COMPROMISE AMENDMENTS
1 - 10

Draft report
Cristian-Silviu Busoi
(PE653.803v01-00)


Proposal for a regulation
Compromise Amendment 1 - Definitions
EPP, S&D, RE, ID, Greens/EFA, ECR, GUE/NGL
Compromise amendment replacing Amendments 424-441, FEMM 34

Amendment 1

Proposal for a regulation
Article 2 – paragraph 3

**Text proposed by the Commission**

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;

**Amendment**

(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;

Or. en

Amendment 2

Proposal for a regulation
Article 2 – paragraph 4

**Text proposed by the Commission**

(4) ‘crisis relevant products’ means products and substances necessary, in the context of a health crisis, to prevent, diagnose or treat a disease and its consequences, included but not limited to: medicinal products - including vaccines - and their intermediates, active pharmaceutical ingredients and raw materials; medical devices; hospital and medical equipment (such as ventilators, protective clothing and equipment, diagnostic materials and tools); personal protective equipment; disinfectants and their intermediary products and raw materials necessary for their production);

**Amendment**

4) ‘crisis relevant products’ means products, tools and substances necessary, in the context of a health crisis, to prevent, diagnose or treat a disease and its consequences, and for the monitoring and the epidemiological surveillance of diseases and infections, including but not limited to: medicinal products - including vaccines - and their intermediates, active pharmaceutical ingredients and raw materials; medical devices; hospital and medical equipment (such as ventilators, protective clothing and equipment, diagnostic materials and tools); personal protective equipment; disinfectants and their intermediary products and raw materials necessary for their production);

Or. en
Amendment 1
Proposal for a regulation
Article 2 – paragraph 1 – point 5

Text proposed by the Commission

(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;

Amendment

(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;

Or. en

Amendment 1
Proposal for a regulation
Article 2 – paragraph 9

Text proposed by the Commission

(9) ‘serious cross-border threat to health’ means a life-threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection;

Amendment

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;

Or. en

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

Text proposed by the Commission

(9) ‘Health in all policies’ means an

Amendment

(9) ‘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;

Or. en

Amendment 1
Proposal for a regulation
Article 2 – paragraph 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;

Or. en

Compromise Amendment 2 - General Objectives
EPP, S&D, RE, ID, Greens/EFA, ECR, GUE/NGL
Compromise amendment replacing Amendments 31-34, 442-493, BUDG 22-25, FEMM 35-37

Amendment 2
Proposal for a regulation
Article 3 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

The Programme shall pursue the following general objectives, in keeping with the “One Health” approach where relevant:

The Programme shall pursue the following general objectives, in keeping with the “Health in all policies” approach where applicable, and with the “One Health” approach:
Amendment 2
Proposal for a regulation
Article 3 – paragraph 1 – point 1

Text proposed by the Commission

1) **protect people** in the Union from serious cross-border threats to health;

Amendment

(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;

Or. en

Amendment 2
Proposal for a regulation
Article 3 – paragraph 1 – point 1 a (new)

Text proposed by the Commission

(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

(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 2

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

Text proposed by the Commission

(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.

Amendment

(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.

Compromise Amendment 3 - Specific Objectives
EPP, S&D, RE, ID, Greens/EFA, ECR, GUE/NGL
Compromise amendment replacing Amendments 35- 48, 494-613, BUDG 26 -30, FEMM 38-44

Amendment 3

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

Text proposed by the Commission

The general objectives referred to in Article 3 shall be pursued through the following specific objectives, in keeping with the ‘One Health’ approach where relevant:

Amendment

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

Text proposed by the Commission
(1) strengthen the capability of the Union for prevention, preparedness and response to serious cross-border threats to health, and the management of health crises, including through coordination, provision and deployment of emergency health care capacity, data gathering and surveillance;

Amendment
(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, and the coordination of stress testing of national healthcare systems;

Or. en

Amendment 3
Proposal for a regulation
Article 4 – paragraph 1 – point 2

Text proposed by the Commission
(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;

Amendment
(2) support actions to allow medical staff to be mobilised in case of a crisis, such as staff of the European Medical Corps, including by, improving the training of health professionals and updating their knowledge;

Or. en

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

Text proposed by the Commission
(3) support actions to ensure appropriate availability, accessibility and affordability of crisis relevant products and other necessary health supplies;

Amendment
(3) strengthen the European Medicines Market, to ensure in a sustainable manner the availability, accessibility and affordability of medicinal products, e-health solutions, medical
(4) strengthen the effectiveness,
accessibility, sustainability and resilience
of health systems, including by supporting
digital transformation, the uptake of digital
tools and services, systemic reforms,
implementation of new care models and
universal health coverage, and address
inequalities in health;

(4a) 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;

devices and other necessary health-related
supplies and crisis-relevant medical
products;
**Amendment 3**

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

**Text proposed by the Commission**  
(5) support actions aimed at strengthening health system’s ability to foster disease prevention and health promotion, patient rights and cross-border healthcare, and promote the excellence of medical and healthcare professionals;

**Amendment**  
(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;

**Or. en**

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**Amendment 3**

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

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

**Or. en**
Amendment 3

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

Text proposed by the Commission

(6b) strengthen the fight against communicable diseases and health threats;

