



2020/0102(COD)

16.7.2020

AMENDMENTS 520 - 1095

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

on the proposal for a regulation of the European Parliament and of the Council on the establishment of a Programme for the Union's action in the field of health –for the period 2021-2027 and repealing Regulation (EU) No 282/2014 (“EU4Health Programme”)

Proposal for a regulation
(COM(2020)0405 – C9-0152/2020 – 2020/0102(COD))

Amendment 520

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Mohammed Chahim

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) support actions to ensure appropriate availability, accessibility, ***sustainability*** and affordability of ***medicines, vaccines, medical devices*** and other necessary health supplies, ***stimulate the development of the health production industry within the Union;***

Or. en

Amendment 521

Michèle Rivasi

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) support actions to ensure appropriate availability, accessibility and affordability of relevant products and other necessary health supplies, ***including via collective safeguards in favour of the public such as transparency, accessibility and affordability clauses and non-exclusive licences for the exploitation of the final products;***

Or. en

Justification

In line with the call of the Parliament in the EU public health strategy post COVID-19 of 10 July 2020, is important to refer to collective safeguards in funding instruments (see paragraph 7) to ensure appropriate availability, accessibility and affordability of relevant products. This should apply to all products, and not just to those relevant for crises.

Amendment 522

Nathalie Colin-Oesterlé

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) support actions to ensure appropriate availability, accessibility and affordability of crisis relevant products and other necessary health supplies, **by improving information systems so as to provide a clear overview of difficulties, shortages and requirements in each Member State, with a view to preventing stockpiling;**

Or. fr

Amendment 523

Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, María Soraya Rodríguez Ramos

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 and** support actions to ensure appropriate availability, accessibility and affordability of crisis relevant products and other necessary health supplies **via a strengthened EU joint procurements on treatments and vaccines;**

Or. en

Amendment 524

Mairead McGuinness

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) support actions to ensure appropriate availability, accessibility and affordability of crisis relevant products and other necessary health supplies, ***including at times of non-crisis***;

Or. en

Amendment 525

Christian Ehler

on behalf of the EPP Group

Dan Nica

on behalf of the S&D Group

Martina Dlabajová

on behalf of the Renew Group

Ville Niinistö

on behalf of the Greens/EFA Group

Marisa Matias

on behalf of the GUE/NGL Group

Cristian-Silviu Buşoi

Proposal for a regulation
Article 4 – paragraph 1 – point 3 a (new)

Text proposed by the Commission

Amendment

(3a) support actions to increase research and development, including for unmet medical needs, in full synergy with Horizon Europe and its Missions and Partnerships, including through clinical trials, in the Union of crisis-relevant products, and access to and analysis on data from the use of such products in healthcare systems, including through the European Open Science Cloud;

Or. en

Amendment 526
Kateřina Konečná

Proposal for a regulation
Article 4 – paragraph 1 – point 3 a (new)

Text proposed by the Commission

Amendment

(3a) support actions to transform the health sector into a sector that comprises person-centred and outcome-based care and health systems, and where patients are meaningfully involved in the development of solutions and decision making that affect them;

Or. en

Justification

Patients' organisations are an essential resource for health services in identifying and implementing the best possible solutions to continued access to quality care and treatment. Patients' organisations channel the voice of patients by representing their interests coherently, helping policymakers understand the lived experience and enhancing the relevance of policymaking. For this reason, patients need to be meaningfully involved in the design and development of healthcare system solutions but also the decision-making process and development of policies.

Amendment 527
Michèle Rivasi

Proposal for a regulation
Article 4 – paragraph 1 – point 3 a (new)

Text proposed by the Commission

Amendment

(3a) provide incentives to increase production of essential APIs and medicines in Europe and to diversify the supply chain to guarantee supply and affordable access at all times;

Or. en

Justification

EU4Health should provide incentives to increase production of essential APIs and medicines

in Europe, as called for by the Parliament in its resolution on the EU public health strategy post COVID-19 of 10 July 2020 (see paragraph 22).

Amendment 528

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Mohammed Chahim, Sándor Rónai

Proposal for a regulation

Article 4 – paragraph 1 – point 3 a (new)

Text proposed by the Commission

Amendment

(3a) support the research and development of new medicines, medical devices and health products, enhance clinical trials and research based on real world data;

Or. en

Amendment 529

Kateřina Konečná

Proposal for a regulation

Article 4 – paragraph 1 – point 3 b (new)

Text proposed by the Commission

Amendment

(3b) develop a transparent framework for fair and equitable access in the short, medium and long term to maximise societal benefit and patient access whilst avoiding unacceptable impact on healthcare budgets, through an inclusive consultative process led by governments, and set up a High Level Strategic Dialogue co-ordinated by the Commission and the participation of all stakeholders including patient organisations, to reflect on and establish concrete and comprehensive strategies to achieve such a framework;

Or. en

Amendment 530

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

Proposal for a regulation

Article 4 – paragraph 1 – point 4

Text proposed by the Commission

(4) strengthen the effectiveness, accessibility, sustainability and resilience of health systems, including by supporting digital transformation, ***the uptake of digital tools and services***, systemic reforms, implementation of new care models and universal health coverage, ***and*** address inequalities in health;

Amendment

(4) strengthen the effectiveness, accessibility, sustainability and resilience of health systems, including by supporting ***green and*** digital transformation, systemic reforms, implementation of new care models ***leading to person-centred systems*** and universal health coverage, address inequalities ***and inequities*** in health ***and promote a set of minimal health services standards and ensure that the right to affordable preventive and curative health and care as set out in the European Pillar of Social Rights is respected***;

Or. en

Amendment 531

Chrysoula Zacharopoulou, Véronique Trillet-Lenoir, María Soraya Rodríguez Ramos, Karen Melchior, Sophia in 't Veld, Samira Rafaela, Hilde Vautmans, Susana Solís Pérez, Maria Noichl

Proposal for a regulation

Article 4 – paragraph 1 – point 4

Text proposed by the Commission

(4) strengthen the effectiveness, accessibility, sustainability and resilience of health systems, including by supporting digital transformation, the uptake of digital tools and services, systemic reforms, implementation of new care models and universal health coverage, and address inequalities in health;

Amendment

(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 ***to reach*** universal health coverage ***objective, encompassing access to sexual and reproductive health and rights***, and

address *social* inequalities in health,
including gender inequalities;

Or. en

Amendment 532

Michèle Rivasi

Proposal for a regulation

Article 4 – paragraph 1 – point 4

Text proposed by the Commission

(4) strengthen the effectiveness, accessibility, sustainability and resilience of health systems, including by supporting digital transformation, the uptake of digital tools and services, systemic reforms, implementation of new care models and universal health coverage, and address inequalities in health;

Amendment

(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 ***the achievement of*** universal health coverage, ***which includes access to sexual and reproductive health and rights***, and address inequalities in health, ***including gender and intersectional inequalities***;

Or. en

Justification

SRHR interventions and services are essential to reaching UHC, and UHC is essential to ensuring universal access to SRHR interventions. The Political Declaration on UHC made at the High Level Meeting in September 2019 included SRHR as an essential component to reach UHC. To reach its aim of contributing to the achievement of UHC, the EU4Health programme should therefore include SRHR.

Amendment 533

Mick Wallace, Clare Daly

Proposal for a regulation

Article 4 – paragraph 1 – point 4

Text proposed by the Commission

(4) strengthen the effectiveness, accessibility, sustainability and resilience

Amendment

(4) strengthen the effectiveness, accessibility, sustainability and resilience

of health systems, including by supporting digital transformation, the uptake of digital tools and services, systemic reforms, implementation of new care models and universal health coverage, and address inequalities in health;

of health systems, including by supporting digital transformation, the uptake of digital tools and services, systemic reforms, implementation of new care models and ***the achievement of*** universal health coverage, ***which includes access to sexual and reproductive health and rights***, and address inequalities in health, ***including gender and intersectional inequalities***;

Or. en

Amendment 534
Mairead McGuinness

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

Text proposed by the Commission

(4) strengthen the effectiveness, accessibility, sustainability and resilience of health systems, including by supporting digital transformation, the uptake of digital tools and services, systemic reforms, implementation of new care models and universal health coverage, and address inequalities in health;

Amendment

(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, ***progressing deinstitutionalisation and moving to community-based care including for older people***, and universal health coverage, and address inequalities in health;

Or. en

Amendment 535
Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, María Soraya Rodríguez Ramos

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

Text proposed by the Commission

(4) strengthen the effectiveness,

Amendment

(4) strengthen the effectiveness,

accessibility, sustainability and resilience of health systems, including by supporting digital transformation, the uptake of digital tools and services, systemic reforms, implementation of new care models and universal health coverage, and **address** inequalities in health;

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 **reduce** inequalities in health;

Or. en

Amendment 536

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

Proposal for a regulation

Article 4 – paragraph 1 – point 4 a (new)

Text proposed by the Commission

Amendment

(4a) support the digitalization of health, increasing the skills of citizens and health workers and services, the interoperability of systems and availability of data, ensuring data comparability, to improve the knowledge and evidence on health, support the creation and implementation of a European Health Data Space while respecting citizens' data protection rights and the Union data protection framework;

Or. en

Amendment 537

Marian-Jean Marinescu

Proposal for a regulation

Article 4 – paragraph 1 – point 4 a (new)

Text proposed by the Commission

Amendment

(4a) strengthen and develop the Union health infrastructure by creating new medical care facilities to handle large flows of patients in circumstances of

cross-border threats to health and at the same time to continue to assure lifesaving treatment for patients with non-communicable diseases, such as cardiovascular diseases, cancer, paediatric cancer;

Or. en

Amendment 538
Michèle Rivasi

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

Text proposed by the Commission

Amendment

(4a) support a collaborative and open approach in the field of research and innovation, with a stronger role for the Commission and Member States in coordinating health and epidemiological research so as to avoid duplication and drive research towards outcomes including needed medicines, vaccines, medical devices and equipment;

Or. en

(Counter-amendment to amendment 39 by the rapporteur, based on paragraph 37 of the EP Resolution of 10 July 2020 on the EU public health strategy post COVID-19.)

Justification

The current innovation system for medicines based on exclusive rights favours private firms and jeopardizes public benefits. Investments are made based on profitability, and not based on public needs. This leads to lack of essential medicines on the one hand and excessive prices on the other hand. In line with the Parliament Resolution of 10 July 2020 on the EU public health strategy post COVID-19, the EU should support a collaborative and open approach to research and innovation.

Amendment 539
Kateřina Konečná

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

Text proposed by the Commission

Amendment

(4a) enhance the equal and timely access to quality, sustainable and affordable person-centred preventive and curative health care and related care and services for all, with no discrimination or stigma;

Or. en

Amendment 540
Antoni Comín i Oliveres

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

Text proposed by the Commission

Amendment

(4a) accompany the Member States in the reformulation of the budgets of their health systems so that they are more clearly redistributed according to the criteria of inequalities in population health;

Or. en

Amendment 541
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

(4a) enhance the equal and timely access to quality, sustainable and affordable person-centred preventive and curative health care and related care and services for all;

Amendment 542
Nicolae Ștefănuță, Véronique Trillet-Lenoir

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

Text proposed by the Commission

Amendment

(4a) support the development and implementation of a European Electronic Health Record;

Amendment 543
Christian Ehler
on behalf of the EPP Group
Dan Nica
on behalf of the S&D Group
Martina Dlabajová
on behalf of the Renew Group
Ville Niinistö
on behalf of the Greens/EFA Group
Marisa Matias
on behalf of the GUE/NGL Group
Cristian-Silviu Bușoi

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

Text proposed by the Commission

Amendment

(4b) support the Union's health related innovation ecosystems in full synergy with Horizon Europe and its Missions and Partnerships to ensure the development and uptake of preventive actions, the next generation of medicines, vaccines and medical devices to meet increasing healthcare challenges and expectations that arise including the ones that come with rare disease prevention, diagnosis, treatment, and innovation;

Amendment 544
Michèle Rivasi

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

Text proposed by the Commission

Amendment

(4b) enhance the equal and timely access to quality, sustainable and affordable person-centred preventive and curative health care and related care and services for all, with no discrimination or stigma;

Amendment 545

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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

Text proposed by the Commission

Amendment

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

(5) support actions aimed at **addressing health inequalities and** strengthening health system's ability to foster **protection**, disease prevention, **early diagnosis and screening, and implement** health promotion **inclusive of mental health**, patient rights **and safety** and cross-border healthcare, and promote the excellence of medical and healthcare professionals **as well as their education, enhance their fixation and mitigate the consequences of the 'brain drain' phenomenon, scale up the occupational health of all workers and address the protection and safety of healthcare professionals;**

Amendment 546
Kateřina Konečn

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 **addressing health inequalities and** strengthening health system’s ability to foster disease prevention, **early diagnosis and screening, and implement** health promotion, **including through the promotion of physical activity, health education literacy,** patient rights and cross-border healthcare;

Amendment 547
Cristian-Silviu Bușoi

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 **addressing health inequalities and** strengthening health system’s ability to foster disease prevention, **early diagnosis and screening, and implement** health promotion, **including through the promotion of physical activity, health literacy,** patient rights and cross-border healthcare, and promote the excellence of medical and healthcare professionals;

Amendment 548
Mick Wallace, Clare Daly

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 and health **information, education and** promotion **with a gender perspective**, patient rights and cross-border healthcare, and promote the excellence of medical and healthcare professionals;

Or. en

Amendment 549
Inese Vaidere

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 **addressing health inequalities and** strengthening health system's ability to foster disease prevention and health promotion, patient rights and **accessible** cross-border healthcare, and promote the excellence of medical and healthcare professionals;

Or. en

Amendment 550
Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, Andreas Glück, María Soraya Rodríguez Ramos

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 and health promotion, patient rights and cross-border healthcare, and promote the excellence of medical and healthcare professionals, ***their education, training and mobility***;

Or. en

Amendment 551

Nicolae Ștefănuță, Véronique Trillet-Lenoir

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 ***addressing health inequality***, 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;

Or. en

Amendment 552

Michèle Rivasi

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 and health promotion, patient rights and cross-border healthcare, and promote the excellence ***and cross-border recognition*** of medical and

healthcare professionals;

Or. en

Justification

It is important to also promote the cross-border recognition of medical and healthcare professionals.

Amendment 553

Margarita de la Pisa Carrión

Proposal for a regulation

Article 4 – paragraph 1 – point 5 a (new)

Text proposed by the Commission

Amendment

(5a) support and promote exchange programmes for healthcare professionals for all specialties and all levels with a view to sharing information and methodologies among countries, thereby benefiting from good experiences;

Or. es

Amendment 554

Tilly Metz, Michèle Rivasi

Proposal for a regulation

Article 4 – paragraph 1 – point 5 a (new)

Text proposed by the Commission

Amendment

(5a) Support actions to ensure the collection of safe blood, and blood components that facilitate a wide range of essential, often live-saving treatments; support actions to raise awareness on the importance of non-remunerated blood donation to this end,

Or. en

Amendment 555

Piernicola Pedicini, Eleonora Evi

Proposal for a regulation

Article 4 – paragraph 1 – point 5 a (new)

Text proposed by the Commission

Amendment

(5a) support actions aimed at primary prevention through the control of exposure to environmental risk factors;

Or. en

Amendment 556

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Christel Schaldemose

Proposal for a regulation

Article 4 – paragraph 1 – point 6

Text proposed by the Commission

Amendment

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, *and notably of cancer;*

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, *including cardiovascular diseases, cancer, chronic respiratory disease, diabetes and mental health conditions, with the aim of reducing the prevalence and improving the quality of life of patients, by providing a European strategic chronic disease framework to support Member States' action addressing the commercial determinants of health;*

Or. en

Amendment 557

Nicolae Ștefănuță, Véronique Trillet-Lenoir

Proposal for a regulation

Article 4 – paragraph 1 – point 6

Text proposed by the Commission

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer;

Amendment

(6) support action for the ***promotion of a healthy lifestyle***, surveillance, prevention, ***early*** diagnosis and treatment and care of non-communicable diseases, and notably of cancer ***and cardio-vascular diseases by providing a European strategic Chronic disease framework to support Member States action addressing the commercial determinants of health***;

Or. en

Amendment 558
Kateřina Konečná

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

Text proposed by the Commission

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer;

Amendment

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer, ***while addressing its synergies with other major non-communicable diseases such as neurological disorders and supporting the implementation of Europe’s Beating Cancer Plan***;

Or. en

Amendment 559
Cristian-Silviu Buşoi

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

Text proposed by the Commission

(6) support action for the surveillance, prevention, diagnosis and treatment and

Amendment

(6) support action for the surveillance, prevention, diagnosis and treatment and

care of non-communicable diseases, and notably of cancer;

care of non-communicable diseases, and notably of cancer, *while addressing its synergies with other major non-communicable diseases such as neurological disorders; the programme should support the implementation of Europe's Beating Cancer Plan;*

Or. en

Amendment 560
Cristian-Silviu Buşoi

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

Text proposed by the Commission

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer;

Amendment

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer *by providing a European strategies Chronic disease framework to support Member States action, while addressing its synergies with other major non-communicable diseases such as neurological disorders.*

Or. en

Amendment 561
Nathalie Colin-Oesterlé

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

Text proposed by the Commission

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, *and notably of* cancer;

Amendment

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, *including cancer, cardiovascular disease, chronic respiratory disease, diabetes and mental health conditions, with the aim of improving the quality of life of EU*

citizens;

Or. fr

Amendment 562

Michèle Rivasi

Proposal for a regulation

Article 4 – paragraph 1 – point 6

Text proposed by the Commission

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, **and** notably of cancer;

Amendment

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, notably of **major chronic diseases such as cardiovascular disease, cancer, chronic respiratory disease, diabetes and mental health conditions proportionate to their prevalence;**

Or. en

Justification

Cardiovascular diseases are the leading cause of mortality in the EU, before cancer. Action should be taken on all non-communicable diseases and in a proportionate manner.

Amendment 563

Biljana Borzan

Proposal for a regulation

Article 4 – paragraph 1 – point 6

Text proposed by the Commission

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer;

Amendment

(6) support action, **including policy,** for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer **by providing a European strategic Chronic disease framework to support Member States action addressing the commercial determinants of health;**

Amendment 564
Bartosz Arłukowicz, Jarosław Duda

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

Text proposed by the Commission

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer;

Amendment

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer, ***cardiovascular disease, chronic respiratory disease, diabetes, neurological disorders and mental health conditions***;

Or. pl

Amendment 565
Linea Sogaard-Lidell, Frédérique Ries, Jan Huitema

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

Text proposed by the Commission

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, ***and notably of cancer***;

Amendment

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, ***including cancer, obesity, cardiovascular disease, chronic respiratory disease, diabetes, neurologic disorder and mental health conditions***;

Or. en

Amendment 566
Mick Wallace

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

Text proposed by the Commission

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer;

Amendment

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of ***major chronic diseases such as cardiovascular disease, cancer, chronic respiratory disease, diabetes and mental health conditions;***

Or. en

Justification

The description of the main chronic diseases in the Programme should be consistent with the UN political declarations on NCDs, WHO NCD action plans and the Union's documents. The Programme must address major chronic diseases in a balanced and proportionate manner.

