



**2020/0102(COD)**

16.7.2020

# **AMENDMENTS 115 - 519**

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

**Proposal for a regulation**

**Recital 2**

*Text proposed by the Commission*

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

*Amendment*

(2) In accordance with Articles 9, **114, 168 and 191** of the Treaty on the Functioning of the European Union (TFEU) and Article 35 of the Charter of Fundamental Rights of the European Union (the Charter), a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities.

Or. en

**Amendment 116**

**Pascal Arimont, Cindy Franssen, Esther de Lange**

**Proposal for a regulation**

**Recital 3**

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 117**

**Joanna Kopcińska**

**Proposal for a regulation**  
**Recital 3**

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 118**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Recital 3 a (new)**

*Text proposed by the Commission*

*Amendment*

*(3a) While the treaties oblige the EU to improve public health, preventing physical, and mental illness and diseases and obviating sources of danger to physical and mental health, the new and upcoming challenges, like COVID-19, have clearly shown that EU needs to take a stronger role ensuring the needed health policies are in place and health and wellbeing for its citizens because the Member States alone don't have the adequate skills, capacities and resources to face the increasing and more complex health challenges.*

Or. en

**Amendment 119**  
**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  
Recital 3 a (new)**

*Text proposed by the Commission*

*Amendment*

***(3a) In its communication of 20 October 2010 entitled ‘Solidarity in Health: Reducing Health Inequalities in the EU’, the Commission considered that there is a social gradient in health status in all the EU Member States. The World Health Organisation defines this social gradient as being the link between socioeconomic inequalities and inequalities in the areas of health and access to healthcare.***

Or. en

**Amendment 120**

**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  
Recital 3 b (new)**

*Text proposed by the Commission*

*Amendment*

***(3b) Health inequalities are rooted in social inequalities in terms of living conditions and models of social behaviour linked to gender, race, educational standards, employment, income and the unequal distribution of access to medical assistance, sickness prevention and health promotion services. The programme should facilitate the establishment of a common set of health determinants to monitor health inequalities by age, sex, socio-economic status and geographic location and introduce a methodology for auditing the health situation in Member States with the aim of identifying and***

*prioritising areas in need of improvement and increased fundings. In its annual implementation assessment report, the Commission should evaluate the effectiveness of measures to reduce health inequalities resulting from policies relating to the social, economic and environmental risk factors. Through the allocation of fundings to the relevant regional and local stakeholders, the Programme should support a 'local care approach' to provide integrated healthcare, accessible at local or regional level, enabling patients to be better supported in their own local and social environment. The programme could also facilitate partnerships between border regions in order to share the cost of infrastructure and personnel and reduce inequalities with regard to health, particularly in respect of access to state-of-the-art equipment. The programme should therefore be implemented in close links with EU cohesion policy and structural funds.*

Or. en

#### **Amendment 121**

**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**

#### **Recital 4 a (new)**

*Text proposed by the Commission*

*Amendment*

**(4a) Article 191 TFEU provides that the Union should contribute to protecting human health through a Union policy on the environment.**

Or. en

## Amendment 122

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

#### Recital 5

##### *Text proposed by the Commission*

(5) On 11 March 2020 the World Health Organization (WHO) declared the novel coronavirus (**COVID-19**) outbreak a global pandemic. **That pandemic has** caused an unprecedented worldwide health crisis with severe socio-economic consequences and human suffering.

##### *Amendment*

(5) On 11 March 2020 the World Health Organization (WHO), **due to an exponential increase of cases**, declared **COVID-19 (the disease resulting from the novel coronavirus SARS-CoV-2)** outbreak a global pandemic. **The COVID-19 pandemic and more specifically the moderate to severe cases of the disease that need intermediate and intensive medical care pushed several health systems to breaking point within and outside Union**, caused an unprecedented worldwide health crisis with severe socio-economic consequences and human suffering, **particularly affecting people with chronic conditions and hitting the most vulnerable, patients, women, carers and the elderly the hardest. The world continues the fight against this unprecedented health crisis, which has led to lock downs and restrictions on the circulation of people, animals, food, medicines and others.**

Or. en

## Amendment 123

Dolors Montserrat

### Proposal for a regulation

#### Recital 5

##### *Text proposed by the Commission*

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

##### *Amendment*

(5) On 11 March 2020 the World Health Organization (WHO) declared the novel **SARS-CoV-2** coronavirus **and**

global pandemic. That pandemic has caused an unprecedented worldwide health crisis with severe socio-economic consequences and human suffering.

*associated respiratory disease (COVID19) outbreak a global pandemic. That pandemic, and more specifically the severe acute respiratory disease causing both premature death and chronic lung conditions that it involves, has caused an unprecedented worldwide health crisis with severe socio-economic consequences and human suffering, particularly affecting people with chronic conditions and hitting the most vulnerable, patients, carers and the elderly the hardest.*

Or. en

#### *Justification*

*Specifying the respiratory aspects of SARS-CoV2 in the draft report is helpful. However, another helpful addition would be necessary as almost all COVID-19 fatalities had an underlying, other chronic health conditions, and older people were particularly affected.*

#### **Amendment 124** **Sirpa Pietikäinen**

#### **Proposal for a regulation** **Recital 5**

##### *Text proposed by the Commission*

(5) On 11 March 2020 the World Health Organization (WHO) declared the novel coronavirus (**COVID-19**) outbreak a global pandemic. That pandemic has caused an unprecedented worldwide health crisis with severe socio-economic consequences and human suffering.

##### *Amendment*

(5) On 11 March 2020 the World Health Organization (WHO) declared the novel **SARS-CoV-2** coronavirus **and associated respiratory disease (COVID19)** outbreak a global pandemic. That pandemic, **and more specifically the severe acute respiratory disease causing both premature death and chronic lung conditions that it involves**, has caused an unprecedented worldwide health crisis with severe socio-economic consequences and human suffering, **particularly affecting the most vulnerable, patients, people suffering from chronic diseases, women and carers.**

Or. en

## *Justification*

*Sex and gender—which includes both biological and social influences—are critical to health. Many diseases affect men and women differently, including diabetes, depression and cardiovascular disease. In addition, women do not present with the same symptoms and respond differently to treatments than do men. Women also have higher rates of disease such as breast cancer, osteoporosis and auto-immune diseases (EIWH 2018a; Eurostat 2017b; ENGENDER 2011; EIWH 2017ab).*

### **Amendment 125** **Joanna Kopcińska**

#### **Proposal for a regulation** **Recital 5**

##### *Text proposed by the Commission*

(5) On 11 March 2020 the World Health Organization (WHO) declared the novel coronavirus (COVID-19) outbreak a global pandemic. ***That*** pandemic has ***caused an unprecedented worldwide*** health crisis ***with*** severe socio-economic consequences and human suffering.

##### *Amendment*

(5) On 11 March 2020 the World Health Organization (WHO) declared the novel coronavirus (COVID-19) outbreak a global pandemic. ***This*** pandemic has ***since become the defining global*** health crisis ***of our time, causing*** severe socio-economic consequences and human suffering. ***The extent, depth and breadth of this crisis has demonstrated the added value of the EU's actions, which serve to complement national policies in the field of public health.***

Or. en

### **Amendment 126** **Mairead McGuinness**

#### **Proposal for a regulation** **Recital 5**

##### *Text proposed by the Commission*

(5) On 11 March 2020 the World Health Organization (WHO) declared the novel coronavirus (COVID-19) outbreak a global pandemic. That pandemic has caused an unprecedented worldwide health

##### *Amendment*

(5) On 11 March 2020 the World Health Organization (WHO) declared the novel coronavirus (COVID-19) outbreak a global pandemic. That pandemic has caused an unprecedented worldwide health

crisis with severe socio-economic consequences and human suffering.

crisis with severe socio-economic consequences and human suffering. ***Its impact has not been evenly felt: people more vulnerable in society, such as those with pre-existing chronic conditions or living in institutionalised care, have been at particular risk from the disease.***

Or. en

#### **Amendment 127**

**Nicolae Ștefănuță, Véronique Trillet-Lenoir**

#### **Proposal for a regulation**

##### **Recital 5**

*Text proposed by the Commission*

(5) On 11 March 2020 the World Health Organization (WHO) declared the novel coronavirus (COVID-19) outbreak a global pandemic. That pandemic has caused an unprecedented worldwide health crisis with severe socio-economic consequences and human suffering.

*Amendment*

(5) On 11 March 2020 the World Health Organization (WHO) declared the novel coronavirus (COVID-19) outbreak a global pandemic. That pandemic has caused an unprecedented worldwide health crisis with severe socio-economic consequences and human suffering, ***particularly affecting people with chronic conditions and hitting the most vulnerable, patients, women, carers and the elderly the hardest.***

Or. en

#### **Amendment 128**

**Sirpa Pietikäinen**

#### **Proposal for a regulation**

##### **Recital 5 a (new)**

*Text proposed by the Commission*

*Amendment*

***(5a) Women have been impacted disproportionately by the pandemic response measures and their long-term effects, must not compound existing inequities. Women across the lifespan***

*remain under-represented in biomedical and health research and data. Consequently, the evidence base is weaker for women as well as for older people, many conditions are underdiagnosed in women, such as cardiovascular disease. Medicinal products are safer and more effective for everyone when clinical research studies include diverse population groups. To reduce inequalities and health disparities, sex and gender should be incorporated throughout the health process from design of clinical trial protocols, data analysis, health technology assessment and access to care.*

Or. en

*Justification*

*Diseases and their treatments affect men and women differently; therefore, sex, and gender factors must be integrated in biomedical and health research to provide effective, equitable and efficient healthcare.*

**Amendment 129**  
**Michèle Rivasi**

**Proposal for a regulation**  
**Recital 5 a (new)**

*Text proposed by the Commission*

*Amendment*

**(5a)** *On 11 March 2020 the World Health Organization (WHO) declared the novel SARS-CoV-2 coronavirus and associated respiratory disease (COVID-19) outbreak a global pandemic. That pandemic, and more specifically the severe acute respiratory disease causing both premature death and chronic lung conditions that it involves, has caused an unprecedented worldwide health crisis with severe socio-economic consequences and human suffering. The severity of the crisis demonstrates also the importance of Union action on the prevention and management of respiratory diseases.*

*Justification*

*Like AM 1 of the rapporteur, with the addition of a reference to "prevention" of respiratory diseases.*

**Amendment 130**

**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**

**Recital 5 a (new)**

*Text proposed by the Commission*

*Amendment*

**(5a) According to the definition of the World Health Organisation (WHO), "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." At this stage, the Union has not yet adopted a common definition of health. Following the COVID-19 crisis. The Commission should propose a broader definition of the "public health" at European level.**

**Amendment 131**

**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, Linea Søgaaard-Lidell, María Soraya Rodríguez Ramos**

**Proposal for a regulation**

**Recital 5 b (new)**

*Text proposed by the Commission*

*Amendment*

**(5b) The Programme should strongly advocate for the promotion of effective prevention and hygiene measures to**

*prevent and control infections, reduce the burden of resistant infections and healthcare-associated infections and secure the availability of effective antimicrobials. Important habits, including hygiene practices, should be developed from an early age when children are best able to integrate them. The Programme should also support educational prevention programmes on health for youth (harmless behaviours, healthy nutrition, sport, etc.)*

Or. en

**Amendment 132**  
**Rob Rooken**

**Proposal for a regulation**  
**Recital 6**

*Text proposed by the Commission*

(6) *While* Member States are responsible for their health policies, *they are expected to protect public health in a spirit of European solidarity*<sup>8</sup>. *Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.*

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<sup>8</sup> *Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak,*

*Amendment*

(6) Member States are responsible for their health policies. *However, the COVID-19 crisis has demonstrated that cooperation among the Member States is welcome in order to prevent and control the spread of severe human diseases across borders.*

**Amendment 133**  
**Joanna Kopcińska**

**Proposal for a regulation**  
**Recital 6**

*Text proposed by the Commission*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is ***a need for a further firm action at Union level*** to support cooperation and coordination among the Member States in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

*Amendment*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is ***scope for the Union to better deliver on public health policy within the existing parameters of the Treaties*** to support cooperation and coordination among the Member States in order to improve the prevention and control of the spread of severe human diseases across borders, to ***develop, test and make available products for the prevention and treatment of diseases***, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

**Amendment 134**  
**Pascal Arimont, Cindy Franssen, Esther de Lange**

**Proposal for a regulation**  
**Recital 6**

*Text proposed by the Commission*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing **COVID-19** crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

*Amendment*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. ***Despite the reintroduction of internal borders at a time where solidarity between Member States was the most needed, several healthcare projects between cross-border regions, funded by Interreg programmes, have contributed to the fight against the COVID-19 crisis.*** Experience from the ongoing crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States ***as well as between neighbouring border regions*** in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

Or. en

**Amendment 135**

**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**  
**Recital 6**

*Text proposed by the Commission*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States in order to improve *the* prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

*Amendment*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States *to support rights- and evidence-based approaches that have a high impact* in order to improve *preparedness for*, prevention and *a timely and effective* control of the spread of severe human *infections and* diseases across borders, *to develop and guarantee the availability and accessibility of products for the prevention and treatment of diseases*, to combat other serious cross-border threats to health and to safeguard *and improve* the health and well-being of people in the Union.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

Or. en

**Amendment 136**

**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**  
**Recital 6**

*Text proposed by the Commission*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

*Amendment*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States in order to improve the prevention and control of the spread of severe human diseases across borders, to ***develop and guarantee the availability and accessibility of products for the prevention and treatment of diseases, to ensure that all Member States have fair access to medical products, to*** combat other serious cross-border threats to health and to ***prevent and respond to medicines shortages in a timely manner that takes fairly and comprehensively into account the individual needs of each Member State, and to*** safeguard the health and well-being of ***all*** people in the Union, ***including by combating vaccine hesitancy that may decrease immunisation coverage among certain population groups.***

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

Or. en

**Amendment 137**  
**Nathalie Colin-Oesterlé**

**Proposal for a regulation**  
**Recital 6**

*Text proposed by the Commission*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health **and** to safeguard the health and well-being of people in the Union.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.2020.

*Amendment*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States, ***as well as a permanent structured and coordinated dialogue between the authorities and the parties concerned***, in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health, to safeguard the health and well-being of people in the Union, ***and to take all necessary measures to combat shortages by increasing the resilience of health systems in order to ensure that European citizens have access to medicines and medical equipment***.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.2020.

Or. fr

**Amendment 138**  
**Michèle Rivasi**

**Proposal for a regulation**  
**Recital 6**

*Text proposed by the Commission*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

*Amendment*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States ***to support rights- and evidence-based approaches with significant impact*** in order to improve the prevention and control of the spread of severe human diseases across borders, to ***develop and make available products for the prevention and treatment of diseases without discrimination, to*** combat other serious cross-border threats to health, ***to prevent and respond to medicines shortages***, and to safeguard the health and well-being of ***all*** people in the Union.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

Or. en

**Amendment 139**  
**Margarita de la Pisa Carrión**

**Proposal for a regulation**  
**Recital 6**

*Text proposed by the Commission*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience

*Amendment*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience

from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.

from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States in order to improve the prevention and control of the spread of severe human diseases across borders, ***as well as to ensure crisis-relevant products for the most affected areas***, to develop and make available products for the prevention and treatment of diseases, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union, ***avoiding any kind of discrimination in terms of hospitalisation and treatment***.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

Or. es

**Amendment 140**  
**Nicolae Ștefănuță, Véronique Trillet-Lenoir**

**Proposal for a regulation**  
**Recital 6**

*Text proposed by the Commission*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States in order to improve the prevention and control of the

*Amendment*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States in order to improve the prevention and control of the

spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

spread of severe human diseases across borders, to ***develop and guarantee the availability and accessibility of products for the prevention and treatment of diseases, to*** combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

Or. en

## **Amendment 141** **Danilo Oscar Lancini**

### **Proposal for a regulation** **Recital 6**

#### *Text proposed by the Commission*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.

#### *Amendment*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States, ***as well as a permanent structured and coordinated dialogue between authorities and relevant stakeholders***, in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.

<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

Or. en

## **Amendment 142** **Cristian-Silviu Buşoi**

### **Proposal for a regulation** **Recital 6**

#### *Text proposed by the Commission*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

#### *Amendment*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States, ***as well as a permanent structured and coordinated dialogue between authorities and relevant stakeholders***, in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

Or. en

**Amendment 143**  
**Frédérique Ries**

**Proposal for a regulation**  
**Recital 6**

*Text proposed by the Commission*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

*Amendment*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States, ***as well as a permanent structured and coordinated dialogue between authorities and relevant stakeholders***, in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

Or. en

**Amendment 144**  
**Adam Jarubas**

**Proposal for a regulation**  
**Recital 6**

*Text proposed by the Commission*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

*Amendment*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States ***and all relevant stakeholders, public, private and civil society, in a structured, regular, manner*** in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

Or. en

**Amendment 145**  
**César Luena**

**Proposal for a regulation**  
**Recital 6**

*Text proposed by the Commission*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to

*Amendment*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to

support cooperation and coordination among the Member States in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

support cooperation and coordination among the Member States ***as well as coordinated dialogue between authorities and relevant stakeholders***, in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

Or. en

## **Amendment 146** **Mairead McGuinness**

### **Proposal for a regulation** **Recital 6**

#### *Text proposed by the Commission*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States ***in order to*** improve the prevention and control of the spread of severe human diseases across borders, ***to*** combat other serious cross-border threats to health and ***to*** safeguard the health and well-being of people in the Union.

#### *Amendment*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States, ***not only in response to the current crisis, but in general. This cooperation should*** improve the prevention and control of the spread of severe human diseases across borders, combat other serious cross-border threats to health and safeguard the health and well-being of people in the Union.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.220.

Or. en

## Amendment 147

Véronique Trillet-Lenoir, Stéphane Bijoux

### Proposal for a regulation

#### Recital 6

##### *Text proposed by the Commission*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.2020.

##### *Amendment*

(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>8</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union, ***regardless of where they are located, so that no one is overlooked.***

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<sup>8</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)112 final of 13.03.2020.

Or. fr

**Amendment 148**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Recital 6 a (new)**

*Text proposed by the Commission*

*Amendment*

***(6a) While the Union's action in the field of health is limited, the Union shall follow a coherent public health strategy in order to respond to existing epidemics taking into consideration regional and national specificities and have the capacity to face future worrying realities and health threats, such as pandemics and cross-border threats, including antimicrobial resistance and the health impacts of the climate crisis. The Union shall support Member States in reducing health inequalities and in achieving universal health coverage, addressing the challenges of an ageing population, of chronic diseases, or disease prevention, in promoting a healthy lifestyle, prevention services and preparing their health systems for emerging technologies.***

Or. en

**Amendment 149**  
**Nicolae Ştefănuţă, Véronique Trillet-Lenoir**

**Proposal for a regulation**  
**Recital 6 a (new)**

*Text proposed by the Commission*

*Amendment*

***(6a) While the Union's action in the field of health is limited, the Union shall follow a coherent public health strategy in order face future worrying realities and health threats, such as pandemics and cross-border threats, including antimicrobial resistance and the health***

*impacts of the climate crisis. The Union shall support Member States in reducing health inequalities and in achieving universal health coverage, addressing the challenges of an ageing population, of chronic diseases, or disease prevention, in promoting a healthy lifestyle, equal from a sex, gender and perspective to health and prevention services and preparing their health systems for emerging technologies.*

Or. en

**Amendment 150**  
**Margarita de la Pisa Carrión**

**Proposal for a regulation**  
**Recital 6 a (new)**

*Text proposed by the Commission*

*Amendment*

*(6a.) Although the Union's action in the field of health is limited, it should have the ability to respond to future realities that may pose a threat to health, such as pandemics or antimicrobial resistance. It should also support the Member States in tackling the challenges of an ageing population, chronic diseases and the prevention of various age-related illnesses. Overall, priority should be given to promoting a healthy lifestyle. New technologies should also be introduced into the health systems.*

Or. es

**Amendment 151**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Recital 6 a (new)**

*Text proposed by the Commission*

*Amendment*

**(6a)** *While the Union's action in the field of health is limited, the Union should have the capacity to face future worrying realities and health threats, such as pandemics and cross-border threats, antimicrobial resistance, and also to support Member States in addressing the challenges of an ageing population, of chronic diseases, or disease prevention, in promoting a healthy lifestyle, including a sex, gender and age perspective and preparing their health systems for emerging technologies.*

Or. en

**Amendment 152**

**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**

**Recital 6 a (new)**

*Text proposed by the Commission*

*Amendment*

**(6a)** *The pandemic has revealed the importance of public health policies, and their benefits for citizens, communities and the economy. Such policies are cost-saving and offer returns in the long term of 14:1, meaning that for each euro invested in public health policies, we have economic return of 14 euros.*

Or. en

**Amendment 153**

**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**  
**Recital 6 b (new)**

*Text proposed by the Commission*

*Amendment*

**(6b)** *While the Union's action in the field of health is limited, the Union should follow a coherent public health strategy in order to flexibly respond to existing epidemics taking into consideration local specificities and having the capacity to face future worrying realities and health threats, such as pandemics and cross-border threats, including antimicrobial resistance and the health impacts of the climate crisis. The Union should support Member States in reducing health inequalities and in achieving universal health coverage, addressing the challenges of an ageing population, of chronic diseases, of disease prevention, in promoting a healthy lifestyle and preparing their health systems for emerging technologies.*

Or. en

**Amendment 154**

**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**

**Recital 6 b (new)**

*Text proposed by the Commission*

*Amendment*

**(6b)** *While the Union's action in the field of health is limited, the Union should*

*have the capacity to face future risks, realities and health threats, such as pandemics and cross-border threats, including antimicrobial resistance and environmental health threats, and also to support Member States in addressing the challenges of an ageing population, of chronic and rare diseases, or disease prevention, and preparing their health systems for emerging technologies in order to fully benefit from the digital revolution while seeking synergies with other relevant EU programmes such as Horizon Europe, Digital Europe, Connecting Europe Facility programme or Space Programme.*

Or. en

**Amendment 155**

**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  
Recital 6 c (new)**

*Text proposed by the Commission*

*Amendment*

***(6c) The Commission's communication of 20 October 2010 entitled 'Solidarity in Health: Reducing Health Inequalities in the EU' underlines that there is a social gradient in health status in the Member States and that the World Health Organisation defines this social gradient as being the link between socioeconomic inequalities and inequalities in the areas of health and access to healthcare. Health inequalities are rooted in social inequalities in terms of living conditions and models of social behaviour linked to gender, race, educational standards, employment, income and the unequal distribution of access to medical assistance, sickness prevention and health***

*promotion services.*

Or. en

#### **Amendment 156**

**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**

##### **Recital 7**

###### *Text proposed by the Commission*

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

###### *Amendment*

(7) It is therefore appropriate to establish a new Programme for the Union's action in the field of health, called EU4Health Programme ('the Programme') for the period 2021 -2027. In line with the goals of the Union action and its competences in the area of public health the Programme should place emphasis on actions in relation to which there are advantages and efficiency gains from collaboration and cooperation at Union level and actions with an impact on the internal market. ***The EU regulates products relevant to health and health outcomes including, amongst others, pharmaceuticals, medical devices, tobacco, alcohol, food and chemicals, therefore the Programme should take into consideration regulation in such areas to improve the health outcomes in the EU. A holistic approach is needed to improve health outcomes, and EU policy-makers should ensure that the principle of 'health in all policies' is applied in all policy-making.***

Or. en

#### **Amendment 157**

**Pascal Arimont, Cindy Franssen, Esther de Lange**

**Proposal for a regulation**  
**Recital 7**

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 158**  
**Nicolae Ștefănuță, Véronique Trillet-Lenoir**

**Proposal for a regulation**  
**Recital 7**

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

## Amendment 159

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

#### Recital 9

*Text proposed by the Commission*

(9) In accordance with Regulation [European Union Recovery Instrument] and within the limits of resources allocated therein, recovery and resilience measures under the Programme should be carried out to address the unprecedented impact of the COVID-19 crisis. Such additional resources should be used in such a way as to ensure compliance with the time limits provided for in Regulation [European Union Recovery Instrument].

*Amendment*

(9) In accordance with Regulation [European Union Recovery Instrument] and within the limits of resources allocated therein, recovery and resilience measures under the Programme should be carried out to address the unprecedented impact of the COVID-19 crisis ***and ensure that resilient healthcare and health systems are in place in preparation for future pandemics, improve the health status in societies and to ensure that people are healthier and therefore less susceptible to health threats.*** Such additional resources should be used in such a way as to ensure compliance with the time limits provided for in Regulation [European Union Recovery Instrument]. ***Preparedness is the key to improving resilience to future threats, and Member States, given their responsibility for the provision of healthcare, should carry out stress tests on their healthcare systems to identify weaknesses and verify that they are prepared for a possible future health crisis, through the support of the Commission and its coordination action to establish common acceptable parameters.***

Or. en

## Amendment 160

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**

**Recital 9**

*Text proposed by the Commission*

(9) In accordance with Regulation [European Union Recovery Instrument] and within the limits of resources allocated therein, recovery and resilience measures under the Programme should be carried out to address the unprecedented impact of the COVID-19 crisis. Such additional resources should be used in such a way as to ensure compliance with the time limits provided for in Regulation [European Union Recovery Instrument].