Or. en

Amendment 3

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

Text proposed by the Commission

(6c) address vaccine hesitancy, and support action for the elimination of vaccine preventable diseases, including cancers;

Or. en

Amendment 3

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

Text proposed by the Commission

(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, as well as 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;

Or. en
Amendment 3

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

Text proposed by the Commission

(8) support the development, implementation and enforcement of Union health legislation and provide high-quality, comparable and reliable data to underpin policy making and monitoring, and promote the use of health impact assessments of relevant policies;

Amendment

(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;

Or. en

Amendment 3
Proposal for a regulation
Article 4 – paragraph 1 – point 9

Text proposed by the Commission

(9) support integrated work among Member States, and in particular their health systems, including the implementation of high-impact prevention practices, and scaling up networking through the European Reference Networks and other transnational networks;

Amendment

(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, in full synergy with Horizon Europe and its Missions and Partnerships, and aim to increase the coverage of patients and the response to diseases, in greater numbers, and health problems;

Or. en
Amendment 3
Proposal for a regulation
Article 4 – paragraph 1 – point 10

Text proposed by the Commission

(10) support the Union’s contribution to international and global health initiatives.

Amendment

(10) support the Union’s contribution to international and global health commitments and initiatives;

Or. en

Compromise Amendment 4 - Budget
EPP, S&D, RE, ID, Greens/EFA, ECR, GUE/NGL
Compromise amendment replacing Amendments 49, 614, 646, BUDG 31- 33, BUDG 36

Amendment 4
Proposal for a regulation
Article 5 – paragraph 1

Text proposed by the Commission

1. The financial envelope for the implementation of the Programme for the period 2021-27 shall be EUR 1 946 614 000 in current prices.

Amendment

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).

Or. en

Amendment 4
Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission

2. The amount referred to in paragraph 1 may be used for technical and administrative assistance for the implementation of the Programme, such as preparatory, monitoring, control, audit and evaluation activities including corporate information technology systems.

Amendment

2. The amount referred to in paragraph 1 may also be used for technical and administrative assistance for the implementation of the Programme, such as preparatory, monitoring, control, audit and evaluation activities including corporate information technology systems. The
administrative expenses related to indirect actions shall not exceed 5% of the total amount under the Programme.

Amendment 4
Proposal for a regulation
Article 6

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
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<tr>
<td><strong>Article 6</strong></td>
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<tr>
<td><strong>Resources from the European Union Recovery Instrument</strong></td>
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<td>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).</td>
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<td>These amounts shall constitute external assigned revenue in accordance with Article 21(5) of Regulation (EU, Euratom) 2018/1046.</td>
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Compromise Amendment 5 - Joint policy implementation
EPP, S&D, RE, ID, Greens/EFA, ECR, GUE/NGL
Compromise amendment replacing Amendments 52-53, 468, 637- 644, 648, BUDG 46, BUDG 47, FEMM 45

Amendment 5
Proposal for a regulation
Article 16 – paragraph 1

<table>
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<tr>
<td>1. 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</td>
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plans established for the Programme and its priorities and strategic orientations and its implementation. 

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 the long-term effectiveness and sustainability of actions.

Amendment 5

Proposal for a regulation
Article 16 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. 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.

Or. en

Amendment 5

Proposal for a regulation
Article 16 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2b. 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.

Or. en
Amendment 5

Proposal for a regulation
Article 16 – paragraph 2 c (new)

Text proposed by the Commission

2c. 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.

Proposal for a regulation
Article 16 a (new)

Text proposed by the Commission

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.

Or. en

Compromise Amendment 6 - Evaluation
EPP, S&D, RE, ID, Greens/EFA, ECR, GUE/NGL
Compromise amendment replacing Amendments 650-657, BUDG 50-53

Amendment 6

Proposal for a regulation
Article 20 – paragraph 4

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<td>4. The Commission shall communicate the conclusions of the evaluations accompanied by its observations, to the European Parliament,</td>
<td>4. The Commission shall publish, communicate and present the conclusions of both the interim and final evaluations accompanied by its observations, to the</td>
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the Council, the European Economic and Social Committee and the Committee of the Regions.

European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

Compromise Amendment 7 – ANNEX I
EPP, S&D, RE, ID, Greens/EFA, ECR, GUE/NGL
Compromise amendment replacing Amendments 57-99, 658-1016, BUDG 59-78, FEMM 49-61

Amendment 7
Proposal for a regulation
Annex I – point a – point ii

Text proposed by the Commission
(ii) Critical health infrastructure relevant in the context of health crises, tools, structures, processes, production and laboratory capacity, including tools for surveillance, modelling, forecast, prevention and management of outbreaks.

Amendment
(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 7
Proposal for a regulation
Annex I – point b

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

Amendment
(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 7

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

Text proposed by the Commission

(i) Surveys, studies, collection of data and statistics, methodologies, classifications, microsimulations, indicators, knowledge brokering and benchmark exercises;

Amendment

(i) Surveys, studies, collection of comparable data and statistics, where relevant including disaggregated data by gender and age, methodologies, classifications, microsimulations, pilot studies, indicators, knowledge brokering and benchmark exercises;

Amendment 7

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

Text proposed by the Commission

(iii) Expert groups and panels providing advice, data and information to support health policy development and implementation;

Amendment

(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 7

Proposal for a regulation
Annex I – point c – point iv
(iv) Studies and analysis, and scientific advice to support policymaking, and support to the scientific committees on "Consumer Safety" and on "Health, Environmental and Emerging Risks".