Amendment 567

César Luena

Proposal for a regulation

Article 4 – paragraph 1 – point 6

Text proposed by the Commission

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer;

Amendment

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, ***such as Structural Heart Diseases,*** and notably of cancer; ***the use of instruments such as Joint Actions to this end is strongly encouraged;***

Or. en

Amendment 568

Luisa Regimenti, Joëlle Mélin, Catherine Griset, Simona Baldassarre, Danilo Oscar Lancini, Lucia Vuolo, Silvia Sardone, Vincenzo Sofo, Marco Dreosto, Aurelia Beigneux

Proposal for a regulation

Article 4 – paragraph 1 – point 6

Text proposed by the Commission

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer;

Amendment

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer, ***while addressing its synergies with other major non-communicable diseases, such as neurological disorders;***

Or. it

Amendment 569

Rob Rooker

Proposal for a regulation

Article 4 – paragraph 1 – point 6

Text proposed by the Commission

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer;

Amendment

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of ***severe chronic diseases such as cardiovascular diseases, cancer, chronic respiratory diseases and diabetes;***

Or. nl

Amendment 570

Joanna Kopcińska

Proposal for a regulation

Article 4 – paragraph 1 – point 6

Text proposed by the Commission

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer;

Amendment

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, ***the early diagnosis of neurogenerative and other brain diseases,*** and notably of cancer;

Amendment 571
Marian-Jean Marinescu

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

Text proposed by the Commission

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer;

Amendment

(6) support action for the surveillance, prevention, ***early diagnosis by screening programmes*** diagnosis and treatment and care of non-communicable diseases, and notably of cancer;

Or. en

Amendment 572
Mairead McGuinness

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

Text proposed by the Commission

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer;

Amendment

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, ***including major chronic diseases*** and notably of cancer;

Or. en

Amendment 573
Frédérique Ries, Linea Søgaaard-Lidell

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

Text proposed by the Commission

Amendment

(6a) support actions to raise awareness

chronic neurological disorders, including migraine, to develop ad-hoc strategies to ensure integration patients at work and more broadly in society, as well as to ensure timely and quality diagnosis and access to available treatments;

Or. en

Amendment 574

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Christel Schaldemose, Mohammed Chahim, Sándor Rónai

Proposal for a regulation

Article 4 – paragraph 1 – point 6 a (new)

Text proposed by the Commission

Amendment

(6a) strengthen the programmes to fight against communicable diseases and health threats, as AMR, HIV/AIDS, tuberculosis, hepatitis, influenza, sexually transmitted infections among others, promoting healthy lifestyles, premature detection, access to treatment and long-life care;

Or. en

Amendment 575

Nicolae Ștefănuță, Véronique Trillet-Lenoir

Proposal for a regulation

Article 4 – paragraph 1 – point 6 a (new)

Text proposed by the Commission

Amendment

(6a) address the unmet needs of children and adolescents with cancer, and of survivors, through dedicated programmes and plans on Paediatric Cancer, fostering research and access to novel treatment;

Amendment 576
Aldo Patriciello

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

Text proposed by the Commission

Amendment

(6a) support action for the elimination of vaccine preventable cancers, such as HPV and Hepatitis B;

Amendment 577
Aldo Patriciello

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

Text proposed by the Commission

Amendment

(6b) support actions to raise awareness on migraine as a chronic neurological disorder and its health, societal and economic impact, to develop ad-hoc strategies to ensure integration of migraine patients at work and more broadly in society, as well as to ensure timely and quality diagnosis and access to available treatments;

Amendment 578
Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Mohammed Chahim

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

Text proposed by the Commission

Amendment

(7) foster and support the prudent and efficient use of medicines, and in particular of antimicrobials, and **more environmentally friendly production and disposal of medicines and** medical devices;

(7) foster and support the **informed,** prudent and efficient use of medicines, and in particular of antimicrobials, and **invest in the protection of the environment and sustainability in the whole value chain of all medicines, vaccines, medical devices and other medical products, from the production to the disposal, guaranteeing that an environmental risk assessment for such products is carried out;**

Or. en

Amendment 579

Michèle Rivasi

Proposal for a regulation

Article 4 – paragraph 1 – point 7

Text proposed by the Commission

Amendment

(7) foster and support the prudent and efficient use of medicines, and in particular of antimicrobials, **and** more environmentally friendly production and disposal of medicines and medical devices;

(7) foster and support the prudent and efficient use of medicines, and in particular of antimicrobials, **including by the use of non-antimicrobial treatment, the development of pharmaceuticals that are intrinsically less harmful for the environment,** more environmentally friendly production and **environmentally sound** disposal of medicines and medical devices;

Or. en

Justification

It is necessary to include the call of the Environment Committee for the development of pharmaceuticals that are intrinsically less harmful for the environment, as adopted in its motion for resolution on the strategic approach to pharmaceuticals in the environment.

Amendment 580

Michèle Rivasi

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 of Union health legislation and provide high-quality, comparable, and reliable, ***comprehensive and disaggregated data by gender and age and gender-specific*** 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 relevant policies;

Or. en

Justification

The collection of gender-disaggregated and gender-specific data is necessary to assess and address women's unmet medical needs. Reliable, compatible, comparable data on the status of women's health is essential to improve information to the public and develop appropriate strategies, policies and actions. The term "gender-specific" is important as simply disaggregating data is not sufficient to assess unmet medical needs that exclusively affect women (e.g. certain aspects sexual and reproductive health).

Amendment 581
Cristian-Silviu Buşoi

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 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, ***as well as dashboards with key metrics to measure progress and reducing inequalities, notably in cancer***;

Amendment 582
Traian Băsescu

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 of Union health legislation and provide high-quality, comparable and reliable data to underpin policy making and monitoring, promote the use of health impact assessments of relevant policies, *and introduce common vaccination rules at EU level to counter the risks associated with the inherent mobility within the Union;*

Or. ro

Amendment 583

Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, María Soraya Rodríguez Ramos

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, enforcement *and when necessary the revision* 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 *to evaluate their impacts on European citizen's health and well-being;*

Or. en

Amendment 584

Mick Wallace, Clare Daly

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 of Union health legislation and provide high-quality, comparable, reliable, **comprehensive and disaggregated data by gender and age and gender-specific** 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 relevant policies;

Or. en

Amendment 585

Jytte Guteland

Proposal for a regulation

Article 4 – paragraph 1 – point 8 a (new)

Text proposed by the Commission

Amendment

(8a) In line with the “One Health” approach and the objectives of the EU Biodiversity Strategy for 2030, support the development, implementation and enforcement of Union legislation to prevent health and biodiversity conservation risks originating from the cross-border and international trade in wild animals kept as pets;

Or. en

Amendment 586
Marian-Jean Marinescu

Proposal for a regulation
Article 4 – paragraph 1 – point 8 a (new)

Text proposed by the Commission

Amendment

(8a) Support the development and implementation of EU health-related legislation to develop fair pricing model for essential medicines, taking in account the public money contribution, the real costs of research & development and the added therapeutic value;

Or. en

Amendment 587
Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, María Soraya Rodríguez Ramos

Proposal for a regulation
Article 4 – paragraph 1 – point 8 a (new)

Text proposed by the Commission

Amendment

(8a) ensure healthy and safe workplaces across the Union and to support EU-OSHA's activities and analysis on occupational safety and health.

Or. en

Amendment 588
Marian-Jean Marinescu

Proposal for a regulation
Article 4 – paragraph 1 – point 8 b (new)

Text proposed by the Commission

Amendment

(8b) support the development and

implementation of an Union harmonized framework for a mechanism for national pricing and reimbursement systems in order to achieve a fair and sustainable pricing and procurement.

Or. en

Amendment 589

Christian Ehler

on behalf of the EPP Group

Dan Nica

on behalf of the S&D Group

Martina Dlabajová

on behalf of the Renew Group

Cristian-Silviu Buşoi

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, *the identification of health technologies meant to benefit from a Union assessment*, and scaling up networking through the *ERNs* and other transnational networks *in full synergy with Horizon Europe and its Missions and Partnerships*;

Or. en

Amendment 590

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Mohammed Chahim, Sándor Rónai

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, ***the identification of health technologies meant to benefit from a European assessment***, and scaling up networking through the European Reference Networks and other transnational networks ***aiming to increase the coverage of patients and the response to more diseases and health problems***;

Or. en

Amendment 591

Antoni Comín i Oliveres

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, and scaling up networking through the European Reference Networks and other transnational networks, ***as well as exchange good practices in order to make it easier for Member States to make the transition towards a healthcare model where aging and chronicity have gained relevance***;

Or. en

Amendment 592

Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, María Soraya Rodríguez Ramos

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, and scaling up networking through the European Reference Networks ***through their extension beyond rare diseases to complex to communicable and non-communicable diseases*** and other transnational networks;

Or. en

Amendment 593
Pascal Arimont, Cindy Franssen, Esther de Lange

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 ***as well as between neighbouring border regions***, 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;

Or. en

Amendment 594
Jessica Polfjärd

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

Or. en

Amendment 595
Kateřina Konečná

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, ***the identification of health technologies meant to benefit from a European assessment***, and scaling up networking through the European Reference Networks and other transnational networks;

Or. en

Amendment 596
Cristian-Silviu Buşoi

Proposal for a regulation
Article 4 – paragraph 1 – point 9 a (new)

Text proposed by the Commission

Amendment

(9a) support the creation of excellence networks in the field of communicable and non-communicable diseases to drive

forward the prevention, diagnosis and linkage to care, thus helping Europe to deliver on the UN SDGs. These networks should work in close cooperation with civil society and also collect much needed data and contribute to the European Health Data Space. This way, they will help monitor progress towards the fight and towards the elimination of these diseases in line with WHO and UN Goals;

Or. en

Amendment 597

Michèle Rivasi

Proposal for a regulation

Article 4 – paragraph 1 – point 9 a (new)

Text proposed by the Commission

Amendment

(9a) support the development of specific European diseases prevention and management guidelines in the area of both communicable and non-communicable diseases, such as cancer, paediatric cancer, cardiovascular diseases, neurodegenerative diseases, respiratory diseases and diabetes, by excellence networks;

Or. en

Justification

Like amendment 48 of the rapporteur, but with the addition of "prevention" into the guidelines.

Amendment 598

Nathalie Colin-Oesterlé

Proposal for a regulation

Article 4 – paragraph 1 – point 9 a (new)

Text proposed by the Commission

Amendment

(9a) Create one or more non-profit-making European pharmaceutical establishments of general interest to produce certain priority medicines that are important from a health and strategic point of view;

Or. fr

Amendment 599

César Luena

Proposal for a regulation

Article 4 – paragraph 1 – point 9 a (new)

Text proposed by the Commission

Amendment

(9a) support the prioritisation and implementation of harmonised plans to ensure that all European citizens have access to a heart health check to ensure that detection and treatment of Structural Heart Diseases contribute to more resilient health systems;

Or. en

Amendment 600

Marian-Jean Marinescu

Proposal for a regulation

Article 4 – paragraph 1 – point 9 a (new)

Text proposed by the Commission

Amendment

(9a) introduce evaluation indicators for the health European partnership activity so that public funds are spent both legally and efficiently;

Or. en

Amendment 601
Joanna Kopcińska

Proposal for a regulation
Article 4 – paragraph 1 – point 9 a (new)

Text proposed by the Commission

Amendment

(9 a) advance health literacy through specific programmes in areas such as health promotion, prevention and patient-centred care;

Or. en

Amendment 602
Nicolae Ștefănuță, Véronique Trillet-Lenoir

Proposal for a regulation
Article 4 – paragraph 1 – point 9 a (new)

Text proposed by the Commission

Amendment

(9a) support the creation of excellence networks in the field of communicable and non-communicable diseases;

Or. en

Amendment 603
Michèle Rivasi

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

Text proposed by the Commission

Amendment

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

(10) support the Union's contribution to international and global health initiatives, ***including support to global initiatives in favour of sexual and reproductive health and rights;***

Justification

The EU and its Member States have played a key role in promoting SRHR on the global stage. The EU must continue to speak up and support strong global, regional and national commitments in favour of SRHR in multilateral fora and in its political dialogue with partner countries. The EU4Health Programme should be a tool for the EU to support a progressive global health agenda which includes SRHR.

Amendment 604**Mick Wallace, Clare Daly****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 initiatives, ***including support to global initiatives in favour of sexual and reproductive health and rights;***

Or. en

Amendment 605

Chrysoula Zacharopoulou, Véronique Trillet-Lenoir, María Soraya Rodríguez Ramos, Karen Melchior, Sophia in 't Veld, Samira Rafaela, Hilde Vautmans, Susana Solís Pérez, Maria Noichl

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 initiatives, ***including access to sexual and reproductive health and services;***

Or. en

Amendment 606
Maria Spyraiki

Proposal for a regulation
Article 4 – paragraph 1 – point 10 a (new)

Text proposed by the Commission

Amendment

(10a) support actions aimed at developing and supporting an EU monitoring and early notification platform for shortages, based on EU harmonised data and national reporting systems;

Or. en

Amendment 607
Jessica Polfjärd

Proposal for a regulation
Article 4 – paragraph 1 – point 10 a (new)

Text proposed by the Commission

Amendment

(10a) ensure that the Union remains a world leader in research and innovation in health care;

Or. en

Amendment 608
Antoni Comín i Oliveres

Proposal for a regulation
Article 4 – paragraph 1 – point 10 a (new)

Text proposed by the Commission

Amendment

(10a) support policies that guarantee the principle "health in all policies";

Or. en

Amendment 609
Antoni Comín i Oliveres

Proposal for a regulation
Article 4 – paragraph 1 – point 10 b (new)

Text proposed by the Commission

Amendment

(10b) strengthen public sector participation in health research strategies, in coherence with the Horizon Europe programme, in order to reinforce the necessary resources so that all strategic health research that cannot be done without public support may be carried out;

Or. en

Amendment 610
Jessica Polfjärd

Proposal for a regulation
Article 4 – paragraph 1 – point 10 b (new)

Text proposed by the Commission

Amendment

(10b) ensure that the Union's health initiatives are people-centred and outcome-driven;

Or. en

Amendment 611
Jessica Polfjärd

Proposal for a regulation
Article 4 – paragraph 1 – point 10 c (new)

Text proposed by the Commission

Amendment

(10c) Support measures to eliminate vaccine preventable diseases;

Or. en

Amendment 612
Aldo Patriciello

Proposal for a regulation
Article 4 – paragraph 1 – point 10 a (new)

Text proposed by the Commission

Amendment

(10a) support actions aimed at creating and developing a EU Platform for shortages, based on one harmonised data-collection model and national reporting systems of shortages interoperability, including the full implementation of an effective EU telematics infrastructure that will link data on medicine and supply chain data through interconnection of SPOR and FMD system;

Or. en

Amendment 613
Aldo Patriciello

Proposal for a regulation
Article 4 – paragraph 1 – point 10 – point a (new)

Text proposed by the Commission

Amendment

(a) support actions aimed at modernise and digitalise the EU regulatory Network at European and national level;

Or. en

Amendment 614
Marian-Jean Marinescu

Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission

Amendment

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

2. The amount referred to in paragraph 1 may be used **also** 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.

Or. en

Amendment 615

Rob Rooker

Proposal for a regulation

Article 7 – paragraph 1 – point 2

Text proposed by the Commission

Amendment

(2) *Acceding countries, candidate countries and potential candidates, in accordance with the general principles and general terms and conditions for the participation of those countries in Union programmes established in the respective framework agreements and Association Council decisions, or similar agreements, and in accordance with the specific conditions laid down in agreements between the Union and those countries;*

deleted

Or. nl

Amendment 616

Rob Rooker

Proposal for a regulation

Article 7 – paragraph 1 – point 3

Text proposed by the Commission

Amendment

(3) *Countries covered by the European Neighbourhood Policy, in*

deleted

accordance with the general principles and general terms and conditions for the participation of those countries in Union programmes established in the respective framework agreements and association council decisions, or similar agreements, and in accordance with the specific conditions laid down in agreements between the Union and those countries;

Or. nl

Amendment 617
Rob Rooker

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

Text proposed by the Commission

Amendment

(4) *Third countries, in accordance with the conditions laid down in a specific agreement covering the participation of the third country to any programme, provided that the agreement:*

deleted

(i) *ensures a fair balance as regards the contributions and benefits of the third country participating in the Union programmes;*

(ii) *lays down the conditions of participation in the programmes, including the calculation of financial contributions to individual programmes and their administrative costs. These contributions shall constitute assigned revenues in accordance with Article 21(5) of Regulation (EU, Euratom 2018/1046);*

(iii) *does not confer to the third country a decisional power;*

(iv) *guarantees the rights of the Union to ensure sound financial management and to protect its financial interests.*

Or. nl

Amendment 618
Joanna Kopcińska

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission

1. The Programme shall be implemented in direct management in accordance with Regulation (EU, Euratom) 2018/1046 or in indirect management with the bodies referred to in Article 62(1) (c) of Regulation (EU, Euratom) 2018/1046.

Amendment

1. The Programme shall be implemented in direct management in accordance with Regulation (EU, Euratom) 2018/1046 or in indirect management with the bodies referred to in Article 62(1) (c) of Regulation (EU, Euratom) 2018/1046, ***to ensure there is no overlap or duplication with other funding programmes at the Union level.***

Or. en

Amendment 619
Kateřina Konečná

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

Text proposed by the Commission

Amendment

4a. Where implementation and monitoring of the programme is carried out by civil society, including participation in institutional structures, and while recognising the specific contribution of patients and their organisations to the programme's objectives, a sustainable funding scheme to ensure the fulfilment of these roles shall be guaranteed.

Or. en

Justification

Funding to civil society broadly should be included in the programme to ensure a strong civil society voice. Patients' organisations and broader civil society will contribute to the

implementation of the programme in many ways. In addition, Patients' organisations and broader civil society will play an important role in the design and monitoring of the health programme and European legislation implementation, conveying both their communities' perspectives into EU policy-making and information about EU policy-making to their communities, thus fostering a two-way dialogue.

Amendment 620
Marian-Jean Marinescu

Proposal for a regulation
Article 9 a (new)

Text proposed by the Commission

Amendment

Article 9a

Award criteria

The award criteria shall be defined in the work programmes referred to in Article 18 and in the calls for proposals taking into account, to the extent applicable, the following elements:

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

Or. en

Amendment 621
Kateřina Konečná

Proposal for a regulation
Article 9 a (new)

Text proposed by the Commission

Amendment

Article 9a

Beneficiaries eligible for grants

1. Grants for the functioning of patient organisations at Union level may be awarded to European patient organisations which comply with all of the following conditions:

(a) they are non-governmental, non-profit-making, and have as their primary objectives and activities the promotion and protection of the health, and representation of the community they represent in the European-level policy processes;

(b) they are mandated to represent the interests of patients at Union level by organisations in at three fourths of the Member States that are representative, in accordance with national rules or practice, of patient organisations, and that are active at regional or national level.

Or. en

Justification

There is a large number of arguments why civil society organisation should be funded with public funds. The European Economic and Social Committee has given an overview of many of them and calls for more EU funding for civil society organisations.

Amendment 622
Marian-Jean Marinescu

Proposal for a regulation
Article 9 b (new)

Text proposed by the Commission

Amendment

Article 9b

Co-financing rate

The amount of Union financial assistance shall not exceed 85 % of the total eligible cost.

Or. en

Amendment 623

Marian-Jean Marinescu

Proposal for a regulation

Article 11 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The total amount used for blending operations shall not be higher than 10 % of the financial envelope specified in Article 5.

Or. en

Amendment 624

Nicolae Ștefănuță, Véronique Trillet-Lenoir

Proposal for a regulation

Article 12 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

A reliable and efficient mechanism shall be created in order to avoid any duplication of funding and to ensure synergies between the different Union programmes and policies that are pursuing health objectives. All the data on funding operations and actions financed under different Union programmes and funds shall be centralised under this mechanism. It shall follow the principles

of transparency and accountability and shall allow better monitoring and evaluation of actions pursuing health objectives.

Or. en

Amendment 625
Marian-Jean Marinescu

Proposal for a regulation
Article 14 – paragraph 1 – point a – introductory part

Text proposed by the Commission

Amendment

(a) legal entities established in any of the following countries:

(a) legal entities **shall be** established in any of the following countries:

Or. en

Amendment 626
Rob Rooken

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

Text proposed by the Commission

Amendment

(ii) a third country associated to the Programme;

deleted

Or. nl

Amendment 627
Rob Rooken

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

Text proposed by the Commission

Amendment

(iii) a third country listed in the work programme under the conditions specified

deleted

in paragraph 2 and 3;

Or. nl

Amendment 628

Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, María Soraya Rodríguez Ramos

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 international organisation ***such as public authorities, public sector bodies, health establishments, research institutes, universities and higher education establishments, patient associations etc.;***

Or. en

Amendment 629

Rob Rooker

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. nl

Amendment 630

Pascal Arimont, Cindy Franssen

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 having a clear Union added value co-financed by the **local, regional and 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.

Or. en

Amendment 631
Pascal Arimont, Cindy Franssen, Esther de Lange

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 may be awarded without a call for proposals to European Reference Networks. Direct grants may also be awarded to other transnational networks **or Interreg programmes** set out in accordance with EU rules.

Or. en

Amendment 632
Kateřina Konečná

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

Text proposed by the Commission

Amendment

6a. Adequate funding shall be ensured to consolidate and expand the ERN model of cross-border healthcare by securing the provision of a range of clinical services through different channels, including online second opinion and specialist advice for patients on treatment and management and virtual “online out-patient” clinics.

Or. en

Justification

Consolidating the provision of cross-border healthcare services by the ERNs will require financial resources to develop the organisational aspects (clinical governance, pricing and reimbursement models), provide the technical means and address the privacy and ethical aspects linked to the provision of routine cross-border healthcare by online means.