*Amendment*

(9) In accordance with Regulation [European Union Recovery Instrument] and within the limits of resources allocated therein, recovery and resilience measures under the Programme should be carried out to address the unprecedented impact of the COVID-19 crisis ***and ensure that resilient healthcare and health systems are in place in preparation for future pandemics and other health crises. Full advantage should be taken of the opportunities that digitalisation, artificial intelligence, robotics and new innovative technologies, in health and care can provide while ensuring the security of data, the right to privacy and data protection, while deploying adequate resources to ensure protection against cyber threats.*** Such additional resources should be used in such a way as to ensure compliance with the time limits provided for in Regulation [European Union Recovery Instrument].

Or. en

**Amendment 161**

**Nicolae Ştefănuţă, Véronique Trillet-Lenoir**

**Proposal for a regulation**

**Recital 9**

*Text proposed by the Commission*

(9) In accordance with Regulation [European Union Recovery Instrument] and within the limits of resources allocated therein, recovery and resilience measures under the Programme should be carried out

*Amendment*

(9) In accordance with Regulation [European Union Recovery Instrument] and within the limits of resources allocated therein, recovery and resilience measures under the Programme should be carried out

to address the unprecedented impact of the COVID-19 crisis. Such additional resources should be used in such a way as to ensure compliance with the time limits provided for in Regulation [European Union Recovery Instrument].

to address the unprecedented impact of the COVID-19 crisis ***and ensure that resilient and responsive healthcare and public health systems are in place in preparation for future pandemics and other cross-border health crises***. Such additional resources should be used in such a way as to ensure compliance with the time limits provided for in Regulation [European Union Recovery Instrument].

Or. en

**Amendment 162**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Recital 9**

*Text proposed by the Commission*

(9) In accordance with Regulation [European Union Recovery Instrument] and within the limits of resources allocated therein, recovery and resilience measures under the Programme should be carried out to address the unprecedented impact of the COVID-19 crisis. Such additional resources should be used in such a way as to ensure compliance with the time limits provided for in Regulation [European Union Recovery Instrument].

*Amendment*

(9) In accordance with Regulation [European Union Recovery Instrument] and within the limits of resources allocated therein, recovery and resilience measures under the Programme should be carried out to address the unprecedented impact of the COVID-19 crisis ***and ensure that resilient and responsive healthcare and public health systems are in place in preparation for future pandemics and other health crises***. Such additional resources should be used in such a way as to ensure compliance with the time limits provided for in Regulation [European Union Recovery Instrument].

Or. en

**Amendment 163**  
**Joanna Kopcińska**

**Proposal for a regulation**  
**Recital 9**

*Text proposed by the Commission*

(9) In accordance with Regulation [European Union Recovery Instrument] and within the limits of resources allocated therein, recovery and resilience measures under the Programme should be carried out to address the unprecedented impact of the COVID-19 crisis. Such additional resources should be used in such a way as to ensure compliance with the time limits provided for in Regulation [European Union Recovery Instrument].

*Amendment*

(9) In accordance with Regulation [European Union Recovery Instrument] and within the limits of resources allocated therein, recovery and resilience measures under the Programme should be carried out to address the unprecedented impact of the COVID-19 crisis ***and ensure that resilient health care systems and services are in place***. Such additional resources should be used in such a way as to ensure compliance with the time limits provided for in Regulation [European Union Recovery Instrument].

Or. en

**Amendment 164**

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

**Proposal for a regulation**

**Recital 10**

*Text proposed by the Commission*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage ***health crisis*** the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the ***Council***<sup>10</sup> and other relevant mechanisms and structures established at Union level. ***This could include*** strategic stockpiling of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination

*Amendment*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage ***any future sanitary crises***, the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the ***Council*** and other relevant mechanisms and structures established at Union level. ***The revision of Decision No 1082/2013/EU could initiate*** strategic stockpiling of essential medical supplies, ***in addition to***

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

*the reactive reserve created under RescEU during the Covid-19 pandemic*, or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. *This revision could also introduce the creation of a European Health Response Mechanism to respond to all types of health crises (infectious, chemical, environmental, biological, food, nuclear), to strengthen operational coordination at European level and to monitor the constitution and the triggering of the strategic reserve of medicines and medical equipment and ensure its proper functioning.* In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” *and “Health in all policies” approaches*. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

Or. en

**Amendment 165**  
**Joanna Kopcińska**

**Proposal for a regulation**  
**Recital 10**

*Text proposed by the Commission*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup> and other relevant mechanisms and structures established at Union level. This could include strategic **stockpiling** of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

*Amendment*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup> and other relevant mechanisms and structures established at Union level. This could include **creating** strategic **reserves** of essential medical supplies or **advancing** capacity building **initiatives** in crisis response **at the Member State level**, preventive measures related to vaccination and immunisation, **and** strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” approach, **which reflects the fact that the health of people, animals and the environment are interconnected and that diseases can be transmitted from people to animals and vice versa**. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

**Amendment 166**

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

**Proposal for a regulation****Recital 10***Text proposed by the Commission*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup> and other relevant mechanisms and structures established at Union level. This could include strategic stockpiling of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

*Amendment*

(10) ***COVID-19 has demonstrated the inter-dependencies between human health and the health of our planet and our vulnerabilities. The emergence of zoonotic diseases which are transmitted from animals to humans is exacerbated by anthropogenic climate change, the destruction of biodiversity and environmental degradation.*** Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup> and other relevant mechanisms and structures established at Union level. This could include strategic stockpiling of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and

preparedness exercises, in keeping with the “One Health” approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

Or. en

## **Amendment 167** **Sirpa Pietikäinen**

### **Proposal for a regulation** **Recital 10**

#### *Text proposed by the Commission*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup> and other relevant mechanisms and structures established at Union level. This could include strategic stockpiling of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management

#### *Amendment*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup> and other relevant mechanisms and structures established at Union level. This could include strategic stockpiling of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management

and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response. ***Further developing the common European crisis preparedness, strategically sufficient manufacturing and stockpiling is essential.***

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

Or. en

## **Amendment 168**

**Michèle Rivasi**

### **Proposal for a regulation**

#### **Recital 10**

#### *Text proposed by the Commission*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup> and other relevant mechanisms and structures established at Union level. This could include strategic ***stockpiling*** of essential medical supplies or

#### *Amendment*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup> and other relevant mechanisms and structures established at Union level. This could include ***creating*** strategic ***reserves*** of essential medical

capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

supplies or capacity building in crisis response, preventive measures related to vaccination, and immunisation **and health promotion**, strengthened surveillance programmes, **platforms to share best practices from conventional and integrative medical approaches**. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

Or. en

## **Amendment 169**

**Véronique Trillet-Lenoir, Stéphane Bijoux**

### **Proposal for a regulation**

#### **Recital 10**

##### *Text proposed by the Commission*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthening the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the

##### *Amendment*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthening the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the

framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup> and other relevant mechanisms and structures established at Union level. This could include strategic stockpiling of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the ‘One Health’ approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup> and other relevant mechanisms and structures established at Union level. This could include strategic stockpiling of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide, ***including in the outermost regions and the overseas countries and territories***, and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the ‘One Health’ approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

Or. fr

## **Amendment 170**

**Nicolae Ștefănuță, Véronique Trillet-Lenoir**

### **Proposal for a regulation**

#### **Recital 10**

*Text proposed by the Commission*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address

*Amendment*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address

different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup> and other relevant mechanisms and structures established at Union level. This could include strategic stockpiling of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup> and other relevant mechanisms and structures established at Union level. This could include strategic stockpiling of essential medical supplies *in addition to the reactive reserve created under rescEU during the Covid-19 pandemic* or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

Or. en

**Amendment 171**  
**Pascal Arimont, Cindy Franssen, Esther de Lange**

**Proposal for a regulation**  
**Recital 10**

*Text proposed by the Commission*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup> and other relevant mechanisms and structures established at Union level. This could include strategic stockpiling of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

*Amendment*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level ***as well as at regional level between regions which share a common border*** to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup> and other relevant mechanisms and structures established at Union level. This could include strategic stockpiling of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

Or. en

## Amendment 172

Mick Wallace, Clare Daly

### Proposal for a regulation

#### Recital 10

##### *Text proposed by the Commission*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup> and other relevant mechanisms and structures established at Union level. This could include strategic stockpiling of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

##### *Amendment*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage ***all aspects of a health crisis in a holistic manner***, the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup> and other relevant mechanisms and structures established at Union level. This could include strategic stockpiling of essential medical supplies or capacity building in crisis response, preventive measures related to ***health education and information***, vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

**Amendment 173**  
**Adam Jarubas**

**Proposal for a regulation**  
**Recital 10**

*Text proposed by the Commission*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup> and other relevant mechanisms and structures established at Union level. This could include strategic stockpiling of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of

*Amendment*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup> and other relevant mechanisms and structures established at Union level. This could include strategic, ***EU financed and coordinated***, stockpiling of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of

**Amendment 174**  
**Jessica Polfjärd**

**Proposal for a regulation**  
**Recital 10**

*Text proposed by the Commission*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup> and other relevant mechanisms and structures established at Union level. This could include strategic **stockpiling** of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

*Amendment*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup> and other relevant mechanisms and structures established at Union level. This could include strategic **and proportionate reserves** of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

response.

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

Or. en

## **Amendment 175**

**Nathalie Colin-Oesterlé**

### **Proposal for a regulation**

#### **Recital 10**

##### *Text proposed by the Commission*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthening the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup> and other relevant mechanisms and structures established at Union level. This could include strategic stockpiling of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the ‘One Health’ approach. It should facilitate

##### *Amendment*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthening the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council and other relevant mechanisms and structures established at Union level. This could include **European** strategic stockpiling of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the ‘One Health’ approach. It should

the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

Or. fr

## **Amendment 176** **Cristian-Silviu Buşoi**

### **Proposal for a regulation** **Recital 10**

#### *Text proposed by the Commission*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup> and other relevant mechanisms and structures established at Union level. This could include strategic **stockpiling** of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the

#### *Amendment*

(10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup> and other relevant mechanisms and structures established at Union level. This could include strategic **EU reserve** of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the

Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

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<sup>10</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

Or. en

**Amendment 177**  
**Nathalie Colin-Oesterlé**

**Proposal for a regulation**  
**Recital 10 a (new)**

*Text proposed by the Commission*

*Amendment*

***(10a) The COVID-19 crisis has highlighted many challenges in ensuring the supply of medicines, medical devices and personal protective equipment needed in the Union during the pandemics. In the event of health crises and pandemics, but also for recurrent shortages, the Programme should promote actions that encourage the production, purchase and management of relevant products by ensuring that they complement other EU instruments.***

Or. fr

**Amendment 178**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Recital 10 a (new)**

*Text proposed by the Commission*

*Amendment*

***(10a) To combat serious threats to the health of European citizens we need to establish communicable diseases regulation. Communicable diseases move freely within whole EU. In more complex and globalised world, the ability to respond to the challenges clearly requires a common regulation to face and tackle the border crossing diseases on EU level. Individual Member States cannot face these global challenges alone.***

Or. en

**Amendment 179**  
**Mick Wallace, Clare Daly**

**Proposal for a regulation**  
**Recital 10 a (new)**

*Text proposed by the Commission*

*Amendment*

***(10a) Given the impact that the COVID-19 crisis had on access to healthcare services, which may not be directly related to the treatment of COVID-19 infections but remain essential healthcare services, including sexual and reproductive healthcare services, the Programme should respond to health crises in a holistic manner and support actions that aim to guarantee access to all essential healthcare services.***

Or. en

**Amendment 180**  
**Kateřina Konečná**

**Proposal for a regulation**  
**Recital 11**

*Text proposed by the Commission*

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

*Amendment*

(11) In the time of health crisis emergency ***Clinical Trials and Health Technology Assessment (HTA)*** can contribute to the rapid development, ***identification and availability*** of medical countermeasures. ***The Commission has presented, in January 2018, a Proposal for a Regulation to support cooperation on HTA at Union level. The European Parliament already provided its position expressing a large support for the Proposal, which is awaiting the position and approval of the European Council. A cooperation among Member States has been running for more than 20 years on a voluntary basis. The Commission Proposal aims at making this coordination fully operational and sustainable under the EU budget. The Proposal profiles the creation of a permanent secretariat (also known as Coordination Group) to support Member States cooperation in the timely identification and assessment of relevant health technologies, so as to ensure the necessary transparency and consistency on the medical and scientific information to be made available to Member States, with the due involvement of experts and patients.*** The programme should provide support to facilitate such actions, ***including the creation of a scientific committee to advise the HTA Coordination Group of Member States on the technologies which are meant to benefit the most from a common assessment. Medical and scientific evidence must override any national administrations' political or industrial interests.***

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<sup>11</sup> ***Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and***

*Justification*

*The importance of HTA for a European integrated health system obliges us to remind the importance of the Commission Proposal, approved by the Parliament and blocked in the Council. The Amendment reminds the terms and the conditions of the Proposal, including transparency, evidence-based medicine, patient engagement, and calls for support by this programme.*

**Amendment 181**  
**Joanna Kopcińska**

**Proposal for a regulation**  
**Recital 11**

*Text proposed by the Commission*

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

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

*Amendment*

(11) In the **context of public health crises**, health technology assessment **and** clinical trials can contribute to the rapid development of medical countermeasures, **and** the Programme should provide support to facilitate such actions. The Commission has adopted a proposal<sup>11</sup> on **HTA** to support cooperation on health technology assessment at Union level. **Notes, however, that there has been limited progress on the proposal in Council as some Member States have challenged its compatibility with the subsidiarity principle and objected to the mandatory uptake of joint HTA reports.**

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

## Amendment 182

Piernicola Pedicini, Eleonora Evi

### Proposal for a regulation

#### Recital 11

*Text proposed by the Commission*

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

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

*Amendment*

(11) As in the time of health crisis emergency health technology assessment as well as clinical trials can contribute to the rapid development of medical countermeasures the Programme should provide support to facilitate such actions. The Commission has adopted a proposal<sup>11</sup> on ***HTA*** to support cooperation on health technology assessment at Union level. ***On 14 February 2019, the European Parliament also adopted its legislative resolution at first reading.***

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

Or. en

## Amendment 183

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

### Proposal for a regulation

#### Recital 11

*Text proposed by the Commission*

(11) As in the time of health crisis emergency health technology assessment as well as clinical trials can contribute to the rapid development of medical countermeasures the Programme should provide support to facilitate such actions. The Commission has adopted a proposal<sup>11</sup>

on **Health Technology Assessment (HTA)** to support cooperation on health technology assessment at Union level.

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

on **HTA** to support cooperation on health technology assessment at Union level. **The Council should adopt a common position and start the negotiations with the Parliament on this proposal.**

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

Or. en

#### **Amendment 184** **Cristian-Silviu Buşoi**

#### **Proposal for a regulation** **Recital 12**

##### *Text proposed by the Commission*

(12) With a view to protect people in vulnerable situations, including those suffering from mental illnesses and chronic diseases, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups.

##### *Amendment*

(12) With a view to protect people in vulnerable situations, including those suffering from mental illnesses, ***living with or most affected by communicable or non-communicable diseases*** and chronic diseases, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups, ***including improving health literacy and supporting patient advocacy groups. With a view to guaranteeing continued high standards of essential healthcare services, including prevention, the Programme should, in particular in times of crisis and pandemics, encourage a transition to accessible and affordable telemedicine, at-home administration of medication and implementation of preventative and self-care plans, where possible and appropriate, while ensuring that access to healthcare and prevention services is provided to chronic patients and patients at risk. The Programme***

*should also ensure that the transition is based on evidence and evaluation of best practices, supported by adequate systems of information and health literacy, infrastructures and careful planning, taking into consideration issues such as access to digital solutions in remote areas or for specific population groups.*

Or. en

**Amendment 185**  
**Kateřina Konečná**

**Proposal for a regulation**  
**Recital 12**

*Text proposed by the Commission*

(12) With a view to protect people in vulnerable situations, including those suffering from mental illnesses and chronic diseases, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups.

*Amendment*

(12) With a view to protect people in vulnerable situations, including those suffering from mental illnesses, ***non-communicable diseases*** and chronic diseases, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups. ***With a view to guaranteeing continued high standards of essential healthcare services, the Programme should, in particular in times of crisis and pandemics, encourage a transition to telemedicine, at-home administration of medication and implementation of preventative and self-care plans, where possible and appropriate, while ensuring that access to healthcare services is provided to chronic patients. The Programme should also ensure that the transition is based on evidence and evaluation of best practices, supported by adequate systems of information and health literacy, infrastructures and careful planning, taking into consideration issues such as access to digital solutions in remote areas or for***

*specific population groups.*

Or. en

### *Justification*

*The COVID-19 crisis revealed once again already existing gaps and weaknesses in our health systems and pushed for the adoption, at least in some cases, of innovative solutions to improve care for patients. However, it will be now fundamental to turn attention to a more systematic strengthening of our health systems, taking into consideration evaluation of best practices – both digital and organisational – adopted during the crisis, evidence-based approach and a more thorough consideration of broader systemic issues.*

### **Amendment 186**

**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**

#### **Recital 12**

#### *Text proposed by the Commission*

(12) With a view to protect people in vulnerable situations, including those suffering from mental illnesses *and chronic diseases*, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups.

#### *Amendment*

(12) With a view to protect people in vulnerable situations, *such as the elderly, children, Roma, migrants, and people living in a socioeconomically precarious situation, amongst others*, including those suffering from *non-communicable diseases, such as cardiovascular diseases, cancer, respiratory diseases, diabetes and mental illnesses amongst others*, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups. *The crisis has revealed that e-health and telemedicine have room to increase and improve the healthcare services and health coverage in a more efficient way. The programme should increase the e-skills of patients and health professionals, improve e-health infrastructures and services, allowing for more competences to be given to patients for the management of their own health and disease treatment, lightening the burden on the healthcare services and*

*increasing their efficiency and availability in responding to demands.*

Or. en

### **Amendment 187**

**Mick Wallace, Clare Daly**

### **Proposal for a regulation**

#### **Recital 12**

#### *Text proposed by the Commission*

(12) With a view to protect people in vulnerable situations, including *those* suffering from mental illnesses and chronic diseases, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups.

#### *Amendment*

(12) With a view to protect people in vulnerable situations, including *people with a disadvantaged socio economic status, women, victims/survivors of sexual and gender-based violence, LGBTI people, ethnic minorities, Roma people, migrant people, people living with disabilities*, suffering from mental illnesses and chronic diseases, *and other marginalised, discriminated against, vulnerable, underserved groups*, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups. *The Programme should therefore support actions which aim to address all social determinants of health including gender with an intersectional approach, with a view of putting an end to all health inequalities including gender-based inequalities, responding to people's specific health needs including women's health needs, and aim to ensure continued access to all health care services.*

Or. en

### **Amendment 188**

**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**  
**Recital 12**

*Text proposed by the Commission*

(12) With a view to protect people in vulnerable situations, including those suffering from mental illnesses and chronic diseases, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups.

*Amendment*

(12) With a view to protect people in vulnerable situations, including those suffering from mental illnesses and chronic diseases, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups ***as well as the varying impacts in terms of gender. With a view to guaranteeing continued high standards of essential healthcare services, the Programme should, in particular in times of crisis and pandemics, encourage a transition to telemedicine taking account of varying levels of digital literacy, at-home administration of medication, promote innovative digital solutions for health and care in synergy with Horizon Europe and its relevant Missions and Partnerships and implementation of preventative and self-care plans, where possible and appropriate, while ensuring that access to healthcare services is provided to chronic patients, .***

Or. en

**Amendment 189**

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

**Proposal for a regulation**  
**Recital 12**

*Text proposed by the Commission*

(12) With a view to protecting people in vulnerable situations, including those

*Amendment*

(12) With a view to protecting people in vulnerable situations, including those

suffering from mental illnesses and chronic diseases, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups.

suffering from mental illnesses, ***non-communicable diseases*** and chronic diseases, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups. ***With a view to guaranteeing continued high standards of essential healthcare services, the Programme should, especially in times of crisis and pandemics, encourage a transition to telemedicine, home administration of medication, and implementation of preventative and self-care plans, where possible and appropriate, while ensuring that access to healthcare services is provided to chronic patients, taking into account the respective levels of digitisation of the Member States and problems of access to digital solutions in remote areas or for certain population groups.***

Or. it

#### **Amendment 190**

**Nicolae Ștefănuță, Véronique Trillet-Lenoir**

#### **Proposal for a regulation**

#### **Recital 12**

*Text proposed by the Commission*

(12) With a view to protect people in vulnerable situations, including those suffering from mental illnesses and chronic diseases, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups.

*Amendment*

(12) With a view to protect people in vulnerable situations, including those suffering from mental illnesses and chronic diseases, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups. ***With a view to guaranteeing continued high standards of essential healthcare services, the Programme should, in particular in times of crisis and pandemics, encourage a transition to accessible and affordable telemedicine, at-home administration of medication and***

*implementation of preventative and self-care plans, where possible and appropriate, while ensuring that access to healthcare and prevention services is provided to chronic patients and patients at risk.*

Or. en

#### **Amendment 191**

**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**

##### **Recital 12**

*Text proposed by the Commission*

(12) With a view to protect *people in* vulnerable *situations*, including those suffering from *mental illnesses and* chronic diseases, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups.

*Amendment*

(12) With a view to protect vulnerable *populations*, including *children, elder people, socioeconomically disadvantaged people, women, LGBTI people, ethnic minorities, people affected by a physical or mental disability*, those suffering from chronic diseases, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups, *taking into account their specific health needs*.

Or. en

#### **Amendment 192**

**Linea Søgaard-Lidell, Frédérique Ries, Jan Huitema**

#### **Proposal for a regulation**

##### **Recital 12**

*Text proposed by the Commission*

(12) With a view to protect people in vulnerable situations, including those suffering from mental illnesses and chronic

*Amendment*

(12) With a view to protect people in vulnerable situations, including those suffering from mental illnesses and chronic

diseases, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups.

diseases, *such as obesity, cancer, diabetes, cardiovascular disease and neurologic disorder*, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups.

Or. en

### **Amendment 193**

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

#### **Proposal for a regulation**

##### **Recital 12**

###### *Text proposed by the Commission*

(12) With a view to protect *people in* vulnerable *situations*, including *those suffering from mental illnesses and* chronic diseases, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups.

###### *Amendment*

(12) With a view to protect vulnerable *populations* including *children, the elderly, pregnant women, people affected by a disability, patients with* chronic diseases, the Programme should also promote actions which address the collateral impacts of the health crisis *and medical products shortages* on people belonging to such vulnerable groups.

