformation of healthcare products and platforms for monitoring and collecting information on medicines. ***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.***

Amendment 29

Proposal for a regulation
Recital 22 a (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 30

Proposal for a regulation
Recital 23

Text proposed by the Commission	*Amendment*
(23) As the optimal use of medicines and antimicrobials in particular yields benefits for individuals and health systems, the Programme should promote their prudent and efficient use. In line with the European One Health Action Plan against Antimicrobial Resistance[14] , adopted in June 2017 following the request from Member States, and given ***the experience with the bacterial secondary*** infections ***related to COVID 19***, it is 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.	(23) As the optimal use of medicines and antimicrobials in particular yields benefits for individuals and health systems, the Programme should promote their prudent and efficient use. In line with the European One Health Action Plan against Antimicrobial Resistance[14] , adopted in June 2017 following the request from Member States, and given ***that*** infections ***and sepsis caused by antibiotic-resistant bacteria are responsible for a high number of deaths in the Union***, it is essential that the Programme supports actions aimed at the prudent use of antimicrobials in humans, animals and crops, ***and actions including the use of non-antibiotic integrative treatments,*** in the framework of an integrated policy on patient safety and prevention of medical errors. ***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.***
[14] Communication from the Commission to the Council and the European Parliament 'A European One Health Action Plan against Antimicrobial Resistance (AMR)', COM(2017)0339 final of 29.6.2017.	[14] Communication from the Commission to the Council and the European Parliament 'A European One Health Action Plan against Antimicrobial Resistance (AMR)', COM(2017)0339 final of 29.6.2017.

Amendment 31

Proposal for a regulation
Recital 24

Text proposed by the Commission	*Amendment*
(24) Since ***environmental*** pollution caused by human and veterinary pharmaceutical substances is an emerging environmental problem that can impact on public health, the Programme should foster measures to strengthen the assessment and appropriate management of environmental risks associated with the production, use and disposal of medicinal products, in line with the European Union Strategic Approach to Pharmaceuticals in the Environment[15] .	(24) Since ***the*** 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].
[15] Communication of the Commission to the European Parliament, the Council and the European economic and Social Committee 'European Union Strategic Approach to Pharmaceuticals in the Environment', COM(2019)128 final of 11.03.2019.	[15] Communication of the Commission to the European Parliament, the Council and the European economic and Social Committee 'European Union Strategic Approach to Pharmaceuticals in the Environment', COM(2019)128 final of 11.03.2019.

Amendment 32

Proposal for a regulation
Recital 25

Text proposed by the Commission	*Amendment*
(25) The Union health legislation has an immediate impact on public health, the lives of citizens, the efficiency and resilience of the health systems and the good functioning of the internal market. The regulatory framework for medical products and technologies (medicinal products, medical devices and substances of human origin), as well as for tobacco legislation, patients' rights in cross-border	(25) The Union health legislation has an immediate impact on public health ***and safety***, the lives of citizens, the efficiency and resilience of the health systems and the good functioning of the internal market. The regulatory framework for medical products and technologies (medicinal products, medical devices and substances of human origin), as well as for tobacco legislation, patients' rights in cross-border

healthcare and serious cross-border threats to health is essential to health protection in the Union. The Programme therefore should support the development, implementation and enforcement of Union health legislation and provide high quality, comparable and reliable data to underpin policymaking and monitoring.	healthcare and serious cross-border threats to health is essential to health protection in the Union. The Programme therefore should support the development, implementation and enforcement of Union health legislation and***, in conjunction with key partners such as EMA and ECDC,*** provide high quality***, unbiased***, comparable and reliable data***, including real-world healthcare data collected locally across Europe, through a well-defined homogeneous methodology,*** to underpin policymaking and monitoring***, set targets and develop tools to measure progress***.

Amendment 33

Proposal for a regulation
Recital 26

Text proposed by the Commission	*Amendment*
(26) Cross-border cooperation in the provision of healthcare to patients moving between Member States, collaboration on health technology assessments (HTA), and European Reference Networks (ERNs) are examples of areas where integrated work among Member States has shown to have strong added value and great potential to increase the efficiency of health systems and thus health in general. The Programme should therefore ***support activities to enable*** such integrated and coordinated work***, which also serves*** to foster the implementation of high-impact practices that are aimed at distributing in the most effective way the available resources to the ***concerned*** population and areas so as to maximise their impact.	(26) Cross-border cooperation in the provision of healthcare to patients moving between Member States ***or living in border regions***, 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 ***be aimed at ensuring that*** such integrated and coordinated work ***is developed and implemented to its full potential in areas such as HTA and ERNs. That work would serve*** to foster the implementation of high-impact practices that are aimed at distributing in the most effective way the available resources to the ***relevant groups of the*** population and areas so as to maximise their impact.

Amendment 34

Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 35

Proposal for a regulation
Recital 27

Text proposed by the Commission	*Amendment*
(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	(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council[16] are virtual networks involving healthcare providers across Europe. They aim to facilitate

discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider ***the extension of ERNs beyond rare*** diseases ***to*** communicable and non-communicable diseases ***such as*** cancer.

discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. ***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 objectives set out in their mission.*** 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 ***also*** contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider ***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*** communicable and non-communicable diseases***, including*** cancer ***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***.

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

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

Amendment 36

Proposal for a regulation
Recital 27 a (new)

Text proposed by the Commission	*Amendment*
	(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"[16a].
	[16a] OJ C 192, 7.6.2019, p. 5.

Amendment 37

Proposal for a regulation
Recital 30

Text proposed by the Commission	*Amendment*
(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	(30) In order to optimise the added value and impact from investments funded wholly or in part through the budget of the Union, synergies should be sought in particular between the Programme for the Union's action in the field of health and other Union programmes, including those

under shared-management. To maximise those synergies, key enabling mechanisms should be ensured, including cumulative funding in an action from the Programme for the Union's action in the field of health and another Union programme, as long as such cumulative funding does not exceed the total eligible costs of the action. For that purpose, this Regulation should set out appropriate rules, in particular on the possibility to declare the same cost or expenditure on a pro-rata basis to Programme for the Union's action in the field of health and another Union programme.	under shared-management***, in particular the Interreg programme, which already 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***. To maximise those synergies***, and avoid duplications***, key enabling mechanisms should be ensured, including cumulative funding in an action from the Programme for the Union's action in the field of health and another Union programme, as long as such cumulative funding does not exceed the total eligible costs of the action. For that purpose, this Regulation should set out appropriate rules, in particular on the possibility to declare the same cost or expenditure on a pro-rata basis to Programme for the Union's action in the field of health and another Union programme***, guaranteeing detailed and transparent reporting***.