Amendment 633
Frédérique Ries

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

Text proposed by the Commission

Amendment

6a. Adequate funding shall be ensured to consolidate and expand the ERN model of cross-border healthcare by securing the provision of a range of clinical services through different channels, including online second opinion and specialist advice for patients on treatment and virtual “online out-patient” clinics.

Or. en

Amendment 634
Marian-Jean Marinescu

Proposal for a regulation
Article 14 – paragraph 7 – point ii

Text proposed by the Commission

(ii) they work in the public health area, pursue at least one of the specific objectives of the Programme and ***play an effective role at Union level;***

Amendment

(ii) they work in the public health area, pursue at least one of the specific objectives of the Programme and ***their proposed project has a high added value;***

Or. en

Amendment 635
Marian-Jean Marinescu

Proposal for a regulation
Article 14 – paragraph 7 – point iii

Text proposed by the Commission

(iii) they are ***active at Union level and in at least half of the Member States, and*** have a balanced geographical coverage of the Union.

Amendment

(iii) they are ***members of a health-related European or international association,*** have a balanced geographical coverage of the Union ***and have actively worked during the last 3 years for reaching Union`s objectives in health sector.***

Or. en

Amendment 636
Marian-Jean Marinescu

Proposal for a regulation
Article 14 – paragraph 7 a (new)

Text proposed by the Commission

Amendment

7a. The total amount of direct grants shall not be higher than 100.000.000 EURO.

Or. en

Amendment 637
Kateřina Konečná

Proposal for a regulation
Article 16 – paragraph 1

Text proposed by the Commission

The Commission shall consult the health authorities of the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases on the work plans established for the Programme and its priorities and strategic orientations and its implementation.

Amendment

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, ***as well as relevant Union decentralised agencies, the EU4Health Steering Board and other relevant stakeholders, such as representatives of civil society organisations, in particular patients' organisations,*** on the work plans established for the Programme and its priorities and strategic orientations and its implementation. ***Promoting synergies between European funds and national funds/resources shall be considered to ensure long-term effectiveness and sustainability of actions.***

Or. en

Justification

In addition to the complementarity with other EU funding instruments, promoting synergies between European health funds and national health funds and resources to ensure long-term effectiveness and sustainability of actions themselves, in our view, also requires serious thought, consultation and coordination.

Amendment 638
Cristian-Silviu Buşoi

Proposal for a regulation
Article 16 – paragraph 1

Text proposed by the Commission

The Commission shall consult the health authorities of the Member States in the Steering Group on Health Promotion,

Amendment

The Commission shall consult the health authorities of the Member States in the Steering Group on Health Promotion,

Disease Prevention and Management of Non-Communicable Diseases on the work plans established for the Programme and its priorities and strategic orientations and its implementation.

Disease Prevention and Management of Non-Communicable Diseases, *as well as relevant Union decentralised agencies, the EU4Health Steering Board and other relevant stakeholders, such as representatives of civil society organisations, in particular patients' organisations*, on the work plans established for the Programme and its priorities and strategic orientations and its implementation. *Promoting synergies between European funds and national funds/resources shall be considered to ensure long-term effectiveness and sustainability of actions.*

Or. en

Amendment 639
Joanna Kopcińska

Proposal for a regulation
Article 16 – paragraph 1

Text proposed by the Commission

The Commission shall consult the health authorities of the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases on the work plans established for the Programme and its priorities and strategic orientations and its implementation.

Amendment

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, *as well as relevant Union decentralised agencies and other relevant stakeholders, such as representatives of civil society organisations, and in particular patients' organisations*, on the work plans established for the Programme and its priorities and strategic orientations and its implementation.

Or. en

Amendment 640

Luisa Regimenti, Joëlle Mélin, Catherine Griset, Simona Baldassarre, Danilo Oscar Lancini, Lucia Vuolo, Silvia Sardone, Vincenzo Sofo, Marco Dreosto, Aurelia Beigneux

Proposal for a regulation
Article 16 – paragraph 1

Text proposed by the Commission

The Commission shall consult the health authorities of the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases on the work plans established for the Programme and its priorities and strategic orientations and its implementation.

Amendment

The Commission shall consult the health authorities of the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases on the work plans established for the Programme and its priorities and strategic orientations and its implementation. ***Consideration should be given to promoting synergies between European funds and national funds/resources to ensure long-term effectiveness and sustainability of the actions.***

Or. it

Amendment 641
Piernicola Pedicini, Eleonora Evi

Proposal for a regulation
Article 16 – paragraph 1

Text proposed by the Commission

The Commission shall consult the health authorities of the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases on the work plans established for the Programme and its priorities and strategic orientations and its implementation.

Amendment

The Commission shall consult the health authorities of the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases on the work plans established for the Programme and its priorities and strategic orientations and its implementation. ***The involvement of civil society representatives, including patient representatives, shall also be ensured.***

Or. en

Amendment 642
Frédérique Ries

Proposal for a regulation
Article 16 – paragraph 1

Text proposed by the Commission

The Commission shall consult the health authorities of the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases on the work plans established for the Programme and its priorities and strategic orientations and its implementation.

Amendment

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, ***as well as representatives of civil society organisations, including patients’ organisations,*** on the work plans established for the Programme and its priorities and strategic orientations and its implementation.

Or. en

Amendment 643
Nicolae Ștefănuță, Véronique Trillet-Lenoir

Proposal for a regulation
Article 16 – paragraph 1

Text proposed by the Commission

The Commission shall consult the health authorities of the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases on the work ***plans*** established for the Programme and its priorities and strategic orientations and its implementation.

Amendment

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, ***the Union agencies, the external independent experts*** on the work ***programmes*** established for the Programme and its priorities and strategic orientations and its implementation.

Or. en

Amendment 644
Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie

Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller,
Susana Solís Pérez, María Soraya Rodríguez Ramos

Proposal for a regulation
Article 16 – paragraph 1

Text proposed by the Commission

The Commission shall consult the health authorities of the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases on the **work plans** established for the Programme and its priorities and strategic orientations and its implementation.

Amendment

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, **the EU agencies** on the **annual work programmes** established for the Programme and its priorities and strategic orientations and its implementation.

Or. en

Amendment 645
Marian-Jean Marinescu

Proposal for a regulation
Article 17 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 646
Marian-Jean Marinescu

Proposal for a regulation
Article 17 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The Commission shall, by means of a delegated act, lay down detailed rules regarding the spending of the resources mentioned in Article 6. The delegated act

shall be adopted in accordance with Article 24 and shall include detailed rules regarding the rules from this Regulation and Regulation [European Union Recovery Instrument] to be applied, the implementation through annual work programmes and the reimbursement plan.

Or. en

Amendment 647
Marian-Jean Marinescu

Proposal for a regulation
Article 18 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 648
Marian-Jean Marinescu

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

Text proposed by the Commission

Amendment

The work programmes shall be adopted by the Commission by means of a delegated act. Those delegated acts shall be adopted in accordance Article 24 of this Regulation.

Or. en

Amendment 649

Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, María Soraya Rodríguez Ramos

Proposal for a regulation

Article 19 – paragraph 1

Text proposed by the Commission

1. Indicators to **report on progress** of the Programme towards the achievement of the general and specific objectives set out in Articles 3 and 4 are set out in Annex II.

Amendment

1. Indicators to **assess the implementation of the actions** of the Programme towards the achievement of the general and specific objectives set out in Articles 3 and 4 are set out in Annex II.

Or. en

Amendment 650

Nathalie Colin-Oesterlé

Proposal for a regulation

Article 20 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Stress tests shall be introduced to assess the resilience of health systems in emergencies with a view to providing an effective means of countering shortages in the event of pandemics and identifying structural risk factors that create shortages.

Or. fr

Amendment 651

Rob Rooker

Proposal for a regulation

Article 20 – paragraph 2

Text proposed by the Commission

Amendment

2. The interim evaluation of the

2. The interim evaluation of the

Programme shall be performed once there is sufficient information available about their implementation, but not later than four years after the start of the implementation.

Programme shall be performed once there is sufficient information available about their implementation, but not later than four years after the start of the implementation ***and before a decision is taken on future work programmes. The findings of the interim evaluation shall be made public.***

Or. nl

Amendment 652

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

Proposal for a regulation Article 20 – paragraph 2

Text proposed by the Commission

2. The interim evaluation of the Programme shall be performed once there is sufficient information available about their implementation, but not later than four years after the start of the implementation.

Amendment

2. The interim evaluation of the Programme shall be performed once there is sufficient information available about their implementation, but not later than four years after the start of the implementation ***and before any decision is taken on future work programmes. The results of the interim evaluation shall be made public.***

Or. en

Amendment 653

Mick Wallace

Proposal for a regulation Article 20 – paragraph 2

Text proposed by the Commission

2. The interim evaluation of the Programme shall be performed once there is sufficient information available about their implementation, but not later than

Amendment

2. The interim evaluation of the Programme shall be performed once there is sufficient information available about their implementation, but not later than

four years after the start of the implementation.

four years after the start of the implementation ***and before any decision is taken on future work programmes. The results of the interim evaluation shall be made public.***

Or. en

Justification

Objectives and actions listed in the current Regulation reflect some of the challenges the COVID-19 pandemic has revealed and political commitments prior to the pandemic. The programme needs to be dynamic, flexible and adaptable to new contexts and serve the Union's and Member States' needs in a proportionate manner. EU4Health evaluation should be aligned with the evaluation practice agreed for missions under Horizon Europe. Findings should provide evidence for future orientations of EU4Health priorities and actions.

Amendment 654

Frédérique Ries

Proposal for a regulation

Article 20 – paragraph 2

Text proposed by the Commission

2. The interim evaluation of the Programme shall be performed once there is sufficient information available about their implementation, but not later than four years after the start of the implementation.

Amendment

2. The interim evaluation of the Programme shall be performed once there is sufficient information available about their implementation, but not later than four years after the start of the implementation ***and before any decision is taken on future work programmes. The results of the interim evaluation shall be made public.***

Or. en

Amendment 655

Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, Linea Sogaard-Lidell, María Soraya Rodríguez Ramos

Proposal for a regulation

Article 20 – paragraph 2

Text proposed by the Commission

2. The interim evaluation of the Programme shall be performed once there is sufficient information available about their implementation, but not later than four years after the start of the implementation.

Amendment

2. The interim evaluation of the Programme shall be performed **and submitted to the European Parliament and to the Council** once there is sufficient information available about their implementation, but not later than four years after the start of the implementation.

Or. en

Amendment 656

Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, Linea Sogaard-Lidell, María Soraya Rodríguez Ramos

**Proposal for a regulation
Article 20 – paragraph 3**

Text proposed by the Commission

3. At the end of the implementation period, but no later than four years after the end of the period specified in Article 1, a final evaluation shall be carried out by the Commission.

Amendment

3. At the end of the implementation period, but no later than four years after the end of the period specified in Article 1, a final evaluation shall be carried out by the Commission **and submitted to the European Parliament and to the Council.**

Or. en

Amendment 657

Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, Linea Sogaard-Lidell, María Soraya Rodríguez Ramos

**Proposal for a regulation
Article 20 – paragraph 4**

Text proposed by the Commission

4. The Commission shall communicate the conclusions of the evaluations accompanied by its

Amendment

4. The Commission shall **publish and** communicate the conclusions of the evaluations accompanied by its

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

observations **and shall present them** to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

Or. en

Amendment 658

Nicolae Ștefănuță, Véronique Trillet-Lenoir

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) Critical health infrastructure relevant in the context of health crises, tools, structures, processes, production, **storage** and laboratory capacity, including tools for surveillance, modelling, forecast, prevention and management of outbreaks, **in particular with investments in the least resilient national health systems;**

Or. en

Amendment 659

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

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) 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 **and relevant medical products.**

Or. en

Amendment 660

Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, María Soraya Rodríguez Ramos

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) Critical health infrastructure 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.

Or. en

Amendment 661

Cristian-Silviu Bușoi

Proposal for a regulation

Annex I – point a – point ii a (new)

Text proposed by the Commission

Amendment

(iia) Development of a single pan-European digital mechanism for better reporting, notifying and monitoring of potential shortages, by starting from supporting the implementation of a European common data repository and interconnection between regulatory information on medicines, contained in SPOR, with supply chain data, in FMD system, in all Member States;

Or. en

Amendment 662

Aldo Patriciello

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

Text proposed by the Commission

Amendment

(ii) Development of a single pan-European digital mechanism for better reporting, notifying and monitoring of potential shortages, by starting from supporting the implementation of a European common data repository and interconnection between regulatory information on medicines, contained in SPOR, with supply chain data, in FMD system, in all Member States;

Or. en

Amendment 663
Adam Jarubas

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

Text proposed by the Commission

Amendment

(ii) Development of a single pan-European digital mechanism for better reporting, notifying and monitoring of potential shortages, by starting from supporting the implementation of a European common data repository and interconnection between regulatory information on medicines, contained in SPOR, with supply chain data, in FMD system, in all Member States;

Or. en

Amendment 664
Michèle Rivasi

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

Text proposed by the Commission

Amendment

(iia) coordination of a collaborative and open approach in the field of research and innovation, driving research towards outcomes including needed medicines, vaccines, medical devices and equipment;

Or. en

Justification

The EU needs to invest into a collaborative and open research that satisfies public needs.

Amendment 665

Nicolae Ștefănuță, Véronique Trillet-Lenoir

Proposal for a regulation

Annex I – point a – point ii a (new)

Text proposed by the Commission

Amendment

(iia) Support the building of hospitals in the less developed regions of the Union; the EU4Health Programme should participate in synergy and complementarity with the funds from the cohesion policy;

Or. en

Amendment 666

Luisa Regimenti, Joëlle Mélin, Catherine Griset, Simona Baldassarre, Danilo Oscar Lancini, Lucia Vuolo, Silvia Sardone, Vincenzo Sofo, Marco Dreosto, Aurelia Beigneux

Proposal for a regulation

Annex I – point a – point ii a (new)

Text proposed by the Commission

Amendment

(iia.) Local production of medicinal plants in the Member States;

Or. it

Amendment 667

Nicolae Ștefănuță, Véronique Trillet-Lenoir

Proposal for a regulation

Annex I – point a – point ii b (new)

Text proposed by the Commission

Amendment

(iib) Strengthening EU institutions, notably EMA and ECDC, to play a bigger role in managing response to cross-border health crises and preventing medicine and medical devices shortages.

Or. en

Amendment 668

Luisa Regimenti, Joëlle Mélin, Catherine Griset, Simona Baldassarre, Danilo Oscar Lancini, Lucia Vuolo, Silvia Sardone, Vincenzo Sofo, Marco Dreosto, Aurelia Beigneux

Proposal for a regulation

Annex I – point a – point ii b (new)

Text proposed by the Commission

Amendment

(iib.) Production of active ingredients and generics within the European Union to reduce the Member States' dependence on certain third countries.

Or. it

Amendment 669

Véronique Trillet-Lenoir, Stéphane Bijoux

Proposal for a regulation

Annex I – point b

Text proposed by the Commission

Amendment

(b) Transfer, adaptation and roll-out of

(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.

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.

Or. fr

Amendment 670

Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, María Soraya Rodríguez Ramos

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, and country-specific tailor made support to countries, or groups of countries *or regions*, with the highest needs, through the funding of specific projects including twinning, expert advice and peer support.

Or. en

Amendment 671

Aldo Patriciello

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,

Amendment

(i) Surveys, studies, *centralized and accessible* collection of data and statistics, methodologies, classifications,

indicators, knowledge brokering and **benchmark** exercises;

microsimulations, **pilots**, indicators, knowledge brokering and **bench mark** exercises;

Or. en

Amendment 672
Adam Jarubas

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, **centralized and accessible** collection of data and statistics, methodologies, classifications, microsimulations, **pilots**, indicators, knowledge brokering and benchmark exercises;

Or. en

Amendment 673
Danilo Oscar Lancini

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, **centralized and accessible** collection of data and statistics, methodologies, classifications, microsimulations, **pilots**, indicators, knowledge brokering and benchmark exercises;

Or. en

Amendment 674
Cristian-Silviu Buşoi

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, **centralized and accessible** collection of data and statistics, methodologies, classifications, microsimulations, **pilots**, indicators, knowledge brokering and benchmark exercises;

Or. en

Amendment 675
Nathalie Colin-Oesterlé

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 **centralised and accessible** data and statistics, methodologies, classifications, microsimulations, indicators, knowledge brokering and benchmark exercises;

Or. fr

Amendment 676
César Luena

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 data and statistics, methodologies, classifications, microsimulations, **pilots**, indicators, knowledge brokering and benchmark exercises;

Or. en

Amendment 677
Cristian-Silviu Buşoi

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 all relevant stakeholders***, providing advice, ***evaluation***, data and information to support health policy development and implementation; ***such expert groups and panels should include representatives of patients and other relevant civil society organisations***;

Or. en

Amendment 678
Michèle Rivasi

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 providing advice, data and information to support health policy development and implementation; ***such expert groups and panels shall include independent patient organisations and other relevant independent civil society organisations***;

Or. en

Amendment 679
Kateřina Konečná

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, providing advice, data and information to support health policy development and implementation; ***such expert groups and panels shall include representatives of patients and other relevant civil society organisations;***

Or. en

Justification

Patients' organisations are connected to their grass-roots communities and can support healthcare services and governments in developing adequate solutions for patients' optimal access to care. Patients' organisations channel the voice of patients by representing their interests coherently, helping policymakers understand the lived experience and enhancing the relevance of policymaking. They also provide services, education, information and capacity-building.

Amendment 680

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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 providing advice, data and information to support health policy development and implementation, ***including the follow-up evaluation of the implementation of health policies;***

Or. en

Amendment 681

Nathalie Colin-Oesterlé

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, ***incorporating all of the relevant stakeholders***, providing advice, ***evaluations***, data and information to support health policy development and implementation;

Or. fr

Amendment 682
Aldo Patriciello

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 all relevant stakeholders***, providing advice, ***evaluation***, data and information to support ***the*** health policy development and implementation;

Or. en

Amendment 683
Danilo Oscar Lancini

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 all relevant stakeholders***, providing advice, ***evaluation***, data and information to support health policy development and implementation;

Or. en

Amendment 684
Adam Jarubas

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 all relevant stakeholders***, providing advice, ***evaluation***, data and information to support health policy development and implementation;

Or. en

Amendment 685
Maria Spyra

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 providing advice, data and information to support ***and evaluate*** health policy development and implementation;

Or. en

Amendment 686
Aldo Patriciello

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

Text proposed by the Commission

Amendment

(iiia) Setting up and management of a High Level Pharmaceuticals Forum at political level composed of authorities and relevant health care stakeholders to define

priorities and concrete measures to be implemented at technical level;

Or. en

Amendment 687
Frédérique Ries

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

Text proposed by the Commission

Amendment

(iiiia) Setting up and management of a High Level Pharmaceuticals Forum at political level composed of authorities and relevant healthcare stakeholders to define priorities and concrete measures to be implemented at technical level;

Or. en

Amendment 688
Adam Jarubas

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

Text proposed by the Commission

Amendment

(iiiia) Setting up and management of a High Level Pharmaceuticals Forum at political level composed of authorities and relevant healthcare stakeholders to define priorities and concrete measures to be implemented at technical level;

Or. en

Amendment 689
Danilo Oscar Lancini

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

Text proposed by the Commission

Amendment

(iii a) Setting up and management of a High Level Pharmaceuticals Forum at political level composed of authorities and relevant healthcare stakeholders to define priorities and concrete measures to be implemented at technical level;

Or. en

Amendment 690
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

(iiia) Setting up and management of a High Level Pharmaceuticals Forum at political level composed of authorities and relevant health stakeholders to define priorities and concrete measures to be implemented at technical level;

Or. en

Amendment 691
Nathalie Colin-Oesterlé

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

Text proposed by the Commission

Amendment

(iiia.) The creation and management of a policy-oriented Pharmaceutical Forum comprising health authorities and stakeholders, with a view to defining specific priorities and measures to be implemented at a technical level;

Amendment 692
Maria Spyra

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

Text proposed by the Commission

(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

(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", ***as well as the Expert Group on "Health Systems Performance Assessment"***.

Or. en

Amendment 693
César Luena

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

Text proposed by the Commission

(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

(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" ***and on "Healthcare systems performance"***.

Or. en

Amendment 694
Danilo Oscar Lancini

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

Text proposed by the Commission

(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

(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" ***and on "Healthcare systems performance"***.

Or. en

Amendment 695
Cristian-Silviu Buşoi

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

Text proposed by the Commission

(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

(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" ***and on "Healthcare systems performance"***.