Or. en

### **Amendment 194**

**Mick Wallace, Clare Daly**

#### **Proposal for a regulation**

##### **Recital 12 a (new)**

###### *Text proposed by the Commission*

###### *Amendment*

*(12a) Article 8 TFEU gives the Union the task of eliminating inequalities and promoting equality between men and women in all of its activities. The principle of gender mainstreaming should*

*be applied to all activities implemented through this Programme, and this Programme should contribute to achieving the common objectives set out in the Council conclusions on women's health of 22 June 2006. This Programme should support actions which promote gender mainstreaming in healthcare, address women's specific health needs as some health issues affect women exclusively or disproportionately, including sexual and gender-based violence as well as certain aspects of sexual and reproductive health, address gender aspects of health including sexual and reproductive health and rights as committed to in the Gender Equality Strategy, aim to reduce gender inequalities in health recognizing gender as a key determinant of health, collect disaggregated and gender-specific data on the status of women's health to measure women's unmet medical needs, and provide gender-sensitive health information, education and promotion, prevention measures and treatment.*

Or. en

#### **Amendment 195**

**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**

#### **Recital 12 a (new)**

*Text proposed by the Commission*

*Amendment*

*(12a) The right to physical and mental health is a fundamental human right. Every person, without discrimination, has the right to access modern and comprehensive healthcare. The EU4Health programme should guarantee that universal health coverage is provided, in line with the international*

*commitments made through SDGs and with WHO policies, and ensure that everyone can use the health services they need without experiencing financial hardship. To continue being a global leader in health and to provide a high standard healthcare across the Union, the Commission should propose a Directive on minimum standards for quality healthcare with a set of criteria that should be reported by Member States, such as hospital beds per capita, critical care capacities, numbers of doctors and nurses per capita, rate of health expenditure and access and affordability of healthcare for all, including for vulnerable people. This would improve patient safety and result in better conditions in healthcare for patients and professionals.*

Or. en

**Amendment 196**  
**Antoni Comín i Oliveres**

**Proposal for a regulation**  
**Recital 12 a (new)**

*Text proposed by the Commission*

*Amendment*

*(12a) Demographic change and technological innovation are some of the most important challenges facing our health systems. The aging of the population is largely due to the success of our healthcare systems and forces them, at the same time, to a structural transformation: from a healthcare model focused mainly on acute diseases, it is necessary to move towards a healthcare model in which chronic diseases gain more weight. It is important that the Member States accompany each other in this process of transformation of the healthcare model, and for this reason it is necessary to strengthen good practices*

*exchanging mechanisms. TheEU4Health programme should play an important role in guiding these exchanges.*

Or. en

**Amendment 197**

**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**

**Recital 12 a (new)**

*Text proposed by the Commission*

*Amendment*

*(12a) Correlations have been observed between health and/or economic crises and a worrying increase in depressive tendencies resulting from the effects of reduced disposable income, uncertainty about the future and growing unemployment. The Programme should therefore provide support for national actions aimed at integrating mental health into all policies and promoting mental health in all areas, including school and work, and for preventive actions to combat depression and suicide.*

Or. it

**Amendment 198**

**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**

**Recital 13**

*Text proposed by the Commission*

*Amendment*

(13) The COVID-19 crisis has highlighted many challenges in ensuring the supply of medicines, medical devices as well as personal protective equipment

(13) The COVID-19 crisis has highlighted many challenges in ensuring the supply of medicines, medical devices as well as personal protective equipment

needed in the Union during the pandemics. The Programme therefore should provide support to actions which foster the production, procurement **and** management of crisis relevant products ensuring complementarity with other Union instruments.

needed in the Union during the pandemics. The Programme therefore should provide support to actions which foster the production, procurement, management **and distribution** of crisis relevant products ensuring complementarity with other Union instruments. ***The Programme should promote the establishment of a specific Joint Action on the prevention of shortages of medical supply to allow the exchange of good practises between Member States and the development of common prevention measures. The Commission should also present a specific strategy for managing shortages of medicines and medical products in Europe in the framework of its Pharmaceutical Strategy.***

Or. en

#### **Amendment 199**

**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**

##### **Recital 13**

###### *Text proposed by the Commission*

(13) The COVID-19 crisis has highlighted many challenges in ensuring the supply of medicines, medical devices as well as personal protective equipment needed in the Union during the pandemics. The Programme therefore should provide support to actions which **foster** the production, procurement and management

###### *Amendment*

(13) The COVID-19 crisis has highlighted many challenges ***including the EU's dependency on third countries*** in ensuring the supply of ***chemical raw and starting materials, active pharmaceutical ingredients***, medicines, medical devices as well as personal protective equipment needed in the Union during the pandemics.

of crisis relevant products ensuring complementarity with other Union instruments.

The Programme therefore should provide support to actions which ***will increase the security of supply of medicines in the EU and reduce dependency on third countries by encouraging the diversification of supply chains, fostering the production in the EU, joint*** procurement and management of crisis relevant products ensuring complementarity with other Union instruments.

Or. en

**Amendment 200**  
**Nathalie Colin-Oesterlé**

**Proposal for a regulation**  
**Recital 13**

*Text proposed by the Commission*

(13) The COVID-19 crisis has highlighted ***many challenges in ensuring*** the supply of medicines, medical devices as well as personal protective equipment needed in the Union during the pandemics. The Programme therefore should ***provide*** support to actions which foster the production, procurement and management of crisis relevant products ensuring complementarity with other Union instruments.

*Amendment*

(13) The COVID-19 crisis has highlighted ***our dependence on third countries for*** the supply of medicines, medical devices as well as personal protective equipment needed in the Union during the pandemics. The Programme therefore should ***enable the Commission and the Member States to take all the necessary measures to guarantee European independence in health matters, by providing*** support to actions which foster the production, procurement and management of crisis relevant products ensuring complementarity with other Union instruments.

Or. fr

**Amendment 201**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Recital 13**

*Text proposed by the Commission*

(13) The COVID-19 crisis has highlighted many challenges in ensuring the supply of medicines, medical devices as well as personal protective equipment needed in the Union during the pandemics. The Programme therefore should provide support to actions which foster the production, procurement and management of crisis relevant products ensuring complementarity with other Union instruments.

*Amendment*

(13) The COVID-19 crisis has highlighted many challenges in ensuring the supply of medicines, medical devices, ***active pharmaceutical ingredients***, as well as personal protective equipment needed in the Union during the pandemics. The Programme therefore should provide support to actions which foster the production, procurement and management of crisis relevant products ensuring complementarity with other Union instruments. ***Upgradable and scalable manufacturing capacity of medicines within European Union should be achieved, to avoid the hindrances in medicine circulation and shortages in supply.***

Or. en

**Amendment 202**  
**Joanna Kopcińska**

**Proposal for a regulation**  
**Recital 13**

*Text proposed by the Commission*

(13) The COVID-19 crisis has highlighted many challenges in ensuring the supply of medicines, medical devices as well as personal protective equipment needed in the Union during the pandemics. The Programme therefore should provide support to actions which foster the production, procurement and management of crisis relevant products ensuring complementarity with other Union instruments.

*Amendment*

(13) The COVID-19 crisis has highlighted many challenges in ensuring the supply of medicines, medical devices as well as personal protective equipment needed in the Union during the pandemics ***noting, in particular, its dependency on third countries for manufacturing capacity, the supply of active pharmaceutical ingredients and starting materials.*** The Programme therefore should provide support to actions which foster the production, procurement and management of crisis relevant products ensuring complementarity with other Union instruments.

### Amendment 203

**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

##### Recital 13

###### *Text proposed by the Commission*

(13) The COVID-19 crisis has highlighted many challenges in ensuring the supply of medicines, medical devices as well as personal protective equipment needed in the Union during the pandemics. The Programme therefore should provide support to actions which foster the production, procurement and management of *crisis* relevant products ensuring complementarity with other Union instruments.

###### *Amendment*

(13) The COVID-19 crisis has highlighted many challenges in ensuring the supply of medicines, medical devices as well as personal protective equipment needed in the Union during the pandemics. The Programme therefore should provide support to actions, which foster the production, procurement and management of *medical and care* relevant products *to mitigate the risk of shortages, especially in times of health crises*, ensuring complementarity with other Union instruments.

### Amendment 204

**Mairead McGuinness**

#### Proposal for a regulation

##### Recital 13

###### *Text proposed by the Commission*

(13) The COVID-19 crisis has highlighted many challenges in ensuring the supply of medicines, medical devices as well as personal protective equipment needed in the Union during the pandemics. The Programme therefore should provide support to actions which foster the production, procurement *and* management of crisis relevant products ensuring

###### *Amendment*

(13) The COVID-19 crisis has highlighted many challenges in ensuring the supply of medicines, medical devices as well as personal protective equipment needed in the Union during the pandemics. The Programme therefore should provide support to actions which foster the production, procurement, management, *accessibility and affordability* of crisis

complementarity with other Union instruments.

relevant products ensuring complementarity with other Union instruments.

Or. en

#### **Amendment 205**

**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**

##### **Recital 14**

###### *Text proposed by the Commission*

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

###### *Amendment*

(14) In order to minimise the public health consequences of serious cross-border threats to health it should be possible for actions supported under the Programme to cover coordination of the activities which strengthen the interoperability and coherence of Member States' health-systems through benchmarking, cooperation and exchange of best practices and ensure their capability to respond to health emergencies, that includes contingency planning, preparedness exercises and the upskilling of health care and public health staff and the establishment of mechanisms for the efficient monitoring and needs-driven distribution or allocation of goods and services needed in time of crisis. ***The benchmarking, cooperation and exchange of best practices should be equally promoted in periods where there are no crises.***

Or. en

#### **Amendment 206**

**Pascal Arimont, Cindy Franssen, Esther de Lange**

**Proposal for a regulation**  
**Recital 14**

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 207**

**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**  
**Recital 14**

*Text proposed by the Commission*

(14) In order to minimise the public health consequences of serious cross-border threats to health it should be possible for actions supported under the Programme to cover coordination of the activities which strengthen the interoperability and coherence of Member States' health-systems through benchmarking, cooperation and exchange

*Amendment*

(14) In order to minimise the public health consequences of serious cross-border threats to health it should be possible for actions supported under the Programme to cover coordination of the activities which strengthen the interoperability and coherence of Member States' health-systems through benchmarking, cooperation and exchange

of best practices and ensure their capability to respond to health emergencies, that includes contingency planning, preparedness exercises and the upskilling of health care and public health staff and the establishment of mechanisms for the efficient monitoring and needs-driven distribution or allocation of goods and services needed in time of crisis.

of best practices ***via an increased number of Joint Actions*** and ensure their capability to respond to health emergencies, that includes contingency planning, preparedness exercises and the upskilling of health care and public health staff and the establishment of mechanisms for the efficient monitoring and needs-driven distribution or allocation of goods and services needed in time of crisis.

Or. en

**Amendment 208**  
**Joanna Kopcińska**

**Proposal for a regulation**  
**Recital 14 a (new)**

*Text proposed by the Commission*

*Amendment*

***(14a) The evaluation by the Commission of Directive 2011/24/EU of the European Parliament and the Council<sup>1a</sup> showed that not all Member States implemented the Directive completely. Obstacles to and limitations of the application of the Directive, such as unduly burdensome authorisation requirements or limitations on reimbursement are restricting access to healthcare for citizens whose medical needs might sometimes be better catered for in a Member State other than their own. Moreover, not all Member States are able to supply data or information regarding patients travelling abroad, given that data collection is not always comparable from one Member State to another. The Programme should therefore support full implementation of Directive 2011/24/EU, guaranteeing a high level of public health protection while respecting the principle of the free movement of persons within the internal market.***

*1<sup>a</sup> Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).*

Or. en

**Amendment 209**

**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**

**Recital 14 a (new)**

*Text proposed by the Commission*

*Amendment*

*(14a) The COVID-19 crisis has revealed the important need for Member States to organize stress tests to assess the resilience of their national health systems to all types of crises. These tests must be carried out on the basis of precise evaluation criteria set by the European Commission. The results of these tests could determine the weaknesses of the national health systems and the areas to be the subject to specific financial support.*

Or. en

**Amendment 210**

**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, Chrysoula Zacharopoulou, María Soraya Rodríguez Ramos**

**Proposal for a regulation**

**Recital 14 b (new)**

*Text proposed by the Commission*

*Amendment*

**(14b) The coordination between national health systems is essential to guarantee solidarity within the Union. Joint procurement, coordinated transfer of equipment, reserve and circulation of blood products and organs, transports of patients for cross-border care should be adequately anticipated.**

Or. en

**Amendment 211**

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

**Proposal for a regulation**

**Recital 14 c (new)**

*Text proposed by the Commission*

*Amendment*

**(14c) In addition to an increased budget, the EU Civil Protection Mechanism (UCPM) and its instrument RescEU should be strengthened to ensure a truly common, coordinated and effective response at EU level.**

Or. en

**Amendment 212**

**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**

**Recital 14 d (new)**

*Text proposed by the Commission*

*Amendment*

**(14d) The Union should be able to rely on the mobilization of health**

*professionals through the “European Medical Corps” created to enable quick medical assistance and public health expertise to all Member States.*

Or. en

**Amendment 213**

**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, Chrysoula Zacharopoulou, María Soraya Rodríguez Ramos**

**Proposal for a regulation  
Recital 14 e (new)**

*Text proposed by the Commission*

*Amendment*

*(14e) European health agencies, in particular the ECDC and the EMA should be granted strengthened competences, resources and personnel to allow them to better and quicker carry out their duties efficiently to the benefit of European citizens. To anticipate any types of crises, the Commission should also evaluate the needs of the other European health agencies such as EFSA, ECHA and EU-OSHA. A stronger coordination between European Agencies should be guaranteed by the Commission.*

Or. en

**Amendment 214**

**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, Chrysoula Zacharopoulou, María Soraya Rodríguez Ramos**

**Proposal for a regulation  
Recital 14 f (new)**

*Text proposed by the Commission*

*Amendment*

***(14f) The Programme should support the revision of ECDC's mandate to extend its competencies to the chronic diseases, to elaborate mandatory guidances for Member States and to be able to coordinate laboratory research in times of health crises.***

Or. en

#### **Amendment 215**

**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, Chrysoula Zacharopoulou, María Soraya Rodríguez Ramos**

#### **Proposal for a regulation**

#### **Recital 14 g (new)**

*Text proposed by the Commission*

*Amendment*

***(14g) The programme should also support the revision of the EMA's mandate to extend its competencies on clinical trial's coordination and management of the shortages of medicines. EMA could therefore meet any future challenges such as monitoring and responding to shortages in coordination with the Member States. In the long term, EMA should be able to make conditional marketing authorizations upon guarantees of supply and accessibility from manufacturers. The reinforcement of the EMA's personnel should enable the Agency to carry out inspections of production sites established in third countries.***

Or. en

## Amendment 216

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

#### Recital 14 h (new)

*Text proposed by the Commission*

*Amendment*

***(14h) In order to facilitate EU Joint Procurement procedures, the Commission could adopt a specific legislation to promote their use to buy vaccines and treatments, to guarantee the efficiency and the transparency of the process and to ensure an equal access to medicines, medical devices, protective equipment and other relevant health products. A part of the medical products purchased via the EU joint procurement procedure could constitute a European contingency reserve of medical products subjected to shortages.***

Or. en

## Amendment 217

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

#### Recital 14 i (new)

*Text proposed by the Commission*

*Amendment*

***(14i) The establishment of a communication portal for the public would allow the Union to share validated information, send alerts to European citizens and fight against disinformation. It could include a wide range of information, prevention campaigns and youth education programs. This portal could also be used to promote, in cooperation with the ECDC, a strong***

**Amendment 218**

**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  
Recital 14 j (new)**

*Text proposed by the Commission*

*Amendment*

**(14j) A digital exchange platform, such as the COVID-19 Data Portal, could facilitate exchanges on epidemiological data, science-based practice recommendations to health professionals and hospitals, and the exact state of mobilizable capacities and medical products stocks.**

**Amendment 219**

**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  
Recital 15**

*Text proposed by the Commission*

*Amendment*

(15) Experience from the COVID-19 crisis has indicated that there is a general need for the support to structural transformation of and systemic reforms of health systems across the Union to improve their effectiveness, accessibility and resilience. In the context of such transformation and reforms, the Programme should promote, in synergy with the Digital Europe Programme,

(15) Experience from the COVID-19 crisis has indicated that there is a general need for the support to structural transformation of and systemic reforms of health systems across the Union to improve their effectiveness, accessibility, **sustainability** and resilience. In the context of such transformation and reforms, the Programme should promote, in synergy with the Digital Europe Programme,

actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide new care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs and ensure an efficient public health workforce equipped with the right skills, including digital skills. The development of a European health data space would provide health care systems, researchers and public authorities with means to improve the availability and quality of healthcare. Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006<sup>12</sup> the Programme should support actions ensuring the universality and inclusivity of health care, meaning that no-one is barred access to health care, and those ensuring that patients' rights, including on the privacy of their data, are duly respected.

actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster **(primordial, primary, secondary, tertiary and quaternary)** disease prevention and health promotion, to provide new **outcome-based** care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs **enhancing citizens' levels of health literacy and digital health literacy** and ensure an efficient public health workforce equipped with the right skills, including digital skills, **regularly updated in the light of scientific and technological progress, as provided for by Directive 2005/36 on the recognition of professional qualifications** . **This synergy between European Health Programme and Digital Europe Programme should contribute to the implementation and expansion of e-health, as telemedicine, reducing unnecessary travel and unmet healthcare needs.** The development of a European health data space **and of a European Electronic Health Record** would provide health care systems, researchers and public authorities with means to improve the **accessibility, affordability,** availability and quality of healthcare, **increasing the amount of data available to patients and health workers therefore improving the quality of healthcare and the patient's freedom of movement around the Union.** . Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006<sup>12</sup> the Programme should support actions ensuring the universality and inclusivity of health care, meaning that no-one is barred access to health care, and those ensuring that patients' rights,

including on the privacy of their data, are duly respected. ***The programme needs to guarantee access to and sharing of personal health data while applying the GDPR rules meticulously and increase the digital skills of patients.***

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<sup>12</sup> Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

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<sup>12</sup> Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

Or. en

## **Amendment 220**

**Mick Wallace, Clare Daly**

### **Proposal for a regulation**

#### **Recital 15**

##### *Text proposed by the Commission*

(15) Experience from the COVID-19 crisis has indicated that there is a general need for the support to structural transformation of and systemic reforms of health systems across the Union to improve their effectiveness, accessibility and resilience. In the context of such transformation and reforms, the Programme should promote, in synergy with the Digital Europe Programme, actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide new care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs and ensure an efficient public health workforce equipped with the right skills, including digital skills. The development of a European health data space would provide health care systems, researchers and public authorities with

##### *Amendment*

(15) Experience from the COVID-19 crisis has indicated that there is a general need for the support to structural transformation of and systemic reforms of health systems across the Union to improve their effectiveness, accessibility and resilience. In the context of such transformation and reforms, the Programme should promote, in synergy with the Digital Europe Programme, actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide new care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs, ***taking an intersectional and gender-sensitive approach to address social determinants of health and differential vulnerabilities leading to inequitable health outcomes***, and ensure an efficient public health workforce

means to improve the availability and quality of healthcare. Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006<sup>12</sup> the Programme should support actions ensuring the universality and inclusivity of health care, meaning that no-one is barred access to health care, **and those ensuring** that patients' rights, including **on** the privacy of their data, **are duly respected**.

equipped with the right skills, including digital skills. The development of a European health data space would provide health care systems, researchers and public authorities with means to improve the availability and quality of healthcare. Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006<sup>12</sup> the Programme should support actions ensuring the universality and inclusivity of health care, meaning that no-one is barred access to health care, **including through the achievement of Universal Health Coverage, as well as solidarity and equity, to ensure accessibility to all and equal access according to need, regardless of ethnicity, gender, age, social status or ability to pay, and to reduce health inequalities. The Programme should support actions that aim to ensure** that patients' rights **are upheld**, including **the right to receive respectful and dignified care, free from all forms of discrimination, mistreatment or violence, the right to patient confidentiality including** the privacy of their data, **the right to receive accurate, unbiased information and education on all aspects of their health including sexual and reproductive health, and to give informed consent**.

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<sup>12</sup> Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

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<sup>12</sup> Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

Or. en

#### **Amendment 221**

**Véronique Trillet-Lenoir, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard**

**Proposal for a regulation**

**Recital 15**

*Text proposed by the Commission*

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

*Amendment*

(15) Experience from the COVID-19 crisis has indicated that there is a general need for the support to structural transformation of and systemic reforms of health systems across the Union to improve their effectiveness, accessibility and resilience. In the context of such transformation and reforms, the Programme should promote, in synergy with the Digital Europe Programme, actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide new care models and to deliver integrated services , from the community and primary health care to the highly specialised services, based on people's needs and ensure an efficient public health workforce equipped with the right skills, including digital skills. ***The programme should facilitate the collection of large clinical and biological databases to better understand emerging threats, rare and low prevalence diseases. Health data, and how it can be securely shared in full respect of General Data Protection Regulation (GDPR)'s requirements, will be critically important to fight any kind of health crisis and to improve the management of communicable and non-communicable diseases. In this regard, the development of the future European health data space will be a crucial step to support patients and their health providers directly, to ensure that citizens have control over their personal data, to facilitate research and to support the development of diagnostics, treatments and services. The European health data***

duly respected.

space would provide health care systems, researchers and public authorities with means to improve the availability and quality of healthcare. Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006<sup>12</sup> the Programme should support actions ensuring the universality and inclusivity of health care, meaning that no-one is barred access to health care, and those ensuring that patients' rights, including on the privacy of their data, are duly respected. ***The more the Union relies on shared data in order to improve European healthcare, the more the EU will increase its independence over the GAFAM, its cybersecurity capabilities to guarantee data safety and to avoid security breaches that would expose personal information of patients.***

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<sup>12</sup> Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

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<sup>12</sup> Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

Or. en

**Amendment 222**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Recital 15**

*Text proposed by the Commission*

(15) Experience from the COVID-19 crisis has indicated that there is a general need for the support to structural transformation of and systemic reforms of health systems across the Union to improve their effectiveness, accessibility and

*Amendment*

(15) Experience from the COVID-19 crisis has indicated that there is a general need for the support to structural transformation of and systemic reforms of health systems across the Union to improve their effectiveness, accessibility and

resilience. In the context of such transformation and reforms, the Programme should promote, in synergy with the Digital Europe Programme, actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide new care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs and ensure an efficient public health workforce equipped with the right skills, including digital skills. The development of a European health data space would provide health care systems, researchers and public authorities with means to improve the availability and quality of healthcare. Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006<sup>12</sup> the Programme should support actions ensuring the universality and inclusivity of health care, meaning that no-one is barred access to health care, and those ensuring that patients' rights, including on the privacy of their data, are duly respected.

resilience. In the context of such transformation and reforms, the Programme should promote, in synergy with the Digital Europe Programme, actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide new care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs, ***enhancing citizens' levels of health literacy and digital health literacy*** and ensure an efficient public health workforce equipped with the right skills, including digital skills. The development of a European health data space ***and of a European Electronic Health Record*** would provide health care systems, researchers and public authorities with means to improve the ***accessibility, availability, affordability*** and quality of healthcare. ***The Programme must ensure, in setting up the European Health Data Space, adequate resources for ECDC/ national agencies to collect data on diagnosis, care and outcomes. It must also provide resources and integrate data collected by civil society.*** Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006<sup>12</sup> the Programme should support actions ensuring the universality and inclusivity of health care, meaning that no-one is barred access to health care, and those ensuring that patients' rights, including on the privacy of their data, are duly respected, ***clear and easy to understand and exercise by patients and adapted to innovation and new technologies.***

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<sup>12</sup> Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

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<sup>12</sup> Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

Or. en

**Amendment 223**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Recital 15**

*Text proposed by the Commission*

(15) Experience from the COVID-19 crisis has indicated that there is a general need for the support to structural transformation of and systemic reforms of health systems across the Union to improve their effectiveness, accessibility and resilience. In the context of such transformation and reforms, the Programme should promote, in synergy with the Digital Europe Programme, actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide new care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs and ensure an efficient public health workforce equipped with the right skills, including digital skills. The development of a European health data space would provide health care systems, researchers and public authorities with means to improve the availability and quality of healthcare. Given the fundamental right to access to preventive *healthcare* and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union

*Amendment*

(15) Experience from the COVID-19 crisis has indicated that there is a general need for the support to structural transformation of and systemic reforms of health systems across the Union to improve their effectiveness, accessibility and resilience. In the context of such transformation and reforms, the Programme should promote, in synergy with the Digital Europe Programme, actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide new care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs and ensure an efficient public health workforce equipped with the right skills, including digital skills. The development of a European health data space ***and of a European Electronic Health Record*** would provide health care systems, researchers and public authorities with means to improve the availability and quality of healthcare. ***Such European Health Record should be standardised, interoperable with different health data systems and accessible for the patients in***

and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006<sup>12</sup> the Programme should support actions ensuring the universality and inclusivity of health care, meaning that no-one is barred access to health care, and those ensuring that patients' rights, including on the privacy of their data, are duly respected.

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<sup>12</sup> Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

***all Member States with privacy ensured and information encoded into the European Health Insurance Card, EHIC.***  
Given the fundamental right to access to preventive ***health care*** and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006<sup>12</sup> the Programme should support actions ensuring the universality and inclusivity of health care, meaning that no-one is barred access to health care, and those ensuring that patients' rights, including on the privacy of their data, are duly respected.

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<sup>12</sup> Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

Or. en

### *Justification*

*We need a European Electronic Health Record, with standardised information, accessible in identified form only to emergency units. Personalised data should be owned and accessible only by the person involved by a passcode comparable to bankcard pin codes. This pin code could be added to the European Health Insurance Card (EHIC) where the patients' health care records 'could be waived over by the patients with the pin code.*

## **Amendment 224** **Kateřina Konečn**

### **Proposal for a regulation** **Recital 15**

#### *Text proposed by the Commission*

(15) Experience from the COVID-19 crisis has indicated that there is a general need for the support to structural transformation of and systemic reforms of health systems across the Union to improve their effectiveness, accessibility and

#### *Amendment*

(15) Experience from the COVID-19 crisis has indicated that there is a general need for the support to structural transformation of and systemic reforms of health systems across the Union to improve their effectiveness, accessibility and

resilience. In the context of such transformation and reforms, the Programme should promote, in synergy with the Digital Europe Programme, actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide new care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs and ensure an efficient public health workforce equipped with the right skills, including digital skills. The development of a European health data space would provide health care systems, researchers and public authorities with means to improve the availability and quality of healthcare. Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006<sup>12</sup> the Programme should support actions ensuring the universality and inclusivity of health care, meaning that no-one is barred access to health care, and those ensuring that patients' rights, including on the privacy of their data, are duly respected.