Amendment 38

Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*
(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	(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.	of calls for proposals. ***Investments from the Programme should be implemented in close cooperation with Member States especially in areas falling under national competences.***

Amendment 39

Proposal for a regulation
Recital 31 a (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 40

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(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	(33) Given the common agreed values of solidarity towards ***accessible,*** equitable and universal coverage of quality health services***, including in a cross-border context,*** 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

inequalities and increase protection against global health threats.	with a view to improve health, address inequalities and increase protection against global health threats.
[19] Council conclusions on the EU role in Global Health, 3011th Foreign Affairs Council meeting, Brussels, 10 May 2010.	[19] Council conclusions on the EU role in Global Health, 3011th Foreign Affairs Council meeting, Brussels, 10 May 2010.

Amendment 41

Proposal for a regulation
Recital 34

Text proposed by the Commission	*Amendment*
(34) In order to maximise the effectiveness and efficiency of actions at Union and international level, cooperation should be developed with relevant international organisations such as the United Nations and its specialised agencies, in particular the WHO, the World Bank, as well as with the Council of Europe and the Organisation for Economic Co-operation and Development (OECD) to implement the Programme. Pursuant to Article 94 of Council Decision 2013/755/EU[20] , persons and entities established in Overseas Countries and Territories (OCTs) are eligible for funding subject to the rules and objectives of the Programme and possible arrangements applicable to the Member State to which the relevant OCTs are linked.	(34) In order to maximise the effectiveness and efficiency of actions at Union and international level, cooperation should be developed ***with the Member States and*** with relevant international organisations such as the United Nations and its specialised agencies, in particular the WHO, the World Bank, as well as with the Council of Europe and the Organisation for Economic Co-operation and Development (OECD) to implement the Programme. Pursuant to Article 94 of Council Decision 2013/755/EU[20] , persons and entities established in Overseas Countries and Territories (OCTs) are eligible for funding subject to the rules and objectives of the Programme and possible arrangements applicable to the Member State to which the relevant OCTs are linked.
[20] Council Decision 2013/755/EU of 25 November 2013 on the association of the overseas countries and territories with the European Union ('Overseas Association Decision') (OJ L 344, 19.12.2013, p. 1).	[20] Council Decision 2013/755/EU of 25 November 2013 on the association of the overseas countries and territories with the European Union ('Overseas Association Decision') (OJ L 344, 19.12.2013, p. 1).

Amendment 42

Proposal for a regulation
Recital 34 a (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 43

Proposal for a regulation
Recital 34 b (new)

Text proposed by the Commission	*Amendment*
	(34 b) To achieve a coherent implementation of the actions included in the Programme, a EU4Health Steering Group should be established.

Amendment 44

Proposal for a regulation
Recital 39 a (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 45

Proposal for a regulation
Recital 40

Text proposed by the Commission	*Amendment*
(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.	(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.

Amendment 46

Proposal for a regulation
Recital 40 a (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 47

Proposal for a regulation
Recital 43

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

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.	***regions,***, and to address inequalities ***and inequities*** in access to health throughout the EU in a manner that creates efficiency gains and value-added impacts that could not be generated by action taken at national level while respecting the Member States' competence and responsibility in the areas covered by the Programme. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

Amendment 49

Proposal for a regulation
Article 2 – paragraph 1 – point 3

Text proposed by the Commission	*Amendment*
3) 'health crisis' means any crisis or serious incident arising from a threat of human, animal, plant, food ***or environment*** origin, having a health dimension and which requires urgent action by authorities;	(3) 'health crisis' means any crisis or serious incident arising from a threat of human, animal, plant, food, ***chemical, biological, radiological***, ***nuclear***, ***environmental or unknown*** origin, having a health dimension and which requires urgent action by authorities;

Amendment 50

Proposal for a regulation
Article 2 – paragraph 1 – point 4

Text proposed by the Commission	*Amendment*
(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,	(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

protective clothing and equipment, diagnostic materials and tools); personal protective equipment; disinfectants and their intermediary products and raw materials necessary for their production);	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 48

Proposal for a regulation
Article 2 – paragraph 1 – point 5

Text proposed by the Commission	*Amendment*
(5) 'One Health approach' means an approach which recognises ***that*** human ***and*** animal ***health are interconnected***, that diseases may be transmitted from ***humans to animals and vice versa*** and must therefore be tackled in ***both, and that the environment links humans and animals***;	(5) 'One Health approach' means an approach which recognises ***the interconnection between the*** human***,*** animal ***and environmental spheres***, that diseases may be transmitted from ***one pillar to another*** and must therefore be tackled in ***a holistic approach***;

Amendment 51

Proposal for a regulation
Article 2 – paragraph 1 – point 9

Text proposed by the Commission	*Amendment*
(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;	(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;

Amendment 52

Proposal for a regulation
Article 2 – paragraph 1 – point 9 a (new)

Text proposed by the Commission	*Amendment*
	(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;

Amendment 53

Proposal for a regulation
Article 2 – paragraph 1– point 9 b (new)

Text proposed by the Commission	*Amendment*
	(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;

Amendment 54

Proposal for a regulation
Article 3 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The Programme shall pursue the following	The Programme shall pursue the following

general objectives, in keeping with the "One Health" approach where relevant:	general objectives, in keeping with the ***"Health in all policies" approach where applicable*** , and with the "One Health" approach ***:***

Amendment 55

Proposal for a regulation
Article 3 – paragraph 1 – point 1

Text proposed by the Commission	*Amendment*
1) protect people in the Union ***from serious cross-border threats*** to health;	***(1) improve and foster health*** in the Union***, by supporting health promotion and disease prevention, reducing health inequalities and ensuring equal and full access*** to health***;***

Amendment 56

Proposal for a regulation
Article 3 – paragraph 1 – point 1 a (new)

Text proposed by the Commission	*Amendment*
	(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;

Amendment 57

Proposal for a regulation
Article 3 – paragraph 1 – point 2

Text proposed by the Commission	*Amendment*
(2) improve the availability ***in the Union of medicines, medical devices and other crisis relevant products, contribute to their*** affordability, and support innovation;	(2) ***supporting existing and future Union legislation and policies, in order to, inter alia, restore pharmaceutical independence and address shortages,*** improve the availability***, accessibility and*** affordability ***of health care and services in***

	the Union, and support ***research and*** innovation ***as well as development in health and healthcare without duplicating efforts under other programmes, including Horizon Europe***;

Amendment 58

Proposal for a regulation
Article 3 – paragraph 1 – point 3

Text proposed by the Commission	*Amendment*
(3) strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, sustained implementation of best ***practice and*** data sharing, to increase the general level of public health.	(3) strengthen health systems and ***their sustainability, as well as*** the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, ***including at national, regional and local level, by*** sustained implementation of best ***practices, and by sharing of comparable and interoperable*** data, ***with the aim*** of increasing the general level of public health***, health literacy and make health systems more resilient and responsive***.