Amendment 7

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

Text proposed by the Commission

(d) Development and implementation of Union health legislation and action, in particular through support to:

Amendment

(d) Development, implementation, and evaluation of Union health legislation and action, in particular through providing support to:

Amendment 7

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

Text proposed by the Commission

(i) Implementation, enforcement, monitoring of Union health legislation and action; and technical support to the implementation of legal requirements;

Amendment

(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 7

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

**Text proposed by the Commission**

(iv) Development and operation of databases and digital tools and their interoperability, including where appropriate with other sensing technologies, such as space-based;

**Amendment**

(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;

Or. en

Amendment 7

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

**Text proposed by the Commission**

(v) Auditing and assessment work in accordance with Union legislation;

**Amendment**

(v) Auditing, assessment and inspection work in accordance with Union legislation;

Or. en

Amendment 7

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

**Text proposed by the Commission**

(x) National contact points providing guidance, information and assistance related the implementation of Union health legislation and of the Programme;

**Amendment**

(x) National contact points providing guidance, information and assistance related to the promotion and implementation of Union health legislation and of the Programme;

Or. en
Amendment 7
Proposal for a regulation
Annex I – point d – point xi

Text proposed by the Commission
(xi) Stakeholders in view of transnational cooperation.

Amendment
(xi) Stakeholders in view of transnational and regional cooperation.

Or. en

Amendment 7
Proposal for a regulation
Annex I – point e

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

Amendment 7

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

Text proposed by the Commission

(i) Actions to foster Union-wide and cross-sectoral health crisis prevention, preparedness, management and response capacity of actors at Union, national, regional and local level, including contingency planning and preparedness exercises and the upskilling of medical, healthcare and public health staff;

Amendment

(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 and the upskilling of medical, healthcare and public health staff;

Amendment 7

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

Text proposed by the Commission

(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

(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 7
Proposal for a regulation
Annex I – point f – point iii

Text proposed by the Commission

(iii) Support and/or procure emergency production of medical countermeasures, including essential chemicals and active substances, and the financing of cooperation on emergency health technology assessments and clinical trials;

Amendment

deleted

Or. en

Amendment 7
Proposal for a regulation
Annex I – point f – point iv

Text proposed by the Commission

(iv) Preventive actions to protect vulnerable groups from health threats and actions to adjust the response to and management of crisis to the needs of those vulnerable groups;

Amendment

(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;

Or. en

Amendment 7
Proposal for a regulation
Annex I – point f – point iv a (new)

Text proposed by the Commission

(iv a) Actions to support e-health, such as the transition to telemedicine, at-home administration of medication and implementation of preventative / self-care
Amendment 7

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

Text proposed by the Commission

(iv b) Actions to support cross-border cooperation to ensure access to rapid treatment to all patients across the Union, particularly to those who suffer from rare diseases;

Amendment

(iv b) Actions to support cross-border cooperation to ensure access to rapid treatment to all patients across the Union, particularly to those who suffer from rare diseases;

Or. en

Amendment 7

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

Text proposed by the Commission

(v) Actions to address the collateral health consequences of a health crisis, in particular those on mental health, on patients suffering from chronic diseases and other vulnerable groups;

Amendment

(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;

Or. en

Amendment 7

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

Or. en

Amendment 7
Proposal for a regulation
Annex I – point f – point viii b (new)

(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 patients;

Or. en

Amendment 7
Proposal for a regulation
Annex I – point g – introductory part

(g) Strengthen national health systems:

(g) Strengthen national health systems, promote and protect health and prevent diseases:

Or. en

Amendment 7
Proposal for a regulation
Annex I – point g – point i
(i) Support knowledge transfer actions and Union level cooperation to assist national reform processes towards improved effectiveness, accessibility, sustainability and resilience, in particular to address the challenges identified by the European Semester 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;

Or. en

Amendment 7
Proposal for a regulation
Annex I – point g – point i a (new)

Text proposed by the Commission

(i a) Support implementing policies and actions to reduce health inequalities and inequities in relation to healthcare;

Amendment

(i a) Support implementing policies and actions to reduce health inequalities and inequities in relation to healthcare;

Or. en

Amendment 7
Proposal for a regulation
Annex I – point g – point ii

Text proposed by the Commission

(ii) Training programmes for medical and healthcare staff, and programmes for temporary exchanges of staff;

Amendment

(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.
(iii) Support to improve the geographical distribution of healthcare workforce and avoidance of ‘medical deserts’;

(iv) Support the establishment and coordination of Union Reference Laboratories and Centres, and of Centres of excellence;

(iv) Support the establishment, coordination and deployment of Union Reference Laboratories and Centres, Centres of Excellence and Union disease-specific platforms for the exchange, comparison and benchmarking of best practices between Member States;
(v) Audit of Member States preparedness and response arrangements (such as crisis management, antimicrobial resistance, vaccination);