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<sup>12</sup> Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

resilience. In the context of such transformation and reforms, the Programme should promote, in synergy with the Digital Europe Programme, actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide new care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs, ***enhancing citizens' levels of health literacy and digital health literacy*** and ensure an efficient public health workforce equipped with the right skills, including digital skills. The development of a European health data space ***and of a European Electronic Health Record*** would provide health care systems, researchers and public authorities with means to improve the availability and quality of healthcare. Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006<sup>12</sup> the Programme should support actions ensuring the universality and inclusivity of health care, meaning that no-one is barred access to health care, and those ensuring that patients' rights, including on the privacy of their data, are duly respected, ***clear and easy to understand and exercise by patients and adapted to innovation and new technologies***.

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<sup>12</sup> Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

Or. en

## *Justification*

*Patients' rights on data protection need to be fully ensured, clearly understandable by patients and adapted to the rapid evolution of technology in healthcare. EU legislation, on top of ensuring adequate protection and safety, should be designed to ensure that the exercise of rights is simple and not overly burdensome.*

### **Amendment 225**

**Mairead McGuinness**

### **Proposal for a regulation**

#### **Recital 15**

#### *Text proposed by the Commission*

(15) Experience from the COVID-19 crisis has indicated that there is a general need for the support to structural transformation of and systemic reforms of health systems across the Union to improve their effectiveness, accessibility and resilience. In the context of such transformation and reforms, the Programme should promote, in synergy with the Digital Europe Programme, actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide new care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs and ensure an efficient public health workforce equipped with the right skills, including digital skills. The development of a European health data space would provide health care systems, researchers and public authorities with means to improve the availability and quality of healthcare. Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in

#### *Amendment*

(15) Experience from the COVID-19 crisis has indicated that there is a general need for the support to structural transformation of and systemic reforms of health systems across the Union to improve their effectiveness, accessibility and resilience. In the context of such transformation and reforms, the Programme should promote, in synergy with the Digital Europe Programme, actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide new care models, ***to progress deinstitutionalisation and move towards community-based care including for older people***, and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs and ensure an efficient public health workforce equipped with the right skills, including digital skills. The development of a European health data space would provide health care systems, researchers and public authorities with means to improve the availability and quality of healthcare. Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the

European Union Health Systems as set out in the Council Conclusions of 2 June 2006<sup>12</sup> the Programme should support actions ensuring the universality and inclusivity of health care, meaning that no-one is barred access to health care, and those ensuring that patients' rights, including on the privacy of their data, are duly respected.

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<sup>12</sup> Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006<sup>12</sup> the Programme should support actions ensuring the universality and inclusivity of health care, meaning that no-one is barred access to health care, and those ensuring that patients' rights, including on the privacy of their data, are duly respected.

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<sup>12</sup> Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

Or. en

## **Amendment 226**

**Nicolae Ștefănuță, Véronique Trillet-Lenoir**

### **Proposal for a regulation**

#### **Recital 15**

##### *Text proposed by the Commission*

(15) Experience from the COVID-19 crisis has indicated that there is a general need for the support to structural transformation of and systemic reforms of health systems across the Union to improve their effectiveness, accessibility and resilience. In the context of such transformation and reforms, the Programme should promote, in synergy with the Digital Europe Programme, actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide new care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs and ensure an efficient

##### *Amendment*

(15) Experience from the COVID-19 crisis has indicated that there is a general need for the support to structural transformation of and systemic reforms of health systems across the Union to improve their effectiveness, accessibility and resilience. In the context of such transformation and reforms, the Programme should promote, in synergy with the Digital Europe Programme, actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide new care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs and ensure an efficient

public health workforce equipped with the right skills, including digital skills. The development of a European health data space would provide health care systems, researchers and public authorities with means to improve the availability and quality of healthcare. Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006<sup>12</sup> the Programme should support actions ensuring the universality and inclusivity of health care, meaning that no-one is barred access to health care, and those ensuring that patients' rights, including on the privacy of their data, are duly respected.

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<sup>12</sup> Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

public health workforce equipped with the right skills, including digital skills. The development of a European health data space ***and of a European Electronic Health Record*** would provide health care systems, researchers and public authorities with means to improve the ***accessibility, availability, affordability*** availability and quality of healthcare. Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006<sup>12</sup> the Programme should support actions ensuring the universality and inclusivity of health care, meaning that no-one is barred access to health care, and those ensuring that patients' rights, including on the privacy of their data, are duly respected.

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<sup>12</sup> Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

Or. en

**Amendment 227**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Recital 15 a (new)**

*Text proposed by the Commission*

*Amendment*

***(15a) The COVID-19 situation has taught us the importance of health as a public good which needs to be preserved by developing coherent approaches to tackle chronic conditions, be they communicable or non-communicable, and by exploiting synergies in approaching people at risk. The COVID-***

*19 situation has also highlighted the imperative to generate and share reliable data on diagnosis, treatment and cure via the ECDC across the EU. It has also confirmed the need to apply innovative solutions to identify people at risk of having an infectious disease, so they can be tested, linked to care and take precautions to prevent further transmissions, leading to disease elimination. Notwithstanding the differences in transmission routes, these learnings also apply to viral hepatitis, where the ECDC report from May 2020 which monitors progress towards the elimination of hepatitis B and C in the EU/EEA highlights that “hepatitis related mortality is high in the region and there is very little evidence of progress towards the 2030 elimination target of a 65% reduction in mortality against the 2015 baseline”. The ECDC report thus confirms that, unless the EU drives forward the prevention of transmission, diagnosis and linkage to care, Europe will fail to meet the WHO elimination target and will fail to deliver on its commitment to the UN SDG.*

Or. en

**Amendment 228**

**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**

**Recital 15 a (new)**

*Text proposed by the Commission*

*Amendment*

*(15a) The value of health data is essential for having more reliable information to improve healthcare services, health policy-making and to evaluate the implementation of actions and policies in our society. The European*

*Health Data Space will represent a strong pillar of health in the Union and should be constructed involving all sectors and stakeholders, taking into account the needs of health professionals and patient. The Programme should capacitate and enlarge the competence of the ECDC to improve the capacity of surveillance of NCDs. The European Health Data should collect data on healthcare use, health behaviour and health problems, including information on rare diseases, vaccination, allergies and others.*

Or. en

**Amendment 229**  
**Adam Jarubas**

**Proposal for a regulation**  
**Recital 15 a (new)**

*Text proposed by the Commission*

*Amendment*

*(15a) Effective use of Information Technology systems, including AI, in full respect of EU data protection and privacy legal framework, is key to improve regulatory efficiency across Europe; it is also necessary to optimize the European regulatory framework by harmonising regulatory telematics projects with a focus on data quality, interoperability and interdependency of the European regulatory framework, and to ensure a fit for purpose regulatory environment that is a key element to protect public health, provide access to high quality medicines and contribute to the prevention of shortages.*

Or. en

**Amendment 230**  
**Sirpa Pietikäinen**

**Proposal for a regulation  
Recital 15 a (new)**

*Text proposed by the Commission*

*Amendment*

***(15a) A regulation on patient's rights is needed to ensure the right to accessible, affordable and high quality patient-centred health care, including relevant, appropriate and value based medicinal care, right to affordable, effective medication, rehabilitation and support for care. The right to cross-border health care and adequate support services should be guaranteed. Patients' right to second opinions should also be ensured.***

Or. en

**Amendment 231**

**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, Chrysoula Zacharopoulou, María Soraya Rodríguez Ramos**

**Proposal for a regulation  
Recital 15 a (new)**

*Text proposed by the Commission*

*Amendment*

***(15a) The programme should support innovations in the digitalization area that could bring concrete benefits to patients and healthcare professionals and provide cost-effective high-quality healthcare whilst reducing inequalities. Important steps could be taken in digital skills, both for healthcare professionals and patients training, especially in rural and sparsely populated areas.***

Or. en

**Amendment 232**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Recital 15 b (new)**

*Text proposed by the Commission*

*Amendment*

***(15b) Generating and sharing reliable data on health systems' management of communicable diseases is essential to track the progress made and tailor national and local systems' responses across Europe in a coordinated manner. The Programme should therefore support the upscaling of the ECDC's competence and resources in monitoring health care systems' responses to transmittable diseases, including HIV, TB and viral hepatitis. In particular, additional resources should be channelled to support the creation of EU-wide databases, with the aim to provide an overview of the existing gaps in the continuum of care. EU-wide data sharing should also help monitor the management of such conditions in the long-term and from a holistic perspective, including the management of relevant comorbidities and the overall progress of the system in improving the health-related quality of life of patients.***

Or. en

**Amendment 233**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Recital 15 b (new)**

*Text proposed by the Commission*

*Amendment*

***(15b) It is important to guarantee equal access for patients in different Member States to effective therapeutics, treatments and prevent individual health care units***

*from excessive and unreasonable costs when treating rare diseases. The Commission should therefore explore the possibility to establish a European fund, co-financed by the Member States, for negotiating and purchasing the orphan medicines and other new, personalised and experimental medication.*

Or. en

**Amendment 234**

**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**

**Recital 15 b (new)**

*Text proposed by the Commission*

*Amendment*

*(15b) The programme should facilitate the reinforcement of e-health and m-health as well as the use of telemedicine and remote monitoring of patients, especially in times of sanitary crises.*

Or. en

**Amendment 235**

**Cristian-Silviu Bușoi**

**Proposal for a regulation**

**Recital 15 c (new)**

*Text proposed by the Commission*

*Amendment*

*(15c) Ensuring a fit for purpose regulatory environment is a key element to protect public health, provide access to high quality medicines and contribute to the prevention of shortages. The effective use of Information Technology systems will improve regulatory efficiency across Europe; it is important therefore to*

*optimize the European regulatory framework by harmonising regulatory telematics projects with a focus on data quality, interoperability and interdependency of the European regulatory framework.*

Or. en

**Amendment 236**  
**Traian Băsescu**

**Proposal for a regulation**  
**Recital 16**

*Text proposed by the Commission*

(16) Keeping people healthy and active longer and empowering them to take an active role in managing their health will have positive effects on health, health inequalities, quality of life, productivity, competitiveness and inclusiveness, while reducing pressures on national budgets. The Commission has committed to help Member States to reach the sustainable development targets set in the ‘UN 2030 Agenda for Sustainable Development’ in particular Sustainable Development Goal 3 ‘Ensure healthy lives and promote well-being for all at all ages’<sup>13</sup>. The Programme therefore should contribute to the actions taken towards reaching these goals.

*Amendment*

(16) Keeping people healthy and active longer and empowering them to take an active role in managing their health will have positive effects on health, health inequalities, quality of life, productivity, competitiveness and inclusiveness, while reducing pressures on national budgets. ***Furthermore, to ensure optimal efficiency of the programme, state paternalism must be accompanied by the conceptualisation of health as a mutual responsibility of both the citizens and state authorities, as health is a partnership that both imposes obligations and confers rights. In developing health education, the programme will have even greater success if it can enhance citizens’ ability to play an active role in managing their own personal health. It is crucial to strengthen medical autonomy in order to better manage self-care. All of the parties concerned have equal responsibility, including the general public, patients, medical professionals, trainers, administrators, researchers, governments, including legislative and regulatory bodies, professional associations, and certification bodies.*** The Commission has committed to help Member States to reach the sustainable development targets set in

the 'UN 2030 Agenda for Sustainable Development' in particular Sustainable Development Goal 3 'Ensure healthy lives and promote well-being for all at all ages'<sup>13</sup>. The Programme therefore should contribute to the actions taken towards reaching these goals.

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<sup>13</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Next steps for a sustainable European future. European action for sustainability COM (2016) 739 final of 22.11.2016.

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<sup>13</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Next steps for a sustainable European future. European action for sustainability COM (2016) 739 final of 22.11.2016.

Or. ro

**Amendment 237**  
**Joanna Kopcińska**

**Proposal for a regulation**  
**Recital 16**

*Text proposed by the Commission*

(16) Keeping people healthy and active longer and empowering them to take an active role in managing their health will have positive effects on health, health inequalities, quality of life, productivity, competitiveness and inclusiveness, while reducing pressures on national budgets. The Commission has committed to help Member States to reach the sustainable development targets set in the 'UN 2030 Agenda for Sustainable Development' in particular Sustainable Development Goal 3 "Ensure healthy lives and promote well-being for all at all ages".<sup>13</sup> The Programme therefore should contribute to the actions taken towards reaching these goals.

*Amendment*

(16) Keeping people healthy and active longer and empowering them to take an active role in managing their health will have positive effects on health, health inequalities, quality of life, productivity, competitiveness and inclusiveness, while reducing pressures on national budgets. ***Recognition of innovation, which has a profound impact on health outcomes and costs, also serves to address the challenges of achieving sustainability in the health sector and the impact of changing demographics. Moreover, action to reduce inequalities in the provision of healthcare in rural and remote areas is important for the purposes of achieving inclusive growth.*** The Commission has committed to help Member States to reach the sustainable development targets set in the 'UN 2030 Agenda for Sustainable

Development' in particular Sustainable Development Goal 3 "Ensure healthy lives and promote well-being for all at all ages".<sup>13</sup> The Programme therefore should contribute to the actions taken towards reaching these goals.

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<sup>13</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Next steps for a sustainable European future. European action for sustainability COM (2016) 739 final of 22.11.2016.

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<sup>13</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Next steps for a sustainable European future. European action for sustainability COM (2016) 739 final of 22.11.2016.

Or. en

#### **Amendment 238**

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

#### **Proposal for a regulation**

#### **Recital 16**

##### *Text proposed by the Commission*

(16) Keeping people healthy and active longer and empowering them to take an active role in managing their health will have positive effects on health, health inequalities, quality of life, productivity, competitiveness and inclusiveness, while reducing pressures on national budgets. The Commission has committed to help Member States to reach the sustainable development targets set in the 'UN 2030 Agenda for Sustainable Development' in particular Sustainable Development Goal 3 "Ensure healthy lives and promote well-being for all at all ages"<sup>13</sup>. The Programme therefore should contribute to the actions taken towards reaching *these* goals.

##### *Amendment*

(16) ***Health is an investment and the Programme should have this concept at its core.*** Keeping people healthy and active longer and empowering them to take an active role in managing their health ***through health literacy in order to take well informed decisions,*** will have positive effects on health, health inequalities, ***health iniquities,*** quality of life, productivity, competitiveness and inclusiveness, while reducing pressures on national ***health systems and*** budgets. The Commission has committed to help Member States to reach the sustainable development targets set in the 'UN 2030 Agenda for Sustainable Development' in particular Sustainable Development Goal 3 "Ensure healthy lives and promote well-being for all at all ages"<sup>13</sup>. The Programme therefore should contribute to the actions

taken towards reaching *the SDGs* goals, *consequently will improve the social determinants of health and enhance the health of the Union.*

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<sup>13</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Next steps for a sustainable European future. European action for sustainability COM (2016) 739 final of 22.11.2016.

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<sup>13</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Next steps for a sustainable European future. European action for sustainability COM (2016) 739 final of 22.11.2016.

Or. en

## **Amendment 239** **Cristian-Silviu Buşoi**

### **Proposal for a regulation** **Recital 16**

#### *Text proposed by the Commission*

(16) Keeping people healthy and active longer and empowering them to take an active role in managing their health will have positive effects on health, health inequalities, quality of life, productivity, competitiveness and inclusiveness, while reducing pressures on national budgets. The Commission has committed to help Member States to reach the sustainable development targets set in the 'UN 2030 Agenda for Sustainable Development' in particular Sustainable Development Goal 3 "Ensure healthy lives and promote well-being for all at all ages".<sup>13</sup> The Programme therefore should contribute to the actions taken towards reaching these goals.

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<sup>13</sup> Communication from the Commission to the European Parliament, the Council, the

#### *Amendment*

(16) Keeping people healthy and active longer and empowering them to take an active role in managing their health, *by improving their health literacy*, will have positive effects on health, health inequalities, quality of life, productivity, competitiveness and inclusiveness, while reducing pressures on national budgets. The Commission has committed to help Member States to reach the sustainable development targets set in the 'UN 2030 Agenda for Sustainable Development' in particular Sustainable Development Goal 3 "Ensure healthy lives and promote well-being for all at all ages".<sup>13</sup> The Programme therefore should contribute to the actions taken towards reaching these goals, *for e.g. by recognizing the strategic role of health literacy in managing personal health.*

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<sup>13</sup> Communication from the Commission to the European Parliament, the Council, the

European Economic and Social Committee and the Committee of the Regions Next steps for a sustainable European future. European action for sustainability COM (2016) 739 final of 22.11.2016.

European Economic and Social Committee and the Committee of the Regions Next steps for a sustainable European future. European action for sustainability COM (2016) 739 final of 22.11.2016.

Or. en

**Amendment 240**  
**Antoni Comín i Oliveres**

**Proposal for a regulation**  
**Recital 16 a (new)**

*Text proposed by the Commission*

*Amendment*

***(16a) We now know that social and economic determinants are a persistent source of inequalities in health. One of the priority objectives of Member States' public health systems should be the fight against these inequalities. The COVID-19 pandemic has threatened the European population as a whole, but once again the most economically vulnerable populations have been the most affected. It is essential that the projects of the EU4Health programme are managed in accordance with the general and transversal objective of reducing health inequalities. Likewise, the EU4Health programme's projects should also serve to assist Member States in the reformulation of the budgets of their health systems, with the aim of making them more clearly redistributed according to the criteria of health inequalities of the population.***

Or. en

**Amendment 241**  
**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**  
**Recital 16 a (new)**

*Text proposed by the Commission*

*Amendment*

**(16a) The Programme should provide for equal access to healthcare. ‘Socioeconomic health inequalities’ cover situations ranging from unequal access to treatment, fragmented access across regions and differences in health status based on economic conditions, to the distribution of health determinants between different population groups. The individual Member States are responsible for developing social and health policies to tackle the national challenges linked to health inequalities.**

Or. it

**Amendment 242**

**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**  
**Recital 16 a (new)**

*Text proposed by the Commission*

*Amendment*

**(16a) The Programme should provide for equal and fair access to healthcare. “Health inequalities” cover situations ranging from unequal access to treatment, fragmented access across regions, differences in health status origin, and to the distribution of health determinants between different population groups. Health inequalities and inequities are avoidable by reasonable means, and thus preventable, and the Programme should improve the knowledge on health inequalities and inequities to tackle them.**

Or. en

**Amendment 243**  
**Michèle Rivasi**

**Proposal for a regulation**  
**Recital 16 a (new)**

*Text proposed by the Commission*

*Amendment*

***(16a) The Programme should provide for equal access to healthcare. "Health inequalities" cover situations ranging from unequal access to prevention, treatment, fragmented access across regions, differences in health status origin, and to the distribution of health determinants between different population groups. Health inequalities are avoidable by reasonable means, and thus preventable.***

Or. en

*Justification*

*Like AM 13 of the rapporteur, with the addition of a reference to "prevention".*

**Amendment 244**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Recital 16 a (new)**

*Text proposed by the Commission*

*Amendment*

***(16a) Gender and sex sensitivity and knowledge needs to be improved in the education of health care professionals, the research, diagnosis, treatment and impact of medicines and therapeutics to better understand and treat both sexes.***

Or. en

**Amendment 245**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Recital 16 b (new)**

*Text proposed by the Commission*

*Amendment*

***(16b) Training for health care professionals and specialised health care facilities needs to be provided so that the needs of groups such as LGBTIQ, Roma and other groups with special needs can be met.***

Or. en

**Amendment 246**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Recital 16 c (new)**

*Text proposed by the Commission*

*Amendment*

***(16c) The programme should provide easy access to basic healthcare to all. Low-threshold guidance, counselling, and access to preventive health care should be available to all citizens. Family doctor system for necessary health checks to provide preventive healthcare should be promoted. Adequacy of this capacity should be monitored in the European Semester.***

Or. en

**Amendment 247**

**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**  
**Recital 17**

*Text proposed by the Commission*

(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and behavioural factors. Such non-communicable diseases as cardiovascular diseases, cancer, chronic respiratory diseases, **and** diabetes, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors **and policy fields**, combined with efforts to strengthen health systems.

*Amendment*

(17) Non-communicable diseases are a result of **commercial determinants of health** a combination of genetic, physiological, environmental and behavioural factors. Such non-communicable diseases as cardiovascular diseases, cancer, chronic respiratory diseases, diabetes **and mental health illness** represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, **with non-communicable diseases (NCDs) were responsible for 87% of Disability-Adjusted Life Years (DALYs) in the EU in 2017**, resulting in considerable social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, **particularly but not exclusively** Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors, **specialities and policy-fields, taking into account the interrelated nature of most non-communicable diseases**, combined with efforts to strengthen health systems **and societies**.

Or. en

**Amendment 248**  
**Michèle Rivasi**

**Proposal for a regulation**  
**Recital 17**

*Text proposed by the Commission*

(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and

*Amendment*

(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and

behavioural factors. Such non-communicable diseases as cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors and policy fields, combined with efforts to strengthen health systems.

behavioural *risk* factors. Such non-communicable diseases as cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors and policy fields, combined with efforts to strengthen health systems. ***SDG Target 3.a, on strengthening the implementation of the WHO Framework Convention on Tobacco Control is crucial to achieving an effective, sustainable reduction in preventable non-communicable diseases.***

Or. en

**Amendment 249**  
**Joanna Kopcińska**

**Proposal for a regulation**  
**Recital 17**

*Text proposed by the Commission*

(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and behavioural factors. Such non-communicable diseases as cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts. To decrease the impact of non-communicable diseases on

*Amendment*

(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and behavioural factors. Such non-communicable diseases as cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts. To decrease the impact of non-communicable diseases on

individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors and policy fields, combined with efforts to strengthen health systems.

individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to ***have sufficient financial resources, follow a "Health in all Policies" (HIAP) approach***, provide an integrated response focusing on ***health promotion and primary*** prevention across sectors and policy fields, combined with efforts to strengthen health systems ***that will have a direct impact on the long-term public health policy of all Member States***.

Or. en

**Amendment 250**  
**Nicolae Ștefănuță**

**Proposal for a regulation**  
**Recital 17**

*Text proposed by the Commission*

(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and behavioural factors. Such non-communicable diseases as cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors and policy fields, combined with efforts to strengthen health systems.

*Amendment*

(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and behavioural factors ***and commercial determinant of health***. Such non-communicable diseases as cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors and policy fields, ***promotion of a healthy lifestyle*** combined with efforts to

strengthen health systems.

Or. en

## **Amendment 251**

**Nathalie Colin-Oesterlé**

### **Proposal for a regulation**

#### **Recital 17**

##### *Text proposed by the Commission*

(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and behavioural factors. Such non-communicable diseases as cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors and policy fields, combined with efforts to strengthen health systems.

##### *Amendment*

(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and behavioural factors. Such non-communicable diseases as cardiovascular diseases, cancer, chronic respiratory diseases, ***rare diseases*** and diabetes represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors and policy fields, combined with efforts to strengthen health systems ***and the supply of appropriate medicines.***

Or. fr

## **Amendment 252**

**Linea Sogaard-Lidell, Frédérique Ries, Jan Huitema**

### **Proposal for a regulation**

#### **Recital 17**

*Text proposed by the Commission*

(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and behavioural factors. Such non-communicable diseases as cardiovascular diseases, cancer, chronic respiratory diseases, **and** diabetes, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors and policy fields, combined with efforts to strengthen health systems.

*Amendment*

(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and behavioural factors. Such non-communicable diseases as cardiovascular diseases, cancer, **obesity**, chronic respiratory diseases, diabetes **and neurologic disorder** represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors and policy fields, combined with efforts to strengthen health systems.

Or. en

**Amendment 253**

**Bartosz Arłukowicz, Jarosław Duda**

**Proposal for a regulation**

**Recital 17**

*Text proposed by the Commission*

(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and behavioural factors. Such non-communicable diseases as cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts. To decrease the

*Amendment*

(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and behavioural factors. Such non-communicable diseases as cardiovascular diseases, cancer, **neurological disorders**, chronic respiratory diseases, and diabetes, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts.

impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors and policy fields, combined with efforts to strengthen health systems.

To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors and policy fields, combined with efforts to strengthen health systems.