Or. en

Amendment 696
Adam Jarubas

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

Text proposed by the Commission

(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

(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" ***and on "Healthcare systems performance"***.

Or. en

Amendment 697
Aldo Patriciello

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

Text proposed by the Commission

(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

(iv) Studies and analysis, and scientific advice to support policymaking, and support to the scientific committees on "Consumer Safety", on "Health, Environmental and Emerging Risks" **and on "Health care systems performance"**

Or. en

Amendment 698
Nathalie Colin-Oesterlé

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

Text proposed by the Commission

(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

(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', **and the Expert Group on Health Systems Performance Assessment.**

Or. fr

Amendment 699
Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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

Text proposed by the Commission

Amendment

(iva) Development and operation of databases and digital tools and their interoperability of health data, including where appropriate with other sensing technologies, such as space-based technology and to support access to and analysis of data from real world healthcare settings; support the implementation of artificial intelligence and other tools in order to improve the quality of health data;

Or. en

Amendment 700

Piernicola Pedicini, Eleonora Evi

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 and implementation of Union health legislation and action, ***and of Union environmental legislation and its impact on public health***, in particular through support to:

Or. en

Amendment 701

Cristian-Silviu Buşoi

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) ***Evaluation***, development and implementation of Union health legislation and action ***for the protection and promotion of health***, in particular through

support to:

Or. en

Amendment 702

Nicolae Ștefănuță, Véronique Trillet-Lenoir

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 and implementation of Union health legislation and action, **for the protection and promotion of health**, in particular through support to:

Or. en

Amendment 703

Adam Jarubas

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) **Evaluation**, development and implementation of Union health legislation and action, in particular through support to:

Or. en

Amendment 704

Danilo Oscar Lancini

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

Amendment

(d) **Evaluation**, development and implementation of Union health legislation

particular through support to:

and action, in particular through support to:

Or. en

Amendment 705
Aldo Patriciello

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) **Evaluation**, development and implementation of Union health legislation and action, in particular through support to:

Or. en

Amendment 706
Nathalie Colin-Oesterlé

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) **Evaluation**, development and implementation of Union health legislation and action, in particular through support to:

Or. fr

Amendment 707
Aldo Patriciello

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**

Amendment

(i) Implementation, enforcement, monitoring of Union health legislation, **including Pharmaco vigilance legislation**,

implementation of legal requirements;

and relative actions; and technical support to *an harmonised* implementation of legal *and operational* requirements *across Member States* **Creation of a central repository for medicines in Europe and modernisation of Regulatory network**;

Or. en

Amendment 708
Cristian-Silviu Buşoi

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) **Development**, implementation, enforcement, monitoring of Union health legislation **including Pharmacovigilance legislation, and relative action for the protection and promotion of health**; and technical support to *an harmonised* implementation of legal *and operational* requirements **across Member States**;

Or. en

Amendment 709
César Luena

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, **including Pharmacovigilance legislation**, and action; and technical support to the implementation of legal *and operational* requirements **across Member States**;

Or. en

Amendment 710

Piernicola Pedicini, Eleonora Evi

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, ***and of Union environmental legislation and its impact on public health***; and technical support to the implementation of legal requirements;

Or. en

Amendment 711

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

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 ***for the protection and promotion of health***; and technical support to the implementation of legal requirements;

Or. en

Amendment 712

Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, María Soraya Rodríguez Ramos

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 **and improvement** of Union health legislation and action and technical support to the implementation of legal requirements;

Or. en

Amendment 713

Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, Andreas Glück, María Soraya Rodríguez Ramos

Proposal for a regulation

Annex I – point d – point i a (new)

Text proposed by the Commission

Amendment

(ia) Strengthening of European Health agencies namely the European Centre for Disease Prevention and Control Centre(ECDC), the European Medicines Agency (EMA), the European Food Safety Authority (EFSA), European Chemicals Agency (ECHA) and European Agency for Safety and Health at Work(EU-OSHA).

Or. en

Amendment 714

Marian-Jean Marinescu

Proposal for a regulation

Annex I – point d – point i a (new)

Text proposed by the Commission

Amendment

(ia) development of a fair pricing model for essential medicines, taking in account the public money contribution, the real costs of research & development

and the added therapeutic value;

Or. en

Amendment 715

Marian-Jean Marinescu

Proposal for a regulation

Annex I – point d – point i b (new)

Text proposed by the Commission

Amendment

(ib) development of an harmonized framework for a mechanism for national pricing and reimbursement systems

Or. en

Amendment 716

Christian Ehler

on behalf of the EPP Group

Dan Nica

on behalf of the S&D Group

Martina Dlabajová

on behalf of the Renew Group

Cristian-Silviu Buşoi

Proposal for a regulation

Annex I – point d – point iv

Text proposed by the Commission

Amendment

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

(iv) Development and operation of databases and digital tools and their interoperability, including where appropriate with other sensing technologies, such as space-based, ***and to support cross-border exchange, access to and analysis of data from real world healthcare settings, including within the framework of the European health data space and the EMVS (European Medicines Verification System) data repositories at aggregated level as a tool to oversee shortages while ensuring respect***

of personal data in line with GDPR and ensuring appropriate cyber security solutions are deployed;

Or. en

Amendment 717
Cristian-Silviu Buşoi

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 project such as creation of a central common repository for all medicines in Europe and SPOR implementation*, including where appropriate with other sensing technologies, such as space-based;

Or. en

Amendment 718
Adam Jarubas

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 project such as creation of a central common repository for all medicines in Europe and SPOR implementation*, including where appropriate with other sensing technologies, such as space-based;

Or. en

Amendment 719

Nathalie Colin-Oesterlé

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 **projects already established, such as the centralised common repository for all medicines in Europe and the SPOR portal**, where appropriate with other sensing technologies, such as space-based;

Or. fr

Amendment 720

Danilo Oscar Lancini

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 and operation **and maintenance** of databases and digital tools and their interoperability, including **already established project such as creation of a central common repository for all medicines in Europe and SPOR implementation**, where appropriate with other sensing technologies, such as space-based;

Or. en

Amendment 721

Aldo Patriciello

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 project such as creation of a central common repository for all medicines in Europe and SPOR implementation, including** where appropriate with other;

Or. en

Amendment 722
Nathalie Colin-Oesterlé

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. fr

Amendment 723
Adam Jarubas

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 724
Cristian-Silviu Buşoi

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 725
Aldo Patriciello

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 726
Véronique Trillet-Lenoir, Nicolae Ştefănuţă, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, María Soraya Rodríguez Ramos

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

Text proposed by the Commission

(viii) Networking by non-governmental organisations and their involvement in projects covered by the Programme;

Amendment

(viii) Networking by non-governmental organisations and their involvement in projects covered by the Programme **and the evaluation of the implementation of the programme**;

Or. en

Amendment 727

Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, María Soraya Rodríguez Ramos

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

Text proposed by the Commission

(ix) Collaboration with third countries on the areas covered by the Programme;

Amendment

(ix) Collaboration with third countries on the areas covered by the Programme *especially with African countries in the framework of the EU- Africa Strategy;*

Or. en

Amendment 728

Aldo Patriciello

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

Text proposed by the Commission

(ix) Collaboration with third countries on the areas covered by the Programme;

Amendment

(ix) Collaboration with third countries on the areas covered by the Programme;

Or. en

Amendment 729

Kateřina Konečná

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

Text proposed by the Commission

Amendment

(ixa) Capacity building activities for, and resourcing of, patient organizations to increase patients' contribution to designing and implementing health policies;

Amendment 730

Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, María Soraya Rodríguez Ramos

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 the *promotion and the* implementation of Union health legislation and of the Programme.

Or. en

Amendment 731

Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, María Soraya Rodríguez Ramos

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 732

Jytte Guteland

Proposal for a regulation

Annex I – point d – point xi a (new)

Text proposed by the Commission

Amendment

(xia) Cross-border efforts to prevent health and conservation risks originating from poorly regulated trade in and keeping of wild animals and domestic pets;

Or. en

**Amendment 733
Inese Vaidere**

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

Text proposed by the Commission

Amendment

(xia) Cross-border cooperation to ensure access to rapid treatment to all patients across the Union, particularly in case of rare disease;

Or. en

**Amendment 734
Adam Jarubas**

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

Text proposed by the Commission

Amendment

(xia) effective public communication, awareness campaigns and stakeholder-led projects, including prevention and fight to disinformation;

Or. en

**Amendment 735
Maria Spyraiki**

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

Text proposed by the Commission

Amendment

(xia) Awareness raising campaigns for the general population as well as targeted groups;

Or. en

Amendment 736

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Mohammed Chahim

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

Text proposed by the Commission

Amendment

(xia) Systematic health impact assessment of other Union policy actions;

Or. en

Amendment 737

Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

(xia) Systematic health impact assessment of other EU policy action;

Or. en

Amendment 738

César Luena

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

Text proposed by the Commission

Amendment

(xia) Population information and awareness campaigns;

Or. en

Amendment 739
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

(xib) Population information and awareness campaigns and stakeholder-led projects.

Or. en

Amendment 740
Luisa Regimenti, Joëlle Mélin, Catherine Griset, Simona Baldassarre, Danilo Oscar Lancini, Lucia Vuolo, Silvia Sardone, Vincenzo Sofo, Marco Dreosto, Aurelia Beigneux

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

Text proposed by the Commission

Amendment

(da.) Development of the capacity and resources of patients' organisations to increase patients' contribution to health policy planning and implementation.

Or. it

Amendment 741
Jessica Polfjärd

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

Text proposed by the Commission

(e) Structural ***stockpile*** and crisis preparation:

Amendment

(e) Structural ***reserves*** and crisis preparation:

Or. en

Amendment 742

Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, María Soraya Rodríguez Ramos

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

Text proposed by the Commission

(i) Establishment ***and support*** of a mechanism ***to develop, procure and manage crisis relevant products;***

Amendment

(i) Establishment of a ***European Health Response Mechanism (EHRM) to respond to all types of health crises (infectious, chemical, environmental, biological, food, nuclear) and to strengthen operational coordination at European level;***

Or. en

Amendment 743

Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, María Soraya Rodríguez Ramos

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

Text proposed by the Commission

(i) Establishment and support of a mechanism to develop, procure ***and*** manage crisis relevant products;

Amendment

(i) Establishment and support of a mechanism to develop, procure, manage ***and secure*** crisis relevant products;

Or. en

Amendment 744

Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, María Soraya Rodríguez Ramos

Proposal for a regulation

Annex I – point e – point i a (new)

Text proposed by the Commission

Amendment

(ia) Establishment of an EU contingency reserve of medicines of major therapeutic interest and medical equipment to be triggered and monitored by the European Health Reaction Mechanism(EHRM);

Or. en

Amendment 745

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex I – point e – point ii

Text proposed by the Commission

Amendment

(ii) Establishment and management of EU reserves **and stockpiles of crisis** relevant products in complementarity with other Union instruments;

(ii) Establishment and management of EU reserves **of medically** relevant products in complementarity with other Union instruments;

Or. en

Amendment 746

Jessica Polfjärd

Proposal for a regulation

Annex I – point e – point ii

Text proposed by the Commission

(ii) Establishment and management of EU reserves **and stockpiles** of crisis relevant products in complementarity with other Union instruments;

Amendment

(ii) Establishment and management of EU reserves of crisis relevant products in complementarity with other Union instruments;

Or. en

Amendment 747
Joanna Kopcińska

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

Text proposed by the Commission

(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;

Amendment

(iv) Procurement of goods and services, **based on the most economically advantageous tender (MEAT) criteria**, necessary for the prevention and management of health crises and action to secure access to those essential goods and services;

Or. en

Amendment 748
Nathalie Colin-Oesterlé

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

Text proposed by the Commission

(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;

Amendment

(iv) Procurement of goods and services, **using the MEAT criteria in particular**, necessary for the prevention and management of health crises and action to secure access to those essential goods and services;

Or. fr

Amendment 749
Aldo Patriciello

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

Text proposed by the Commission

(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;

Amendment

(iv) Procurement, of goods and services, **including MEAT criteria**, necessary for the prevention and management of health crises and action to secure access to those essential goods and services;

Or. en

Amendment 750
Cristian-Silviu Buşoi

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

Text proposed by the Commission

(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;

Amendment

(iv) Procurement of goods and services, **including MEAT criteria**, necessary for the prevention and management of health crises and action to secure access to those essential goods and services;

Or. en

Amendment 751
Adam Jarubas

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

Text proposed by the Commission

(iv) Procurement of goods and services necessary for the prevention and

Amendment

(iv) Procurement of goods and services, **including MEAT criteria**, necessary for

management of health crises and action to secure access to those essential goods and services;

the prevention and management of health crises and action to secure access to those essential goods and services;

Or. en

Amendment 752
Danilo Oscar Lancini

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

Text proposed by the Commission

(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;

Amendment

(iv) Procurement of goods and services ***including MEAT criteria***, necessary for the prevention and management of health crises and action to secure access to those essential goods and services;

Or. en

Amendment 753
Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

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

Text proposed by the Commission

(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

(v) Establishment and operation ***of a Union health response mechanism coordinated by the ECDC and with the assistance of other health-related agencies (EMA, EFSA, ECHA, EEA)*** 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 on request by the Commission in the case of a ***potential health crisis or health threat***;

Amendment 754

Véronique Trillet-Lenoir, Stéphane Bijoux

Proposal for a regulation

Annex I – point e – point v

Text proposed by the Commission

(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

(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, ***including in the outermost regions and the overseas countries and territories***; 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.

Or. fr

Amendment 755

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex I – point e – point v a (new)

Text proposed by the Commission

Amendment

(va) Strengthening mechanisms that ensure the availability of blood components, organs, tissues and cells at European level;

Or. en

Amendment 756
Michèle Rivasi

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) ***Stress tests and follow-up*** 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;

Or. en

Amendment 757
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

(***ii***) ***Support tools and platforms to collect real-world data on the safety, effectiveness and impact of vaccines after use while guaranteeing robust evidence generation in the pre-approval phase;***

Or. en

Amendment 758
Maria Spyraiki

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

Text proposed by the Commission

Amendment

(iii) Support and/or procure emergency

(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;

medical countermeasures, including essential ***medicines***, chemicals and active substances, and the financing of cooperation on emergency health technology assessments and clinical trials; ***and secure financing in case of exceptional measures to free capacity of production lines that can be used to provide ICU medicines and equipment;***

Or. en

Amendment 759
Aldo Patriciello

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

(iii) Support and/or procure emergency medical countermeasures, including essential ***medicines***, chemicals and active substances, and the financing of cooperation on emergency health technology assessments and clinical trials; ***and secure financing of exceptional measures to free capacity of lines that can be utilised to provide ICU medicines;***

Or. en

Amendment 760
Cristian-Silviu Buşoi

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

Amendment

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

technology assessments and clinical trials;

and clinical trials; ***and secure financing of exceptional measures to free capacity of lines that can be utilised to provide ICU medicines;***

Or. en

Amendment 761

Danilo Oscar Lancini

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

(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; ***and secure financing of exceptional measures to free capacity of lines that can be utilised to provide ICU medicines;***

Or. en

Amendment 762

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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, taking into consideration and paying special attention to*** vulnerable ***and risk*** groups from health threats and actions to adjust the response to and management of ***the health*** crisis ***in view of the ensuing*** needs, ***and ensure that*** those vulnerable groups ***receive uninterrupted basic care***

and avoid their health status being degraded;

Or. en

Amendment 763
Cristian-Silviu Buşoi

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 vulnerable groups from health threats and actions to adjust the response to and management of crisis to the needs of those vulnerable groups, ***with the commitment to leave no one behind, such as while safeguarding continued access to quality care and patient safety, and securing basic care for non-communicable and chronic disease patients, including for those in need of palliative care and pain management treatment;***

Or. en

Amendment 764
Kateřina Konečná

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 vulnerable groups from health threats and actions to adjust the response to and management of crisis to the needs of those vulnerable groups, ***with the commitment to leave no one behind, such as while safeguarding continued access to quality care and patient safety, and securing basic care for chronic disease patients in***

need of palliative care and pain management treatment;

Or. en

Justification

It is important to highlight the determination to leave no one behind – a critical commitment pledged by the UN SDGs.

Amendment 765

Luisa Regimenti, Joëlle Mélin, Catherine Griset, Simona Baldassarre, Danilo Oscar Lancini, Lucia Vuolo, Silvia Sardone, Vincenzo Sofo, Marco Dreosto, Aurelia Beigneux

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 the collateral health consequences of a health crisis, in particular those on mental health, **in addition to social exclusion and financial hardship, often experienced by** patients suffering from chronic diseases and other vulnerable groups;

Or. it

Amendment 766

Kateřina Konečná

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 consequences of a health crisis, in particular those on mental health, **in addition to social exclusion and financial hardship, often experienced by** patients **with** chronic diseases and other vulnerable groups;

Amendment 767

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

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 groups, ***such as people living with addiction, with HIV/AIDS, tuberculosis or in socially vulnerable situations;***

Amendment 768

Luisa Regimenti, Joëlle Mélin, Catherine Griset, Simona Baldassarre, Danilo Oscar Lancini, Lucia Vuolo, Silvia Sardone, Vincenzo Sofo, Marco Dreosto, Aurelia Beigneux

Proposal for a regulation

Annex I – point f – point v a (new)

Text proposed by the Commission

Amendment

(va.) With patient safety as a top priority, actions to facilitate the availability of accessible and affordable telemedicine services for all patients throughout Europe, and to support digital literacy and a transition to telemedicine, home administration of treatment and medication, and implementation of preventative and self-care plans, while involving patients' organisations in evaluating, identifying and implementing the best possible solutions in terms of continued access to high-quality care and

treatment;

Or. it

Amendment 769
Kateřina Konečná

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

Text proposed by the Commission

Amendment

(va) While keeping patient safety a top priority, actions to facilitate the availability of accessible and affordable telemedicine services throughout Europe to all patients, support digital literacy and a transition to telemedicine, at home administration of treatment and medication and implementation of preventative and self-care plans, while involving patients' organisations in evaluating, identifying and implementing the best possible solutions to continued access to quality care and treatment;

Or. en

Amendment 770
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

(va) While keeping patient safety a top priority, actions to facilitate the availability of accessible and affordable telemedicine services throughout Europe to all patients, support digital literacy and a transition to telemedicine, at-home administration of treatment and medication and implementation of preventative and self-care plans, while

involving patients' organisations in evaluating, identifying and implementing the best possible solutions to continued access to quality care and treatment;

Or. en

Amendment 771

Sara Cerdas, Tudor Ciuhodaru, Rovana Plumb, Milan Brglez, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

Proposal for a regulation

Annex I – point f – point v a (new)

Text proposed by the Commission

Amendment

(v a) Actions to support e-health, the transition to telemedicine, the use of digital health tools, enabling patients to use e-health solutions and implement self-care plans, empowering citizens and patients to self-manage as regards their health;

Or. en

Amendment 772

Aldo Patriciello

Proposal for a regulation

Annex I – point f – point v a (new)

Text proposed by the Commission

Amendment

(va) Support actions to foster innovation on in repurposing, reformulation and combinations of off-patent medicines that that deliver relevant improvements for patients, healthcare professionals and/or healthcare systems;

Or. en

Amendment 773
Danilo Oscar Lancini

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

Text proposed by the Commission

Amendment

(va) Actions to support harmonised implementation of electronic product information in all Members States;

Or. en

Amendment 774
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

(vb) Actions to support harmonised implementation of electronic product information in all Members States , transition to telemedicine, at-home administration of medication and implementation of preventative and self-care plans, where possible and appropriate;

Or. en

Amendment 775
Aldo Patriciello

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

Text proposed by the Commission

Amendment

(vb) Actions to support harmonised implementation of electronic product information in all Members States, transition to telemedicine, at-home

administration of medication and implementation of preventative and self-care plans, where possible and appropriate;

Or. en

Amendment 776

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex I – point f – point vi

Text proposed by the Commission

(vi) Actions to strengthen surge capacity, research, development, laboratory capacity, production and deployment of *crisis-relevant* niche products;

Amendment

(vi) Actions to strengthen surge capacity, research, development, laboratory capacity, production and deployment of *relevant* niche products;

Or. en

Amendment 777

Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, María Soraya Rodríguez Ramos

Proposal for a regulation

Annex I – point f – point vii

Text proposed by the Commission

(vii) Establishment and operation of a mechanism for cross-sectorial One-Health coordination.