Amendment 59

Proposal for a regulation
Article 4 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
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:	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***:***

Amendment 226

Proposal for a regulation
Article 4 – paragraph 1 – point 1

Text proposed by the Commission	*Amendment*
(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;	(1) strengthen the capability of the Union for prevention, preparedness and ***rapid*** 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***, the coordination of stress testing of national healthcare systems and the development of quality healthcare standards***;

Amendment 250

Proposal for a regulation
Article 4 – paragraph 1 – point 2

Text proposed by the Commission	*Amendment*
(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;	(2) ***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***;

Amendment 62

Proposal for a regulation
Article 4 – paragraph 1 – point 3

Text proposed by the Commission	*Amendment*
(3) ***support actions*** to ensure ***appropriate*** availability, accessibility and affordability of ***crisis relevant*** products and other necessary health supplies;	(3) ***strengthen the European Medicines Market,*** to ensure ***in a sustainable manner the*** availability, accessibility and affordability of ***medicinal*** products***, e-health solutions, medical devices*** and other necessary health ***related*** supplies ***and crisis relevant medical products***;

Amendment 222

Proposal for a regulation
Article 4 – paragraph 1 – point 4

Text proposed by the Commission	*Amendment*
(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;	(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;

Amendment 64

Proposal for a regulation
Article 4 – paragraph 1 – point 4 a (new)

Text proposed by the Commission	*Amendment*
	(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;

Amendment 65

Proposal for a regulation
Article 4 – paragraph 1 – point 5

Text proposed by the Commission	*Amendment*
(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***;	(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;

Amendment 245

Proposal for a regulation
Article 4 – paragraph 1 – point 6

Text proposed by the Commission	*Amendment*
(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer;	(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, ***the early diagnosis of neurodegenerative disorders and other brain diseases,*** and notably of cancer;

Amendment 66

Proposal for a regulation
Article 4 – paragraph 1 – point 6 a (new)

Text proposed by the Commission	*Amendment*
	(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;

Amendment 67

Proposal for a regulation
Article 4 – paragraph 1 – point 6 b (new)

Text proposed by the Commission	*Amendment*
	(6b) strengthen the fight against communicable diseases and health threats;

Amendment 68

Proposal for a regulation
Article 4 – paragraph 1 – point 6 c (new)

Text proposed by the Commission	*Amendment*
	(6c) address vaccine hesitancy, and support action for the elimination of vaccine preventable diseases, including

cancers;

Amendment 69

Proposal for a regulation
Article 4 – paragraph 1 – point 7

Text proposed by the Commission	*Amendment*
(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;	(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;

Amendment 70

Proposal for a regulation
Article 4 – paragraph 1 – point 8

Text proposed by the Commission	*Amendment*
(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;	(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;

Amendments 246 and 71

Proposal for a regulation
Article 4 – paragraph 1 – point 9

Text proposed by the Commission	*Amendment*
(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;	(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 to increase the coverage of patients and the response to diseases , and health problems, in greater numbers***;

Amendment 223

Proposal for a regulation
Article 4 – paragraph 1 – point 10

Text proposed by the Commission	*Amendment*
(10) support the Union's contribution to international and global health initiatives.	(10) support the Union's contribution to international and global health ***commitments and*** initiatives***, including access to sexual and reproductive health and rights***.

Amendment 73

Proposal for a regulation
Article 5 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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)***.

Amendment 74

Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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.***

Amendment 75
Proposal for a regulation
Article 6

Text proposed by the Commission	*Amendment*
Article 6	***deleted***
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.

Amendment 76

Proposal for a regulation
Article 7 – paragraph 1 – point 1 a (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 77

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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.

Amendment 78

Proposal for a regulation
Article 8 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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.***

Amendment 79

Proposal for a regulation
Article 8 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	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.
	For that purpose, they shall:
	(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;

(b) optimise coordination mechanisms to avoid duplication of effort;

(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.

Amendment 80

Proposal for a regulation
Article 8 – paragraph 4 b (new)

Text proposed by the Commission	*Amendment*
	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.

Amendment 81

Proposal for a regulation
Article 8 – paragraph 4 c (new)

Text proposed by the Commission	*Amendment*
	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 .

Amendment 82

Proposal for a regulation
Article 9 a (new)

Text proposed by the Commission	*Amendment*
	Article 9a
	Award criteria
	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:
	(a) consistency with the specific objectives provided for in Article 4;
	(b) contribution to the accessibility and affordability of the health system;
	(c) cross-border dimension;
	(d) contribution to digital transformation;
	(e) social impact (benefits and costs);
	(f) consistency with the provisions of Annex 1;
	(g) contribution to the prevention of diseases and notably of cancer;
	(h) contribution to access to medicine;
	(i) maturity of the action in the project development;
	(j) soundness of the implementation plan proposed.

Amendment 83

Proposal for a regulation
Article 12 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	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.

Amendment 84

Proposal for a regulation
Article 14 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) any legal entity created under Union law or any international organisation;	(b) any legal entity created under Union law or any ***relevant*** international organisation ***such as public authorities, public sector bodies, health establishments, research institutes, universities and higher education establishments, patient associations***;

Amendment 85

Proposal for a regulation
Article 14 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Legal entities established in a third country which is not associated to the Programme should ***in principle*** bear the cost of their participation.	3. Legal entities established in a third country which is not associated to the Programme should bear the cost of their participation.

Amendment 86

Proposal for a regulation
Article 14 – paragraph 5

Text proposed by the Commission	*Amendment*
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.	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.

Amendment 87

Proposal for a regulation
Article 14 – paragraph 6

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

Amendment 88

Proposal for a regulation
Article 14 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	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.