Or. pl

**Amendment 254**  
**Mairead McGuinness**

**Proposal for a regulation**  
**Recital 17**

*Text proposed by the Commission*

(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and behavioural factors. Such non-communicable diseases as cardiovascular diseases, cancer, chronic respiratory diseases, **and** diabetes, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors and policy fields, combined with efforts to strengthen health systems.

*Amendment*

(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and behavioural factors. Such non-communicable diseases as cardiovascular diseases, cancer, chronic respiratory diseases, diabetes **and mental health conditions**, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors and policy fields, combined with efforts to strengthen health systems.

Or. en

## Amendment 255

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

#### Recital 17

##### *Text proposed by the Commission*

(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and behavioural factors. Such non-communicable diseases as cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors and policy fields, combined with efforts to strengthen health systems.

##### *Amendment*

(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and behavioural factors. Such non-communicable diseases as cardiovascular diseases, cancer, **neurological disorders**, chronic respiratory diseases, and diabetes, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors and policy fields, combined with efforts to strengthen health systems.

Or. it

## Amendment 256

Kateřina Konečná

### Proposal for a regulation

#### Recital 17

##### *Text proposed by the Commission*

(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and behavioural factors. Such non-communicable diseases as cardiovascular diseases, cancer, chronic respiratory

##### *Amendment*

(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and behavioural factors. Such non-communicable diseases as cardiovascular diseases, cancer, **neurological disorders**,

diseases, and diabetes, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors and policy fields, combined with efforts to strengthen health systems.

chronic respiratory diseases, and diabetes, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors and policy fields, combined with efforts to strengthen health systems.

Or. en

#### *Justification*

*Due to their exceptional disease burden and increased global prioritisation, neurological disorders should become one of the priorities in the EU4Health Programme.*

#### **Amendment 257**

**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**

#### **Recital 17**

##### *Text proposed by the Commission*

(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and behavioural factors. Such non-communicable diseases as cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable

##### *Amendment*

(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and behavioural factors. Such non-communicable diseases as cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable ***affective***, social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable

Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors and policy fields, combined with efforts to strengthen health systems.

Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors and policy fields, combined with efforts to strengthen health systems.

Or. en

**Amendment 258**  
**Mick Wallace**

**Proposal for a regulation**  
**Recital 17 a (new)**

*Text proposed by the Commission*

*Amendment*

***(17a) Chronic diseases develop slowly, are long-lasting and often incurable. Chronic disease patients often live with several comorbidities, which makes it complex to treat and manage them. The Union and the Member States can greatly reduce the burden of Member States by working together to achieve a better and more effective management of diseases, and the Programme should support actions in this area. The Programme should support the development of specific European Diseases Management Guidelines, such as cardiovascular disease, neurodegenerative diseases, respiratory diseases and diabetes. Moreover, a significant proportion of chronic diseases are preventable by addressing major risk factors such as tobacco use, unhealthy diets, physical inactivity and air quality. Chronic diseases develop slowly, are long-lasting and often incurable. Chronic disease patients often live with several comorbidities, which makes it complex to treat and manage them. The Union and the Member States can greatly reduce the burden of Member States by working together to achieve a better and more***

*effective management of diseases, and the Programme should support actions in this area. The Programme should support the development of specific European Diseases Management Guidelines, such as cardiovascular disease, neurodegenerative diseases, respiratory diseases and diabetes. Moreover, a significant proportion of chronic diseases are preventable by addressing major risk factors such as tobacco use, unhealthy diets, physical inactivity and air quality.*

Or. en

#### *Justification*

*To stem the burden from chronic diseases, it is essential to invest both in primary population-based prevention and control and management of patients.*

#### **Amendment 259**

**Michèle Rivasi**

#### **Proposal for a regulation**

**Recital 17 a (new)**

*Text proposed by the Commission*

*Amendment*

*(17a) Prevention and health promotion are key in achieving sustainable health systems by ensuring that citizens live disease-free longer and by reducing the pressure of preventable diseases, especially of non-communicable diseases, on health systems. In order to enhance the health status and quality of life of Union citizens, primary care healthcare professionals, including community pharmacists, and community groups should be involved in raising public health awareness, participating in disease prevention and control. The Programme should support Union actions and support Member States in developing and implementing prevention and health promotion, early diagnosis and screening strategies. This includes healthy public*

*policies, community action for health, supportive environments and reorienting disease prevention services as part of primary health care services towards health promotion. Screening programmes need to be evidence-based and avoid adverse effects and unnecessary burden on health services.*

Or. en

#### *Justification*

*The strategies of WHO Ottawa Charter on Health Promotion – healthy public policies, supportive environments, community action for health and healthy lifestyles, and reorienting health services – should be a framework for public health. Health care needs to be reoriented towards a more integrative holistic model, which includes health education and promotion.*

#### **Amendment 260**

**Linea Sogaard-Lidell, Jan Huitema**

#### **Proposal for a regulation**

**Recital 17 a (new)**

*Text proposed by the Commission*

*Amendment*

*(17a) Chronic diseases develop slowly, are long-lasting and often incurable. Chronic disease patients often live with several comorbidities, which makes it complex to treat and manage them. The Union and the Member States can greatly reduce the burden on Member States by working together to achieve a better and more effective management of diseases, and the Programme should support actions in this area. The Programme should support the development of specific European Diseases Management Guidelines, for diseases such as cardiovascular disease, neurodegenerative diseases, respiratory diseases, obesity and diabetes. In making these guidelines, special attention should be given to major risk factors such as tobacco use, alcohol consumption, unhealthy diet, physical inactivity and air quality.*

**Amendment 261**  
**Margarita de la Pisa Carrión**

**Proposal for a regulation**  
**Recital 17 a (new)**

*Text proposed by the Commission*

*Amendment*

***(17a) Communicable diseases such as HIV/AIDS, tuberculosis and viral hepatitis have a social dimension that needs to be addressed in a multidisciplinary manner. They should be tackled not only with antivirals and vaccines, but also with education, information, and appropriate social and psychological measures. This approach is well understood for problems such as drug or alcohol addiction. To this end, it is essential to invest in innovative community-based approaches to communicable disease control and prevention strategies for sexually transmitted infections.***

Or. es

**Amendment 262**  
**Nicolae Ștefănuță, Véronique Trillet-Lenoir**

**Proposal for a regulation**  
**Recital 17 a (new)**

*Text proposed by the Commission*

*Amendment*

***(17a) The role of primary prevention and health promotion is key to address long term, common European challenges such as non-communicable and communicable diseases, ageing and cross-border health threats such as future pandemics, antimicrobial resistance. The Union can bring additional added-value***

*to offer an overall public health strategy based on identified best practices and the European dimension of identified health challenges in the area of access to healthcare, health prevention and promotion in order to reduce health inequalities and health differences in Europe.*

Or. en

**Amendment 263**

**César Luena**

**Proposal for a regulation**

**Recital 17 a (new)**

*Text proposed by the Commission*

*Amendment*

*(17a) Early detection and screening of non-communicable diseases, such as heart diseases, plays a crucial role in all treatment and prevention strategies. The Programme should support Union actions and support Member States in developing and implementing prevention, early diagnosis and screening strategies. Joint Actions and similar initiatives with the goal of improving early detection, especially of non-communicable diseases such as Structural Heart Disease, are strongly encouraged.*

Or. en

**Amendment 264**

**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**

**Recital 17 a (new)**

*Text proposed by the Commission*

*Amendment*

***(17a) Mental and psychological well-being is crucial for good mental health. The Programme should be aimed at improving the mental health of individuals and society, including the promotion of mental well-being, the prevention of mental disorders, the protection of human rights and the care of people affected by mental disorders and neurological diseases.***

Or. en

**Amendment 265**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Recital 17 a (new)**

*Text proposed by the Commission*

*Amendment*

***(17a) In the implementation of those prevention, vaccination, early diagnosis and screening strategies, it is imperative that the Programme exploit synergies with the ESF+ and other programmes.***

Or. en

**Amendment 266**  
**Michèle Rivasi**

**Proposal for a regulation**  
**Recital 17 b (new)**

*Text proposed by the Commission*

*Amendment*

***(17b) Early detection and screening plays a crucial role in all treatment and prevention strategies. Prevention is key in achieving sustainable health systems by ensuring that citizens live disease-free***

*longer and by reducing the pressure of preventable diseases, especially of non-communicable diseases, on health systems. In order to enhance the health status and quality of life of Union citizens, primary care healthcare professionals, including community pharmacists, should be involved in raising public health awareness, participating in disease prevention and control. The Programme should support Union actions and support Member States in developing and implementing prevention, early diagnosis and screening strategies. This includes disease prevention services as part of primary healthcare services and the implementation of population level policies to address social, environmental and behavioural risk factors.*

Or. en

#### *Justification*

*Like amendment 16 of the rapporteur with the addition of population level policies.*

#### **Amendment 267**

**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**

#### **Recital 17 b (new)**

*Text proposed by the Commission*

*Amendment*

*(17b) Early detection and screening plays a crucial role in prevention strategies and in timely treatment and health outcomes. Prevention is key in achieving sustainable health systems by ensuring that citizens live disease-free longer and by reducing the pressure of preventable diseases, especially of non-communicable diseases, on health systems. In order to enhance the health status, well-being, and quality of life of*

*Union citizens, primary care healthcare professionals, including community pharmacists, local authorities and citizens should be involved in raising public health awareness, participating in disease prevention and control. The Programme should support Union actions and support Member States in developing and implementing prevention, early diagnosis and screening strategies. This includes disease prevention services as part of primary healthcare services.*

Or. en

**Amendment 268**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Recital 17 b (new)**

*Text proposed by the Commission*

*Amendment*

*(17b) The role of primary prevention and health promotion is key to address long term, common European challenges such as non-communicable and communicable diseases, ageing and cross-border health threats such as future pandemics or health crises, and antimicrobial resistance. The Union can bring additional added-value to offer an overall public health strategy based on identified best practices and the European dimension of identified health challenges in the area of access to healthcare, health prevention and promotion in order to reduce health inequalities and health differences in Europe.*

Or. en

**Amendment 269**  
**Margarita de la Pisa Carrión**

**Proposal for a regulation**  
**Recital 17 b (new)**

*Text proposed by the Commission*

*Amendment*

***(17b) Sexually transmitted diseases represent a growing health burden, with added risks of cancer and multi-resistance.***

Or. es

**Amendment 270**  
**Michèle Rivasi**

**Proposal for a regulation**  
**Recital 17 c (new)**

*Text proposed by the Commission*

*Amendment*

***(17c) To achieve Universal Health Coverage as highlighted in the Political Declaration on UHC adopted by the United Nations in September 2019, the EU and its Member States will strive to achieve all targets of SDG 3. In addition to SDG 3.4, it will be essential to achieve SDG3.7 on sexual and reproductive health and rights, as this is a crucial component of UHC. This Programme should therefore contribute to the universal access to and full respect of sexual and reproductive health and rights at the Union and international level.***

Or. en

**Amendment 271**

**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**  
**Recital 18**

*Text proposed by the Commission*

(18) The Programme therefore should **contribute to** disease prevention throughout the lifetime of an individual **and to health promotion** by addressing health risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of **illicit** drugs. The Programme should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits **and** physical **inactivity**, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also **therefore** contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.

*Amendment*

(18) The Programme therefore should **have a holistic approach to individual health and the link with all the health determinants: socio-economic, environmental, health system, commercial and individual determinants of health. To achieve the best health status possible, the Programme should tackle all the determinants. Health promotion, health protection and** disease prevention throughout the lifetime of an individual **should be at the core of the programme** by addressing health **and mental** risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of **harmful** drugs **and other addictive behaviours**. The Programme should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits, **lack of physical activity that can lead to a person becoming overweight and suffering from obesity**, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme **therefore should contribute to a high level of human health promotion and protection, throughout the entire lifetime of an individual, including through the promotion of physical activity, nutritional care and promotion of health education and health literacy. The Programme should also strengthen and support Health in All Policies and support the implementation of health assessment of EU policies. The Programme should also** contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy **and these policies should take into account the Programme objectives.**

Or. en

**Amendment 272**  
**Biljana Borzan**

**Proposal for a regulation**  
**Recital 18**

*Text proposed by the Commission*

(18) The Programme therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health **risk factors**, such as the use of tobacco and related products and exposure to their emissions, **the harmful use of alcohol**, and the consumption of illicit drugs. The Programme should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits **and** physical inactivity, and exposure to environmental pollution, and foster supportive environments **for healthy lifestyles** in order to complement Member States action in these areas. The Programme should also **therefore** contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.

*Amendment*

(18) The Programme therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing **commercial determinants of health**, such as the use of tobacco and related products and exposure to their emissions, alcohol **use**, **the unhealthy food environment** and the consumption of illicit drugs **and psychoactive substances**. The Programme should also contribute to the reduction of drugs-related health damage, **obesity and** unhealthy dietary habits, physical inactivity, and exposure to environmental pollution, and foster **health** supportive environments in order to complement Member States action in these areas. The Programme **therefore should contribute to a high level of human health protection and prevention, throughout the entire lifetime of an individual, including through the promotion of physical activity, nutritional care and promotion of health education. The Programme** should also **strengthen and support EU health related legislation, including in the area of environmental health, and foster Health in All Policies. The Programme** should also contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.

Or. en

**Amendment 273**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Recital 18**

*Text proposed by the Commission*

(18) The Programme therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health **risk factors**, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of **illicit** drugs. The Programme should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits and physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also **therefore** contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.

*Amendment*

(18) The Programme therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing **determinants of health**, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of drugs **and psychoactive substances**. The Programme should also contribute to the reduction of drugs-related health damage, **obesity and** unhealthy dietary habits and physical inactivity, and exposure to environmental pollution, and foster **health** supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme **therefore should contribute to a high level of human health protection and prevention, throughout the entire lifetime of an individual, including through the promotion of physical activity, nutritional care and promotion of health education. The Programme** should also **strengthen and support EU health related legislation, including in the area of environmental health, and foster Health in All Policies. The Programme** should also contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.

Or. en

**Amendment 274**  
**Piernicola Pedicini, Eleonora Evi**

**Proposal for a regulation**  
**Recital 18**

*Text proposed by the Commission*

(18) The Programme therefore should

*Amendment*

(18) The Programme therefore should

contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of illicit drugs. The Programme should *also* contribute to the reduction of drugs-related health damage, unhealthy dietary habits and physical inactivity, *and exposure to* environmental pollution, *and* foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also therefore contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.

contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of illicit drugs. The Programme should contribute to the reduction of drugs-related health damage, unhealthy dietary habits and physical inactivity. ***The Programme should also address environmental risk factors, minimising exposure to air pollution, to water or land contamination, to physical, chemical or biological hazards, and reduce the impact of climate change disruptions on human and animal health. The Programme should*** foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also therefore contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.

Or. en

#### **Amendment 275**

**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 Recital 18**

##### *Text proposed by the Commission*

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

##### *Amendment*

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

unhealthy dietary habits and physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also therefore contribute to the objectives of the European Green Deal, the Farm to Fork Strategy **and** the Biodiversity Strategy.

unhealthy dietary habits **via the adoption of a mandatory harmonized nutrition label such as the Nutri-Score** and physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also therefore contribute to the objectives of the European Green Deal, the Farm to Fork Strategy, the Biodiversity Strategy **and Chemicals Strategy for Sustainability**.

Or. en

### **Amendment 276**

**Frédérique Ries, Linea Sogaard-Lidell**

#### **Proposal for a regulation**

#### **Recital 18**

##### *Text proposed by the Commission*

(18) The Programme therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of illicit drugs. The Programme should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits **and** physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also therefore contribute to the objectives of the European Green Deal, the Farm to Fork Strategy **and** the Biodiversity Strategy.

##### *Amendment*

(18) The Programme therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of illicit drugs. The Programme should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits, physical inactivity **and obesity**, and exposure to environmental **and indoor** pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also therefore contribute to the objectives of the European Green Deal, the Farm to Fork Strategy, the Biodiversity Strategy **and the Chemicals strategy for sustainability**.

Or. en

## Amendment 277

Linea Sogaard-Lidell, Jan Huitema

### Proposal for a regulation

#### Recital 18

##### *Text proposed by the Commission*

(18) The Programme therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of illicit drugs. The Programme should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits and physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also therefore contribute to the objectives of the European Green Deal, the Farm to Fork Strategy *and* the Biodiversity Strategy.

##### *Amendment*

(18) The Programme therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of illicit drugs. The Programme should also contribute to the reduction of drugs-related health damage, ***obesity***, unhealthy dietary habits and physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also therefore contribute to the objectives of the European Green Deal, the Farm to Fork Strategy, the Biodiversity Strategy *and Chemicals Strategy for Sustainability*.

Or. en

## Amendment 278

Joanna Kopcińska

### Proposal for a regulation

#### Recital 18

##### *Text proposed by the Commission*

(18) The Programme therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health risk factors, such as the use of tobacco and

##### *Amendment*

(18) The Programme therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health risk factors, such as the use of tobacco and

related products and exposure to their emissions, the harmful use of alcohol, and the consumption of illicit drugs. The Programme should also contribute to the reduction of drugs-related health damage, **unhealthy dietary habits and** physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also therefore contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.

related products and exposure to their emissions, the harmful use of alcohol and the consumption of illicit drugs. The Programme should also contribute to the reduction of drugs-related health damage, **unbalanced diets and obesity**, physical inactivity, **mental health** and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also therefore contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.

Or. en

## **Amendment 279**

**Michèle Rivasi**

### **Proposal for a regulation**

#### **Recital 18**

##### *Text proposed by the Commission*

(18) The Programme therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of illicit drugs. The Programme should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits and physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also therefore contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.

##### *Amendment*

(18) The Programme therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of illicit drugs. The Programme should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits and physical inactivity, and exposure to environmental pollution ***in light of the zero-pollution ambition for a toxic-free environment***, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also therefore contribute to the objectives of the European Green Deal, the Farm to Fork

**Amendment 280**  
**Jytte Guteland**

**Proposal for a regulation**  
**Recital 18**

*Text proposed by the Commission*

(18) The Programme therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of illicit drugs. The Programme should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits and physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also **therefore** contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.

*Amendment*

(18) The Programme therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of illicit drugs. The Programme should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits and physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. ***Since zoonoses regularly emerge as a result of frequent and closer interactions between animals, humans, and ecosystems, due to loss of habitat for agricultural purposes - especially for the intensification of animal farming - and wildlife exploitation,*** the Programme should also contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.

**Amendment 281**  
**Nicolae Ștefănuță, Véronique Trillet-Lenoir**

**Proposal for a regulation**  
**Recital 18**

*Text proposed by the Commission*

(18) **The Programme** therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of illicit drugs. The Programme should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits and physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also therefore contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.

*Amendment*

(18) **Health promotion and health prevention are vastly more cost-efficient than treatment, both in terms of money and of quality-adjusted life years,** therefore **the program** should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of illicit drugs. The Programme should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits and physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also therefore contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.

Or. en

**Amendment 282**

**Rob Rooker**

**Proposal for a regulation**

**Recital 18**

*Text proposed by the Commission*

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

*Amendment*

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

unhealthy dietary habits and physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. ***The Programme should also therefore contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.***

unhealthy dietary habits and physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas.

Or. nl

**Amendment 283**  
**Margarita de la Pisa Carrión**

**Proposal for a regulation**  
**Recital 18**

*Text proposed by the Commission*

(18) The Programme therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of illicit drugs. The Programme should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits and physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. ***The Programme should also therefore contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.***

*Amendment*

(18) The Programme therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of illicit drugs. The Programme should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits and physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas.

Or. es

**Amendment 284**  
**Mairead McGuinness**

**Proposal for a regulation**  
**Recital 18**

*Text proposed by the Commission*

(18) The Programme therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of illicit drugs. The Programme should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits and physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also therefore contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.

*Amendment*

(18) The Programme therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of illicit drugs. The Programme should also contribute to the reduction of drugs-related health damage, **obesity**, unhealthy dietary habits and physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also therefore contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.

Or. en

**Amendment 285**  
**Mick Wallace**

**Proposal for a regulation**  
**Recital 18**

*Text proposed by the Commission*

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

*Amendment*

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

Programme should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits and physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also therefore contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.

Programme should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits and physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also therefore contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.

Or. en

**Amendment 286**  
**Michèle Rivasi**

**Proposal for a regulation**  
**Recital 18 a (new)**

*Text proposed by the Commission*

*Amendment*

***(18a) The burden of chronic diseases is still significant in the Union. Chronic diseases develop slowly, are long-lasting and often incurable. Chronic diseases are, in many cases, associated with more than one comorbidity, which makes them even more difficult to treat and manage. They have caused great human suffering and placed an enormous burden on health systems, as well. However, many chronic diseases, such as cardiovascular diseases and type 2 diabetes, could be prevented by healthy lifestyle choices through well-evidenced measures to address risk factors, while other illnesses, for instance neurological diseases, can be managed to slow the onset if detected early, or helping patients feel their best and remain active for longer. The Union and the Member States can therefore greatly reduce the burden of Member States by working together to achieve a better and more effective prevention and management of diseases, and the Programme should support actions in this area. The***

***Programme should support the development of specific European Diseases Prevention and Management Guidelines in the area of both communicable and non-communicable diseases, such as cardiovascular diseases, neurodegenerative diseases, respiratory diseases and diabetes. The Programme should also support actions at national and local level to support the implementation of the WHO “Best Buys for tackling NCDs <sup>1a</sup>”.***

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*1a*

***<https://apps.who.int/iris/handle/10665/259232>***

Or. en

#### *Justification*

*Like amendment 18 of the rapporteur, but referring to addressing risk factors rather than healthy lifestyle choices, adding "prevention" into the guidelines and adding the reference to the WHO's recommendation on non-communicable diseases.*

**Amendment 287**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Recital 18 a (new)**

*Text proposed by the Commission*

*Amendment*

***(18a) A holistic long-term health care approach is necessary in view of the growing prevalence of chronic diseases among an ageing EU population. As many conditions that were once fatal, such as HIV, increasingly become chronic and manageable conditions thanks to innovative treatments, healthcare systems need to adapt and provide a comprehensive model of care that takes into account the specific needs of people affected by chronic diseases, thereby improving their health-related***

*quality of life. The Programme should support the development of integrated systems of care that allow for multidisciplinary, cross-disease cooperation between health practitioners in order to ensure that people living with chronic diseases receive adequate support, including in the management of co-morbidities and other health-related issues, such as mental health conditions.*

Or. en

**Amendment 288**

**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  
Recital 18 a (new)**

*Text proposed by the Commission*

*Amendment*

*(18a) Given that health needs differ during a person's lifetime, the Programme should also support Member States to create and implement health programmes that are aligned with the needs of population, and should work to achieve a minimum standard in health programmes that tackle specific populations, such as children's health, maternal health and ageing-related health, as programmes that are horizontal to the lifetime as mental health and reproductive and sexual health.*

Or. en

**Amendment 289**

**Nathalie Colin-Oesterlé**

**Proposal for a regulation  
Recital 18 a (new)**

*Text proposed by the Commission*

*Amendment*

***(18a) Today, there is a lack of awareness about chronic diseases, such as migraines, despite their psychological and socioeconomic impact; it is important to ensure that neurological disorders, including migraines, are given proper consideration in European policies. The EU and the Member States should include migraines and other chronic diseases in their health priorities.***

Or. fr

**Amendment 290**

**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**

**Recital 18 a (new)**

*Text proposed by the Commission*

*Amendment*

***(18a) The Programme should continue supporting actions in the area of reducing and preventing alcohol related harm in the perspective of a revised EU alcohol strategy. Protecting children from alcohol commercial communication as well as product placement and sponsorship of alcohol brands, especially in the online environment, should be one of the Programme's priorities.***

Or. en

**Amendment 291**

**Inese Vaidere**

**Proposal for a regulation**

**Recital 18 a (new)**

*Text proposed by the Commission*

*Amendment*

***(18a) The Programme should aim to reduce health inequalities including unequal access to treatment and medicines across Member States;***

Or. en

**Amendment 292**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Recital 18 b (new)**

*Text proposed by the Commission*

*Amendment*

***(18b) The burden of chronic diseases is still significant in the Union. Chronic diseases develop slowly, are long-lasting and often incurable. Chronic diseases are, in many cases, associated with more than one comorbidity, which makes them even more difficult to treat and manage. They have caused great human suffering and placed an enormous burden on health systems, as well. However, many chronic diseases, such as cardiovascular diseases, cancer and type 2 diabetes, could be prevented through access to prevention services, affordability of healthy nutrition and healthy lifestyle, while other illnesses, for instance neurological diseases, can be managed to slow from the onset, if detected early, or helping patients feel their best and remain active for longer. The Union and the Member States can therefore greatly reduce the burden of Member States by working together to achieve a better and more effective management of diseases, including prevention and the Programme should support actions in this area. The Programme should support the development of specific European Diseases Management Guidelines in the***