Amendment

(vii) Establishment and operation of a mechanism for cross-sectorial One-Health *and Health in all policies* coordination *via a systematic health impact assessment, built on cross-sectorial indicators, of all EU policies and funding to evaluate their impact on improving health and well-being of our citizens.*

Or. en

Amendment 778

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Mohammed Chahim, Sándor Rónai

Proposal for a regulation

Annex I – point f – point vii a (new)

Text proposed by the Commission

Amendment

(vii a) Establishment and operation of a mechanism responsible for procurement and development of countermeasures against biological threats, including bioterrorism, and chemical, nuclear and radiological threats;

Or. en

Amendment 779

Cristian-Silviu Buşoi

Proposal for a regulation

Annex I – point f – point viii

Text proposed by the Commission

Amendment

(viii) Actions to support investigation, risk assessment and risk management work on the link between animal health, environmental factors, and human diseases, including during health crises.

(viii) Actions to support investigation, risk assessment and risk management work ***related to all medicinal products but with focus to priority, science and current taking into account existing knowledge*** on the link between animal health, environmental factors, and human diseases, including during health crises.

Or. en

Amendment 780

Tilly Metz, Michèle Rivasi

Proposal for a regulation

Annex I – point f – point viii

Text proposed by the Commission

(viii) Actions to support investigation, risk assessment and risk management work on the link between animal health, environmental factors, and human diseases, including during health crises.

Amendment

(viii) Actions to support investigation, risk assessment and risk management work on the link between animal health, **wildlife trade**, environmental factors, and human diseases, including during health crises, **also through the development of ambitious EU coordinated actions to improve animal welfare**.

Or. en

Amendment 781

Michèle Rivasi, Tilly Metz

Proposal for a regulation

Annex I – point f – point viii

Text proposed by the Commission

(viii) Actions to support investigation, risk assessment and risk management work on the link between animal health, environmental factors, and human diseases, including during health crises.

Amendment

(viii) Actions to support investigation, risk assessment and risk management work on the link between animal health, **animal welfare, wildlife trade, pet trade, intensive farming**, environmental factors, and human diseases, including during health crises.

Or. en

Amendment 782

Cristian-Silviu Buşoi

Proposal for a regulation

Annex I – point f – point viii a (new)

Text proposed by the Commission

Amendment

(viii a) Actions to support better crisis management for critical medicines, including the creation, development of an EU central portal to monitoring shortages and an effective EU telematics

infrastructure to make data on medicine and supply chain data interoperable via the full implementation of SPOR and connection to the FMD system;

Or. en

Amendment 783
Danilo Oscar Lancini

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

Text proposed by the Commission

Amendment

(viii a) The creation, development of an EU central portal to monitoring shortages and an effective EU telematics infrastructure to make data on medicine and supply chain data interoperable via the full implementation of SPOR and connection to the FMD system;

Or. en

Amendment 784
Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Mohammed Chahim

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

Text proposed by the Commission

Amendment

(viii a) Support action regarding epidemiological surveillance, focusing on national health entities, thus contributing to assessment of factors that affect or determine the health of citizens;

Or. en

Amendment 785
Maria Spyraiki

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

Text proposed by the Commission

Amendment

(viii a) Actions to secure continuity of uninterrupted access to medicines, of care and treatment and in particular of chronic conditions during a health crisis;

Or. en

Amendment 786
César Luena

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

Text proposed by the Commission

Amendment

(viii a) Actions to secure continuity of care and treatment and in particular of chronic conditions during health crisis;

Or. en

Amendment 787
Aldo Patriciello

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

Text proposed by the Commission

Amendment

(viii a) Actions to secure continuity of care and treatment and in particular of chronic conditions during health crisis;

Or. en

Amendment 788
Adam Jarubas

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

Text proposed by the Commission

Amendment

(viiia) Actions to secure continuity of care and treatment, in particular of chronic conditions during health crisis;

Or. en

Amendment 789

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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

Text proposed by the Commission

Amendment

(viiib) Support actions aimed at preventing the risks for individual and collective health that are associated with human organ trafficking and human trafficking for the purpose of organ procurement;

Or. en

Amendment 790
Danilo Oscar Lancini

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

Text proposed by the Commission

Amendment

(viiib) Actions to secure continuity of care and treatment and in particular of chronic conditions during health crisis;

Amendment 791
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

(viii b) Actions to secure continuity of care and treatment and in particular of chronic conditions during health crisis;

Or. en

Amendment 792

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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

Text proposed by the Commission

Amendment

(g) Strengthen national health systems:

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

Or. en

Amendment 793

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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

Text proposed by the Commission

Amendment

(i) Support knowledge transfer actions

(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;

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, **regarding citizens' biopsychosocial needs, and harmonise minimum standards for quality healthcare;**

Or. en

Amendment 794
Cristian-Silviu Buşoi

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

Text proposed by the Commission

(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;

Amendment

(i) Support knowledge transfer actions and Union level cooperation to assist national reform processes towards improved effectiveness, accessibility, sustainability and resilience, **while linking available EU 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 and aim at universal health coverage and equal access to healthcare;

Or. en

Amendment 795
Kateřina Konečná

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

Text proposed by the Commission

(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;

Amendment

(i) Support knowledge transfer actions, and Union level cooperation to assist national reform processes towards improved effectiveness, accessibility, sustainability and resilience, **while linking available EU 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 and **reach** universal health coverage and equal access to healthcare;

Or. en

Amendment 796

Michèle Rivasi

Proposal for a regulation

Annex I – point g – point i a (new)

Text proposed by the Commission

Amendment

(ia) Support implementing policies, national programmes and guidelines to overcome inequalities in access to healthcare, including health equity assessments;

Or. en

Amendment 797

Nicolae Ștefănuță, Véronique Trillet-Lenoir

Proposal for a regulation

Annex I – point g – point ii

Text proposed by the Commission

Amendment

(ii) Training programmes for medical and healthcare staff, and programmes for

(ii) **Harmonize and standardise** training **and educational** programmes for

temporary exchanges of staff;

medical and healthcare staff, and programmes for temporary exchanges of staff, *with the aim to better match health workers skills with the needs of the health system*;

Or. en

Amendment 798
Margarita de la Pisa Carrión

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) Training programmes for medical and healthcare staff, *including online programmes*, and programmes for temporary exchanges of staff;

Or. es

Amendment 799
Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, María Soraya Rodríguez Ramos

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) Training *and mobility* programmes for medical and healthcare staff, and programmes for temporary exchanges of staff;

Or. en

Amendment 800
Aldo Patriciello

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

Or. en

Amendment 801

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

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

Text proposed by the Commission

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

Amendment

(iii) Support *actions to address the decision of qualified health workers to leave their Member State of origin to work elsewhere*, improve the geographical distribution of healthcare workforce, *avoid* ‘medical deserts’ *and the phenomenon of ‘brain drain’, and promote and implement retention policies in the healthcare sector as well in the health investigation and development sector*;

Or. en

Amendment 802
Inese Vaidere

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

Text proposed by the Commission

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

Amendment

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

deserts’;

deserts’ *and 'brain drain'*; *extra support to Member States with lowest incomes to attract and retain qualified medical workforce*;

Or. en

Amendment 803

Véronique Trillet-Lenoir, Stéphane Bijoux

Proposal for a regulation

Annex I – point g – point iii

Text proposed by the Commission

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

Amendment

(iii) Support to improve the geographical distribution of healthcare workforce and avoidance of ‘medical deserts’, *paying special attention to the EU’s outermost regions*;

Or. fr

Amendment 804

Stanislav Polčák

Proposal for a regulation

Annex I – point g – point iii

Text proposed by the Commission

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

Amendment

(iii) Support to improve the geographical distribution of healthcare workforce and avoidance of ‘medical deserts’, *i.e. areas with inadequate access to medical care and health services*;

Or. cs

Amendment 805

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

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

Text proposed by the Commission

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

Amendment

(iv) Support the establishment and coordination *and deployment* of Union Reference Laboratories and Centres of excellence, *improve the access of and the coverage to all citizens that need it , and support the establishment of Union disease-specific platforms for the exchange, comparison and benchmarking of best practices between Member States*;

Or. en

Amendment 806

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

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

Text proposed by the Commission

(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 implementation of health programmes that address health promotion and disease prevention and tackle communicable and non-communicable diseases*;

Or. en

Amendment 807
Kateřina Konečná

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

Text proposed by the Commission

Amendment

(via) Improve the current EU monitoring system to measure the extent of healthcare exclusion, collect data and report publicly on access barriers experienced by patients, and develop more accurate indicators where needed to capture these;

Or. en

Justification

The 2019 State of Health in the EU Country Health Profiles and companion report published by the Commission, WHO European Observatory and OECD and Médecins du Monde's 2019 Observatory Report present findings which conclude that gaps in the accessibility of health care and a lack of data are undermining universal health coverage across the European Union, in every European country, something EPF has been highlighting for many years. Moreover, the 2019 companion report acknowledges that current indicators do not fully capture barriers to access as experienced by patients.

Amendment 808
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

(via) Improve the current EU monitoring system to measure the extent of healthcare exclusion, collect data and report publicly on access barriers experienced by patients, and develop more accurate indicators where needed to capture these;

Or. en

Amendment 809
Luisa Regimenti, Joëlle Mélin, Catherine Griset, Simona Baldassarre, Danilo Oscar Lancini, Lucia Vuolo, Silvia Sardone, Vincenzo Sofo, Marco Dreosto, Aurelia Beigneux

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

Text proposed by the Commission

Amendment

(via.) Support actions promoting mental health in the workplace and in schools; promote actions to combat depression and suicide; develop socially inclusive forms of mental health care;

Or. it

Amendment 810
Michèle Rivasi

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

Text proposed by the Commission

Amendment

(via) Improve the current EU monitoring system to measure the extent of healthcare exclusion, including by developing adequate indicators, and collect data and report publicly on barriers experienced by patients;

Or. en

Amendment 811
Joanna Kopcińska

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

Text proposed by the Commission

Amendment

(viii) Support capacity building of national systems for the implementation of legislation on substances of human origin, and for the promotion of the sustainable and safe supply of such substances through networking activities;

(viii) Support a Union framework to cooperation among Member States in order to enable Member States to deliver and exchange timely, reliable and high quality joint clinical assessments, joint scientific consultations and other relevant activities to support decision-makers;

Amendment 812
Cristian-Silviu Buşoi

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

Text proposed by the Commission

(ix) Support the establishment and implementation of programmes assisting Member States and their action to improve health promotion and disease prevention (for communicable and non-communicable diseases);

Amendment

(ix) Support the establishment and implementation of ***programmes and in particular 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 hospitals and communities***;

Amendment 813
Piernicola Pedicini, Eleonora Evi

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

Text proposed by the Commission

(ix) Support the establishment and implementation of programmes assisting Member States and their action to improve health promotion and disease prevention (for communicable and non-communicable diseases);

Amendment

(ix) Support the establishment and implementation of programmes assisting Member States and their action to improve health promotion and disease prevention (for communicable and non-communicable diseases), ***including by reducing the burden of diseases caused or impacted by modifiable environmental factors***;

Amendment 814
Adam Jarubas

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

Text proposed by the Commission

(ix) Support the establishment and implementation of programmes assisting Member States and their action to improve health promotion and disease prevention (for communicable and non-communicable diseases);

Amendment

(ix) Support the establishment and implementation of ***national and pan-European*** programmes, ***in particular utilising digital solutions***, assisting Member States and their action to improve health promotion and disease prevention (for communicable and non-communicable diseases) ***in hospitals and communities***;

Or. en

Amendment 815
Danilo Oscar Lancini

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

Text proposed by the Commission

(ix) Support the establishment and implementation of programmes assisting Member States and their action to improve health promotion and disease prevention (for communicable and non-communicable diseases);

Amendment

(ix) Support the establishment and implementation of ***programmes and in particular digital*** programmes assisting Member States and their action to improve health promotion and disease prevention (for communicable and non-communicable diseases) ***in hospitals and communities***;

Or. en

Amendment 816
Aldo Patriciello

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

Text proposed by the Commission

(ix) Support the establishment and implementation of programmes assisting Member States and their action to improve

Amendment

(ix) Support the establishment and implementation of ***programmes and in particular digital*** programmes assisting

health promotion and disease prevention (for communicable and non-communicable diseases);

Member States and their action to improve health promotion and disease prevention (for communicable and non-communicable diseases) *in hospitals and communities*;

Or. en

Amendment 817

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Christel Schaldemose, Sándor Rónai

Proposal for a regulation

Annex I – point g – point ix

Text proposed by the Commission

(ix) Support the establishment and implementation of programmes assisting Member States and their action to improve health promotion and disease prevention (for communicable and non-communicable diseases);

Amendment

(ix) Support the establishment and implementation of programmes assisting Member States and their action to improve health promotion and disease prevention (for communicable and non-communicable diseases) *and mitigate the main risk factors of chronic diseases*;

Or. en

Amendment 818

Michèle Rivasi

Proposal for a regulation

Annex I – point g – point ix a (new)

Text proposed by the Commission

Amendment

(ixa) Support the development and the implementation of the European Disease Prevention and Management Guidelines in the area of both communicable and noncommunicable diseases, such as cancer, paediatric cancer, cardiovascular diseases, neurodegenerative diseases, respiratory diseases and diabetes;

Justification

Like amendment 70 of the rapporteur, but with the addition of "prevention".

Amendment 819

Luisa Regimenti, Joëlle Mélin, Catherine Griset, Simona Baldassarre, Lucia Vuolo, Silvia Sardone, Vincenzo Sofo, Marco Dreosto, Aurelia Beigneux

Proposal for a regulation

Annex I – point g – point ix a (new)

Text proposed by the Commission

Amendment

(ixa.) Support the establishment and implementation of evidence-based programmes assisting Member States and their actions to improve health promotion, health literacy and disease prevention (for communicable and non-communicable diseases);

Or. it

Amendment 820

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex I – point g – point ix a (new)

Text proposed by the Commission

Amendment

(ixa) Support the development and the implementation of European disease management guidelines in the area of both communicable and non-communicable diseases, such as cancer, paediatric cancer, cardiovascular diseases, neurodegenerative diseases, respiratory diseases and diabetes, among others;

Amendment 821
Cristian-Silviu Buşoi

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 enable healthy life choices and promote healthy diets taking into account the needs of vulnerable groups. ***Reduce inequalities in health literacy of patients and citizens by including health literacy in European and national health strategies, e.g. including Europe's Beating Cancer Plan and National Cancer Control Plans;***

Amendment 822
Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

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 enable healthy life choices and promote ***the regular practice of physical activity and*** healthy diets taking into account the needs of vulnerable groups;

Amendment 823
Kateřina Konečná

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

Text proposed by the Commission

(xi) Support the functioning of the European Reference Networks and the establishment and operation of new transnational networks set out in accordance with Union health legislation, and support Member States' actions to coordinate the activities of these networks with the operation of national health systems;

Amendment

(xi) Support the functioning of the European Reference Networks and the establishment and operation of new transnational networks set out in accordance with Union health legislation, ***such as upscaling ERNs and expanding to other chronic disease areas***, and support Member States' actions to coordinate the activities of these networks with the operation of national health systems;

Or. en

Justification

European Reference Networks for rare diseases create a clear governance structure for knowledge sharing and care coordination across the EU to improve access to diagnosis and treatment, as well as the provision of high-quality healthcare for patients. Given the ERN's objectives and success, EPF believes that other chronic diseases areas and ultimately patients would also benefit from such transnational networks.

Amendment 824
Cristian-Silviu Buşoi

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

Text proposed by the Commission

(xi) Support the functioning of the European Reference Networks and the establishment and operation of new transnational networks set out in accordance with Union health legislation, and support Member States' actions to coordinate the activities of these networks with the operation of national health systems;

Amendment

(xi) Support the functioning of the European Reference Networks and the establishment and operation of new transnational networks set out in accordance with Union health legislation, ***such as upscaling ERNs and expanding to other chronic disease areas***, and support Member States' actions to coordinate the activities of these networks with the operation of national health systems;

Amendment 825

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex I – point g – point xi a (new)

Text proposed by the Commission

Amendment

(xia) Advance the integration of ERNs into national health systems, by supporting the organisation of national multi-stakeholder workshops on integration to stimulate local discussions, as well as the development and implementation of the set of policies, rules and procedures required to anchor the ERN system to the national level;

Amendment 826

Kateřina Konečná

Proposal for a regulation

Annex I – point g – point xi a (new)

Text proposed by the Commission

Amendment

(xia) Advance the integration of ERNs into national health systems, by supporting the organisation of national multi-stakeholder workshops on integration to stimulate local discussions, as well as the development and implementation of the set of policies, rules and procedures required to anchor the ERN system to the national level;

Amendment 827
Danilo Oscar Lancini

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

Text proposed by the Commission

Amendment

(xia) Support the development and implementation of programmes assisting Member States to improve their generic and biosimilar use while guaranteeing the prescribing autonomy of the physician to increase healthcare system efficiency;

Or. en

Amendment 828
Nicolae Ștefănuță, Véronique Trillet-Lenoir

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 enact the necessary financial and organisational arrangements to integrate effectively ERNs system into national health systems;

Or. en

Amendment 829
Adam Jarubas

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

Text proposed by the Commission

Amendment

(xia) Support the development and implementation of programmes assisting Member States to improve their generic

and biosimilar use to increase healthcare system efficiency;

Or. en

Amendment 830
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

(xiiia) Support the development and implementation of programmes assisting Member States to improve their generic and biosimilar use to increase healthcare system efficiency;

Or. en

Amendment 831
Nicolae Ştefănuţă, Véronique Trillet-Lenoir

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

Text proposed by the Commission

Amendment

(xiiia) 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;

Or. en

Amendment 832
Maria Spyraiki

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

Text proposed by the Commission

Amendment

(xiiia) Support the development and implementation of programmes assisting Member States to improve their generic and biosimilar use to increase healthcare system resilience and efficiency;

Or. en

Amendment 833

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Mohammed Chahim, Sándor Rónai

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

Text proposed by the Commission

Amendment

(xiiia) Support actions to combat all types of discrimination concerning patients and to ensure that there is equal access for all to health;

Or. en

Amendment 834

Bartosz Arłukowicz, Jarosław Duda

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

Text proposed by the Commission

Amendment

(xiiia.)Support the Member States in ensuring continuity of care and treatment, in particular for chronic conditions.

Or. pl

Amendment 835
Margarita de la Pisa Carrión

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

Text proposed by the Commission

Amendment

(xiiia.) Support for Member States to make the leap into precision medicine (genomic medicine and predictive medicine).

Or. es

Amendment 836
Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

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

Text proposed by the Commission

Amendment

(xiiib) Support actions to adopt a common set of health determinants and methodologies, and support Member States to collect, analyse and report these data and improve the knowledge, and support Union actions to mitigate health inequalities and inequities;

Or. en

Amendment 837
Maria Spyraiki

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

Text proposed by the Commission

Amendment

(xiiib) Support the measurement, collection and analysis of patient

outcomes, including by expanding the scope of data collection in routine clinical practice in a way that is standardised across the EU;

Or. en

Amendment 838

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Mohammed Chahim

Proposal for a regulation

Annex I – point g – point xiii c (new)

Text proposed by the Commission

Amendment

(xiiic) Improve the current monitoring system of the Union to measure the extent of healthcare exclusion, collect data and report publicly on access barriers experienced by patients, and develop more accurate indicators where needed to capture these;

Or. en

Amendment 839

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Mohammed Chahim, Sándor Rónai

Proposal for a regulation

Annex I – point g – point xiii d (new)

Text proposed by the Commission

Amendment

(xiiid) Support Member States' actions to boost health education and health literacy, creating well-informed societies, enhancing healthier lifestyles;

Or. en

Amendment 840

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

Proposal for a regulation

Annex I – point g – point xiii e (new)

Text proposed by the Commission

Amendment

(xiii e) Support the creation and promotion of a Union platform for reliable and updated health information, available in all official languages of the Union, with food, medicines, health, sports and data on other issues;

Or. en

Amendment 841

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

Proposal for a regulation

Annex I – point g – point xiii f (new)

Text proposed by the Commission

Amendment

(xiii f) Support the development and implementation of guidelines on health promotion and disease prevention in different stages of a person's lifetime and needs; creating quality standards to focus on, inter alia, child health, maternal health, aging health, mental health and reproductive and sexual health;

Or. en

Amendment 842

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Christel Schaldemose, Mohammed Chahim

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

Text proposed by the Commission

Amendment

(xiig) Support action to reduce health inequalities and inequities and reduce the unmet needs of vulnerable people, people living with chronic diseases, disabilities or incapacities;

Or. en

Amendment 843

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

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

Text proposed by the Commission

Amendment

(xiiah) Support collaboration between different sectors to improve health determinants and enhance the benefits in health outcomes;

Or. en

Amendment 844

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

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

Text proposed by the Commission

Amendment

(xiii) Support the establishment of quality assurance schemes for disease-specific centres;

Or. en

Amendment 845

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Christel Schaldemose, Sándor Rónai

Proposal for a regulation

Annex I – point g – point xiii j (new)

Text proposed by the Commission

Amendment

(xiii j) Actions supporting the quality of life of chronic disease patients, care givers and informal carers;

Or. en

Amendment 846

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

Proposal for a regulation

Annex I – point g – point xiii k (new)

Text proposed by the Commission

Amendment

(xiii k) Actions supporting continuity of care (integrated care approaches for prevention, diagnosis, treatment and follow-up care);

Or. en

Amendment 847

Linea Søgaard-Lidell, Frédérique Ries, Jan Huitema

Proposal for a regulation

Annex I – point h – introductory part

Text proposed by the Commission

Amendment

(h) Actions on cancer:

(h) Actions on cancer **and other major chronic diseases:**

Amendment 848
Michèle Rivasi

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

Text proposed by the Commission

Amendment

(h) Actions on *cancer*:

(h) Actions on *major chronic diseases*:

Or. en

Amendment 849
Mick Wallace

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

Text proposed by the Commission

Amendment

(h) Actions on *cancer*:

(h) Actions on *major chronic diseases*:

Or. en

Justification

The Programme should ensure the actions it supports will benefit equitably all chronic disease patients in the Union. While the current EU mandate has a strong focus on cancer, it should be acknowledged that the Programme goes beyond the current EU mandate, running well into the next EU mandate as it comes to an end in 2027. But, even in the context of the current mandate, it would be more equitable to extend support for the sort of actions listed in Annex I (h) to the benefit of all chronic disease patients. Indeed, the majority of actions listed in this section are not only applicable and relevant for cancer, but equally for other major chronic diseases.