Amendment

(v) Audit of Member States preparedness and response arrangements (such as crisis management, antimicrobial resistance, vaccination) and of the implementation of their health promotion and disease prevention national strategies or programmes;

Amendment 7

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

Text proposed by the Commission

(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

(viii a) Support the establishment and implementation of programmes assisting Member States and their action to improve health promotion and disease prevention 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 7

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

Text proposed by the Commission

(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;

Or. en

Amendment 7

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

Text proposed by the Commission

(ix b) Support the development of guidelines for preventing and managing diseases in the area of both communicable and non-communicable diseases;

Or. en
Amendment 7

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

Text proposed by the Commission

(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;

Amendment

(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;

Or. en

Amendment 7

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

Text proposed by the Commission

(x a) Support Member States’ actions to address health determinants, including reducing alcohol-related harm and the tobacco use;

Amendment

(x a) 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,

Or. en

Amendment 7

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

Text proposed by the Commission

(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 7
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;

Or. en

Amendment 7
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 to care for people with disabilities;

Or. en

Amendment 7
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;

Or. en

Amendment 7
Proposal for a regulation
Annex I – point g – point xi b (new)

Text proposed by the Commission

(xi b) Support the implementation of the ERNs’ system of continuous assessment, monitoring, evaluation and quality improvement system;

Or. en

Amendment 7
Proposal for a regulation
Annex I – point g – point xi c (new)

Text proposed by the Commission

(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;

Or. en

Amendment 7
Proposal for a regulation
Annex I – point g – point xi d (new)
Text proposed by the Commission

(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

(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;

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

Text proposed by the Commission

(h) Actions on cancer:

Amendment

(h) Actions on cancer, including paediatric cancers:
Amendment 7

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

(Text proposed by the Commission)

(i) Support Member States and NGOs in the promotion and implementation of the recommendations of the European Code against Cancer;

(AMendment)

(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;

Or. en

Amendment 7

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

(Text proposed by the Commission)

(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 and paediatric cancer;

(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 and paediatric cancer;

Or. en

Amendment 7

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

(Text proposed by the Commission)

(iii) Support prevention programmes on the main cancer risk factors;

(AMendment)

(iii) Support prevention programmes on the main cancer risk factors and that are of

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demonstrated effectiveness and supported by established evidence;

Amendment 7
Proposal for a regulation
Annex I – point h – point iv a (new)

Text proposed by the Commission

(iv a) Action to support the implementation of cancer registries in all Member States;

Amendment

Or. en

Amendment 7
Proposal for a regulation
Annex I – point h – point v

Text proposed by the Commission

(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

Or. en

Amendment 7
Proposal for a regulation
Annex I – point h – point v a (new)
(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;

Or. en

Amendment 7

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

(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;

Or. en

Amendment 7

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

(vii) Actions supporting quality in cancer prevention and care including diagnosis and treatment;

(vii) Actions supporting quality in cancer prevention and care including diagnosis, treatment, follow-up, and supportive and palliative care;

Or. en
### Amendment 7

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(viii) Actions supporting the quality of life of cancer survivors and care givers;</td>
<td>(viii) Actions supporting the quality of life of cancer survivors and care givers, <em>including provision of psychological support, pain management, and professional re-integration</em>;</td>
</tr>
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</table>

*Or. en*

### Amendment 7

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(ix) Support to the implementation of the Union’s tobacco control policy and legislation;</td>
<td>(ix) Support to the implementation of the Union’s tobacco control policy and legislation <em>and other related legislation in the area of prevention and health promotion, including aimed at reducing alcohol related harm</em>;</td>
</tr>
</tbody>
</table>

*Or. en*

### Amendment 7

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(x) Establishment and support of a mechanisms for cross-specialty capacity building and continuous education in the area of cancer care.</td>
<td>(x) Establishment and support of a mechanisms for cross-specialty capacity building and continuous education of healthcare professionals and informal carers in the area of cancer care, <em>screening and early diagnosis, in particular in the area of paediatric cancer, with the aim of improving the quality of care</em>;</td>
</tr>
</tbody>
</table>
Amendment 7

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

Text proposed by the Commission

(x a) Actions to support an integrative, coordinated, multi-disciplinary and patient-centred approach concerning cancer patients and survivors;

Amendment

Or. en

Amendment 7

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

Text proposed by the Commission

(ii) Support actions to fight vaccine hesitancy;

Amendment

(ii) Support actions to fight vaccine hesitancy and disinformation, and promote immunization throughout all stages of a person’s lifetime;

Or. en

Amendment 7

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

Text proposed by the Commission

(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 7
Proposal for a regulation
Annex I – point i – point ii b (new)

Text proposed by the Commission

(ii b) support action for the elimination of vaccine preventable diseases;

Amendment

Or. en

Amendment 7
Proposal for a regulation
Annex I – point i – point iii

Text proposed by the Commission

(iii) Support clinical trials to speed up the development, authorisation and access to innovative, safe and effective medicines and vaccines;

Amendment

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

Or. en

Amendment 7
Proposal for a regulation
Annex I – point i – point iii a (new)

Text proposed by the Commission

(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 7

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

Text proposed by the Commission

(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 7

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

Text proposed by the Commission

(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;