*area of both communicable and non-communicable diseases, such as cardiovascular diseases, neurodegenerative diseases, cancer, respiratory diseases and diabetes.*

Or. en

**Amendment 293**

**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  
Recital 18 b (new)**

*Text proposed by the Commission*

*Amendment*

*(18b) The burden of chronic diseases is still significant in the Union. Chronic diseases develop slowly, are long-lasting and often incurable. Chronic diseases are, in many cases, associated with more than one comorbidity, which makes them even more difficult to treat and manage. They have caused great human suffering and placed an enormous burden on health systems, as well. However, many chronic diseases, such as cardiovascular diseases, cancer and type 2 diabetes, could be prevented through access to prevention services, affordability of healthy nutrition and healthy lifestyle, while other illnesses, for instance neurological diseases, can be managed to slow their onset if detected early, or helping patients feel their best and remain active for longer. The Union and Member States can therefore greatly reduce the burden of Member States by working together to achieve a better and more effective management of diseases, including prevention, and the Programme should support actions in this area. The Programme should support the development of specific European Diseases Management Guidelines in the area of both communicable and non-*

*communicable diseases, such as cardiovascular diseases, neurodegenerative diseases, cancer, respiratory diseases and diabetes.*

Or. en

**Amendment 294**

**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  
Recital 18 b (new)**

*Text proposed by the Commission*

*Amendment*

*(18b) Vaccination prevents an estimated 2,5 million deaths each year worldwide and reduces disease-specific treatment costs. The introduction of large-scale protective vaccinations in Europe has significantly contributed to the eradication or decline of many infectious diseases. Nevertheless, the worrying phenomenon of vaccine hesitancy and the disinformation on vaccination should be addressed by the Programme to reassure European citizens.*

Or. en

**Amendment 295**

**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  
Recital 18 c (new)**

*Text proposed by the Commission*

*Amendment*

*(18c) The International Agency for Research on Cancer (IARC) considered classified diesel engine exhaust as*

*carcinogenic to humans. The Programme should make sure that the health impacts and costs of air pollution are integrated into the Union action against cancer, while ensuring full coherence with the European zero emission strategy.*

Or. en

#### Amendment 296

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

#### Recital 19

##### *Text proposed by the Commission*

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

##### *Amendment*

(19) Cancer is the second leading cause of mortality in the Member States after cardiovascular diseases. ***Cancer is caused by many factors in multiple stages and therefore requires a new prevention paradigm that addresses individual health determinants (genetic, lifestyle) and wider (populations) determinants related to occupational, environmental and social exposure factors***; It is also one of non-communicable diseases that share common risk factors ***with others*** and the prevention and control of which would benefit the majority of citizens. ***Poor nutrition, physical inactivity, obesity, tobacco and alcohol are risk factors common to other chronic diseases, such as cardiovascular diseases, type 2 diabetes, and respiratory diseases, and therefore cancer prevention programmes should be conducted within the context of an integrated chronic disease prevention programme***. In 2020 the Commission announced the ‘Europe’s Beating Cancer Plan’ which would cover ***every key stage*** of the disease :prevention, diagnosis, treatment, ***life as a cancer survivor, reinsertion and palliative care***. ***The programme should promote actions***

*to improve cancer patients' rights including the return to work with a disability, the right to be forgotten, the access to preserved fertility and provide optimal relief during the end-of-life stage.*  
The measures should benefit from the Programme and from Horizon Europe's Mission on Cancer *which will work in close link.*

Or. en

**Amendment 297**  
**Michèle Rivasi**

**Proposal for a regulation**  
**Recital 19**

*Text proposed by the Commission*

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

*Amendment*

(19) *Cardiovascular disease is the leading cause of mortality in the Member States (36% of all deaths in the EU), followed by cancer as the second leading cause of mortality in the Member States (26% of all deaths in the EU). They are also amongst the* non-communicable diseases that share common risk factors and the prevention and control of which would benefit the majority of citizens. In 2020 the Commission announced the 'Europe's Beating Cancer Plan' which would cover the entire cycle of the disease starting from prevention and early diagnosis to treatment and quality of life of patients and survivors. The measures should benefit from the Programme and from Horizon Europe's Mission on Cancer. *The Programme should ensure that patients living with other major chronic diseases such as cardiovascular disease, chronic respiratory disease, diabetes and mental health conditions benefit from it in a proportionate manner.*

Or. en

**Amendment 298**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Recital 19**

*Text proposed by the Commission*

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

*Amendment*

(19) Cancer is the second leading cause of mortality in the Member States after cardiovascular diseases. It is also one of non-communicable diseases that share common risk factors and the prevention and control of which would benefit the majority of citizens. ***Currently no broadly accepted tools such as a “Cancer Dashboard” exist which can serve to measure progress (e.g. EU Cancer Targets) and address inequalities (e.g. in Central and South-Eastern Europe versus the rest of Europe).*** In 2020 the Commission announced the ‘Europe’s Beating Cancer Plan’ which would cover the entire cycle of the disease starting from prevention and early diagnosis to treatment and quality of life of patients and survivors. The measures should benefit from the Programme and from Horizon Europe’s Mission on Cancer, ***in particular by initiatives which support the mid- and long-term goals of the Plan. The actions on cancer should equally address its common shared risk factors and synergies with other major non-communicable diseases such as neurological disorders, as well as reflect upon devising a template for other major disease areas based on the ‘Europe’s Beating Cancer Plan’.***

Or. en

**Amendment 299**  
**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**  
**Recital 19**

*Text proposed by the Commission*

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

*Amendment*

(19) Cancer is the second leading cause of mortality in the Member States after cardiovascular diseases. It is also one of non-communicable diseases that share common risk factors and the prevention and control of which would benefit the majority of citizens. In 2020 the Commission announced the ‘Europe’s Beating Cancer Plan’ which would cover the entire cycle of the disease starting from prevention and early diagnosis to treatment and quality of life of patients and survivors. The measures should benefit from the Programme and from Horizon Europe’s Mission on Cancer. ***The actions on cancer should also address its common risk factors and synergies with other major non-communicable diseases, such as neurological diseases, and consider devising a template for other major disease areas based on the ‘Europe’s Beating Cancer Plan’.***

Or. it

**Amendment 300**

**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**  
**Recital 19**

*Text proposed by the Commission*

(19) Cancer is the second leading cause of mortality in the Member States after cardiovascular diseases. It is also one of non-communicable diseases that share common risk factors and the prevention and control of which would benefit the majority of citizens. In 2020 the

*Amendment*

(19) Cancer is the second leading cause of mortality in the Member States after cardiovascular diseases. It is also one of ***several*** non-communicable diseases that share common risk factors. ***Addressing the prevention of cancer along with other NCDs in a coordinated fashion*** and the

Commission announced the ‘Europe’s Beating Cancer Plan’ which would cover the entire cycle of the disease starting from prevention and early diagnosis to treatment and quality of life of patients and survivors. The measures should benefit from the Programme and from Horizon Europe’s Mission on Cancer.

prevention and control of which would benefit the majority of citizens. In 2020 the Commission announced the ‘Europe’s Beating Cancer Plan’ which would cover the entire cycle of the disease starting from prevention and early diagnosis to treatment and quality of life of patients and survivors ***also improving palliative care and pain management.*** The measures should benefit from the Programme and from Horizon Europe’s Mission on Cancer ***and should endeavour to include cancer action into a broader NCD framework to move away from a disease-centred approach and towards a patient-focused approach.***

Or. en

**Amendment 301**  
**Kateřina Konečná**

**Proposal for a regulation**  
**Recital 19**

*Text proposed by the Commission*

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

*Amendment*

(19) Cancer is the second leading cause of mortality in the Member States after cardiovascular diseases. It is also one of non-communicable diseases that share common risk factors and the prevention and control of which would benefit the majority of citizens. In 2020 the Commission announced the ‘Europe’s Beating Cancer Plan’ which would cover the entire cycle of the disease starting from prevention and early diagnosis to treatment and quality of life of patients and survivors. The measures should benefit from the Programme and from Horizon Europe’s Mission on Cancer. ***The actions on cancer should equally address its common shared risk factors and synergies with other major non-communicable diseases such as neurological disorders, as well as reflect upon devising a template for other major disease areas based on the***

**Amendment 302**

**Bartosz Arłukowicz, Jarosław Duda**

**Proposal for a regulation**

**Recital 19**

*Text proposed by the Commission*

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

*Amendment*

(19) Cancer is the second leading cause of mortality in the Member States after cardiovascular diseases. It is also one of non-communicable diseases that share common risk factors and the prevention and control of which would benefit the majority of citizens. In 2020 the Commission announced the 'Europe's Beating Cancer Plan' which would cover the entire cycle of the disease starting from prevention and early diagnosis to treatment and quality of life of patients and survivors. The measures should benefit from the Programme and from Horizon Europe's Mission on Cancer. ***The actions on cancer should also address its common, shared risk factors and synergies with other major non-communicable diseases, such as neurological disorders, and consider devising a template for other major disease areas.***

**Amendment 303**

**Margarita de la Pisa Carrión**

**Proposal for a regulation**

**Recital 19**

*Text proposed by the Commission*

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

*Amendment*

(19) Cancer is the second leading cause of mortality in the Member States after cardiovascular diseases. It is also one of non-communicable diseases that share common risk factors and the prevention and control of which would benefit the majority of citizens. In 2020 the Commission announced the ‘Europe’s Beating Cancer Plan’ which would cover the entire cycle of the disease starting from prevention and early diagnosis to treatment and quality of life of patients and survivors, ***as well as better palliative care and pain management.*** The measures should benefit from the Programme and from Horizon Europe’s Mission on Cancer. ***The EU is in a position to take the lead in providing humanitarian support to terminally ill patients by developing and implementing palliative care measures.***

Or. es

**Amendment 304**  
**Linea Søgaard-Lidell, Jan Huitema**

**Proposal for a regulation**  
**Recital 19**

*Text proposed by the Commission*

(19) Cancer *is* the second leading cause of mortality in the Member States after cardiovascular diseases. It is also one of non-communicable diseases that share common risk factors and the prevention and control of which would benefit the majority of citizens. In 2020 the Commission announced the ‘Europe’s Beating Cancer Plan’ which would cover the entire cycle of the disease starting from prevention and early diagnosis to treatment and quality of life of patients and survivors. The measures should benefit

*Amendment*

(19) Cancer ***causes 26 % of all deaths in EU and is thereby*** the second leading cause of mortality in the Member States after cardiovascular diseases ***that represent 36 % of all deaths in the EU.*** It is also one of non-communicable diseases that share common risk factors ***such as obesity for 20 % of cancers*** and the prevention and control of which would benefit the majority of citizens. In 2020 the Commission announced the ‘Europe’s Beating Cancer Plan’ which would cover the entire cycle of the disease starting from

from the Programme and from Horizon Europe's Mission on Cancer.

prevention and early diagnosis to treatment and quality of life of patients and survivors. The measures should benefit from the Programme and from Horizon Europe's Mission on Cancer.

Or. en

**Amendment 305**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Recital 19 a (new)**

*Text proposed by the Commission*

*Amendment*

***(19a) It is well recognised that cancer is often diagnosed late, which means that fewer treatment options are available for people affected by an advanced stage of the disease. If more patients were diagnosed earlier, it could lead to much more effective treatment outcomes, better quality of life, as well as improved overall survival rates. An earlier diagnosis means also a reduction in the healthcare burden. Compared to early diagnosis, cancer screening is a distinct and more complex public health strategy that mandates additional resources, infrastructure and coordination. When planned effectively, appropriately financed and implemented, screening can reduce deaths from cancer and, in the case of some cancer types, can also reduce the risk of developing cancer. The Programme should therefore contribute to the investment in early diagnosis and screening, and to promotion and awareness raising in relation to the benefits of such early diagnosis and screening. The EU should have extensive cancer screening recommendations and guidelines for all major cancers to be implemented in all Member States.***

**Amendment 306**  
**Michèle Rivasi**

**Proposal for a regulation**  
**Recital 19 a (new)**

*Text proposed by the Commission*

*Amendment*

***(19a) It is well recognised that cancer is often diagnosed late, which means that fewer treatment options are available for people affected by an advanced stage of the disease. If more patients were diagnosed earlier, it could lead to much more effective treatment outcomes, better quality of life, as well as improved overall survival rates. An earlier diagnosis means also a reduction in the healthcare burden. Compared to early diagnosis, cancer screening is a distinct and more complex public health strategy that mandates additional resources, infrastructure and coordination. When evidence-based, planned effectively, appropriately financed and implemented, screening can reduce deaths from cancer and, in the case of some cancer types, can also reduce the risk of developing cancer. The Programme should therefore contribute to the investment in early diagnosis and evidence-based screening, and to promotion and awareness raising in relation to the benefits and adverse effects of such early diagnosis and screening.***

Or. en

*Justification*

*Not all screening is beneficial. Sweden has stopped prostate cancer screening for over 50's because it is considered unethical. Health screening should be ethical and evidence-based.*

**Amendment 307**

**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**

**Recital 19 a (new)**

*Text proposed by the Commission*

*Amendment*

***(19a) Under Article 153 TFEU, the Union is to support and complement the activities of Member States concerning improvement of the working environment, and protection of workers' health, safety and working conditions. Considering the large amount of time that the workers spend in their workplaces and the possible risk they could have, such as exposure to health hazard substances and carcinogens and to repeated movements, leading to a high burden of incapacity and number of work days lost, which in turn has consequences for the individual, family and society. The Programme should also reflect the importance of occupational health and its impact on health workers and societies. The Commission should work with Member States to create new legislation to improve workers health conditions, improve their working conditions, the balance between work and life, promote wellbeing and better mental health, prevent early-retirement due to ill health and poor health management.***

Or. en

**Amendment 308**

**Mick Wallace**

**Proposal for a regulation**

**Recital 19 a (new)**

*Text proposed by the Commission*

*Amendment*

***(19a) While the Union currently has a strong focus on cancer as expressed in ‘Europe’s Beating Cancer Plan’ and Horizon Europe’s Mission on Cancer, the Programme must ensure that patients living with other major chronic diseases such as cardiovascular disease, chronic respiratory disease, diabetes and mental health conditions benefit from it in a proportionate manner. In Europe, chronic diseases are responsible for 77% of the total disease burden (measured in DALYs = disability-adjusted life years). Of these, cardiovascular disease makes up 23%, neuropsychiatric conditions 20% and cancer 11%. The Programme should ensure that the actions it supports will benefit equitably all chronic disease patients. In that context, 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.***

Or. en

*Justification*

*In Europe, chronic diseases are responsible for 77% of the total disease burden (measured in DALYs = disability-adjusted life years). Of these, cardiovascular disease makes up 23%, neuropsychiatric conditions 20% and cancer 11%. The Programme should ensure that the actions it supports will benefit equitably all chronic disease patients. In that context 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.*

**Amendment 309**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Recital 19 a (new)**

*Text proposed by the Commission*

*Amendment*

***(19a) A recent study by authors from***

*IARC published in the February 2020 edition of the Lancet Global Health Journal, highlights a crucial need for resources directed towards cancer prevention programmes that target infection, namely helicobacter pylori, human papillomavirus, Hepatitis B virus and Hepatitis C virus, particularly in high-risk populations. Such interventions can markedly reduce the increasing cancer burden and associated mortality. The Programme should just ensure that will promote measures to tackle infectious diseases, helping their prevention, through vaccination, if available, awareness raising, early diagnosis/screening, and linkage to care, with a view to promoting the prevention of cancer as a key European Commission goal.*

Or. en

**Amendment 310**  
**Antoni Comín i Oliveres**

**Proposal for a regulation**  
**Recital 19 a (new)**

*Text proposed by the Commission*

*Amendment*

*(19a) There is plenty of scientific evidence that shows that health prevention and promotion policies (public health policies) are central to guaranteeing the right to health of citizens, and those are also the most efficient in terms of cost effectiveness. However, even today most of the budgets of the health systems of the majority of Member States are given very little space to policies for the prevention and promotion of health. The COVID-19 pandemic has firmly confirmed the importance of public health policies for our societies. For this reason, it is necessary that the projects of the*

*EU4Health programme accompany Member States to reformulate the budgets of their health systems in order to fulfil greater financial strength to these policies.*

Or. en

**Amendment 311**  
**Véronique Trillet-Lenoir**

**Proposal for a regulation**  
**Recital 19 a (new)**

*Text proposed by the Commission*

*Amendment*

*(19a) The programme could participate to the establishment of a European Cancer Institute (ECI) which would provide a platform for the implementation of the 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 to provide comparable data on cancer.*

Or. en

**Amendment 312**  
**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**  
**Recital 19 a (new)**

*Text proposed by the Commission*

*Amendment*

*(19a) Heart attacks and strokes often occur in people previously undiagnosed*

*with cardiovascular diseases. Many of these are due to undetected genetic conditions, such as familial hypercholesterolaemia, arrhythmias, congenital heart disease and cardiomyopathies, and conditions such as hypertension. The Programme should support the development of policies and interventions to identify and manage individuals at high risk of developing cardiovascular disease in order to prevent the onset of the disease and reduce mortality.*

Or. it

**Amendment 313**  
**César Luena**

**Proposal for a regulation**  
**Recital 19 a (new)**

*Text proposed by the Commission*

*Amendment*

*(19a) Late diagnosis of cancer and Structural Heart Diseases reduces treatment options available for people affected by an advanced stage of the disease. Early diagnosis is crucial for effective treatment outcomes, better quality of life and reduction of the healthcare burden. The Programme should therefore contribute to the investment in early diagnosis and screening, and to the promotion and awareness raising in relation to the benefits of such early diagnosis and screening for cancer and Structural Heart Diseases.*

Or. en

**Amendment 314**  
**Pernille Weiss**

**Proposal for a regulation**  
**Recital 19 a (new)**

*Text proposed by the Commission*

*Amendment*

***(19a) Obesity is the fourth largest direct cause of premature mortality in the EU. In this context, obesity acts as a gateway chronic disease to the onset of 80% of Type 2 Diabetes cases and 20% of cancers. Obesity has been recognised as one of the high risk pre-existing chronic diseases in the EU and must be subject to evidence-based policymaking, which should be aligned with international standards and national implementation trends.***

Or. en

**Amendment 315**  
**Linea Søgaard-Lidell, Frédérique Ries, Jan Huitema**

**Proposal for a regulation**  
**Recital 19 a (new)**

*Text proposed by the Commission*

*Amendment*

***(19a) The Programme should ensure that patients living with and suffering from any chronic disease such as cardiovascular disease, cancer, obesity, chronic respiratory disease, neurologic disorder, diabetes or mental health disorder benefit from it in a proportionate manner.***

Or. en

**Amendment 316**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Recital 19 b (new)**

***(19b) The IARC shows that more than 35,000 children and young people are diagnosed with cancer and over than 6,000 young patients die annually in Europe. Paediatric cancers are a category of age- and biologically specific rare malignancies that cannot be appropriately addressed by extrapolation of adult cancer approaches and require a dedicated effort across the research and care continuum. There is a lack of innovative therapies to treat children with cancer. Even for older off-patent medicines used off-label on children, there are still pronounced access issues including shortages across the Union and budget limitations in some Member States, as well as major differences among countries in pain control accessibility for children undergoing treatment for cancer. Hence, there is an urgent need to appropriately revise the regulatory environment so that the needs of children and adolescents are met. The Programme should therefore provide for actions in this regard, in particular aiming to reinforce Regulation (EC) No 1901/2006 of the European Parliament and of the Council, and support cross-border research collaboration by granting appropriate allocations and to amend Article 10 of the directive 2001/83/EC, in order to include a paragraph to stimulate innovation on the off-patented medicines.***

Or. en

**Amendment 317**  
**Michèle Rivasi**

**Proposal for a regulation**  
**Recital 19 b (new)**

***(19b) The health workforce has a vital role in building resilient health systems and in reaching the highest attainable standard of health. The Programme should therefore underpin the Commission's work on effective, accessible and resilient healthcare and health systems, and support the development and implementation of a strategy on the health workforce. In synergy with ESF+ and in particular EaSI, the Programme should provide under the Strategy the means for harmonized training and education for the purpose of improving the curricula of health professionals, in particular with regard to health promotion and disease prevention as well as digital skills, in order to obtain a patient-oriented and outcome-based health approach. The Programme should also support, via the Strategy, Member States to address the brain drain and migration of the healthcare workforce from less-developed countries and implement retention policies. Being able to deliver high quality, personalised, targeted and integrated care, and improve health service coverage depends on the availability, accessibility, acceptability, adaptability and quality of the health workforce.***

Or. en

**Amendment 318**  
**Antoni Comín i Oliveres**

**Proposal for a regulation**  
**Recital 19 b (new)**

*Text proposed by the Commission*

*Amendment*

***(19b) Likewise, it is absolutely necessary to remember that these prevention and promotion strategies concern all sectoral policies: fiscal, commercial, economic, educational, housing, cultural, social assistance, etc. "Health in all policies" (HiAP) should be a non-negotiable principle of all public policies. An instrument already used at the national level is the so-called Health Test to assess the health impact of the different sectoral policies. It is necessary to deploy a Health Test methodology of all the programmes managed by the Union.***

Or. en

**Amendment 319**  
**Mick Wallace**

**Proposal for a regulation**  
**Recital 19 b (new)**

*Text proposed by the Commission*

*Amendment*

***(19b) Heart attacks and strokes often occur in people previously undiagnosed with cardiovascular disease. Many of these are due to undetected genetic conditions, such as familial hypercholesterolaemia, arrhythmias, congenital heart disease and cardiomyopathies and conditions, such as hypertension. The Programme should support the development of policies and interventions for reaching out to and managing individuals at high risk of developing cardiovascular disease to prevent the onset of the disease and reduce mortality.***

Or. en

## *Justification*

*A sizeable number of premature deaths from cardiovascular disease (CVD), just like from cancer and other chronic diseases, can be prevented by controlling the main risk factors: tobacco, unhealthy diet and physical inactivity. To tackle CVD comprehensively both primary and secondary prevention is needed.*

### **Amendment 320**

**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**

#### **Recital 19 b (new)**

*Text proposed by the Commission*

*Amendment*

***(19b) While the Union currently has a strong focus on cancer as expressed in ‘Europe’s Beating Cancer Plan’ and Horizon Europe’s Mission on Cancer, the Programme should ensure that patients living with other major chronic diseases such as cardiovascular disease, chronic respiratory disease, diabetes and mental health conditions benefit from it in a proportionate manner.***

Or. en

### **Amendment 321**

**Mick Wallace**

### **Proposal for a regulation**

#### **Recital 19 c (new)**

*Text proposed by the Commission*

*Amendment*

***(19c) A crucial part of treatment for cardiovascular disease is rehabilitation after an event, including counselling, medical treatment, exercise and psychological support. These programmes help prevent recurrence, optimise quality of life, reintegrate patients into the job***

*market and reduce the burden on health services by reducing hospital readmissions. Although the considerable benefits of cardiac and stroke rehabilitation for patients, as well as the wider society, are well-documented, access to and uptake of quality rehabilitation is patchy in most of the Union's Member States and is considered an underutilised resource. The Programme should support increased uptake of rehabilitation and secondary prevention.*

Or. en

### *Justification*

*The benefits that rehabilitation bestows on patients as well as the wider society are considerable. Cardiovascular rehabilitation must be an integral part of the patient's treatment plan and must be accessible by all eligible patients throughout the Union. Cardiovascular rehabilitation increases the chances of patients getting back to work and have the potential to reduce disability allowances.*

### **Amendment 322**

**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**

#### **Recital 19 c (new)**

*Text proposed by the Commission*

*Amendment*

*(19c) A crucial part of treatment of diseases is rehabilitation, including counselling, medical treatment, exercise and psychological support. These programmes help prevent recurrence, optimise quality of life, reintegrate patients into the job market and reduce the burden on health services by reducing hospital readmissions. Although there are considerable benefits for patients, as well as the wider society, the access to and uptake of quality rehabilitation is patchy in most of the Member States and is*

*considered an underutilised resource. The Programme should support increased uptake of rehabilitation and secondary prevention reducing the burden of diseases.*

Or. en

**Amendment 323**

**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**

**Recital 19 c (new)**

*Text proposed by the Commission*

*Amendment*

*(19c) It is well recognised that cancer is often diagnosed late, which means that fewer treatment options are available for people affected by an advanced stage of the disease. The Programme should therefore contribute to the investment in early diagnosis and screening, and to promotion and awareness raising in relation to the benefits of early diagnosis and screening, in line with or going beyond WHO, UN and EU recommendations, and in synergy with Horizon Europe, its Mission on Cancer and the relevant partnerships.*