Amendment 850
Mick Wallace

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 and NGOs in the promotion and **implementation** of the recommendations of the European Code against Cancer, **as well as WHO recommendations on the prevention and control of chronic diseases**;

Or. en

Amendment 851

Michèle Rivasi

**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 and NGOs in the promotion and **implementation** of the recommendations of the European Code against Cancer, **as well as WHO recommendations on the prevention and control of chronic diseases**;

Or. en

Amendment 852

Kateřina Konečná

**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, **the IARC** and NGOs in the promotion and **implementation** of the recommendations of the European Code against Cancer;

Or. en

Amendment 853
Linea Søgaard-Lidell, Frédérique Ries, Jan Huitema

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 and NGOs in the promotion and implementation of the recommendations of the European Code against Cancer ***as well as WHO recommendations on preventing and controlling chronic diseases;***

Or. en

Amendment 854
Cristian-Silviu Buşoi

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;

Or. en

Amendment 855
Véronique Trillet-Lenoir

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

Text proposed by the Commission

Amendment

(ia) Support the establishment of a European Cancer Institute (ECI) which would provide a platform for the implementation of the best standards of practices through European Reference

Cancer Networks, the collection of clinical data among centres from all participating countries across Europe and beyond and the prioritisation of academic and clinical research programmes of excellence. The programme could support the development of national cancer registries in all Member States which are essential with a view to providing comparable data on cancer;

Or. en

Amendment 856
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

(ia) Support the revision and continuous update of the current edition of the European Code against Cancer accompanied by a systematic evaluation of the impact of the European Code against Cancer;

Or. en

Amendment 857
Kateřina Konečná

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

Text proposed by the Commission

Amendment

(ia) Support the revision and continuous update of the current edition of the European Code against Cancer accompanied by a systematic evaluation of the impact of the European Code against Cancer;

Amendment 858
Mick Wallace

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

Text proposed by the Commission

(ii) Support the *establishment* of quality assurance schemes for cancer centres;

Amendment

(ii) Support the *establishment* of quality assurance schemes for cancer centres *and other disease-specific centres*;

Or. en

Amendment 859
Linea Søgaard-Lidell, Frédérique Ries, Jan Huitema

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

Text proposed by the Commission

(ii) Support the establishment of quality assurance schemes for cancer centres;

Amendment

(ii) Support the establishment of quality assurance schemes for cancer centres *and for other disease specific centres*;

Or. en

Amendment 860
Michèle Rivasi

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

Text proposed by the Commission

(ii) Support the establishment of quality assurance schemes for cancer centres;

Amendment

(ii) Support the establishment of quality assurance schemes for cancer centres *and other disease-specific centres*;

Amendment 861
Linea Søgaard-Lidell, Frédérique Ries, Jan Huitema

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 risk factors *for cancer and other chronic diseases*;

Or. en

Amendment 862
Michèle Rivasi

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 risk factors *of chronic diseases*;

Or. en

Amendment 863
Mick Wallace

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 risk factors *of chronic diseases*;

Or. en

Amendment 864
Cristian-Silviu Buşoi

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 ***that are of demonstrated effectiveness and supported by established evidence***;

Or. en

Amendment 865
Piernicola Pedicini, Eleonora Evi

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, ***including the environmental ones***;

Or. en

Amendment 866
Michèle Rivasi

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

Text proposed by the Commission

(iv) Actions to support secondary prevention of ***cancer***, such as early detection and diagnosis through screening;

Amendment

(iv) Actions to support secondary prevention of ***chronic diseases***, such as early detection and diagnosis through screening;

Or. en

Amendment 867
Mick Wallace

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

Text proposed by the Commission

(iv) Actions to support secondary prevention of **cancer**, such as early detection and diagnosis through screening;

Amendment

(iv) Actions to support secondary prevention of **chronic diseases**, such as early detection and diagnosis through screening;

Or. en

Amendment 868
Linea Sogaard-Lidell, Frédérique Ries, Jan Huitema

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

Text proposed by the Commission

(iv) Actions to support secondary prevention of cancer, such as early detection and diagnosis through screening;

Amendment

(iv) Actions to support secondary prevention of cancer **as well as chronic diseases**, such as early detection and diagnosis through screening;

Or. en

Amendment 869
Kateřina Konečná

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

Text proposed by the Commission

Amendment

(iva) Ensure the continuous monitoring and evaluation of Council Recommendation on cancer screening (2003) enabling links to the European Cancer Information System and European Network of Cancer Registries;

Amendment 870
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

(iva) Ensure the continuous monitoring and evaluation of Council Recommendation on cancer screening (2003) enabling links to the European Cancer Information System and European Network of Cancer Registries;

Or. en

Amendment 871
Aldo Patriciello

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

Text proposed by the Commission

Amendment

(iva) Actions to ensure broad implementation of effective screening and vaccination programs and strengthening of infrastructure to achieve elimination of infection-related cancers;

Or. en

Amendment 872
Kateřina Konečná

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

Text proposed by the Commission

Amendment

(ivb) Actions to support the implementation of the WHO Global Call for the Elimination of Cervical Cancer;

Or. en

Amendment 873
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

(ivb) Actions to support the implementation of the WHO Global Call for the Elimination of Cervical Cancer;

Or. en

Amendment 874
Mick Wallace

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

Text proposed by the Commission

Amendment

(v) Actions supporting access to ***cancer*** services and to innovative medicines for ***cancer***;

(v) Actions supporting access to ***chronic disease*** services and to innovative medicines for ***all major chronic diseases***;

Or. en

Amendment 875
Michèle Rivasi

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

Text proposed by the Commission

(v) Actions supporting access to **cancer** services and to innovative medicines for **cancer**;

Amendment

(v) Actions supporting access to **chronic disease** services and to innovative medicines for **all major chronic diseases**;

Or. en

Amendment 876
Kateřina Konečná

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

Text proposed by the Commission

(v) Actions supporting access to cancer services and to innovative **medicines** for cancer;

Amendment

(v) Actions supporting access to cancer services, **including psycho-social support, rehabilitation and palliative care**, and to **both essential medicines and high quality innovative treatments** for cancer;

Or. en

Amendment 877
Aldo Patriciello

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

Text proposed by the Commission

(v) Actions supporting access to cancer services and to innovative **medicines** for cancer;

Amendment

(v) Actions supporting access to cancer services and to innovative, **cost-effective and supportive screening and treatments** for cancer;

Or. en

Amendment 878
Danilo Oscar Lancini

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

Text proposed by the Commission

(v) Actions supporting access to cancer services and to innovative medicines for cancer;

Amendment

(v) Actions supporting access to cancer services and to innovative, ***cost-effective and supportive care*** medicines for cancer;

Or. en

Amendment 879
Linea Søgaard-Lidell, Frédérique Ries, Jan Huitema

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

Text proposed by the Commission

(v) Actions supporting access to cancer services and to innovative medicines for cancer;

Amendment

(v) Actions supporting access to cancer ***and chronic disease*** services and to innovative medicines for cancer ***and other major chronic diseases***;

Or. en

Amendment 880
Maria Spyraiki

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

Text proposed by the Commission

(v) Actions supporting access to cancer services and to innovative medicines for cancer;

Amendment

(v) Actions supporting access to cancer services and to innovative ***and cost-effective*** medicines for cancer;

Or. en

Amendment 881
Piernicola Pedicini, Eleonora Evi

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

Text proposed by the Commission

(v) Actions supporting access to cancer services and to innovative medicines for cancer;

Amendment

(v) Actions supporting access to cancer services and to innovative medicines for cancer, ***including actions to improve the affordability of oncology medications and treatments;***

Or. en

Amendment 882
Nicolae Ștefănuță, Véronique Trillet-Lenoir

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

Text proposed by the Commission

Amendment

(va) Support implementing policies, national programmes and guidelines to overcome inequalities in access to essential therapies and medicines, supportive and palliative care of paediatric cancers across Europe, including availability and affordability of such healthcare and service;

Or. en

Amendment 883
Adam Jarubas

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

Text proposed by the Commission

Amendment

(va) Actions supporting access to the effective European standard of cancer treatment and care across all Member States;

Or. en

Amendment 884
Aldo Patriciello

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

Text proposed by the Commission

Amendment

(va) Actions supporting access to the standard of cancer screening, treatment and care;

Or. en

Amendment 885

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Mohammed Chahim, Sándor Rónai

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

Text proposed by the Commission

Amendment

(va) Support equal and timely access to truly innovative medicines and therapies;

Or. en

Amendment 886

Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

(va) Actions supporting access to the standard of cancer treatment and care;

Or. en

Amendment 887

Danilo Oscar Lancini

Proposal for a regulation

Annex I – point h – point v a (new)

Text proposed by the Commission

Amendment

(va) Actions supporting access to the standard of cancer treatment and care;

Or. en

Amendment 888

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

Proposal for a regulation

Annex I – point h – point v b (new)

Text proposed by the Commission

Amendment

(vb) Support implementing policies, national programmes and guidelines regarding reducing inequalities in access to essential therapies and medicines, supportive and palliative care of paediatric cancers across Europe, including availability and affordability of such health care and services;

Or. en

Amendment 889

Christian Ehler

on behalf of the EPP Group

Dan Nica

on behalf of the S&D Group

Ville Niinistö

on behalf of the Greens/EFA Group

Marisa Matias

on behalf of the GUE/NGL Group

Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

(vb) Support implementing policies, national programmes and guidelines to overcome inequalities in access to essential therapies and medicines, supportive and palliative care of paediatric cancers across Europe in full synergy with Horizon Europe and its missions and partnerships;

Or. en

Amendment 890
Aldo Patriciello

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

Text proposed by the Commission

Amendment

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

Or. en

Amendment 891
Aldo Patriciello

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

Text proposed by the Commission

Amendment

(vc) Actions to promote health and safety for healthcare workers involved in cancer treatment;

Or. en

Amendment 892
Aldo Patriciello

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

Text proposed by the Commission

(vi) Actions supporting the continuity of care (integrated care approaches for prevention, diagnosis, treatment and ***follow-up*** care);

Amendment

(vi) Actions supporting the continuity of care (integrated care approaches for prevention, diagnosis, treatment and ***follow up*** care);

Or. en

Amendment 893
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

(via) Support the establishment of a Cancer Dashboard to reduce systemic health inequalities and improve patient access to cancer care, with a focus on prevention, screening, early diagnosis, access to cancer diagnosis and treatment;

Or. en

Amendment 894
Linea Søgaard-Lidell, Frédérique Ries, Jan Huitema

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

Text proposed by the Commission

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

Amendment

(vii) Actions supporting quality in prevention ***against cancer and chronic diseases*** and care including diagnosis and

treatment;

Or. en

Amendment 895

Michèle Rivasi

Proposal for a regulation

Annex I – point h – point viii

Text proposed by the Commission

(viii) Actions supporting the quality of life of *cancer survivors* and care givers;

Amendment

(viii) Actions supporting the quality of life of *chronic disease patients* and care givers;

Or. en

Amendment 896

Joanna Kopcińska

Proposal for a regulation

Annex I – point h – point vii

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 897

Mick Wallace

Proposal for a regulation

Annex I – point h – point vii

Text proposed by the Commission

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

Amendment

(vii) Actions supporting quality in *chronic disease* prevention and care including diagnosis and treatment;

Amendment 898
Michèle Rivasi

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

Text proposed by the Commission

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

Amendment

(vii) Actions supporting quality in **chronic disease** prevention and care including diagnosis and treatment;

Or. en

Amendment 899
Aldo Patriciello

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

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 900
Mick Wallace

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

Text proposed by the Commission

(viii) Actions supporting the quality of life of cancer survivors and care givers;

Amendment

(viii) Actions supporting the quality of life of cancer survivors and **of chronic disease patients and** care givers;

Or. en

Amendment 901

Linea Søgaard-Lidell, Frédérique Ries, Jan Huitema

Proposal for a regulation

Annex I – point h – point viii

Text proposed by the Commission

(viii) Actions supporting the quality of life of cancer survivors and care givers;

Amendment

(viii) Actions supporting the quality of life of cancer survivors, ***chronic disease patients*** and care givers;

Or. en

Amendment 902

Michèle Rivasi

Proposal for a regulation

Annex I – point h – point ix

Text proposed by the Commission

(ix) Support to the implementation of the Union's tobacco control policy and legislation;

Amendment

(ix) Support to the implementation, ***monitoring and enforcement*** of the Union's tobacco control policy and legislation, ***and other related legislation in the area of prevention in line with the obligations in the WHO Framework Convention on Tobacco Control;***

Or. en

Justification

It is important to specify that the implementation of the Union's tobacco control policy should be in line with the obligations under the WHO FCTC.

Amendment 903

Nicolae Ștefănuță, Véronique Trillet-Lenoir

Proposal for a regulation

Annex I – point h – point ix

Text proposed by the Commission

(ix) Support to the implementation of the Union's tobacco control policy and legislation;

Amendment

(ix) Support to the implementation of the Union's tobacco control policy and ***other related*** legislation ***in the area of prevention and health promotion***;

Or. en

Amendment 904
Michèle Rivasi

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

Text proposed by the Commission

Amendment

(ixa) Actions to support a coordinated and integrative, multi-disciplinary and patient-centred approach regarding chronic disease patients, in particular in the area of paediatric cancer;

Or. en

Justification

Integrative oncology uses conventional treatments, such as chemotherapy, in conjunction with complementary treatments, designed to ease the patient's suffering and address the damaging emotional and psychological impact of the cancer. Multiple studies have demonstrated the benefit of integrative cancer care.

Amendment 905

Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, María Soraya Rodríguez Ramos

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

Text proposed by the Commission

Amendment

(ixa) Support actions in the area of reducing and preventing alcohol abuse in

the perspective of a revised EU alcohol strategy;

Or. en

Amendment 906

Mick Wallace

Proposal for a regulation

Annex I – point h – point x

Text proposed by the Commission

(x) Establishment and support of a mechanisms for cross-specialty capacity building and continuous education in the area of *cancer* care.

Amendment

(x) Establishment and support of a mechanisms for cross-specialty capacity building and continuous education in the area of *chronic disease* care.

Or. en

Amendment 907

Michèle Rivasi

Proposal for a regulation

Annex I – point h – point x

Text proposed by the Commission

(x) Establishment and support of a mechanisms for cross-specialty capacity building and continuous education in the area of *cancer* care.

Amendment

(x) Establishment and support of a mechanisms for cross-specialty capacity building and continuous education in the area of *chronic disease* care.

Or. en

Amendment 908

Linea Sogaard-Lidell, Frédérique Ries, Jan Huitema

Proposal for a regulation

Annex I – point h – point x

Text proposed by the Commission

(x) Establishment and support of a mechanisms for cross-specialty capacity building and continuous education in the area of cancer care.

Amendment

(x) Establishment and support of a mechanisms for cross-specialty capacity building and continuous education in the area of cancer ***and chronic disease*** care.

Or. en

Amendment 909
Joanna Kopcińska

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

Text proposed by the Commission

(x) Establishment and support of ***a*** mechanisms for cross-specialty capacity building and continuous education in the area of cancer care.

Amendment

(x) Establishment and support of mechanisms for cross-specialty capacity building and continuous education in the area of cancer care.

Or. en

Amendment 910
Luisa Regimenti, Joëlle Mélin, Catherine Griset, Simona Baldassarre, Danilo Oscar Lancini, Lucia Vuolo, Silvia Sardone, Vincenzo Sofo, Marco Dreosto, Aurelia Beigneux

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

Text proposed by the Commission

Amendment

(xa.) Support actions to tackle common, shared risk factors and synergies between cancer and other major non-communicable diseases, such as neurological disorders, and to render the European cancer plan a template for other major disease areas;

Or. it

Amendment 911
Kateřina Konečná

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

Text proposed by the Commission

Amendment

(xa) Actions to support addressing common shared risk factors and synergies that cancer has with other major non-communicable diseases such as neurological disorders, as well as making EU cancer plan a template for other major disease areas;

Or. en

Amendment 912
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

(x a) Actions to support addressing common shared risk factors and synergies that cancer has with other major non-communicable diseases such as neurological disorders, as well as making EU cancer plan a template for other major disease areas;

Or. en

Amendment 913
Bartosz Arłukowicz, Jarosław Duda

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

Text proposed by the Commission

Amendment

(xa.) Actions to support addressing

common, shared risk factors and synergies that cancer has with other major non-communicable diseases, such as neurological disorders.

Or. pl

Amendment 914
Adam Jarubas

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

Text proposed by the Commission

Amendment

(xa) Promote use of MEAT criteria in procurement mechanisms to enhance safe and timely usage of generic and biosimilar medicines in cancer care;

Or. en

Amendment 915
Danilo Oscar Lancini

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

Text proposed by the Commission

Amendment

(xa) Promote use of MEAT criteria in procurement mechanisms to enhance safe and timely usage of generic and biosimilar medicines in cancer care;

Or. en

Amendment 916
Maria Spyraiki

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

Text proposed by the Commission

Amendment

(xa) actions to promote health and safety for healthcare workers involved in cancer treatment;

Or. en

Amendment 917

Michèle Rivasi

Proposal for a regulation

Annex I – point h – point x a (new)

Text proposed by the Commission

Amendment

(xa) Establishment and support of a competence network on integrative treatment;

Or. en

Amendment 918

Luisa Regimenti, Joëlle Mélin, Catherine Griset, Simona Baldassarre, Danilo Oscar Lancini, Lucia Vuolo, Silvia Sardone, Vincenzo Sofo, Marco Dreosto, Aurelia Beigneux

Proposal for a regulation

Annex I – point h – point x b (new)

Text proposed by the Commission

Amendment

(xb) Building on Europe's cancer plan, support the creation of a template for other major disease areas, such as neurological disorders;

Or. it

Amendment 919

Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

(xb) Promote use of MEAT criteria in procurement mechanisms to enhance safe and timely usage of generic and biosimilar medicines in cancer care;

Or. en

Amendment 920
Kateřina Konečná

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

Text proposed by the Commission

Amendment

(xb) Building on the EU cancer plan, support the establishment of a template for other major diseases areas such as neurological disorders;

Or. en

Amendment 921
Maria Spyraiki

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

Text proposed by the Commission

Amendment

(xb) Support to Member States in setting up and implementing up-to-date National Cancer Plans in line with the EU Beating Cancer plan;

Or. en

Amendment 922
Adam Jarubas

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

Text proposed by the Commission

Amendment

(xb) actions to promote health and safety for healthcare workers involved in cancer treatment;

Or. en

Amendment 923
Danilo Oscar Lancini

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

Text proposed by the Commission

Amendment

(xb) actions to promote health and safety for healthcare workers involved in cancer treatment;

Or. en

Amendment 924
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

(xc) actions to promote health and safety for healthcare workers involved in cancer treatment;

Or. en

Amendment 925
Aldo Patriciello

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

Text proposed by the Commission

(i) Actions on medicines, vaccines and medical devices:

Amendment

(i) Actions on medicines, vaccines and medical devices:

(i) Support to initiatives to improve vaccination coverage rates in the Member States; support initiatives to ensure that vaccine coverage is extended beyond early childhood and that all population groups can be included in a lifelong vaccination approach;

(ia) Ensure high vaccination coverage rates to achieve herd immunity to protect vulnerable members of the society who cannot be vaccinated due to medical reasons;

(iib) Support building and sustaining resilient immunisation system to maintain high vaccine uptake;

(iic) Make access to vaccination convenient – integrating vaccination into non-health care settings such as workplace and schools to encourage vaccination through all stages in life;

Support a clear framework for expanding vaccine delivery and information to all relevant health care professionals, incl. nurses and pharmacists;

(iicd) Establish Electronic Immunisation Records, as set out in the Council;

Or. en

Amendment 926
Aldo Patriciello

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;

(ii a) Support tools and platforms to collect real-world evidence on the safety, effectiveness and impact of vaccines after use to fight vaccine hesitancy

(iib) Develop appropriate metrics to track programme progress, including changes in the legislative environment and attitudes toward vaccination requirements.