Amendment

(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 7
Proposal for a regulation
Annex I – point i – point v

Text proposed by the Commission
(v) Support action to encourage the development of innovative products and of less commercially interesting products such as antimicrobials;

Amendment
(v) Support action to encourage the discovery and development of innovative medicines and vaccines to meet rising healthcare challenges and patients’ needs;

Or. en

Amendment 7
Proposal for a regulation
Annex I – point i – point v a (new)

Text proposed by the Commission
(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
(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;

Or. en

Amendment 7
Proposal for a regulation
Annex I – point i – point v b (new)

Text proposed by the Commission
(v b) Action to address market failures with regard to antibiotics and encourage sustainable investment in 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
(v b) Action to address market failures with regard to antibiotics and encourage sustainable investment in 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 7

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

Text proposed by the Commission
(vi) Support action to monitor shortages of medicines and medical devices occurring in hospitals and community pharmacies, to address such shortages, and to increase security of supplies;

Amendment
(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 centralised database, interoperable with databases that contained regulatory data on medicines, to address such shortages, and to increase security of supplies;

Amendment 7

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

Text proposed by the Commission
(viii) Action to strengthen the environmental risk assessment of pharmaceuticals;

Amendment
(viii) Action to strengthen the environmental risk assessment of pharmaceuticals and medical devices;

Amendment 7

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

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

Amendment
(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);

Or. en

Amendment 7
Proposal for a regulation
Annex I – point i – point x

Text proposed by the Commission
(x) Support action to foster international regulatory convergence on medicines and medical devices.

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

Or. en

Amendment 7
Proposal for a regulation
Annex I – point j – point i

Text proposed by the Commission
(i) Support for the deployment, operation and maintenance of mature interoperable digital service infrastructures and data quality assurance processes for data exchange, access, use and reuse; support for cross border networking, including through the use of electronic health records, registries and other databases;

Amendment
(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;

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

Text proposed by the Commission

(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

Or. en

Amendment 7

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

Text proposed by the Commission

(i b) Support Member States to improve and further develop and implement ERN registries;

Amendment

Or. en

Amendment 7

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

Text proposed by the Commission

(ii) Support to the digital transformation of health care and health systems including through benchmarking and capacity building for the uptake of innovative tools and technologies; digital upskilling of health care professionals;

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 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 7

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

Text proposed by the Commission

(iii) Support the deployment and interoperability of digital tools and infrastructures within and between Member States and with Union Institutions and bodies; develop appropriate governance structures and sustainable, interoperable Union health information systems, as part of the European Health Data Space and strengthen citizens’ access to and control over their health data;

Amendment

(iii) Support the deployment and interoperability of digital tools and infrastructures within and between Member States and with Union Institutions, agencies and bodies; develop appropriate governance structures and sustainable, interoperable Union health information systems, as part of the European Health Data Space 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 7

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

Text proposed by the Commission

(iv) Support optimal use of telemedicine/telehealth, including through satellite communication for remote areas, foster digitally-driven organisational innovation in healthcare facilities and promote digital tools supporting citizen empowerment and person-centred care.

Amendment

(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 7
Proposal for a regulation
Annex I – point k – point iii

Text proposed by the Commission

(iii) Communication to promote disease prevention and healthy lifestyles, in cooperation with all concerned actors at international, Union and national level.

Amendment

(iii) Communication to promote health, healthy lifestyles and disease prevention, in cooperation with all concerned actors at international, Union, national and regional level;

Amendment 7
Proposal for a regulation
Annex I – point k – point iii a (new)

Text proposed by the Commission

(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

(iii a) Communication activities aimed at
combating misinformation and disinformation, such as fake news, regarding medicines, vaccines, health products, and causes and treatments of diseases;

Amendment 7
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 7
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.

Compromise Amendment 8
EPP, S&D, RE, ID, Greens/EFA, ECR, GUE/NGL
Compromise amendment replacing Amendments 50-51, 625-636, BUDG 43-45

Amendment 8
Proposal for a regulation
Article 14 – paragraph 1 – point b
Text proposed by the Commission

(b) any legal entity created under Union law or any international organisation;

Amendment

(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;

Or. en

Amendment 8

Proposal for a regulation
Article 14 – paragraph 3

Text proposed by the Commission

3. Legal entities established in a third country which is not associated to the Programme should in principle bear the cost of their participation.

Amendment

3. Legal entities established in a third country which is not associated to the Programme should bear the cost of their participation.

Or. en

Amendment 8

Proposal for a regulation
Article 14 – paragraph 5

Text proposed by the Commission

5. Under the Programme, direct grants may be awarded without a call for proposals to fund actions having a clear Union added value co-financed by the competent authorities that are responsible for health in the Member States or in the third countries associated to the Programme, relevant international health organisations or by public sector bodies and non-governmental bodies, acting individually or as a network, mandated by those competent authorities.

Amendment

5. Under the Programme, direct grants may be awarded without a call for proposals to fund actions if such grants are duly justified and if 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 8

Proposal for a regulation
Article 14 – paragraph 6

Text proposed by the Commission

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.

Amendment

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 8

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

Text proposed by the Commission

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

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.