Or. en

**Amendment 324**

**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**

### **Recital 19 d (new)**

*Text proposed by the Commission*

*Amendment*

***(19d) Paediatric cancers are a category of age- and biologically-specific rare malignancies that cannot be appropriately addressed by extrapolation of adult cancer approaches and require a dedicated effort across the research and care continuum. The Programme should provide for actions oriented at paediatric cancer, in particular aiming to address the limitations of the Regulation (EC) No 1901/2006 of the European Parliament and of the Council<sup>1a</sup> in this disease area and support cross-border research collaboration by granting appropriate allocations in synergy with Horizon Europe, its Mission on Cancer and the relevant partnerships.***

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***<sup>1a</sup> Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (Text with EEA relevance) (OJ L 378, 27.12.2006, p. 1).***

Or. en

**Amendment 325**  
**Joanna Kopcińska**

**Proposal for a regulation**  
**Recital 20**

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

## Amendment 326

Pascal Arimont, Cindy Franssen, Esther de Lange

### Proposal for a regulation

#### Recital 20

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

## Amendment 327

Joanna Kopcińska

**Proposal for a regulation  
Recital 20 a (new)**

*Text proposed by the Commission*

*Amendment*

***(20a) The health workforce has a vital role in building resilient health systems and in reaching the highest attainable standard of health. The Programme should therefore underpin the Commission’s work on effective, accessible and resilient healthcare and health systems, and support the development and implementation of a strategy on the health workforce. In synergy with European Social Fund Plus (ESF+), and in particular Employment and Social Innovation (EaSI), the Programme should provide under the Strategy the means for harmonized training and education for the purpose of improving the curricula of health professionals and their digital skills, in order to obtain a patient-oriented and outcome-based health approach. The Programme should also support, via the Strategy, Member States to address the brain drain and migration of the healthcare workforce from Member States of the eastern flank of the European Union and implement retention policies. Being able to deliver high quality, standardised, targeted and integrated care, and improve health service coverage depends on the availability, accessibility, acceptability, adaptability and quality of the health workforce.***

Or. en

**Amendment 328**

**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**  
**Recital 20 a (new)**

*Text proposed by the Commission*

*Amendment*

**(20a) *The programme should encompass a “Health in all policies” and “Health in all fundings” approaches in its implementation and evaluation. In the programme’s framework, the Commission should proceed to a systematic health impact assessment, built on cross-sectorial indicators, of all EU policies and fundings in order to evaluate their impact on improving health and well-being of our citizens.***

Or. en

**Amendment 329**

**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**  
**Recital 20 a (new)**

*Text proposed by the Commission*

*Amendment*

**(20a) *The programme should support vulnerable population groups that have more difficulty in accessing healthcare, due to their socio-economic or geographic characteristics. Synergies between the Programme and ESF+ and ERDF are crucial, and the Commission should take into account the particularity of remotes areas and more concretely, the outermost regions based on Article 349 TFEU.***

Or. en

**Amendment 330**

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

**Susana Solís Pérez, Chrysoula Zacharopoulou, María Soraya Rodríguez Ramos**

**Proposal for a regulation  
Recital 20 b (new)**

*Text proposed by the Commission*

*Amendment*

***(20b) The programme should guarantee a strong involvement of the civil society (in particular patients' associations) and academics (in particular healthcare professionals' societies) to ensure a balanced representation and participation in achieving public health goals. European health organizations should contribute to the implementation and the evaluation of the programme.***

Or. en

**Amendment 331**

**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  
Recital 20 c (new)**

*Text proposed by the Commission*

*Amendment*

***(20c) The evaluations of the last and current programmes should be taken into consideration in the framework of the Conference on the Future of Europe, which could come forward with clear proposals to strengthen the European Health Policy.***

Or. en

**Amendment 332  
Jessica Polfjärd**

**Proposal for a regulation  
Recital 21**

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 333**

**Pascal Arimont, Cindy Franssen, Esther de Lange**

**Proposal for a regulation**

**Recital 21**

*Text proposed by the Commission*

(21) In accordance with Article 114 TFEU, a high level of health protection should be ensured in the legislation adopted by the Union for the establishment and the functioning of the internal market. On the basis of Article 114 TFEU and point (c) of Article 168(4) TFEU, a

*Amendment*

(21) In accordance with Article 114 TFEU, a high level of health protection should be ensured in the legislation adopted by the Union for the establishment and the functioning of the internal market. On the basis of Article 114 TFEU and point (c) of Article 168(4) TFEU, a

considerable body of Union *acquis* was developed which guarantees the high standards of quality and safety for medicinal products and medical devices. Given the rising healthcare demand, Member States' healthcare systems face challenges in the availability and affordability of medicines and medical devices. To ensure a better public health protection as well as the safety and empowerment of patients in the Union, it is essential that patients and health systems have access to high quality healthcare products and can fully benefit from them.

considerable body of Union *acquis* was developed which guarantees the high standards of quality and safety for medicinal products and medical devices. Given the rising healthcare demand, Member States' healthcare systems face challenges in the availability and affordability of medicines and medical devices. To ensure a better public health protection as well as the safety and empowerment of patients in the Union, it is essential that patients and health systems have access to high quality healthcare ***services and products, including in a cross-border context***, and can fully benefit from them.

Or. en

#### **Amendment 334**

**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**

##### **Recital 21**

###### *Text proposed by the Commission*

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

###### *Amendment*

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

essential that patients and health systems have access to high quality healthcare products and can fully benefit from them.

essential that patients and health systems have access to *sustainable, efficient, equitable and* high quality healthcare products and can fully benefit from them.

Or. en

#### **Amendment 335**

**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**

##### **Recital 21**

###### *Text proposed by the Commission*

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

###### *Amendment*

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

Or. en

#### **Amendment 336**

**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  
Recital 21 a (new)**

*Text proposed by the Commission*

*Amendment*

**(21a) *The programme should contribute to the strengthening of the European Medicines Market to speed up equitable access to medicines, make care more affordable, maximize savings in national health budgets and avoid obstacles for generic and biosimilar use.***

Or. en

**Amendment 337**

**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  
Recital 22**

*Text proposed by the Commission*

*Amendment*

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

(22) The Programme should therefore support actions to monitor **and mitigate** shortages of medicines, medical devices and other healthcare products and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet medical needs, the Programme should provide support to clinical trials so as to speed up the development, authorisation and access to innovative and effective medicines **and treatment**, promote incentives to **boost the production capacity for** antimicrobials, **personalized treatment and vaccination**, and foster the

monitoring and collecting information on medicines.

*digital* transformation of healthcare products and platforms for monitoring and collecting information on medicines. ***The programme should also strengthen decision-making on medicines by enabling access to and analysis of real-world healthcare data by regulators and HTA bodies. The Programme should also help to ensure best use of research results and facilitate the uptake, scaling-up and deployment of health innovation, including innovations in rare diseases, in healthcare systems and clinical practice. In 2020, the Commission announced the ‘Pharmaceutical strategy for Europe’ with the overall goal of helping to ensure the Union’s supply of safe and affordable medicines to meet patients’ needs and support the European pharmaceutical industry’s innovation efforts in the Union and globally. The Programme should support the implementation of the Pharmaceutical strategy for Europe to foster a competitive pharmaceutical industry taking into account that EU remains by far the world’s first manufacturing region of active ingredients for patent medicines.***

Or. en

**Amendment 338**  
**Michèle Rivasi**

**Proposal for a regulation**  
**Recital 22**

*Text proposed by the Commission*

(22) The Programme should therefore support actions to monitor shortages of medicines, medical devices and other healthcare products and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet

*Amendment*

(22) The Programme should therefore support actions to monitor shortages of medicines, medical devices and other healthcare products and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet

medical needs, the Programme should provide support to clinical trials so as to speed up the development, authorisation and access to innovative and effective medicines, promote incentives to **develop such medicinal products as** antimicrobials and foster the **digital** transformation of healthcare products and platforms for monitoring and collecting information on medicines.

medical needs, the Programme should provide support to clinical trials so as to speed up the development, authorisation and access to innovative, **holistic** and effective medicines **and treatment**, promote incentives to **boost the production capacity for** antimicrobials, **personalized treatment and vaccination**, and foster the **digital** transformation of healthcare products and platforms for monitoring and collecting information on medicines. **The programme should also strengthen decision-making on medicines by enabling access to and analysis of real-world healthcare data by regulators and HTA bodies. The Programme should also help to ensure best use of research results and facilitate the uptake, scaling-up and deployment of health innovation in healthcare systems and clinical practice. In 2020, the Commission announced the ‘Pharmaceutical strategy for Europe’ with the overall goal of helping to ensure the Union’s supply of safe and affordable medicines to meet patients’ needs and support the European pharmaceutical industry’s innovation efforts in the Union and globally. The Programme should support the implementation of the Pharmaceutical strategy for Europe and the reduction of the medication-related burden.**

Or. en

**Amendment 339**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Recital 22**

*Text proposed by the Commission*

(22) The Programme should therefore support actions to monitor shortages of medicines, medical devices and other healthcare products and to ensure greater

*Amendment*

(22) The Programme should therefore support actions to monitor shortages of medicines, medical devices and other healthcare products and to ensure greater

availability and affordability of those products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet medical needs, the Programme should provide support to clinical trials so as to speed up the development, authorisation and access to innovative and effective medicines, promote incentives to *develop such medicinal products as* antimicrobials and foster the *digital* transformation of *healthcare* products and platforms for monitoring and collecting information on medicines.

availability and affordability of those products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet medical needs, the Programme should provide support to clinical trials so as to speed up the development, authorisation and access to innovative and effective medicines *and treatment*, promote incentives to *boost the production capacity for* antimicrobials, *personalized medicines and care, treatment and vaccination*, and foster the *digital* transformation of *health care* products and platforms for monitoring and collecting information on medicines. *The programme should also strengthen decision-making on medicines by enabling access to and analysis of real-world healthcare data by regulators and HTA bodies. The Programme should also help to ensure best use of research results and facilitate the uptake, scaling-up and deployment of health innovation in health care systems and clinical practice. In 2020, the Commission announced the ‘Pharmaceutical strategy for Europe’ with the overall goal of helping to ensure the Union’s supply of safe and affordable medicines to meet patients’ needs and support the European pharmaceutical industry’s innovation efforts in the Union and globally. The Programme should support the implementation of the Pharmaceutical strategy for Europe.*

Or. en

**Amendment 340**  
**Joanna Kopcińska**

**Proposal for a regulation**  
**Recital 22**

*Text proposed by the Commission*

(22) The Programme should therefore support actions to monitor shortages of

*Amendment*

(22) The Programme should therefore support actions to monitor, *prevent and*

medicines, medical devices and other healthcare products and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet medical needs, the Programme should provide support to clinical trials so as to speed up the development, authorisation and access to innovative and effective medicines, promote incentives to **develop such medicinal products as** antimicrobials and foster the **digital** transformation of healthcare products and platforms for monitoring and collecting information on medicines.

**manage** shortages of medicines, medical devices and other healthcare products and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet medical needs, the Programme should provide support to clinical trials so as to speed up the development, authorisation and access to innovative and effective medicines **and treatment**, promote incentives to **boost the production capacity for** antimicrobials, **personalised treatment and vaccination**, and foster the **digital** transformation of healthcare products and platforms for monitoring and collecting information on medicines. **The Programme should also help to ensure best use of research results and facilitate the uptake, scaling-up and deployment of clinical practice. In 2020, the Commission announced the ‘Pharmaceutical strategy for Europe’ with the overall goal of helping to ensure the Union’s supply of safe and affordable medicines to meet patients’ needs and support the European pharmaceutical industry’s innovation efforts in the Union and globally. The Programme should offer some support to the implementation of the Pharmaceutical strategy for Europe.**

Or. en

#### **Amendment 341**

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

#### **Proposal for a regulation**

##### **Recital 22**

*Text proposed by the Commission*

(22) The Programme should therefore support actions to monitor shortages of medicines, medical devices and other

*Amendment*

(22) The Programme should therefore support actions to monitor shortages of medicines, medical devices and other

healthcare products and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet medical needs, the Programme should provide support to clinical trials so as to speed up the development, authorisation and access to innovative and effective medicines, promote *incentives to* develop such medicinal products as *antimicrobials and foster the digital* transformation of healthcare products and platforms for monitoring and collecting information on medicines.

healthcare products and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet medical needs, the Programme should provide support to clinical trials so as to speed up the development, authorisation and access to innovative and effective medicines *and medical devices*, promote *research and the development of new medical products, with particular attention to antimicrobials and vaccines to tackle AMR and vaccine-preventable diseases, boost the production of essential medicines and the active pharmaceutical ingredient (API)*, develop such medicinal products as transformation of healthcare products and platforms for monitoring and collecting information on *patients health, increasing self-management of their health, and information about the use of healthcare services*, medicines *and medical devices*.

Or. en

**Amendment 342**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Recital 22**

*Text proposed by the Commission*

(22) The Programme should *therefore support actions to monitor* shortages of medicines, medical devices and other healthcare products and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet medical needs, the Programme should provide support to clinical *trials so as to speed up* the development, authorisation and access to *innovative and* effective

*Amendment*

(22) The Programme should *develop a single pan-European monitoring, reporting and notification system for* shortages of medicines, medical devices and other healthcare products, *to avoid fragmentation of the single market* and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet medical needs, the Programme should provide support to clinical *and real*

medicines, *promote incentives to develop such medicinal products as antimicrobials and foster the digital transformation of healthcare products and platforms for monitoring and collecting information on medicines.*

*world evidence generation to enable the development, authorisation, evaluation and access to effective new medicines. the programme should foster the digital transformation of healthcare products and platforms for single pan-European monitoring and collecting information on medicines. The Programme should support the implementation of the new Pharmaceutical Strategy for Europe and the work of the EMA.*

Or. en

**Amendment 343**  
**Edina Tóth**

**Proposal for a regulation**  
**Recital 22**

*Text proposed by the Commission*

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

*Amendment*

(22) The Programme should therefore support actions to monitor shortages of medicines, medical devices and other healthcare products and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet medical needs, the Programme should provide support to clinical trials so as to speed up the development, authorisation and access to innovative and effective medicines, promote incentives to develop such medicinal products as antimicrobials and foster the *digital* transformation of healthcare products and platforms for monitoring and collecting information on medicines. ***The Program should support action against the spread of falsified medicines from unauthorised website sand vendors that are raising concerns nowadays; this practice can cause serious harm and can lead to severe health problems or worsen the health condition of citizens; EU coordination in mapping***

*and combatting of counterfeit of medicines is essential.*

Or. en

#### **Amendment 344**

**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**

##### **Recital 22**

*Text proposed by the Commission*

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

*Amendment*

(22) The Programme should therefore support actions to monitor ***and respond to*** shortages of medicines, medical devices, ***vaccines and diagnostic tools*** and other healthcare products and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet medical needs, the Programme should provide support to clinical trials so as to ***speed up*** the development, authorisation and access to innovative and effective medicines, promote incentives to develop such medicinal products as antimicrobials and foster the ***digital*** transformation of healthcare products and platforms for monitoring and collecting information on medicines. ***The full and rapid application of Regulation (EU) N° 536/ 2014 on clinical trials for medicinal products for human use should facilitate the launch of large clinical trials carried out in a harmonized and coordinated manner at European level.***

Or. en

#### **Amendment 345**

**Luisa Regimenti, Joëlle Mélin, Catherine Griset, Danilo Oscar Lancini, Lucia Vuolo,**

**Silvia Sardone, Vincenzo Sofo, Marco Dreosto, Aurelia Beigneux**

**Proposal for a regulation**  
**Recital 22**

*Text proposed by the Commission*

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

*Amendment*

(22) The Programme should therefore support actions to monitor shortages of medicines, medical devices and other healthcare products and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries, ***in particular actions, where necessary in synergy with other programmes, to encourage local production of medicinal plants in the Member States, and to encourage and support production of active ingredients and generics within the European Union.*** In particular, in order to address unmet medical needs, the Programme should provide support to clinical trials so as to speed up the development, authorisation and access to innovative and effective medicines, promote incentives to develop such medicinal products as antimicrobials and foster the **digital** transformation of healthcare products and platforms for monitoring and collecting information on medicines.

Or. it

**Amendment 346**  
**Kateřina Konečná**

**Proposal for a regulation**  
**Recital 22**

*Text proposed by the Commission*

(22) The Programme should therefore support actions to monitor shortages of medicines, medical devices and other healthcare products and to ensure greater

*Amendment*

(22) The Programme should therefore support actions to monitor, ***prevent and manage*** shortages of medicines, medical devices and other healthcare products and

availability and affordability of those products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet medical needs, the Programme should provide support to clinical trials so as to speed up the development, authorisation and access to innovative and effective medicines, promote incentives to develop such medicinal products as antimicrobials and foster the *digital* transformation of healthcare products and platforms for monitoring and collecting information on medicines.

to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet medical needs, the Programme should provide support to clinical trials so as to speed up the development, authorisation and access to innovative and effective medicines, promote incentives to develop such medicinal products as antimicrobials and foster the *digital* transformation of healthcare products and platforms for monitoring and collecting information on medicines. ***The Programme should support the implementation of the new Pharmaceutical Strategy for Europe and the work of the EMA.***

Or. en

**Amendment 347**  
**Maria Spyra**

**Proposal for a regulation**  
**Recital 22**

*Text proposed by the Commission*

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

*Amendment*

(22) The Programme should therefore support actions to ***establish and support the creation of a central monitoring and early notification mechanism for*** shortages of medicines, medical devices and other healthcare products and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries ***and avoid the fragmentation of the internal market.*** In particular, in order to address unmet medical needs, the Programme should provide support to clinical trials so as to speed up the development, authorisation and access to innovative and effective medicines, promote incentives to develop such medicinal products as antimicrobials and

medicines.

foster the **digital** transformation of healthcare products and platforms for monitoring and collecting information on medicines.

Or. en

#### **Amendment 348**

**Adam Jarubas**

#### **Proposal for a regulation**

##### **Recital 22**

###### *Text proposed by the Commission*

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

###### *Amendment*

(22) The Programme should therefore support actions to **develop a single pan-European monitoring, reporting and notification system for** shortages of medicines, medical devices and other healthcare products **to avoid fragmentation of the single market** and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet medical needs, the Programme should provide support to clinical trials so as to speed up the development, authorisation and access to innovative and effective medicines, promote incentives to develop such medicinal products as antimicrobials and foster the **digital** transformation of healthcare products and platforms for **unified pan-European** monitoring and collecting information on medicines.

Or. en

#### **Amendment 349**

**Danilo Oscar Lancini**

#### **Proposal for a regulation**

##### **Recital 22**

*Text proposed by the Commission*

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

*Amendment*

(22) The Programme should therefore support actions to **develop a single pan-European monitoring, reporting and notification system** for shortages of medicines, medical devices and other healthcare products **to avoid fragmentation of the single market** and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet medical needs, the Programme should provide support to clinical trials so as to speed up the development, authorisation and access to innovative and effective medicines, promote incentives to develop such medicinal products as antimicrobials and foster the **digital** transformation of healthcare products and platforms for monitoring and collecting information on medicines.

Or. en

**Amendment 350**

**Nathalie Colin-Oesterlé**

**Proposal for a regulation**

**Recital 22**

*Text proposed by the Commission*

(22) The Programme should therefore support actions to monitor shortages of medicines, medical devices and other healthcare products and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet medical needs, the Programme should provide support to clinical trials so as to speed up the development, authorisation and access to innovative and effective

*Amendment*

(22) The Programme should therefore support actions **to develop a pan-European monitoring, reporting and notification system** to monitor shortages of medicines, medical devices and other healthcare products **to strengthen the Single Market**, and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet medical needs, the Programme should provide support to

medicines, promote incentives to develop such medicinal products as antimicrobials and foster the *digital* transformation of healthcare products and platforms for monitoring and collecting information on medicines.

clinical trials so as to speed up the development, authorisation and access to innovative and effective medicines, promote incentives to develop such medicinal products as antimicrobials and foster the *digital* transformation of healthcare products and platforms for monitoring and collecting information on medicines.

Or. fr

**Amendment 351**  
**César Luena**

**Proposal for a regulation**  
**Recital 22**

*Text proposed by the Commission*

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

*Amendment*

(22) The Programme should therefore support actions to *develop an European monitoring, reporting and notification system for* shortages of medicines, medical devices and other healthcare products *to avoid fragmentation of the single market* and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet medical needs, the Programme should provide support to clinical trials so as to speed up the development, authorisation and access to innovative and effective medicines, promote incentives to develop such medicinal products as antimicrobials and foster the *digital* transformation of healthcare products and platforms for monitoring and collecting information on medicines.

Or. en

**Amendment 352**  
**Jessica Polfjärd**

**Proposal for a regulation**  
**Recital 22**

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 353**  
**Piernicola Pedicini, Eleonora Evi**

**Proposal for a regulation**  
**Recital 22**

*Text proposed by the Commission*

(22) The Programme should therefore support actions to *monitor* shortages of medicines, medical devices and other healthcare products and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries. In

*Amendment*

(22) The Programme should therefore support actions to *address the root causes of the* shortages of medicines, medical devices and other healthcare products, *to monitor shortages in Member States and at Union's level* and to ensure greater availability and affordability of those

particular, in order to address unmet medical needs, the Programme should provide support to clinical trials so as to speed up the development, authorisation and access to innovative and effective medicines, promote incentives to develop such medicinal products as antimicrobials and foster the **digital** transformation of healthcare products and platforms for monitoring and collecting information on medicines.

products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet medical needs, the Programme should provide support to clinical trials so as to speed up the development, authorisation and access to innovative and effective medicines, promote incentives to develop such medicinal products as antimicrobials and foster the **digital** transformation of healthcare products and platforms for monitoring and collecting information on medicines.

Or. en

#### **Amendment 354** **Mairead McGuinness**

#### **Proposal for a regulation** **Recital 22**

##### *Text proposed by the Commission*

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

##### *Amendment*

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

Or. en

## Amendment 355

Nicolae Ștefănuță, Véronique Trillet-Lenoir

### Proposal for a regulation

#### Recital 22

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

## Amendment 356

Michèle Rivasi

### Proposal for a regulation

#### Recital 22 a (new)

*Text proposed by the Commission*

*Amendment*

***(22a) Resolution WHA 67.18 of the World Health Assembly urges parties to 1) adapt, adopt and implement, where appropriate, the WHO Traditional Medicine Strategy 2014 – 2023, as a basis for national traditional and complementary medicine programmes or work plans; and to 2) develop and implement working plans to integrate traditional and complementary medicine***

*into health services, particularly primary health care services. The WHO Traditional Medicine Strategy 2014 – 2023 aims to support Member States in developing policies and implementing action plans to promote health with the support of traditional, complementary and integrative medicine.*

Or. en

**Amendment 357**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Recital 22 a (new)**

*Text proposed by the Commission*

*Amendment*

*(22a) Support actions to ensure the implementation of cross-cutting EU policy initiatives aimed at building a sustainable Europe with a high level of human health protection, such as the European Green Deal and its component strategies.*

Or. en

**Amendment 358**  
**Véronique Trillet-Lenoir, Nicolae Ştefănuţă, Irena Joveva, Sylvie Brunet, Nathalie Loiseau, Bernard Guetta, Stéphanie Yon-Courtin, Ilana Cicurel, Fabienne Keller, María Soraya Rodríguez Ramos**

**Proposal for a regulation**  
**Recital 22 a (new)**

*Text proposed by the Commission*

*Amendment*

*(22a) In its Pharmaceutical Strategy, the Commission should introduce the revision of the orphan and paediatric legislation and of the Directive 2001/83/EC establishing a Community code relating to medicinal products for human use.*

**Amendment 359**  
**Michèle Rivasi**

**Proposal for a regulation**  
**Recital 22 b (new)**

*Text proposed by the Commission*

*Amendment*

***(22b) To expand access to health technologies, the Programme should support actions that contribute to the implementation of the 2019 Resolution by the World Health Assembly on improving the transparency of markets for medicines, vaccines and other health products.***

Or. en

**Amendment 360**  
**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**  
**Recital 22 b (new)**

*Text proposed by the Commission*

*Amendment*

***(22b) To ensure effective controls and full transparency of the procedures used to determine the prices of medicines, the Commission should propose a revision of Directive 89/105/EEC on the transparency of measures regulating the price of medicinal products.***

Or. en

**Amendment 361**  
**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  
Recital 22 c (new)**

*Text proposed by the Commission*

*Amendment*

***(22c) To reduce its dependence on third countries for certain biological and medicinal products such as blood and plasma derived medicinal products, the Union should increase its capacity to collect and stockpile blood and plasma. To avoid the risk of shortages on those products, the Union should rapidly revise the Blood, Tissues and Cells legislations, Directive 2002/98/EC and Directive 2004/23/EC.***

Or. en

**Amendment 362  
Joanna Kopcińska**

**Proposal for a regulation  
Recital 23**

*Text proposed by the Commission*

*Amendment*

(23) As the optimal use of medicines and antimicrobials in particular yields benefits for individuals and health systems, the Programme should promote their prudent and efficient use. In line with the European One Health Action Plan against Antimicrobial Resistance<sup>14</sup>, adopted in June 2017 following the request from Member States, and given the experience with the bacterial secondary infections related to COVID 19, it is essential that the Programme supports actions aimed at the prudent use of antimicrobials in humans, animals and crops, in the framework of an integrated policy on patient safety and prevention of medical errors.