(iic) Strengthen healthcare training and provide a continuous medical training for all health workers.

Healthcare workers play an essential role in rebuilding population's confidence in vaccination.

(iicd) Support Member States in developing social media and awareness programmes to promote the public health impact of vaccination and present a clear and balanced explanations of any potential risks and benefits to individuals;

Or. en

Amendment 927

Piernicola Pedicini, Eleonora Evi

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 ***through ongoing community engagement, addressing of individual and group concerns, trust-building activities;***

Or. en

Amendment 928

Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, Linea Sogaard-Lidell, María Soraya Rodríguez Ramos

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**;

Or. en

Amendment 929

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

Proposal for a regulation

Annex I – point i – point ii a (new)

Text proposed by the Commission

Amendment

(ii) Support tools and platforms to collect real-world data to produce real-world evidence, promote research and evidence on the safety, effectiveness and impact of vaccines, while guaranteeing robust evidence generation in the pre-approval phase;

Or. en

Amendment 930

Michèle Rivasi

Proposal for a regulation

Annex I – point i – point ii a (new)

Text proposed by the Commission

Amendment

(ii) Support tools and platforms to collect real-world anonymised data on the

quality, safety and efficacy of vaccines in use, without prejudice to the generation of robust evidence in the pre-approval phase;

Or. en

Amendment 931
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

(ii) Support actions to promote the use of generic and biosimilar medicines;

Or. en

Amendment 932
Nicolae Ştefănuţă, Véronique Trillet-Lenoir

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

Text proposed by the Commission

Amendment

(ii) Establish of a EU vaccination card;

Or. en

Amendment 933
Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

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, ***including those involving increased coordination at Union level and with EMA***, to speed up the development, authorisation and access to innovative, safe and effective medicines and vaccines; ***support publication of all clinical reports (including CSRs) on the day marketing authorisation is granted for such medicines and vaccines***;

Or. en

Amendment 934
Joanna Kopcińska

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, ***including those involving collaboration between Member States, increased coordination at Union level and with the European Medicines Agency***, to speed up the development, authorisation and access to innovative, safe and effective medicines and vaccines;

Or. en

Amendment 935
Piernicola Pedicini, Eleonora Evi

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

Amendment

(iii) Support clinical trials, ***in particular support to their transparency and to the full implementation of the EU database***

and vaccines;

with publicly accessible data, to speed up the development, authorisation and access to innovative, safe and effective medicines and vaccines;

Or. en

Amendment 936

Nicolae Ștefănuță, Véronique Trillet-Lenoir

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 to speed up the development, authorisation and access to innovative, safe and effective medicines and vaccines; ***support publication of all clinical reports (including CSRs) on the day of marketing authorisation;***

Or. en

Amendment 937

Michèle Rivasi

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 to speed up the development, authorisation and ***equitable*** access to innovative, ***affordable*** safe and effective medicines and vaccines, ***including timely public access to clinical study reports;***

Or. en

Amendment 938

Cristian-Silviu Bușoi

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*** to speed up the development, authorisation and ***a pan EU*** access to innovative, safe and effective medicines and vaccines;

Or. en

Amendment 939
Kateřina Konečná

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

Text proposed by the Commission

Amendment

(iiia) Support action to ensure greater availability in the Union of medicines and medical devices and contribute to their affordability for patients and health systems;

Or. en

Amendment 940
Michèle Rivasi

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

Text proposed by the Commission

Amendment

(iiia) support action for traceability rules on medicines both with regard to the final product and its components;

Or. en

Amendment 941

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Mohammed Chahim, Sándor Rónai

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 ***and affordability*** in the Union of medicines, ***vaccines***, and medical devices and contribute to their affordability for patients and health systems, ***using the Union mechanism as joint procurement at the same time enhance the transparency of the process***;

Or. en

Amendment 942

Michèle Rivasi

Proposal for a regulation

Annex I – point i – point iv a (new)

Text proposed by the Commission

Amendment

(iva) Support action to modify the regulatory framework in the Union, to foster public health driven research and innovation and to encourage the discovery and development, production and fair distribution of innovative quality and affordable medicines, treatments, devices and vaccines for unmet medical needs in a transparent manner;

Or. en

Amendment 943

Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

(iva) Support action to strengthen the regulatory framework in the Union to encourage the discovery and development of medicines and vaccines to meet the patient and public health needs and guaranteed the efficacy and safety of newly approved products;

Or. en

Amendment 944

Luisa Regimenti, Joëlle Mélin, Catherine Griset, Simona Baldassarre, Danilo Oscar Lancini, Lucia Vuolo, Silvia Sardone, Vincenzo Sofo, Marco Dreosto, Aurelia Beigneux

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

Text proposed by the Commission

Amendment

(iva) Foster a supportive environment for meaningful patient and public involvement in clinical trials, starting with the design phase and ending with dissemination;

Or. it

Amendment 945
Kateřina Konečná

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

Text proposed by the Commission

Amendment

(iva) Foster a supportive environment for meaningful patient and public involvement in clinical trials, starting with the design phase and ending with dissemination;

Amendment 946
Michèle Rivasi

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

Text proposed by the Commission

Amendment

(ivb) Support the assessment of the impact of intellectual property incentives on biomedical innovation in general and to explore credible and effective alternatives to exclusive protections for the financing of medical R&D, such as the numerous tools based on delinkage mechanisms;

Or. en

Justification

This is a direct implementation of paragraph 39 of the EP Resolution of 10 July 2020 on the EU public health strategy post COVID-19.

Amendment 947
Michèle Rivasi

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

Text proposed by the Commission

Amendment

(ivc) Support action for implementing an EU wide list of approved medicines, indicating which products are interchangeable and key information on their composition, description, prescription requirements and administration;

Or. en

Amendment 948
Michèle Rivasi

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

Text proposed by the Commission

Amendment

(ivd) Support action to enable information-sharing among Member States on medicines prices, including discounts and rebates, and on their pricing and reimbursement policies;

Or. en

Amendment 949

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Mohammed Chahim

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

Text proposed by the Commission

Amendment

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

(v) Support action to encourage the *production* of less commercially interesting products; *encourage the development of medicines for rare diseases and making access to them affordable, and investment in the research and development of new* antimicrobials *and other medicines to fight against communicable diseases;*

Or. en

Amendment 950
Joanna Kopcińska

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 **that builds on EU achievements including the launch of the New Drugs for Bad Bugs (ND4BB) programme and the Joint Programming Initiative on Antimicrobial Resistance (JPIAMR)**, to encourage the **development** of innovative products and of less commercially interesting products such as antimicrobials;

Or. en

Amendment 951

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Mohammed Chahim, Sándor Rónai

Proposal for a regulation

Annex I – point i – point v a (new)

Text proposed by the Commission

Amendment

(va) **Support actions to implement models of R&D and IP ownership and management which prioritise the public interest and ensure that there are societal benefits, for example by including binding safeguards to ensure availability, accessibility and affordability of medical products developed with public funds;**

Or. en

Amendment 952

Biljana Borzan

Proposal for a regulation

Annex I – point i – point v a (new)

Text proposed by the Commission

Amendment

(v a) **Support actions to implement**

models of R&D and IP ownership and management which prioritize the public interest and guarantee societal benefit, for example by including binding safeguards to ensure availability, accessibility and affordability of medical products developed with public funds;

Or. en

Amendment 953
Danilo Oscar Lancini

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

Text proposed by the Commission

Amendment

(va) Support actions to foster innovation on in repurposing, reformulation and combinations of off-patent medicines that that deliver relevant improvements for patients, healthcare professionals and/or healthcare systems;

Or. en

Amendment 954
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

(va) Support actions to foster innovation on in repurposing, reformulation and combinations of off-patent medicines that that deliver relevant improvements for patients, healthcare professionals and/or healthcare systems;

Or. en

Amendment 955

Adam Jarubas

Proposal for a regulation

Annex I – point i – point v a (new)

Text proposed by the Commission

Amendment

(va) Support actions to foster innovation in repurposing, reformulation and combinations of off-patent medicines that that deliver relevant improvements for patients, healthcare professionals and/or healthcare systems;

Or. en

Amendment 956

Bartosz Arłukowicz, Jarosław Duda

Proposal for a regulation

Annex I – point i – point v a (new)

Text proposed by the Commission

Amendment

(va.) Create favourable conditions for significant patient and social engagement with clinical research;

Or. pl

Amendment 957

Cristian-Silviu Buşoi

Proposal for a regulation

Annex I – point i – point v b (new)

Text proposed by the Commission

Amendment

(vb) Action to sustain a strong intellectual property framework, incentives and reward mechanisms for R&D, in order to attract investments in the Union for the development of the next generation of medicines, vaccines and

medical devices;

Or. en

Amendment 958

Christian Ehler

on behalf of the EPP Group

Dan Nica

on behalf of the S&D Group

Martina Dlabajová

on behalf of the Renew Group

Cristian-Silviu Buşoi

Proposal for a regulation

Annex I – point i – point v c (new)

Text proposed by the Commission

Amendment

(vc) Action to sustain a strong, balanced and adequate intellectual property framework, incentives and reward mechanisms for R&D, in order to attract investments in the Union for the development, manufacturing and distribution of the next generation of medicines, vaccines and medical devices, including personalised medicine;

Or. en

Amendment 959

Cristian-Silviu Buşoi

Proposal for a regulation

Annex I – point i – point vi

Text proposed by the Commission

Amendment

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

(vi) Support action to monitor, ***prevent, manage, report and notify*** shortages of medicines and medical devices occurring in hospitals and community pharmacies, to ***collect reported shortages in a centralized database, interoperable with databases that contained regulatory data on***

medicines, to address such shortages, and to increase security of supplies;

Or. en

Amendment 960

Nathalie Colin-Oesterlé

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, **report and notify** shortages of medicines and medical devices occurring in hospitals and community pharmacies, **to compile the identified shortages in a centralised database that is interoperable with the drug regulatory databases**, to address such shortages, and to increase security of supplies;

Or. fr

Amendment 961

Adam Jarubas

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, **report and notify** shortages of medicines and medical devices occurring in hospitals and community pharmacies, **to collect reported shortages in a centralized database, interoperable with databases that contained regulatory data on medicines**, **to** address such shortages, and to increase security of supplies;

Or. en

Amendment 962
Piernicola Pedicini, Eleonora Evi

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 shortages of medicines and medical devices occurring in hospitals and community pharmacies, to address such shortages **at their roots**, and to increase security of supplies;

Or. en

Amendment 963
Danilo Oscar Lancini

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

Text proposed by the Commission

(vii) Support actions to encourage the development of innovative medicines and medical devices less harmful for the environment and promote greener manufacturing;

Amendment

(vii) Support actions to encourage the development of innovative medicines and medical devices less harmful for the environment and promote greener manufacturing **and reward investments in procurement processes**;

Or. en

Amendment 964
Adam Jarubas

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

Text proposed by the Commission

(vii) Support actions to encourage the

Amendment

(vii) Support actions to encourage the

development of *innovative* medicines and medical devices less harmful for the environment and promote greener manufacturing;

development of medicines and medical devices less harmful for the environment and promote greener manufacturing **and reward investments in procurement processes**;

Or. en

Amendment 965
Cristian-Silviu Buşoi

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

Text proposed by the Commission

(vii) Support actions to encourage the development of *innovative* medicines and medical devices less harmful for the environment and promote greener manufacturing;

Amendment

(vii) Support actions to encourage the development of medicines and medical devices less harmful for the environment and promote greener manufacturing **and reward investments in procurement processes**;

Or. en

Amendment 966
Michèle Rivasi

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

Text proposed by the Commission

(vii a) Support actions for a sustainability assessment of applications of synthetic biology;

Amendment

Or. en

Amendment 967
Cristian-Silviu Buşoi

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 to centrally collect and provide access to relevant stakeholders to all known environmental risk assessment data in a uniform way, avoiding unnecessary duplications; including the use of raw materials and impact of REACH on the supply chain using alternate production methods to circumvent processes eg enzymic and using reg flex to be able to commercialise as well as using alternate technology to deliver safer solutions whilst encouraged through purchasing incentives;***

Or. en

Amendment 968

Véronique Trillet-Lenoir, Nicolae Ștefănuță, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, Susana Solís Pérez, María Soraya Rodríguez Ramos

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 ***pollution factors, such as air, water and soil pollution, chemical exposures, climate change, ultraviolet radiation and*** pharmaceuticals;

Or. en

Amendment 969

Nathalie Colin-Oesterlé

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 to reward such investments in contract award procedures;***

Or. fr

Amendment 970

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

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;***

Or. en

Amendment 971

Nathalie Colin-Oesterlé

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; technological incentives to neutralise waste in production plants;***

Or. fr

Amendment 972
Danilo Oscar Lancini

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 **medicinal products**, **including** antimicrobials; **create technology incentives to neutralise waste in manufacturing plants;**

Or. en

Amendment 973
Cristian-Silviu Buşoi

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 **medicinal products**, **including** antimicrobials; **create technology incentives to neutralise waste in manufacturing plants;**

Or. en

Amendment 974
Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

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 antimicrobials, **surveillance of antimicrobial use,**

*antimicrobial resistance and support
action to fight against AMR;*

Or. en

Amendment 975

Michèle Rivasi

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 significantly reduce overall use of antimicrobials*, to promote the prudent use and disposal of antimicrobials, *and the use of non-antibiotic treatments*;

Or. en

Amendment 976

Nicolae Ștefănuță, Véronique Trillet-Lenoir

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 antimicrobials, *setting up traceable targets for reduction in antibiotics use*;

Or. en

Amendment 977

Cristian-Silviu Bușoi

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 **development and convergence and reliance** on medicines and medical devices **and to improve regulatory oversight;**

Or. en

Amendment 978

Danilo Oscar Lancini

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 **development and convergence and reliance** on medicines and medical devices **and to improve regulatory oversight;**

Or. en

Amendment 979

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

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** on medicines, **vaccines**, medical devices **and products and e-health solutions;**

Or. en

Amendment 980
Joanna Kopcińska

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** on medicines and medical devices.

Or. en

Amendment 981
Inese Vaidere

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

Text proposed by the Commission

Amendment

(xa) Support action to establish joint procurement for medicines to treat rare diseases in order to ensure that these medicines are available in all Member States and at an equal price;

Or. en

Amendment 982
Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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

Text proposed by the Commission

Amendment

(xa) Support the creation of national tools to implement the health technology assessments (HTA);

Or. en

Amendment 983

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

Proposal for a regulation

Annex I – point i – point x b (new)

Text proposed by the Commission

Amendment

(xb) action to promote data transparency in the entire value chain of medicines;

Or. en

Amendment 984

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex I – point i – point x c (new)

Text proposed by the Commission

Amendment

(xc) action to create scientific advisory systems at national and Union level that support SMEs, Start-ups and others in the health sector;

Or. en

Amendment 985

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

Proposal for a regulation

Annex I – point i – point x d (new)

Text proposed by the Commission

Amendment

(xd) Support actions aimed at strengthening the fight against counterfeiting and piracy of medicines and medical devices;

Or. en

Amendment 986

Sara Cerdas, Tudor Ciuhodaru, Rovana Plumb, Milan Brglez, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

Proposal for a regulation

Annex I – point i – point x e (new)

Text proposed by the Commission

Amendment

(xe) Support actions to promote the reinforcement of investment in a joint R&D policy;

Or. en

Amendment 987

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

Proposal for a regulation

Annex I – point i – point x f (new)

Text proposed by the Commission

Amendment

(xf) Support the strengthening of investment in instruments for monitoring the commerce and availability of medicines for human use and medical devices, at national and Union level;

Or. en

Amendment 988

Sara Cerdas, Tudor Ciuhodaru, Rovana Plumb, Milan Brglez, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

Proposal for a regulation

Annex I – point i – point x g (new)

Text proposed by the Commission

Amendment

(xg) Support research into possible repurposing of existing drugs, exploring new uses and indications of therapies for existing drugs;

Or. en

Amendment 989

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

Proposal for a regulation

Annex I – point j – point i

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 990

Cristian-Silviu Buşoi

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

Amendment 991
Kateřina Konečná

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

Amendment 992
Kateřina Konečná

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

Text proposed by the Commission

Amendment

(ia) Actions to ensure that Electronic Health Records are designed for the support of clinical care and research and to support National health systems in ensuring the integration with the patient registries and the incorporation of EHR data into those registries;

Or. en

Amendment 993
Kateřina Konečná

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

Text proposed by the Commission

Amendment

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

(ii) Support ***investments for*** the digital transformation of health care and health systems including through, ***health systems digital health receptivity research***, benchmarking and capacity building for the uptake of innovative tools and technologies; digital upskilling of health care ***professionals, as part of a strategy on the health workforce, and citizens, through enhanced education, training and (digital) health literacy measures***;

Or. en

Justification

To achieve digital transformation of health, the EU4Health programme should also focus on supporting initiatives to improve not only professionals but also citizens and patients digital skills and digital health literacy. Enhancing digital health literacy and data literacy levels is crucial to support patients' control of their data and enable them to understand and exercise their rights while realising the societal benefits of data-driven innovation in healthcare.

Amendment 994
Cristian-Silviu Buşoi

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 *investment for* the digital transformation of health care and health systems including through *health systems digital health receptivity research*, benchmarking and capacity building for the uptake of innovative tools and technologies; digital upskilling of health care *professionals, as part of a strategy on the health workforce, and citizens, through enhanced education, training and (digital) health literacy measures*;

Or. en

Amendment 995
Maria Spyra

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 *investments in* to the digital transformation of health care and health systems, including through benchmarking and capacity building for the uptake of innovative tools and technologies; *support investments in infrastructures, digital tools and methodologies to collect and analyse health data and real-world evidence*; *support* digital upskilling of *healthcare professionals*;

Or. en

Amendment 996
Christian Ehler
on behalf of the EPP Group

Dan Nica

on behalf of the S&D Group

Martina Dlabajová

on behalf of the Renew Group

Ville Niinistö

on behalf of the Greens/EFA Group

Cristian-Silviu Buşoi

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 *investments for the sustainable* 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*;

Or. en

Amendment 997

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

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 *investments for* 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 and citizens*;

Or. en

Amendment 998

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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; ***including support for the implementation of an Electronic European Health Record***; develop appropriate governance structures and sustainable, interoperable Union health information systems, as part of the European Health Data Space and ***with a view to the safe and efficient deployment of AI in healthcare***; strengthen ***and facilitate*** 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***;

Or. en

Amendment 999

Cristian-Silviu Buşoi

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

Amendment

(iii) Support the deployment and interoperability of digital tools and infrastructures within and between Member States and with Union Institutions, ***Agencies*** and bodies; ***including support for the implementation of an Electronic European Health***

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

Record; develop appropriate governance structures and sustainable, interoperable Union health information systems, as part of the European Health Data Space and ***in view of safe and efficient deployment of AI in health care***; strengthen ***and facilitate*** 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***;

Or. en

Amendment 1000
Kateřina Konečná

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; ***including support for the implementation of an Electronic European Health Record***; develop appropriate governance structures and sustainable, interoperable Union health information systems, as part of the European Health Data Space and ***in view of safe and efficient deployment of AI in healthcare***; strengthen ***and facilitate*** 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***;

Or. en

Justification

The EU4Health programme should support actions to the development and implementation of the European Health Data Space and to support efficient and safe deployment of AI in

healthcare, ensuring that such actions would be also aimed at improving and facilitating citizens' access and control to their health data. Furthermore, EU4Health supported actions should be developed and designed to facilitate uptake of already existing initiatives and projects in order to increase efficient use of EU resources and take advantage of successful best practices.