Amendment 89

Proposal for a regulation
Article 16 – paragraph 1

Text proposed by the Commission	*Amendment*
The Commission shall consult the health authorities of the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of	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.	Non-Communicable Diseases on the ***annual*** work plans established for the Programme and its priorities and strategic orientations and its implementation ***and on possible synergies with Member States' own resources to ensure long-term effectiveness and sustainability of actions.***

Amendment 90

Proposal for a regulation
Article 16 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	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.

Amendment 91

Proposal for a regulation
Article 16 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	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.

Amendment 92

Proposal for a regulation
Article 16 – paragraph 1 c (new)

Text proposed by the Commission	*Amendment*
	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.

Amendment 93

Proposal for a regulation
Article 16 a (new)

Text proposed by the Commission	*Amendment*
	Article 16 a
	Establishment of EU4Health Steering Group
	1. The Commission shall establish a EU4Health Steering Group ('the Steering Group').
	2. The Steering Group shall:
	(i) provide input, in the form of a comprehensive strategy and steering, and contribute to the annual work plans for the Programme;
	(ii) elaborate a blueprint for steering coordination, cooperation and synergies between the Programme and other Programmes in which a health dimension is integrated;
	(iii) provide value-oriented health actions, sustainability, better health solutions, foster access to health and reduce health inequalities, promote engagement by patients and society.
	3. 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.

4. 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.

5. 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.

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.

6. The Steering Group shall meet at least three times a year, which allows regular and transparent exchanges of views.

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.

The Commission may consult the Steering Group on matters other than those referred to in paragraph 2.

Amendment 94

Proposal for a regulation
Article 18 – paragraph 1

Text proposed by the Commission	*Amendment*
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	The Programme shall be implemented by ***annual*** 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.	reserved for blending operations.

Amendment 95

Proposal for a regulation
Article 18 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	The work programmes shall be informed by a gender impact assessment.

Amendment 96

Proposal for a regulation
Article 19 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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.

Amendment 97

Proposal for a regulation
Article 19 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. 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:
	(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.
	(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.

Amendment 98

Proposal for a regulation
Article 19 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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***, including programme- and action-specific ones,*** where considered necessary.

Amendment 99

Proposal for a regulation
Article 19 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2 a. Indicators shall be collected, where relevant, dissagregated by gender.

Amendment 100

Proposal for a regulation
Article 19 – paragraph 3

Text proposed by the Commission	*Amendment*
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 ***without increasing the administrative burden for beneficiaries***. To that end, proportionate reporting requirements shall be imposed on recipients of Union funds and, where relevant, on Member States.

Amendment 101

Proposal for a regulation
Article 20 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	4. The Commission shall ***publish,*** communicate ***and present*** the conclusions of ***both*** the ***interim and final*** evaluations accompanied by its observations, to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

Amendment 102

Proposal for a regulation
Article 21 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	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.

Amendment 103

Proposal for a regulation
Article 21 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	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.

Amendment 104

Proposal for a regulation
Article 21 – paragraph 1 c (new)

Text proposed by the Commission	*Amendment*
	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.[1a] 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.
	[1a] Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directive 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC (OJ L 157, 9.6.2006, p. 87)

Amendment 105

Proposal for a regulation
Article 21 – paragraph 1 d (new)

Text proposed by the Commission	*Amendment*
	Audits may be carried out up to two years after the payment of the balance.

Amendment 106

Proposal for a regulation
Article 21 – paragraph 1 e (new)

Text proposed by the Commission	*Amendment*
	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.

Amendment 107

Proposal for a regulation
Article 24 – paragraph 2

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

Amendment 108

Proposal for a regulation
Annex I – point a – point ii

Text proposed by the Commission	*Amendment*
(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.	(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.

Amendment 109

Proposal for a regulation
Annex I – point b

Text proposed by the Commission	*Amendment*
(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.	(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.

Amendment 110

Proposal for a regulation
Annex I – point c – point i

Text proposed by the Commission	*Amendment*
(i) Surveys, studies, collection of data and statistics, methodologies, classifications, microsimulations,	(i) Surveys, studies, collection of ***comparable*** data and statistics, ***where relevant including disaggregated data by***

indicators, knowledge brokering and benchmark exercises;	***gender and age,*** methodologies, classifications, microsimulations***, pilot studies***, indicators, knowledge brokering and benchmark exercises;

Amendment 111

Proposal for a regulation
Annex I – point c – point iii

Text proposed by the Commission	*Amendment*
(iii) Expert groups and panels providing advice, data and information to support health policy development and implementation;	(iii) Expert groups and panels***, including representatives of relevant stakeholders where applicable,*** providing advice***, evaluation***, data and information to support health policy development and implementation***, including follow-up evaluations of the implementation of health policies***;

Amendment 112

Proposal for a regulation
Annex I – point c – point iv

Text proposed by the Commission	*Amendment*
(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".	(iv) Studies and analysis, ***systematic health impact assessment of other Union policy actions*** and scientific advice to support ***evidence-based*** policymaking, and support to the scientific committees on "Consumer Safety" and on "Health, Environmental and Emerging Risks"***, as well as the expert group on "Health Systems Performance Assessment"***.

Amendment 113

Proposal for a regulation
Annex I – point d – introductory part

Text proposed by the Commission	*Amendment*
(d) Development ***and*** implementation of Union health legislation and action, in particular through support to:	(d) Development***,*** implementation***, and evaluation,*** of Union health legislation and action, in particular through support to:

Amendment 114

Proposal for a regulation
Annex I – point d – point i

Text proposed by the Commission	*Amendment*
(i) Implementation, enforcement, monitoring of Union health legislation and action; and technical support to the implementation of legal requirements;	(i) Implementation, enforcement, monitoring of Union health legislation and action***, including promotion of health***; and technical support to the ***full*** implementation of legal ***and operational*** requirements ***throughout Member States***;

Amendment 115

Proposal for a regulation
Annex I – point d – point iv

Text proposed by the Commission	*Amendment*
(iv) Development ***and*** operation of databases and digital tools and their interoperability, including where appropriate with other sensing technologies, such as space-based;	(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***;

Amendment 116

Proposal for a regulation
Annex I – point d – point v

Text proposed by the Commission	*Amendment*
(v) Auditing ***and*** assessment work in accordance with Union legislation;	(v) Auditing***,*** assessment ***and inspection*** work in accordance with Union legislation;

Amendment 117

Proposal for a regulation
Annex I – point d – point x

Text proposed by the Commission	*Amendment*
(x) National contact points providing guidance, information and assistance related ***the*** implementation of Union health legislation and of the Programme;	(x) National contact points providing guidance, information and assistance related ***to the promotion and*** implementation of Union health legislation and of the Programme;

Amendment 118

Proposal for a regulation
Annex I – point d – point xi

Text proposed by the Commission	*Amendment*
(xi) Stakeholders in view of transnational	(xi) Stakeholders in view of transnational

cooperation.	***and regional*** cooperation.