Compromise Amendment 9 – ANNEX II
EPP, S&D, RE, ID, Greens/EFA, ECR, GUE/NGL
Compromise amendment replacing Amendments 1017 - 1095, FEMM 62 - 67,

Amendment 9

Proposal for a regulation
Annex II – part 1 – point I

*Text proposed by the Commission*

I. Quality and completeness of EU and MS preparedness and response planning for serious cross border threats to health

*Amendment*

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*

*Or. en*

Amendment 9

Proposal for a regulation
Annex II – part 1 – point II

*Text proposed by the Commission*

II. Access to centrally authorised medicines, e.g. number of orphan authorisations, Advanced Therapy Medicinal Products, Paediatric Use Medicinal Products or vaccines, for unmet needs

*Amendment*

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

*Or. en*

Amendment 9

Proposal for a regulation
Annex II – part 1 – point III

*Text proposed by the Commission*

III. Number of actions and best practices directly contributing to the SDG 3.4/Member State

*Amendment*

III. Number of actions and best practices directly contributing to achieve Universal Health Coverage / Member State

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Amendment 9

Proposal for a regulation
Annex II – part 1 – point IV

Text proposed by the Commission

IV. Implementation of best practices by EU Member States

Amendment

IV. Implementation of health programmes by Member States, that promote health, prevent diseases and address health inequalities

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

Text proposed by the Commission

IV a. Implementation of the European Health Data Space (EHDS)

Amendment

Proposal for a regulation
Annex II – part 2 – point 1 a (new)

Text proposed by the Commission

1 a. Number of new procedures for accelerated development and assessment of medicines for major public health needs, where relevant taking into account novel technologies

Amendment

Proposal for a regulation
Annex II – part 2 – point 1 b (new)
Text proposed by the Commission

Amendment

1 b. Number of Member States with adequate level of digital health infrastructure

Or. en

Amendment 9
Proposal for a regulation
Annex II – part 2 – point 1 c (new)

Text proposed by the Commission

Amendment

1 c. Number of Member States that implemented the European Electronic Health Record

Or. en

Amendment 9
Proposal for a regulation
Annex II – part 2 – point 1 d (new)

Text proposed by the Commission

Amendment

1 d. Proportion of Member States’ citizens with access to their data on the EHDS, per Member State

Or. en

Amendment 9
Proposal for a regulation
Annex II – part 2 – 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 9
Proposal for a regulation
Annex II – part 2 – point 3 a (new)

*Text proposed by the Commission*

3 a. Vaccination coverage, by age, and by vaccine-preventable-disease

Or. en

Amendment 9
Proposal for a regulation
Annex II – part 2 – point 6

*Text proposed by the Commission*

6. Age-standardised five-year net survival of cervical, breast and colorectal cancer

*Amendment*

6. Age-standardised five-year net survival of cancer by type, age, gender and Member State

Or. en

Amendment 9
Proposal for a regulation
Annex II – part 2 – point 6 a (new)

*Text proposed by the Commission*

6 a. Age-standardised five-year net survival rate for paediatric cancer by type, age, gender and Member State

*Amendment*

6 a. Age-standardised five-year net survival rate for paediatric cancer by type, age, gender and Member State

Or. en

Amendment 9
Proposal for a regulation
Annex II – part 2 – point 6 b (new)

Text proposed by the Commission

6 b. Screening coverage for breast, cervical and colorectal cancer screening programmes, by type, age, gender and Member State

Amendment

Proposal for a regulation
Annex II – part 2 – point 7

Text proposed by the Commission

7. Ratio of Cancer Registries (CRs) and number of Member States (MSs) reporting information on cervical, breast, and colorectal cancer stage at diagnosis

Amendment

Proposal for a regulation
Annex II – part 2 – point 7 a (new)

Text proposed by the Commission

7 a. Ratio of palliative care admissions and outcome result for cancer, and paediatric cancer, by type, age, gender and Member State

Amendment

Proposal for a regulation
Annex II – part 2 – point 7 b (new)
7 b. Ratio of Paediatric Cancer Registries (CRs) /Member State and number of Member States (MSs) reporting information on paediatric cancer stage at diagnosis

Amendment 9

Proposal for a regulation
Annex II – part 2 – point 7 c (new)

7 c. Prevalence of major chronic diseases per Member State, by disease, gender and age

Amendment 9

Proposal for a regulation
Annex II – part 2 – point 7 d (new)

7 d. Age-standardized NCD mortality rate (per 100 000 people), by disease

Amendment 9

Proposal for a regulation
Annex II – part 2 – point 7 e (new)

7 e. Percentage of HIV/AIDS patients
with access to adequate treatment, by Member State, gender and age

Amendment 9

Proposal for a regulation
Annex II – part 2 – point 7 f (new)

Text proposed by the Commission

7 f. Proportion of tuberculosis patients with access to adequate treatment, by Member State, gender and age

Or. en

Amendment 9

Proposal for a regulation
Annex II – part 2 – point 8

Text proposed by the Commission

8. Smoking prevalence
8. Age standardized prevalence of tobacco use, by gender

Or. en

Amendment 9

Proposal for a regulation
Annex II – part 2 – point 9

Text proposed by the Commission

9. Number of shortages of medicines in the single point of contact network
9. Number of shortages of medicines in the Member States