Amendment 1001

Nicolae Ștefănuță, Véronique Trillet-Lenoir

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, ***standardization*** 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;

Or. en

Amendment 1002

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex I – point j – point iii a (new)

Text proposed by the Commission

Amendment

(iiia) Support actions to promote a European cohesion and coherence policy for digital health in order to harmonize the legal, organizational, semantic and technical components necessary for a functional and efficient cross-border ecosystem;

Amendment 1003

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

Proposal for a regulation

Annex I – point j – point iii b (new)

Text proposed by the Commission

Amendment

(iiib) Support the development of digital tools and digital solutions to increase the use of e-health and improve the sustainability and resilience of healthcare systems;

Amendment 1004

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

Proposal for a regulation

Annex I – point j – point iii c (new)

Text proposed by the Commission

Amendment

(iiic) Support action to scale up cross-border information exchange services and commence the implementation of projects such as Patient Summary and ePrescription;

Amendment 1005

Sara Cerdas, Tudor Ciuhodaru, Rovana Plumb, Milan Brglez, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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 **and other e-health tools**, including through **boosting the coverage of internet and satellite communications** for remote areas, foster digitally-driven organisational innovation in healthcare facilities and promote digital tools supporting citizen empowerment, and person-centred care **and self-management of health; promote the involvement of patients in the co-design and co-development of user-friendly telemedicine and tele-health solutions;**

Or. en

Amendment 1006
Kateřina Konečná

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 in the co-design and co-development of user-friendly telemedicine/telehealth solutions;**

Or. en

Justification

Telemedicine/telehealth are crucial in the digital transformation of health. However, to increase accessibility, facilitate use and ensure added value, such solutions should be evaluated, co-designed and developed in collaboration with end-users including patients.

Simple products, interfaces and platforms can partially bridge health literacy gaps, increase trust levels and enable people with low health literacy levels to still benefit from digital health innovation.

Amendment 1007

Cristian-Silviu Buşoi

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 in the co-design and co-development of user-friendly telemedicine/telehealth solutions;***

Or. en

Amendment 1008

Cristian-Silviu Buşoi

Proposal for a regulation

Annex I – point j – point iv a (new)

Text proposed by the Commission

(iva) Actions to support the involvement of patients and health care professionals in the development, design and deployment of user-centred accessible, secure and efficient digital health innovation;

Or. en

Amendment 1009

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

Proposal for a regulation

Annex I – point j – point iv a (new)

Text proposed by the Commission

Amendment

(iva) Actions to support the involvement of patients and healthcare professionals in the development, design and deployment of user-centred accessible, secure and efficient digital health innovation;

Or. en

Amendment 1010

Kateřina Konečná

Proposal for a regulation

Annex I – point j – point iv a (new)

Text proposed by the Commission

Amendment

(iva) Actions to support the involvement of patients and healthcare professionals in the development, design and deployment of user-centred accessible, secure and efficient digital health innovation;

Or. en

Justification

As previously mentioned in our amendment to point Annex I – point j – point IV, the EU4Health programme should play an important role in supporting the involvement of patients and healthcare professionals in the development, design and deployment of digital health innovation solution, not only telemedicine/telehealth, to drive person-centredness, increase trust levels in digital health and secure a more accessible and safe digitalisation of healthcare in Europe.

Amendment 1011
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

(iiia) Communication campaign and awareness raising addressed to citizens and stakeholders to promote trust in generic and biosimilar medicines;

Or. en

Amendment 1012

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Sándor Rónai

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

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 1013

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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

Text proposed by the Commission

Amendment

(iiia) Communication, information and awareness campaigns on blood, organs,

tissues and cells donation, that alert the public to the importance of such donation, in terms of solidarity, health policy and therapeutical benefits;

Or. en

Amendment 1014

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Mohammed Chahim

Proposal for a regulation

Annex I – point k – point iii b (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 1015

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex I – point k – point iii c (new)

Text proposed by the Commission

Amendment

(iiic) Communication addressed to citizens on health risks from environmental and food issues;

Or. en

Amendment 1016
Véronique Trillet-Lenoir, Stéphane Bijoux

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

Text proposed by the Commission

Amendment

(ka) Specific support for the outermost regions and the overseas countries and territories, in particular through:

(i) Investment in health infrastructures and support for the procurement of new medical supplies;

(ii) Establishment and management of reserves of products needed during crises so that the EU's action can be deployed from those territories;

(iii) Support for research, drug development, treatments, and measures to provide information on, and raise awareness of, tropical diseases, but also the diseases that particularly affect those territories, especially diabetes and obesity;

(iv) Establishment of specific strategies for repatriation to continental Europe in the case of a major health crisis;

(v) Support for better understanding, assessment, use and appreciation of endemic medicinal plants and the therapeutic potential of biodiversity.

Or. fr

Amendment 1017
Maria Spyraiki

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

Text proposed by the Commission

Amendment

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

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

health

health, *including harmonized resilience assessment indicators across the EU*

Or. en

Amendment 1018

Sara Cerdas, Tudor Ciuhodaru, Rovana Plumb, Milan Brglez, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex II – part A – point II a (new)

Text proposed by the Commission

Amendment

IIa. Review existing fast-track flexibilities in the Union approval framework and support pragmatic clinical trials

Or. en

Amendment 1019

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex II – part A – point III

Text proposed by the Commission

Amendment

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

III. Universal Health Care (UHC) service coverage index

Or. en

Amendment 1020

Cristian-Silviu Buşoi

Proposal for a regulation

Annex II – part A – point III

Text proposed by the Commission

Amendment

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

III. Number of actions and best practices directly contributing to the SDG 3.4 **and SDG 10/Member State**

Or. en

Amendment 1021

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex II – part A – point IV

Text proposed by the Commission

Amendment

IV. Implementation of **best practices** by EU Member States

IV. Implementation of **health programmes** by EU Member States **that promote health and prevent diseases**

Or. en

Amendment 1022

Cristian-Silviu Buşoi

Proposal for a regulation

Annex II – part A – point IV

Text proposed by the Commission

Amendment

IV. Implementation of best practices by EU Member States

IV. Implementation of best practices by EU Member States **addressing health inequalities (SDG 10)**

Or. en

Amendment 1023

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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

Text proposed by the Commission

Amendment

IVa. Unmet needs in terms of the access to centrally authorised medicines, vaccines or medical devices, due to the lack of affordability, availability and time

Or. en

Amendment 1024

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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

Text proposed by the Commission

Amendment

IVb. Universal Health Care (UHC) service coverage index

Or. en

Amendment 1025

Nicolae Ștefănuță, Véronique Trillet-Lenoir

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

Text proposed by the Commission

Amendment

1a. Number of Member States that implemented the European Electronic Health Record, while providing stronger guarantees for personal data protection

Or. en

Amendment 1026

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Mohammed Chahim

Proposal for a regulation

Annex II – part B – point 1 a (new)

Text proposed by the Commission

Amendment

1a. Number of strategic reserves of medicines, vaccines, medical devices and other medical products

Or. en

Amendment 1027

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel, Mohammed Chahim

Proposal for a regulation

Annex II – part B – point 1 b (new)

Text proposed by the Commission

Amendment

1b. Number of strategic reserves of health professionals with training and preparedness to respond to health threats and health crises

Or. en

Amendment 1028

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex II – part B – point 1 c (new)

Text proposed by the Commission

Amendment

1c. Unmet needs in terms of medicines, vaccines, medical devices, due

to the lack of availability, affordability or time

Or. en

Amendment 1029

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex II – part B – point 1 d (new)

Text proposed by the Commission

Amendment

1d. The ratio of new medicines or vaccines in the market compared to the number of clinical trials in the Union and per Member State

Or. en

Amendment 1030

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex II – part B – point 1 e (new)

Text proposed by the Commission

Amendment

1e. Universal Health Care (UHC) service coverage index

Or. en

Amendment 1031

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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

Text proposed by the Commission

Amendment

***1f. Creation of the European Health
Data Space (EHDS)***

Or. en

Amendment 1032

Sara Cerdas, Tudor Ciuhodaru, Rovana Plumb, Milan Brglez, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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

Text proposed by the Commission

Amendment

***1g. Coverage of citizens with access to
their data on the EHDS, per Member
State***

Or. en

Amendment 1033

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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

Text proposed by the Commission

Amendment

***1h. Number of breaches of security of
the EHDS***

Or. en

Amendment 1034

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert

Hajšel

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

Text proposed by the Commission

Amendment

***1i. Coverage of health professionals
with digital skills, per Member State***

Or. en

Amendment 1035

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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

Text proposed by the Commission

Amendment

***1j. Coverage of citizens having the
digital skills necessary to use e-health
technology, per Member State***

Or. en

Amendment 1036

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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

Text proposed by the Commission

Amendment

***1k. Number of health promotion
programmes implemented per Member
State, based on health issues covered,
using the WHO International
Classification of diseases (ICD10)***

Or. en

Amendment 1037

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex II – part B – point 1 l (new)

Text proposed by the Commission

Amendment

1l. Coverage of workers with access to occupational healthcare services, per Member State

Or. en

Amendment 1038

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex II – part B – point 1 m (new)

Text proposed by the Commission

Amendment

1m. Ratio of environmental health assessments compared to the number of medicines, vaccines and medical devices that entered into the market

Or. en

Amendment 1039

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex II – part B – point 1 n (new)

Text proposed by the Commission

Amendment

In. Vaccination coverage, by vaccine-preventable-disease, age and sex

Or. en

Amendment 1040

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex II – part B – point 1 o (new)

Text proposed by the Commission

Amendment

1o. Number of Member States that implemented the European Electronic Health Record while providing stronger guarantees for personal data protection

Or. en

Amendment 1041

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex II – part B – point 1 p (new)

Text proposed by the Commission

Amendment

1 p. Age-standardised five-year net survival of cancer, in total, by type of cancer, gender and age

Or. en

Amendment 1042

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López,

Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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

Text proposed by the Commission

Amendment

1q. Ratio of Cancer Registries (CRs) to number of Member States (MSs) reporting information of the cancer stage at diagnosis

Or. en

Amendment 1043

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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

Text proposed by the Commission

Amendment

1r. Age-standardized DALYs attributable to the NCDs (per 100 000 people), by disease, gender and age

Or. en

Amendment 1044

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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

Text proposed by the Commission

Amendment

1s. Age-standardized NCD mortality rate (per 100 000 people), by disease, by gender and age

Amendment 1045

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex II – part B – point 1 t (new)

Text proposed by the Commission

Amendment

1t. Age-standardized deaths attributable to the environment (per 100 000 people) by gender and age

Or. en

Amendment 1046

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex II – part B – point 1 u (new)

Text proposed by the Commission

Amendment

1u. Number of medical doctors (per 10 000 people), by Member State and region

Or. en

Amendment 1047

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex II – part B – point 1 v (new)

Text proposed by the Commission

Amendment

Iv. Number of nurses (per 10 000 people), by Member State and region

Or. en

Amendment 1048

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex II – part B – point 1 w (new)

Text proposed by the Commission

Amendment

Iw. Number of healthcare professionals (per 10 000 people), by Member State and region

Or. en

Amendment 1049

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex II – part B – point 1 x (new)

Text proposed by the Commission

Amendment

Ix. Age-standardised obesity prevalence, by gender and age

Or. en

Amendment 1050

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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

Text proposed by the Commission

Amendment

1 y. Age-standardised prevalence of people who are overweight, by gender and age

Or. en

Amendment 1051

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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

Text proposed by the Commission

Amendment

1z. Age-standardised harmful use of alcohol prevalence, by gender and age

Or. en

Amendment 1052

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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

Text proposed by the Commission

Amendment

1aa. Age-standardised gambling prevalence, by gender and age

Or. en

Amendment 1053

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex II – part B – point 1 ab (new)

Text proposed by the Commission

Amendment

1ab. Age-standardised proportion of citizens who do not exercise, by gender and age

Or. en

Amendment 1054

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex II – part B – point 1 ac (new)

Text proposed by the Commission

Amendment

1ac. Proportion of HIV/AIDS patients with access to adequate treatment, by gender and age

Or. en

Amendment 1055

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex II – part B – point 1 ad (new)

Text proposed by the Commission

Amendment

1ad. Proportion of Tuberculosis patients with access to adequate treatment, by gender and age

Amendment 1056

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex II – part B – point 1 ae (new)

Text proposed by the Commission

Amendment

1ae. Proportion of viral hepatitis patients with access to adequate treatment, by gender and age

Or. en

Amendment 1057

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex II – part B – point 1 af (new)

Text proposed by the Commission

Amendment

1af. Maternal mortality ratio (per 100 000 live births)

Or. en

Amendment 1058

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex II – part B – point 1 ag (new)

Text proposed by the Commission

Amendment

1ag. Infant mortality rate (per 100 000 live births);

Or. en

Amendment 1059
Maria Spyraiki

Proposal for a regulation
Annex II – part 2 – point 3

Text proposed by the Commission

Amendment

3. *Number of vaccine doses distributed*

3. ***Vaccination coverage rates for all vaccinations included in the national immunization programmes***

Or. en

Amendment 1060
Jessica Polfjärd

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 distributed ***and immunisation coverage rates***

Or. en

Amendment 1061
Michèle Rivasi

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

Text proposed by the Commission

3. Number of vaccine doses distributed

Amendment

3. Number of vaccine doses distributed ***[by type and MS]***

Or. en

Amendment 1062

Adam Jarubas

Proposal for a regulation

Annex II – part B – point 3 a (new)

Text proposed by the Commission

Amendment

3a. Ratio of use of generic and biosimilar medicines

Or. en

Amendment 1063

Michèle Rivasi

Proposal for a regulation

Annex II – part B – point 5 a (new)

Text proposed by the Commission

Amendment

5a. Number of cancer cases [by organ and MS]

Or. en

Amendment 1064

Michèle Rivasi

Proposal for a regulation

Annex II – part B – point 6

Text proposed by the Commission

Amendment

6. Age-standardised five-year net

6. Age-standardised five-year net

survival of cervical, breast and colorectal cancer

survival of cervical, breast, **lung, blood, brain** and colorectal cancer **as well as of heart attacks and stroke**

Or. en

Amendment 1065
Mick Wallace

Proposal for a regulation
Annex II – part B – 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 cervical, breast and colorectal cancer, **heart attacks and stroke**

Or. en

Amendment 1066
Mick Wallace

Proposal for a regulation
Annex II – part B – 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

7. Ratio of Cancer Registries (CRs) and number of Member States (MSs) reporting information on cervical, breast, and colorectal cancer stage at diagnosis **as well as other major chronic diseases**

Or. en

Amendment 1067
Linea Søgaard-Lidell, Frédérique Ries, Jan Huitema

Proposal for a regulation
Annex II – part B – 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

7. Ratio of Cancer Registries (CRs) and number of Member States (MSs) reporting information on cervical, breast, and colorectal cancer stage at diagnosis *as well as other major chronic diseases*

Or. en

Amendment 1068

Michèle Rivasi

**Proposal for a regulation
Annex II – part B – 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

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

Or. en

Amendment 1069

Nicolae Ștefănuță, Véronique Trillet-Lenoir

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

Text proposed by the Commission

Amendment

7a. Ratio of palliative care admissions and outcome result for cancer and paediatric cancer

Or. en

Amendment 1070

Cristian-Silviu Bușoi

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

Text proposed by the Commission

8. ***Smoking*** prevalence

Amendment

8. ***Age-standardized prevalence of current tobacco use among persons aged 15 years and older [SDG 3.a.1]***

Or. en

Amendment 1071

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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

Text proposed by the Commission

8. Smoking prevalence

Amendment

8. ***Age-standardised smoking prevalence, by gender and age***

Or. en

Amendment 1072

Nathalie Colin-Oesterlé

Proposal for a regulation
Annex II – part 2 – point 8 a (new)

Text proposed by the Commission

Amendment

8a. Common and shared approach to notification, reporting and definition of shortages, reflecting the real impact on patients

Or. fr

Amendment 1073
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

**8a. Percentage of adults (aged 18+)
classified as overweight or obese**

Or. en

Amendment 1074
Linea Sogaard-Lidell, Frédérique Ries, Jan Huitema

Proposal for a regulation
Annex II – part 2 – point 8 a (new)

Text proposed by the Commission

Amendment

**8a. Prevalence of overweight and
obesity**

Or. en

Amendment 1075
Mick Wallace

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

Text proposed by the Commission

Amendment

**8a. Prevalence of overweight and
obesity**

Or. en

Amendment 1076
Michèle Rivasi

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

Text proposed by the Commission

Amendment

8a. Prevalence of overweight and obesity

Or. en

Amendment 1077
Mairead McGuinness

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

Text proposed by the Commission

Amendment

8a. Prevalence of overweight and obesity

Or. en

Amendment 1078
Margarita de la Pisa Carrión

Proposal for a regulation
Annex II – part 2 – point 8 a (new)

Text proposed by the Commission

Amendment

8a. Sexually transmitted infections

Or. es

Amendment 1079
Nicolae Ștefănuță, Véronique Trillet-Lenoir

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

Text proposed by the Commission

Amendment

8a. Obesity prevalence

Or. en

Amendment 1080
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

8b. Common and shared approach to shortages reporting, notification and definition, reflecting the real impact on patients

Or. en

Amendment 1081
Michèle Rivasi

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

Text proposed by the Commission

Amendment

8b. Prevalence of major chronic diseases as defined by WHO

Or. en

Amendment 1082
Nicolae Ştefănuţă, Véronique Trillet-Lenoir

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

Text proposed by the Commission

Amendment

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

9. Number of shortages of medicines
in *Member States*

Or. en

Amendment 1083

Jessica Polfjärd

Proposal for a regulation

Annex II – part 2 – point 12

Text proposed by the Commission

Amendment

12. Deaths attributable to antimicrobial
resistant infections

12. Deaths *and diseases* attributable to
antimicrobial resistant infections

Or. en

Amendment 1084

Michèle Rivasi

Proposal for a regulation

Annex II – part B – point 12 a (new)

Text proposed by the Commission

Amendment

**12 a. Quantity of antimicrobial use [by
type and MS, separately for humans and
animals]**

Or. en

Amendment 1085

Joanna Kopcińska

Proposal for a regulation

Annex II – part B – point 14

Text proposed by the Commission

Amendment

14. Number of Health Technology Assessment reports jointly carried out

deleted

Or. en

Amendment 1086
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

14a. ECDC reports on progress on elimination of viral hepatitis, HIV/ AIDS and Tuberculosis in line with WHO Strategies and UN SDGs

Or. en

Amendment 1087
Michèle Rivasi

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

Text proposed by the Commission

Amendment

14a. Relative compliance with WHO air quality limits and environmental quality standards under EU water legislation

Or. en

Amendment 1088
Linea Søgaard-Lidell, Frédérique Ries, Jan Huitema

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

Text proposed by the Commission

Amendment

14a. Prevalence of major chronic diseases as defined by WHO

Or. en

Amendment 1089

Mick Wallace

Proposal for a regulation

Annex II – part B – point 14 a (new)

Text proposed by the Commission

Amendment

14a. Prevalence of major chronic diseases as defined by WHO

Or. en

Amendment 1090

Mairead McGuinness

Proposal for a regulation

Annex II – part B – point 14 a (new)

Text proposed by the Commission

Amendment

14a. Prevalence of major chronic diseases as defined by the WHO

Or. en

Amendment 1091

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

Proposal for a regulation

Annex II – part B – point 14 a (new)

Text proposed by the Commission

Amendment

14a. Number of health impact assessments of Union policies

Or. en

Amendment 1092
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

14b. Avoidable deaths attributed to cardiovascular disease, cancer, diabetes & chronic respiratory disease for persons aged less than 75 years [SDG 3.4.1]

Or. en

Amendment 1093
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

14c. Total alcohol per capita (age 15+ years) consumption [SDG 3.5.2]

Or. en

Amendment 1094
Cristian-Silviu Buşoi

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

Text proposed by the Commission

Amendment

14d. Screening coverage (by examination & invitation) for breast, cervical and colorectal cancer screening programmes

Or. en

Amendment 1095

Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López, Łukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel

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

Text proposed by the Commission

Amendment

Ba. Age-standardized QALYs attributable to the NCDs (per 100 000 people), by disease, gender and age

Or. en