Amendment 119

Proposal for a regulation
Annex I – point e

Text proposed by the Commission	*Amendment*
(e) Structural stockpile and crisis preparation:	***deleted***
(i) Establishment and support of a mechanism to develop, procure and manage crisis relevant products;	
(ii) Establishment and management of EU reserves and stockpiles of crisis relevant products in complementarity with other Union instruments;	
(iii) Establishment and support of mechanisms for the efficient monitoring and allocation of available care facilities (such as hospital beds and places in ICUs), for the distribution or allocation of goods and services needed in the case of a health crisis, and to ensure the supply and safe use of medicines, investigational medicines and medical devices;	
(iv) Procurement of goods and services necessary for the prevention and management of health crises and action to secure access to those essential goods and services;	
(v) Establishment and operation of a Union reserve of medical and healthcare staff and experts and of a mechanism to deploy such staff and experts as necessary to prevent or respond to a health crisis throughout the Union; establishment and operation of a Union Health Emergency team to provide expert advice and technical assistance on request by the Commission in the case of a health crisis;	

Amendment 227

Proposal for a regulation
Annex I – point f – point i

Text proposed by the Commission	*Amendment*
(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;	(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;

Amendment 121

Proposal for a regulation
Annex I – point f – point i a (new)

Text proposed by the Commission	*Amendment*
	(i a) 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 ;

Amendment 251

Proposal for a regulation

Annex I – point f – point i b (new)

Text proposed by the Commission	*Amendment*
	(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;

Amendment 122

Proposal for a regulation
Annex I – point f – point iii

Text proposed by the Commission	*Amendment*
(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;	***deleted***

Amendment 123

Proposal for a regulation
Annex I – point f – point iv

Text proposed by the Commission	*Amendment*
(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;	(iv) Preventive actions to protect ***all citizens, in particular*** vulnerable groups from health threats and actions to adjust the response to and management of crisis to the needs of those vulnerable groups***, such***

as securing basic care for chronic disease patients in need of palliative care and pain management treatment ;

Amendment 124

Proposal for a regulation
Annex I – point f – point iv a (new)

Text proposed by the Commission	*Amendment*
	(iv a) 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;

Amendment 125

Proposal for a regulation
Annex I – point f – point iv b (new)

Text proposed by the Commission	*Amendment*
	(iv b) 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;

Amendment 126

Proposal for a regulation
Annex I – point f – point v

Text proposed by the Commission	*Amendment*
(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***;	(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***;

Amendment 127

Proposal for a regulation
Annex I – point f – point viii a (new)

Text proposed by the Commission	*Amendment*
	(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;

Amendment 128

Proposal for a regulation
Annex I – point f – point viii b (new)

Text proposed by the Commission	*Amendment*
	(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;

Amendment 129

Proposal for a regulation
Annex I – point g – introductory part

Text proposed by the Commission	*Amendment*
(g) Strengthen national health systems:	(g) Strengthen national health systems***, promote and protect health and prevent diseases***:

Amendment 130

Proposal for a regulation
Annex I – point g – point i

Text proposed by the Commission	*Amendment*
(i) Support knowledge transfer actions and Union level cooperation to assist national reform processes towards improved effectiveness, accessibility, sustainability and resilience, in particular to address the challenges identified by the European Semester and to strengthen primary care, reinforce the integration of care and aim at universal health coverage and equal access to healthcare;	(i) Support knowledge transfer actions and Union level cooperation to assist national reform processes towards improved effectiveness, accessibility, sustainability and resilience, ***while linking available Union funding,*** in particular to address the challenges identified by the European Semester ***and Country Specific Recommendations on health,*** and to strengthen primary care, reinforce the integration of care***,*** aim at universal health coverage and ***reach*** equal access to ***good quality*** healthcare;

Amendment 131

Proposal for a regulation
Annex I – point g – point i a (new)

Text proposed by the Commission	*Amendment*
	(i a) Support implementing policies and actions to reduce health inequalities and inequities in relation to healthcare;

Amendment 132

Proposal for a regulation
Annex I – point g – point ii

Text proposed by the Commission	*Amendment*
(ii) Training programmes for medical and healthcare staff, and programmes for temporary exchanges of staff;	(ii) ***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***;

Amendment 133

Proposal for a regulation
Annex I – point g – point iii

Text proposed by the Commission	*Amendment*
(iii) Support to improve the geographical distribution of healthcare workforce ***and avoidance of*** 'medical deserts';	(iii) Support ***in synergy with other Programmes*** to improve the geographical distribution of ***the*** healthcare workforce***, while ensuring that such distribution of the workforce is also proportionate to the population of the area or region in question, and thus avoiding*** 'medical deserts' ***and promote and implement***

retention policies;

Amendment 134

Proposal for a regulation
Annex I – point g – point iv

Text proposed by the Commission	*Amendment*
(iv) Support the establishment ***and*** coordination of Union Reference Laboratories and Centres, ***and of*** Centres of excellence;	(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***;

Amendment 135

Proposal for a regulation
Annex I – point g – point v

Text proposed by the Commission	*Amendment*
(v) Audit of Member States preparedness and response arrangements (such as crisis management, antimicrobial resistance, vaccination);	(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***;

Amendment 136

Proposal for a regulation
Annex I – point g – point viii a (new)

Text proposed by the Commission	*Amendment*
	(viii a) 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;

Amendment 137

Proposal for a regulation
Annex I – point g – point ix

Text proposed by the Commission	*Amendment*
(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);	(ix) Support the establishment and implementation of ***national and European*** programmes***, including digital and evidence-based programmes,*** assisting Member States and their action to improve health promotion***, health literacy*** and disease prevention (for communicable and non-communicable diseases) ***in health units and communities, and mitigate the main risk factors of chronic diseases***;

Amendment 138

Proposal for a regulation
Annex I – point g – point ix a (new)

Text proposed by the Commission	*Amendment*
	(ix a) 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;

Amendment 139

Proposal for a regulation
Annex I – point g – point ix b (new)

Text proposed by the Commission	*Amendment*
	(ix b) Support the development of guidelines for preventing and managing diseases in the area of both communicable and non-communicable diseases;