Or. en
Proposal for a regulation
Annex II – part 2 – point 9 a (new)

Text proposed by the Commission

9. Actions aimed at stimulating the production of essential APIs and medicinal products in the EU

Amendment

Or. en

Amendment 9

Proposal for a regulation
Annex II – part 2 – point 12 a (new)

Text proposed by the Commission

12 a. Antimicrobial use by ATC type and per Member States

Amendment

Or. en

Amendment 9

Proposal for a regulation
Annex II – part 2 – point 12 b (new)

Text proposed by the Commission

12 b. Attributable mortality to healthcare associated infections, by age, gender and Member State

Amendment

Or. en
Proposal for a regulation
Annex II – part 2 – point 12 c (new)

Text proposed by the Commission

12 c. 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

Proposal for a regulation
Annex II – part 2 – point 13

Text proposed by the Commission

13. Number of hospital units involved in ERN and of patients diagnosed and treated by the members of ERN networks

Amendment

Proposal for a regulation
Annex II – part 2 – point 14 a (new)

Text proposed by the Commission

14 a. Number of health impact assessments of Union policies

Amendment

Proposal for a regulation
Annex II – part 2 – point 14 b (new)
14 b. Age-standardised obesity prevalence, by gender, age and Member State

Amendment

Proposal for a regulation
Annex II – part 2 – point 14 c (new)

14 c. Maternal mortality rate, by age and by Member State

Amendment

Proposal for a regulation
Annex II – part 2 – point 14 d (new)

14 d. Infant mortality rate by Member State

Proposal for a regulation
Recital 2
(2) In accordance with Articles 9 and 168 of the Treaty on the Functioning of the European Union (TFEU) and Article 35 of the Charter of Fundamental Rights of the European Union (the Charter), a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities.

Amendment

(2) 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.

Or. en

Amendment 10
Proposal for a regulation
Recital 3

Text proposed by the Commission

(3) Article 168 TFEU provides that the Union is to complement and support national health policies, encourage cooperation between Member States and promote the coordination between their programmes, in full respect of the responsibilities of the Member States for the definition of their health policies and the organisation and delivery of health services and medical care.

Amendment

(3) Article 168 TFEU provides that the Union is to complement and support national health policies, encourage cooperation between Member States, particularly in border regions, and promote the coordination between their programmes, in full respect of the responsibilities of each Member State to define their own health policy and to organise, deliver and manage health services and medical care.

Or. en

Amendment 10
Proposal for a regulation
Recital 5

Text proposed by the Commission

(5) On 11 March 2020 the World Health Organization (WHO) declared the novel coronavirus (COVID-19) outbreak a

Amendment

(5) On 11 March 2020 the World Health Organization (WHO), due to an exponential increase of cases, declared
global pandemic. *That* pandemic *has* caused an unprecedented worldwide health crisis with severe socio-economic consequences and human suffering.

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, 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.

Or. en

Amendment 10

Proposal for a regulation

Recital 6

*Text proposed by the Commission*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity⁸. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States 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

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity⁸. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States, in particular between neighbouring border regions, as well as between authorities and relevant stakeholders. This cooperation should improve the preparedness, prevention and
the health and well-being of people in the Union.

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.

Amendment 10

Proposal for a regulation
Recital 6 a (new)

Text proposed by the Commission

(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, 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 10

Proposal for a regulation
Recital 7

*Text proposed by the Commission*

(7) It is therefore appropriate to establish a new Programme for the Union's action in the field of health, called EU4Health Programme ('the Programme') for the period 2021 -2027. In line with the goals of the Union action and its competences in the area of public health the Programme should place emphasis on actions in relation to which there are advantages and efficiency gains from collaboration and cooperation at Union level and actions with an impact on the internal market.

*Amendment*

(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 Union 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**

(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 and other relevant mechanisms and structures established at Union level. This could include strategic stockpiling of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. 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.

**Amendment**

(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 and other relevant mechanisms and structures established at Union level. This could include capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes, health information, and platforms to share best practices. 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.

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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 10
Proposal for a regulation
Recital 11

Text proposed by the Commission

(11) As in the time of health crisis emergency health technology assessment as well as clinical trials can contribute to the rapid development of medical countermeasures the Programme should provide support to facilitate such actions. The Commission has adopted a proposal on Health Technology Assessment (HTA) to support cooperation on health technology assessment at Union level.

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Amendment

(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 on Health Technology Assessment (HTA) to support cooperation on health technology assessment at Union level. The programme should provide support to facilitate such actions.

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collateral impacts of the health crisis on people belonging to such vulnerable groups.

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 10
Proposal for a regulation
Recital 13

Text proposed by the Commission

(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.

Amendment

(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 10**

Proposal for a regulation

Recital 14

*Text proposed by the Commission*

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

*Amendment*

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

**Amendment 10**

Proposal for a regulation

Recital 15

*Text proposed by the Commission*

(15) Experience from the COVID-19

*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 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.
common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006\(^\text{12}\) 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.


**Amendment 10**

**Proposal for a regulation**

**Recital 16**

*Text proposed by the Commission*

(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".\(^\text{13}\) The Programme therefore should contribute to the actions taken towards reaching these goals.