Amendment 140

Proposal for a regulation
Annex I – point g – point x

Text proposed by the Commission	*Amendment*
(x) Support Member States' actions to put in place healthy and safe urban, work and school environments, to enable healthy life choices and promote healthy diets taking into account the needs of ***vulnerable groups***;	(x) Support Member States' actions to put in place healthy and safe urban, work and school environments, to ***promote mental health, health education,*** enable healthy life choices and promote ***regular physical activity and*** healthy diets taking into account the needs of ***people at every***

stage of their life with the aim of promoting life-long health;

Amendment 141

Proposal for a regulation
Annex I – point g – point x a (new)

Text proposed by the Commission	*Amendment*
	(x a) Support Member States actions to address health determinants, including reducing alcohol related harm and tobacco use;

Amendment 142

Proposal for a regulation
Annex I – point g – point x b (new)

Text proposed by the Commission	*Amendment*
	(x b) 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;

Amendment 143

Proposal for a regulation
Annex I – point g – point x c (new)

Text proposed by the Commission	*Amendment*
	(x c) Actions promoting care and support for victims of gender-based violence;

Amendment 144

Proposal for a regulation
Annex I – point g – point x d (new)

Text proposed by the Commission	*Amendment*
	(x d) Actions promoting equal access to health services and related facilities and care for people with disabilities;

Amendment 145

Proposal for a regulation
Annex I – point g – point xi a (new)

Text proposed by the Commission	*Amendment*
	(xi a) 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;

Amendment 146

Proposal for a regulation
Annex I – point g – point xi b (new)

Text proposed by the Commission	*Amendment*
	(xi b) Support the implementation of the ERNs' system for continuous assessment, monitoring, evaluation and quality improvement;

Amendment 147

Proposal for a regulation
Annex I – point g – point xi c (new)

Text proposed by the Commission	*Amendment*
	(xi c) 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;

Amendment 148

Proposal for a regulation
Annex I – point g – point xi d (new)

Text proposed by the Commission	*Amendment*
	(xi d) 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;

Amendment 149

Proposal for a regulation
Annex I – point g – point xii a (new)

Text proposed by the Commission	*Amendment*
	(xii a) 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;

Amendment 150

Proposal for a regulation
Annex I – point h – introductory part

Text proposed by the Commission	*Amendment*
(h) Actions on cancer:	(h) Actions on cancer***, including paediatric cancer***:

Amendment 151

Proposal for a regulation
Annex I – point h – point i

Text proposed by the Commission	*Amendment*
(i) Support Member States and NGOs in the promotion and ***implemention*** of the recommendations of the European Code against Cancer;	(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;***

Amendment 152

Proposal for a regulation
Annex I – point h – point i a (new)

Text proposed by the Commission	*Amendment*
	(i a) 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;

Amendment 153

Proposal for a regulation
Annex I – point h – point iii

Text proposed by the Commission	*Amendment*
(iii) Support prevention programmes on the main cancer risk factors;	(iii) Support prevention programmes on the main cancer risk factors ***that are of demonstrated effectiveness and supported***

by established evidence;

Amendment 154

Proposal for a regulation
Annex I – point h – point iv a (new)

Text proposed by the Commission	*Amendment*
	(iv a) Action to support the implementation of cancer registries in all Member States;

Amendment 155

Proposal for a regulation
Annex I – point h – point v

Text proposed by the Commission	*Amendment*
(v) Actions supporting access to cancer services and to innovative medicines for cancer;	(v) Actions supporting ***implementing policies, national programmes and guidelines, in line with the Europe's Beating Cancer plan, to reduce inequalities and grant*** access to cancer services***, supportive and palliative care,*** and to innovative***, accessible and effective screening, treatments and*** medicines for cancer ***across all Member States, in full synergy with Horizon Europe and its missions and partnerships***;

Amendment 156

Proposal for a regulation
Annex I – point h – point v a (new)

Text proposed by the Commission	*Amendment*
	(v a) 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;

Amendment 157

Proposal for a regulation
Annex I – point h – point v b (new)

Text proposed by the Commission	*Amendment*
	(v b) 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;

Amendment 158

Proposal for a regulation
Annex I – point h – point vii

Text proposed by the Commission	*Amendment*
(vii) Actions supporting quality in cancer prevention and care including diagnosis and treatment;	(vii) Actions supporting quality in cancer prevention and care including diagnosis and treatment***, follow-up, and supportive and palliative care***;

Amendment 159

Proposal for a regulation
Annex I – point h – point viii

Text proposed by the Commission	*Amendment*
(viii) Actions supporting the quality of life of cancer survivors and care givers;	(viii) Actions supporting the quality of life of cancer survivors and care givers***, including provision of psychological support, pain management, and professional re-integration***;

Amendment 160

Proposal for a regulation
Annex I – point h – point ix

Text proposed by the Commission	*Amendment*
(ix) Support to the implementation of the Union's tobacco control policy and legislation;	(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***;

Amendment 161

Proposal for a regulation
Annex I – point h – point x

Text proposed by the Commission	*Amendment*
(x) Establishment and support of a mechanisms for cross-specialty capacity building and continuous education in the	(x) Establishment and support of a mechanisms for cross-specialty capacity building and continuous education ***of***

area of cancer care**.**	***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;***

Amendment 162

Proposal for a regulation
Annex I – point h – point x a (new)

Text proposed by the Commission	*Amendment*
	(x a) Actions to support an integrative, coordinated, multi-disciplinary and patient-centred approach concerning cancer patients and survivors;

Amendment 163

Proposal for a regulation
Annex I – point i – point ii

Text proposed by the Commission	*Amendment*
(ii) Support actions to fight vaccine hesitancy;	(ii) Support actions to fight vaccine hesitancy ***and disinformation, and promote immunization throughout all stages of a person's lifetime***;

Amendment 164

Proposal for a regulation
Annex I – point i – point ii a (new)

Text proposed by the Commission	*Amendment*
	(ii a) 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;

Amendment 165

Proposal for a regulation
Annex I – point i – point ii b (new)

Text proposed by the Commission	*Amendment*
	(ii b) support action for the elimination of vaccine preventable diseases;

Amendment 166

Proposal for a regulation
Annex I – point i – point iii

Text proposed by the Commission	*Amendment*
(iii) Support clinical trials to speed up the development, authorisation and access to innovative, safe and effective medicines and vaccines;	(iii) Support clinical trials ***and the use of real world data, including those involving increased coordination at Union level and with EMA,*** to speed up the development, authorisation and access to innovative, safe and effective medicines and vaccines;

Amendment 167

Proposal for a regulation
Annex I – point i – point iii a (new)

Text proposed by the Commission	*Amendment*
	(iii a) 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;

Amendment 168

Proposal for a regulation
Annex I – point i – point iii b (new)

Text proposed by the Commission	*Amendment*
	(iii b) 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;

Amendment 169

Proposal for a regulation
Annex I – point i – point iv

Text proposed by the Commission	*Amendment*
(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;	(iv) Support action to ensure greater availability in the Union of ***medicinal products*** and medical devices and contribute to their affordability for patients and health systems;

Amendment 170

Proposal for a regulation
Annex I – point i – point v

Text proposed by the Commission	*Amendment*
(v) Support action to encourage the ***develoment*** of innovative ***products and of less commercially interesting products such as antimicrobials***;	(v) Support action to encourage the ***discovery and development*** of innovative ***medicines and vaccines to meet rising healthcare challenges and patients' needs***;

Amendment 171

Proposal for a regulation
Annex I – point i – point v a (new)

Text proposed by the Commission	*Amendment*
	(v a) 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;

Amendment 172

Proposal for a regulation
Annex I – point i – point v b (new)

Text proposed by the Commission	*Amendment*
	(v b) 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;

Amendment 173

Proposal for a regulation
Annex I – point i – point vi

Text proposed by the Commission	*Amendment*
(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;	(vi) Support action to monitor***, prevent, manage, report and notify*** shortages of medicines and medical devices occurring in hospitals and community pharmacies, to ***collect reported shortages in a centralized database, interoperable with databases that contained regulatory data on medicines, to*** address such shortages, and to increase security of supplies;

Amendment 174

Proposal for a regulation
Annex I – point i – point viii

Text proposed by the Commission	*Amendment*
(viii) Action to strengthen the environmental risk assessment of pharmaceuticals;	(viii) Action to strengthen the environmental risk assessment of pharmaceuticals ***and medical devices***;

Amendment 175

Proposal for a regulation
Annex I – point i – point ix

Text proposed by the Commission	*Amendment*
(ix) Action to promote the prudent use and disposal of antimicrobials;	(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)***;

Amendment 176

Proposal for a regulation
Annex I – point i – point x

Text proposed by the Commission	*Amendment*
(x) Support action to foster international regulatory ***covergence on medicines*** and medical devices.	(x) Support action to foster international regulatory ***convergence and reliance on medicinal products*** and medical devices***, and to improve regulatory oversight by the Union***.

Amendment 177

Proposal for a regulation
Annex I – point j – point i

Text proposed by the Commission	*Amendment*
(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;	(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;

Amendment 178

Proposal for a regulation
Annex I – point j – point i a (new)

Text proposed by the Commission	*Amendment*
	(i a) 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;

Amendment 179

Proposal for a regulation
Annex I – point j – point i b (new)

Text proposed by the Commission	*Amendment*
	(i b) Support Member States to improve and further develop and implement ERN registries;

Amendment 180

Proposal for a regulation
Annex I – point j – point ii

Text proposed by the Commission	*Amendment*
(ii) Support to the digital transformation of health care and health systems including through benchmarking and capacity building for the uptake of innovative tools and technologies; digital upskilling of health care ***professsionals***;	(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 ***and strengthening the safe use and re-use of health data, in line with GDPR; support and implement*** digital upskilling of health care ***professionals and citizens, through enhanced education, training and (digital) health literacy measures***;

Amendment 181

Proposal for a regulation
Annex I – point j – point iii

Text proposed by the Commission	*Amendment*
(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,	(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

interoperable Union health information systems, as part of the European Health Data Space and strengthen citizens' access to and control over their health data;	sustainable, interoperable Union health information systems, as part of the European Health Data Space 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;***

Amendment 182

Proposal for a regulation
Annex I – point j – point iv

Text proposed by the Commission	*Amendment*
(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.	(iv) Support ***access to and*** 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***; 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***.

Amendment 183

Proposal for a regulation
Annex I – point k – point iii

Text proposed by the Commission	*Amendment*
(iii) Communication to promote ***disease prevention and*** healthy lifestyles, in cooperation with all concerned actors at international, Union ***and*** national level***.***	(iii) Communication to promote ***health,*** healthy lifestyles ***and disease prevention***, in cooperation with all concerned actors at international, Union***,*** national ***and regional*** level***;***

Amendment 184

Proposal for a regulation
Annex I – point k – point iii a (new)

Text proposed by the Commission	*Amendment*
	(iii a) Awareness-raising campaigns for the general population as well as for targeted groups and stakeholder-led projects, including prevention of and combating disinformation;

Amendment 185

Proposal for a regulation
Annex I – point k – point iii b (new)

Text proposed by the Commission	*Amendment*
	(iii b) Communication activities aimed at fighting against misinformation and disinformation, such as fake news, regarding medicines, vaccines, health products, causes and treatment of diseases;

Amendment 186

Proposal for a regulation
Annex I – point k – point iii c (new)

Text proposed by the Commission	*Amendment*
	(iii c) Communication to citizens on health risks and health determinants;

Amendment 187

Proposal for a regulation
Annex I – point k – point iii d (new)

Text proposed by the Commission	*Amendment*
	(iii d) 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.

Amendment 188

Proposal for a regulation
Annex II – part A – point I

Text proposed by the Commission	*Amendment*
I. Quality and completeness of EU and MS preparedness and response planning for serious cross border threats to health	I. Quality and completeness of the preparedness and response planning of the Union and of Member States for serious cross border threats to health***, including resilience assessment indicators across the Union***

Amendment 189

Proposal for a regulation
Annex II – part A – point II

Text proposed by the Commission	*Amendment*
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	II. Access to centrally authorised medicines ***and medical devices***, e.g. number of ***existing and new*** orphan authorisations, Advanced Therapy Medicinal Products, Paediatric Use Medicinal Products or vaccines, for unmet needs

Amendment 190

Proposal for a regulation
Annex II – part A – point III

Text proposed by the Commission	*Amendment*
III. Number of actions and best practices directly contributing to ***the SDG 3.4/Member*** State	III. Number of actions and best practices directly contributing to ***achieve Universal Health Coverage / Member*** State

Amendment 191

Proposal for a regulation
Annex II – part A – point IV

Text proposed by the Commission	*Amendment*
IV. Implementation of ***best practices*** by EU Member States	IV. Implementation of ***health programmes*** by EU Member States***, that***

	promote health, prevent diseases and address health inequalities

Amendment 192

Proposal for a regulation
Annex II – part A – point IV a (new)