*Amendment*

(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 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”. 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.

Amendment 10

Proposal for a regulation
Recital 17

Text proposed by the Commission

(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 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

Amendment

(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 neurologic disorder 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 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
efforts to strengthen health systems.

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.

Or. en

Amendment 10

Proposal for a regulation
Recital 18

Text proposed by the Commission

(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, 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 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 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 the health determinants. Health promotion, health
European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.

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 Union’s health-related legislation, including in the area of environmental health, and fostering 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.

Or. en

Amendment 10

Proposal for a regulation
Recital 18 a (new)

Text proposed by the Commission

(18 a) 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 diseases management guidelines in the area of both communicable and non-communicable diseases, such as cardiovascular diseases, neurodegenerative diseases, respiratory diseases and diabetes.

Amendment 10

Proposal for a regulation
Recital 19

Text proposed by the Commission

(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.

Amendment

(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 survivors. The measures should benefit from the Programme and from Horizon Europe’s Mission on Cancer.

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 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 10

Proposal for a regulation
Recital 20

Text proposed by the Commission

(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

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 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+.

Or. en

Amendment 10

Proposal for a regulation
Recital 21

Text proposed by the Commission

(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

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, Member States’ healthcare systems face challenges in the availability and affordability of medicines and medical
devices. To ensure a better public health protection as well as the safety and empowerment of patients in the Union, it is essential that patients and health systems have access to high quality healthcare products and can fully benefit from them.

Amendment 10
Proposal for a regulation
Recital 22

Text proposed by the Commission

(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 digital transformation of healthcare products and platforms for monitoring and collecting information on medicines.

Amendment

(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.

Proposal for a regulation
Recital 22a (new)

Text proposed by the Commission

(22) 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.
(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.


**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 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 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.


Or. en

**Amendment 10**

Proposal for a regulation
Recital 24
(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\(^\text{15}\).


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**Proposal for a regulation**

**Recital 25**

(25) The Union health legislation has an immediate impact on public health, the lives of citizens, the efficiency and resilience of the health systems and the good functioning of the internal market. The regulatory framework for medical products and technologies (medicinal products, medical devices and substances of human 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.

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 10

Proposal for a regulation
Recital 26

Text proposed by the Commission

(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.

Amendment

(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.

Or. en
Amendment 10

Proposal for a regulation
Recital 27

Text proposed by the Commission

(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council\(^\text{16}\) 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.

Amendment

(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council\(^\text{16}\) 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. 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.


Amendment 10
Proposal for a regulation
Recital 30

Text proposed by the Commission

(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

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 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
field of health and another Union programme.

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 10

Proposal for a regulation
Recital 31

Text proposed by the Commission

(31) Given the specific nature of the objectives and actions covered by the Programme, the respective competent authorities of the Member States are best placed in some cases to implement the related activities. Those authorities, designated by the Member States themselves, should therefore be considered to be identified beneficiaries for the purpose of Article 195 of the Financial Regulation and the grants be awarded to such authorities without prior publication of calls for proposals.

Amendment

(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. Investments from EU4Health programme should be implemented in close cooperation with Member States especially in areas falling under national competences.

Amendment 10

Proposal for a regulation
Recital 31 a (new)
(31 a) In order to ensure that each of these objectives is implemented at the 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 EU4Health Programme.

Amendment 10
Proposal for a regulation
Recital 33

Text proposed by the Commission

(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, the Programme should support the Union’s contribution to international and global health initiatives with a view to improve health, address inequalities and increase protection against global health threats.

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

Amendment

(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, the Programme should support the Union’s contribution to international and global health initiatives with a view to improve health, address inequalities and increase protection against global health threats.

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

Or. en
Proposal for a regulation
Recital 34

**Text proposed by the Commission**

(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, persons and entities established in Overseas Countries and Territories (OCTs) are eligible for funding subject to the rules and objectives of the Programme and possible arrangements applicable to the Member State to which the relevant OCTs are linked.

**Amendment**

(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, 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.

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**Amendment 10**

Proposal for a regulation
Recital 34 a (new)

**Text proposed by the Commission**

(34 a) **To achieve a coherent implementation of the actions included in the EU4Health programme, a EU4Health Steering Group should be established.**

**Amendment**

(34 a) **To achieve a coherent implementation of the actions included in the EU4Health programme, a EU4Health Steering Group should be established.**

Amendment 10

Proposal for a regulation
Recital 40

Text proposed by the Commission

(40) Reflecting the importance of tackling climate change in line with the Union's commitments to implement the Paris Agreement and the United Nations Sustainable Development Goals, this Programme will contribute to mainstream climate action in the Union's policies and to the achievement of an overall target of 25% of the EU budget expenditures supporting climate objectives. Relevant actions will be identified during the Programme's preparation and implementation, and reassessed in the context of its mid-term evaluation.

Amendment

(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.
relevant products, to support innovation and to support integrated and coordinated work and implementation of best practices among Member States, and to address inequalities in access to health throughout the EU in a manner that creates efficiency gains and value-added impacts that could not be generated by action taken at national level while respecting the Member States’ competence and responsibility in the areas covered by the Programme. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

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 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.

Or. en