Text proposed by the Commission	*Amendment*
	IV a. Implementation of the European Health Data Space (EHDS)

Amendment 193

Proposal for a regulation
Annex II – part B – point 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Number of new procedures for accelerated development and assessment of medicines for major public health needs, where relevant taking into account novel technologies

Amendment 194

Proposal for a regulation
Annex II – part B – point 1b (new)

Text proposed by the Commission	*Amendment*
	1b. Number of Member States with adequate level of digital health infrastructure

Amendment 195

Proposal for a regulation
Annex II – part B – point 1 c (new)

Text proposed by the Commission	*Amendment*
	1c. Number of Member States that implemented the European Electronic Health Record

Amendment 196

Proposal for a regulation
Annex II – part B – point 1d (new)

Text proposed by the Commission	*Amendment*
	1d. Proportion of Member States' population of citizens with access to their data on the EHDS, per Member State

Amendment 197

Proposal for a regulation
Annex II – part B – point 3

Text proposed by the Commission	*Amendment*
3. Number of vaccine doses ***distributed***	3. Number of vaccine doses ***made available by type and by Member State***

Amendment 198

Proposal for a regulation
Annex II – part B – point 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Vaccination coverage, by age, and by vaccine-preventable-disease

Amendment 199

Proposal for a regulation
Annex II – part B – point 6

Text proposed by the Commission	*Amendment*
6. Age-standardised five-year net survival of ***cervical, breast and colorectal*** cancer	6. Age-standardised five-year net survival of cancer ***by type, age, gender and Member State***

Amendment 200

Proposal for a regulation
Annex II – part B – point 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. Age-standardised five-year net survival rate for paediatric cancer by type, age, gender and Member State

Amendment 201

Proposal for a regulation
Annex II – part B – point 6 b (new)

Text proposed by the Commission	*Amendment*
	6b. Screening coverage for breast, cervical and colorectal cancer screening programmes, by type, age, gender and Member State

Amendment 202

Proposal for a regulation
Annex II – part B – point 7

Text proposed by the Commission	*Amendment*
7. Ratio of Cancer Registries (CRs) and number of Member States (MSs) reporting information on ***cervical, breast, and colorectal*** cancer stage at diagnosis	7. Ratio of Cancer Registries (CRs) and number of Member States (MSs) reporting information on cancer stage at diagnosis

Amendment 203

Proposal for a regulation
Annex II – part B – point 7 a (new)

Text proposed by the Commission	*Amendment*
	7a. Ratio of palliative care admissions and outcome result for cancer and paediatric cancer, by type, age, gender and Member State

Amendment 204

Proposal for a regulation
Annex II – part B – point 7 b (new)

Text proposed by the Commission	*Amendment*
	7b. Ratio of Paediatric Cancer Registries (CRs) /Member State and number of Member States (MSs) reporting information on paediatric cancer stage at diagnosis

Amendment 205

Proposal for a regulation
Annex II – part B – point 7 c (new)

Text proposed by the Commission	*Amendment*
	7c. Prevalence of major chronic diseases per Member State, by disease, gender and age

Amendment 206

Proposal for a regulation
Annex II – part B – point 7 d (new)

Text proposed by the Commission	*Amendment*
	7d. Age-standardized NCD mortality rate (per 100 000 people), by disease

Amendment 207

Proposal for a regulation
Annex II – part B – point 7 e (new)

Text proposed by the Commission	*Amendment*
	7e. Percentage of HIV/AIDS patients with access to adequate treatment, by Member State, gender and age

Amendment 208

Proposal for a regulation
Annex II – part B – point 7 f (new)

Text proposed by the Commission	*Amendment*
	7f. Proportion of tuberculosis patients with access to adequate treatment, by Member State, gender and age

Amendment 209

Proposal for a regulation
Annex II – part B – point 8

Text proposed by the Commission	*Amendment*
8. ***Smoking*** prevalence	8. ***Age standardized*** prevalence ***of tobacco use, by gender***

Amendment 228

Proposal for a regulation
Annex II – part B – point 8 a (new)

Text proposed by the Commission	*Amendment*
	8a. Age-standardised prevalence of harmful use of alcohol, by gender and age

Amendment 210

Proposal for a regulation
Annex II – part B – point 9

Text proposed by the Commission	*Amendment*
9. Number of shortages of medicines in the ***single point of contact network***	9. Number of shortages of medicines in the ***Member States***

Amendment 211

Proposal for a regulation
Annex II – part B – point 9 a (new)

Text proposed by the Commission	*Amendment*
	9a. Actions aimed at stimulating the production of essential APIs and medicinal products in the EU

Amendment 212

Proposal for a regulation
Annex II – part B – point 12 a (new)

Text proposed by the Commission	*Amendment*
	12a. Antimicrobial use by ATC type and per Member States

Amendment 213

Proposal for a regulation
Annex II – part B – point 12 b (new)

Text proposed by the Commission	*Amendment*
	12b. Attributable mortality to Healthcare Associated Infections, by age, gender and Member State

Amendment 214

Proposal for a regulation
Annex II – part B – point 12 c (new)

Text proposed by the Commission	*Amendment*
	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

Amendment 215

Proposal for a regulation
Annex II – part B – point 13

Text proposed by the Commission	*Amendment*
13. Number of ***hospital*** units involved in ERN and of patients diagnosed and treated by the members of ERN networks	13. Number of ***health*** units involved in ERN and of patients diagnosed and treated by the members of ERN networks

Amendment 216

Proposal for a regulation
Annex II – part B – point 14 a (new)

Text proposed by the Commission	*Amendment*
	14a. Number of health impact assessments of Union policies

Amendment 217

Proposal for a regulation
Annex II – part B – point 14 b (new)

Text proposed by the Commission	*Amendment*
	14b. Age-standardised obesity prevalence, by gender, age and Member State

Amendment 218

Proposal for a regulation
Annex II – part B – point 14 c (new)

Text proposed by the Commission	*Amendment*
	14c. Maternal mortality ratio, by age and by Member State

Amendment 219

Proposal for a regulation
Annex II – part B – point 14 d (new)

Text proposed by the Commission	*Amendment*
	14d. Infant mortality rate by Member State

Amendment 229

Proposal for a regulation
Annex II – part B – point 14 e (new)

Text proposed by the Commission	*Amendment*
	14e. Age-standardized deaths attributable to environmental pollution (per 100 000 people), by gender and age