(23) As the optimal use of medicines and antimicrobials in particular yields benefits for individuals and health systems, the Programme should promote their prudent and efficient use. In line with the European One Health Action Plan against Antimicrobial Resistance<sup>14</sup>, adopted in June 2017 following the request from Member States, and given ***that infections caused by antibiotic-resistant bacteria were responsible for 33,110 deaths in the European Union and European Economic Area in 2015, according to data from the European Center for Disease Control, as well as*** the experience with the bacterial secondary infections related to COVID 19, it is essential that the

Programme supports actions aimed at the prudent use of antimicrobials in humans, animals and crops, in the framework of an integrated policy on patient safety and prevention of medical errors. *Notes moreover that the spread of Antimicrobial Resistance will require a greater emphasis in the Programme on preventing infections due to Gram-negative bacteria because there are relatively few existing treatment options for them and a limited number of new antibiotics in development.*

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<sup>14</sup> Communication from the Commission to the Council and the European Parliament ‘A European One Health Action Plan against Antimicrobial Resistance (AMR)’, COM(2017)0339 final of 29.6.2017.

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<sup>14</sup> Communication from the Commission to the Council and the European Parliament ‘A European One Health Action Plan against Antimicrobial Resistance (AMR)’, COM(2017)0339 final of 29.6.2017.

Or. en

### **Amendment 363**

**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**

#### **Recital 23**

#### *Text proposed by the Commission*

(23) As the optimal use of medicines and antimicrobials in particular yields benefits for individuals and health systems, the Programme should promote their prudent and efficient use. In line with the European One Health Action Plan against Antimicrobial Resistance<sup>14</sup>, adopted in June 2017 following the request from Member States, and given the experience with the bacterial secondary infections related to COVID 19, it is essential that the Programme supports actions aimed at the prudent use of antimicrobials in humans, animals and crops, in the framework of an

#### *Amendment*

(23) As the optimal use of medicines and antimicrobials in particular yields benefits for individuals and health systems, the Programme should promote their prudent and efficient use. In line with the European One Health Action Plan against Antimicrobial Resistance<sup>14</sup>, adopted in June 2017 following the request from Member States, and given the experience with the bacterial secondary infections related to COVID 19, it is essential that the Programme supports actions aimed at the prudent use of antimicrobials in humans, animals and crops, in the framework of an

integrated policy on patient safety and prevention of medical errors.

integrated policy on patient safety and prevention of medical errors. ***The Programme should support the ECDC monitoring and surveillance programmes concerning usage of antimicrobials and AMR, and the support to the implementation of local, regional and national plans to fight against AMR, supported by evidence-based strategies and the sharing of good practices within the Union.***

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<sup>14</sup> Communication from the Commission to the Council and the European Parliament ‘A European One Health Action Plan against Antimicrobial Resistance (AMR)’, COM(2017)0339 final of 29.6.2017.

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<sup>14</sup> Communication from the Commission to the Council and the European Parliament ‘A European One Health Action Plan against Antimicrobial Resistance (AMR)’, COM(2017)0339 final of 29.6.2017.

Or. en

## **Amendment 364** **Sirpa Pietikäinen**

### **Proposal for a regulation** **Recital 23**

#### *Text proposed by the Commission*

(23) As the optimal use of medicines and antimicrobials in particular yields benefits for individuals and health systems, the Programme should promote their prudent and efficient use. In line with the European One Health Action Plan against Antimicrobial Resistance<sup>14</sup>, adopted in June 2017 following the request from Member States, and given the experience with the bacterial secondary infections related to COVID 19, it is essential that the Programme supports actions aimed at the prudent use of antimicrobials in humans, animals and crops, in the framework of an integrated policy on patient safety and prevention of medical errors.

#### *Amendment*

(23) As the optimal use of medicines and antimicrobials in particular yields benefits for individuals and health systems, the Programme should promote their prudent and efficient use. In line with the European One Health Action Plan against Antimicrobial Resistance<sup>14</sup>, adopted in June 2017 following the request from Member States, and given the experience with the bacterial secondary infections related to COVID 19, it is essential that the Programme supports actions aimed at the prudent use of antimicrobials in humans, animals and crops, in the framework of an integrated policy on patient safety and prevention of medical errors. ***Regulation (EU) 2019/6 on veterinary medicinal products should be reviewed in this regard***

*to use antibiotic medicinal products and other medication only for treatment of disease prescribed by a veterinary for a limited period of time and not to be used for prophylaxis.*

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<sup>14</sup> Communication from the Commission to the Council and the European Parliament ‘A European One Health Action Plan against Antimicrobial Resistance (AMR)’, COM(2017)0339 final of 29.6.2017.

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<sup>14</sup> Communication from the Commission to the Council and the European Parliament ‘A European One Health Action Plan against Antimicrobial Resistance (AMR)’, COM(2017)0339 final of 29.6.2017.

Or. en

**Amendment 365**  
**Nicolae Ștefănuță, Véronique Trillet-Lenoir**

**Proposal for a regulation**  
**Recital 23**

*Text proposed by the Commission*

(23) As the optimal use of medicines and antimicrobials in particular yields benefits for individuals and health systems, the Programme should promote their prudent and efficient use. In line with the European One Health Action Plan against Antimicrobial Resistance<sup>14</sup>, adopted in June 2017 following the request from Member States, and given the experience with the bacterial secondary infections related to COVID 19, it is essential that the Programme supports actions aimed at the prudent use of antimicrobials in humans, animals and crops, in the framework of an integrated policy on patient safety and prevention of medical errors.

*Amendment*

(23) As the optimal use of medicines and antimicrobials in particular yields benefits for individuals and health systems, the Programme should promote their prudent and efficient use. In line with the European One Health Action Plan against Antimicrobial Resistance<sup>14</sup>, adopted in June 2017 following the request from Member States, and given the experience with the bacterial secondary infections related to COVID 19, it is essential that the Programme supports actions aimed at the prudent use of antimicrobials in humans, animals and crops, in the framework of an integrated policy on patient safety and prevention of medical errors.  
***The EU4health programme funding should be based on actions that are traceable, setting Union-wide reduction targets for antibiotics and medicine use, and support the research and development of new antibiotics***

<sup>14</sup> Communication from the Commission to the Council and the European Parliament ‘A European One Health Action Plan against Antimicrobial Resistance (AMR)’, COM(2017)0339 final of 29.6.2017.

<sup>14</sup> Communication from the Commission to the Council and the European Parliament ‘A European One Health Action Plan against Antimicrobial Resistance (AMR)’, COM(2017)0339 final of 29.6.2017.

Or. en

## **Amendment 366** **Michèle Rivasi**

### **Proposal for a regulation** **Recital 23**

#### *Text proposed by the Commission*

(23) As the optimal use of medicines and antimicrobials in particular yields benefits for individuals and health systems, the Programme should promote their prudent and efficient use. In line with the European One Health Action Plan against Antimicrobial Resistance<sup>14</sup>, adopted in June 2017 following the request from Member States, and given the experience with the bacterial secondary infections related to COVID 19, it is essential that the Programme supports actions aimed at the prudent use of antimicrobials in humans, animals and crops, in the framework of an integrated policy on patient safety and prevention of medical errors.

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<sup>14</sup> Communication from the Commission to the Council and the European Parliament ‘A European One Health Action Plan against Antimicrobial Resistance (AMR)’, COM(2017)0339 final of 29.6.2017.

#### *Amendment*

(23) As the optimal use of medicines and antimicrobials in particular yields benefits for individuals and health systems, the Programme should promote their prudent and efficient use. In line with the European One Health Action Plan against Antimicrobial Resistance<sup>14</sup>, adopted in June 2017 following the request from Member States, and given the experience with the bacterial secondary infections related to COVID 19, it is essential that the Programme supports actions aimed at the prudent use of antimicrobials in humans, animals and crops, **and actions including the use of non-antibiotic integrative treatments**, in the framework of an integrated **and integrative** policy on patient safety and prevention of medical errors..

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<sup>14</sup> Communication from the Commission to the Council and the European Parliament ‘A European One Health Action Plan against Antimicrobial Resistance (AMR)’, COM(2017)0339 final of 29.6.2017.

Or. en

**Amendment 367**  
**Kateřina Konečná**

**Proposal for a regulation**  
**Recital 23 a (new)**

*Text proposed by the Commission*

*Amendment*

***(23a) Health associated infections ('HAI') are infections that patients get while receiving healthcare for another condition. The ECDC has estimated that, on average, healthcare associated infections occur in one hospitalised patient in 20, that is to say 4,1 million patients a year in the Union, and that 37 000 deaths are caused every year as a result of such infections. Poor patient safety represents both a severe public health problem and a high economic burden on limited health resources. HAI can happen in any healthcare facility, including hospitals, ambulatory surgical centres, end-stage renal disease facilities, and long-term care facilities It is therefore important that the Commission, under the Programme, develops guidelines for preventing HAI, and that the Programme supports investment in modernizing health systems to overcome and reduce HAI and supports interventions to improve patient safety, including the implementation of Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections. European-level collaboration and coordination on patient safety should be enhanced through the creation of a European Network on Patient Safety, supported through the Health Programme and with direct involvement of patients' organisations.***

Or. en

**Amendment 368**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Recital 23 a (new)**

*Text proposed by the Commission*

*Amendment*

***(23a) HAI are infections that patients get while receiving healthcare for another condition. The ECDC has estimated that, on average, health care associated infections occur in one hospitalised patient in 20, that is to say 4,1million patients a year in the Union, and that 37 000 deaths are caused every year as a result of such infections. Poor patient safety represents both a severe public health problem and a high economic burden on limited health resources. HAI can happen in any healthcare facility, including hospitals, ambulatory surgical centres, end-stage renal disease facilities, and long-term care facilities It is therefore important that the Commission, under the Programme, develops guidelines for preventing HAI, and that the Programme supports investment in modernizing health systems to overcome and reduce HAI and supports interventions to improve patient safety, including the implementation of Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections. European-level collaboration and coordination on patient safety should be enhanced through the creation of a European Network on Patient Safety, supported through the Health Programme and with direct involvement of patients' organisations.***

Or. en

**Amendment 369**  
**Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López,**

**Lukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel**

**Proposal for a regulation  
Recital 23 a (new)**

*Text proposed by the Commission*

*Amendment*

***(23a) HAI are infections that patients get while receiving healthcare for another condition or infections suffered by inhabitants of long-term residences. The ECDC has estimated that, on average, healthcare associated infections occur in one hospitalised patient in 20, that is to say 4,1 million patients a year in the Union, and that 37 000 deaths are caused every year as a result of such infections. Poor patient safety represents both a severe public health problem and a high economic burden on limited health resources. HAI can happen in any healthcare facility, including hospitals, ambulatory surgical centres, end-stage renal disease facilities, and long-term care facilities It is therefore important that the Commission, under the Programme, develops guidelines for preventing HAI, and that the Programme supports investment in modernizing health systems to overcome and reduce HAI and supports interventions to improve patient safety, including the implementation of the Council's Recommendation of 9 June 2009 on patient safety, including the prevention and control of HAI 1a.***

Or. en

**Amendment 370  
Joanna Kopcińska**

**Proposal for a regulation  
Recital 23 a (new)**

*Text proposed by the Commission*

*Amendment*

***(23a) Effective international collaboration is key to controlling HAIs and Antimicrobial Resistance and the EU has an important role in supporting Member States in this area, for example through research programmes, the surveillance systems operated by the ECDC and the development of EU wide point prevalence survey methodology.***

Or. en

**Amendment 371**

**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  
Recital 23 a (new)**

*Text proposed by the Commission*

*Amendment*

***(23a) According to WHO, 12.6 million people died as a result of living or working in an unhealthy environment in 2012 – nearly 1 in 4 of total global deaths. Environmental pollution factors, such as air, water and soil pollution, chemical exposures, climate change, and ultraviolet radiation, contribute to more than 100 diseases and injuries.***

Or. en

**Amendment 372**

**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  
Recital 23 b (new)**

**(23b) *The Programme should promote and guarantee via its actions the environmental health of European citizens in the framework of the European Green Deal. The Union should adopt the WHO definition which describes environmental health as the inclusion of “aspects of human health, such as the quality of life, which are determined by the physical, chemical, biological, social, psychosocial and aesthetic factors of our environment. It also concerns the policy and practices for the prevention, management and control of environmental factors likely to affect the health of present and future generations”.***

Or. en

**Amendment 373**

**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**

**Recital 24**

*Text proposed by the Commission*

*Amendment*

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

(24) Since environmental pollution caused by human and veterinary pharmaceutical substances is an emerging environmental problem that can impact on public health, the Programme should foster measures to strengthen the assessment and appropriate management of environmental risks associated with the production, use and disposal of medicinal products, in line with the European Union Strategic Approach to Pharmaceuticals in the Environment<sup>15</sup>. ***The Programme will reinforce the need to have health impact assessments in the EU policies and should promote health promotion and protection***

*in all EU policies, taking into account the European Green Deal, The Farm to Fork Strategy, The Biodiversity Strategy and the Pharmaceutical Strategy for Europe and others.*

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<sup>15</sup> Communication of the Commission to the European Parliament, the Council and the European economic and Social Committee ‘European Union Strategic Approach to Pharmaceuticals in the Environment’, COM(2019)128 final of 11.03.2019.

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<sup>15</sup> Communication of the Commission to the European Parliament, the Council and the European economic and Social Committee ‘European Union Strategic Approach to Pharmaceuticals in the Environment’, COM(2019)128 final of 11.03.2019.

Or. en

#### **Amendment 374**

**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**

##### **Recital 24**

###### *Text proposed by the Commission*

(24) Since **environmental** pollution caused by human and veterinary pharmaceutical substances is an emerging environmental problem that can impact on public health, the Programme should foster measures to strengthen the assessment and appropriate management of environmental risks associated with the production, use and disposal of medicinal products, in line with the European Union Strategic Approach to Pharmaceuticals in the Environment<sup>15</sup>.

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<sup>15</sup> Communication of the Commission to the European Parliament, the Council and the European economic and Social Committee ‘European Union Strategic Approach to Pharmaceuticals in the Environment’, COM(2019)128 final of

###### *Amendment*

(24) Since **the** pollution caused by human and veterinary pharmaceutical substances is an emerging environmental problem that can impact on public health, the Programme should foster measures to strengthen the assessment and appropriate management of environmental risks associated with the production, use and disposal of medicinal products, in line with the European Union Strategic Approach to Pharmaceuticals in the Environment<sup>15</sup>.

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<sup>15</sup> Communication of the Commission to the European Parliament, the Council and the European economic and Social Committee ‘European Union Strategic Approach to Pharmaceuticals in the Environment’, COM(2019)128 final of

11.03.2019.

11.03.2019.

Or. en

### **Amendment 375**

**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**

#### **Recital 25**

#### *Text proposed by the Commission*

(25) The Union health legislation has an immediate impact on public health, the lives of citizens, the efficiency and resilience of the health systems and the good functioning of the internal market. The regulatory framework for medical products and technologies (medicinal products, medical devices and substances of human origin), as well as for tobacco legislation, patients' rights in cross-border healthcare and serious cross-border threats to health is essential to health protection in the Union. The Programme therefore should support the development, implementation and enforcement of Union health legislation and provide high quality, comparable and reliable data to underpin policymaking and monitoring.

#### *Amendment*

(25) The Union health legislation has an immediate impact on public health, the lives of citizens, the efficiency and resilience of the health systems and the good functioning of the internal market. The regulatory framework for ***the recognition of professional qualifications***, medical products and technologies (medicinal products, medical devices and substances of human origin), as well as for tobacco legislation, patients' rights in cross-border healthcare and serious cross-border threats to health is essential to health protection in the Union. The Programme therefore should support the development, implementation and enforcement of Union health legislation and provide high quality, ***unbiased***, comparable and reliable data to underpin policymaking and monitoring. ***Union health legislation needs to be based on current scientific evidence-based data, that should be collected locally across Europe, through a well-defined homogeneous methodology. The legislation and its implementation and consequences should be evaluated and reported, resulting in a cycle of quality improvement of health in the Union.***

Or. en

**Amendment 376**  
**Joanna Kopcińska**

**Proposal for a regulation**  
**Recital 25**

*Text proposed by the Commission*

(25) The Union health legislation has an immediate impact on public health, the lives of citizens, the efficiency and resilience of the health systems and the good functioning of the internal market. The regulatory framework for medical products and technologies (medicinal products, medical devices and substances of human origin), as well as for tobacco legislation, patients' rights in cross-border healthcare and serious cross-border threats to health is essential to health protection in the Union. The Programme therefore should support the development, implementation and enforcement of Union health legislation and provide high quality, comparable and reliable data to underpin policymaking and monitoring.

*Amendment*

(25) The Union health legislation has an immediate impact on public health, the lives of citizens, the efficiency and resilience of the health systems and the good functioning of the internal market. The regulatory framework for medical products and technologies (medicinal products, medical devices and substances of human origin), as well as for tobacco legislation, patients' rights in cross-border healthcare and serious cross-border threats to health is essential to health protection in the Union. The Programme therefore should support the development, implementation and enforcement of Union health legislation and, ***working in conjunction with key partners such as the EMA and the ECDC***, provide high quality, comparable and reliable data to underpin policymaking and monitoring.

Or. en

**Amendment 377**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Recital 25**

*Text proposed by the Commission*

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

*Amendment*

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

of human origin), as well as for tobacco legislation, patients' rights in cross-border healthcare and serious cross-border threats to health is essential to health protection in the Union. The Programme therefore should support the development, implementation and enforcement of Union health legislation and provide high quality, comparable and reliable data to underpin policymaking and monitoring.

of human origin), as well as for tobacco legislation, patients' rights in cross-border healthcare and serious cross-border threats to health is essential to health protection in the Union. The Programme therefore should support the development, implementation and enforcement of Union health legislation and provide high quality, ***unbiased, including real-world health care data, to underpin policymaking and monitoring, set targets and develop tools to measure progress (e.g. a Cancer Dashboard).***

Or. en

#### **Amendment 378**

**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**

##### **Recital 25**

###### *Text proposed by the Commission*

(25) The Union health legislation has an immediate impact on public health, the lives of citizens, the efficiency and resilience of the health systems and the good functioning of the internal market. The regulatory framework for medical products and technologies (medicinal products, medical devices and substances of human origin), as well as for tobacco legislation, patients' rights in cross-border healthcare and serious cross-border threats to health is essential to health protection in the Union. The Programme therefore should support the development, implementation and enforcement of Union

###### *Amendment*

(25) The Union health legislation has an immediate impact on public health, the lives of citizens, the efficiency and resilience of the health systems and the good functioning of the internal market. The regulatory framework for medical products and technologies (medicinal products, medical devices and substances of human origin), as well as for tobacco legislation, patients' rights in cross-border healthcare and serious cross-border threats to health is essential to health protection in the Union. The Programme therefore should support the development, implementation and enforcement of Union

health legislation and provide high quality, comparable and reliable data to underpin policymaking and monitoring.

health legislation and provide high quality, comparable and reliable data, **including real-world healthcare data, thereby contributing to the development of the European health data space**, to underpin policymaking and monitoring.

Or. en

#### **Amendment 379**

**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**

#### **Recital 25**

##### *Text proposed by the Commission*

(25) The Union health legislation has an immediate impact on public health, the lives of citizens, the efficiency and resilience of the health systems and the good functioning of the internal market. The regulatory framework for medical products and technologies (medicinal products, medical devices and substances of human origin), as well as for tobacco legislation, patients' rights in cross-border healthcare and serious cross-border threats to health is essential to health protection in the Union. The Programme therefore should support the development, implementation **and** enforcement of Union health legislation and provide high quality, comparable and reliable data to underpin policymaking and monitoring.

##### *Amendment*

(25) The Union health legislation has an immediate impact on public health **and safety**, the lives of citizens, the efficiency and resilience of the health systems and the good functioning of the internal market. The regulatory framework for medical products and technologies (medicinal products, medical devices and substances of human origin), as well as for tobacco legislation, patients' rights in cross-border healthcare and serious cross-border threats to health is essential to health protection in the Union. The Programme therefore should support the development, implementation, enforcement **and improvement** of Union health legislation, **adopt early and long-term evaluation criteria in order to assess its implementation** and provide high quality, comparable and reliable data to underpin policymaking and monitoring.

Or. en

#### **Amendment 380**

**Kateřina Konečná**

**Proposal for a regulation**  
**Recital 25**

*Text proposed by the Commission*

(25) The Union health legislation has an immediate impact on public health, the lives of citizens, the efficiency and resilience of the health systems and the good functioning of the internal market. The regulatory framework for medical products and technologies (medicinal products, medical devices and substances of human origin), as well as for tobacco legislation, patients' rights in cross-border healthcare and serious cross-border threats to health is essential to health protection in the Union. The Programme therefore should support the development, implementation and enforcement of Union health legislation and provide high quality, comparable and reliable data to underpin *polymaking* and monitoring.

*Amendment*

(25) The Union health legislation has an immediate impact on public health, the lives of citizens, the efficiency and resilience of the health systems and the good functioning of the internal market. The regulatory framework for medical products and technologies (medicinal products, medical devices and substances of human origin), as well as for tobacco legislation, patients' rights in cross-border healthcare and serious cross-border threats to health is essential to health protection in the Union. The Programme therefore should support the development, implementation and enforcement of Union health legislation and provide high quality, ***unbiased***, comparable and reliable data, ***including real-world healthcare data***, to underpin ***policy making*** and monitoring.

Or. en

**Amendment 381**  
**Antoni Comín i Oliveres**

**Proposal for a regulation**  
**Recital 25 a (new)**

*Text proposed by the Commission*

*Amendment*

***(25a) The COVID-19 crisis has confirmed the perspective according to which it is convenient to strengthen the participation of the public sector in health research strategies to avoid that these are limited by strictly commercial criteria. In line with Horizon Europe, the EU4Health programme needs to help strengthen the resources necessary so that all strategic health research that cannot be done***

*without public support may be carried out.*

Or. en

**Amendment 382**

**Piernicola Pedicini, Eleonora Evi**

**Proposal for a regulation**

**Recital 25 a (new)**

*Text proposed by the Commission*

*Amendment*

***(25a) The Union environmental legislation has an indirect, albeit important impact on public health and the resilience of national health systems. A strong and well-functioning EU environmental regulatory framework is essential to health protection. The Programme therefore should support the development, implementation and enforcement of Union environmental legislation towards a non-toxic environment.***

Or. en

**Amendment 383**

**Sirpa Pietikäinen**

**Proposal for a regulation**

**Recital 26**

*Text proposed by the Commission*

*Amendment*

(26) Cross-border cooperation in the provision of healthcare to patients moving between Member States, collaboration on health technology assessments (HTA), and European Reference Networks (ERNs) are examples of areas where integrated work among Member States has shown to have strong added value and great potential to increase the efficiency of health systems and thus health in general. The Programme

(26) Cross-border cooperation in the provision of healthcare to patients moving between Member States, collaboration on health technology assessments (HTA), and European Reference Networks (ERNs) are examples of areas where integrated work among Member States has shown to have strong added value and great potential to increase the efficiency of health systems and thus health in general. ***Those are***

should therefore *support activities to enable* such integrated and coordinated work, *which also serves* to foster the implementation of high-impact practices that are aimed at distributing in the most effective way the available resources to the *concerned* population and areas so as to maximise their impact.

*examples of areas where integrated work among Member States has already been shown to have strong added-value and great potential to increase the efficiency of health systems and thus of health in general. Nevertheless, those areas are not yet developed, not in terms of Union legislation, nor its implementation or resources.* The Programme should therefore *aim at ensuring that* such integrated and coordinated work *is developed and implemented to its full potential in areas such as HTA and ERN.* *That work would serve* to foster the implementation of high-impact practices that are aimed at distributing in the most effective way the available resources to the *relevant sector of the* population and areas so as to maximise their impact, *reducing inequalities, through the consideration of sex, gender and age and the establishing of a Reference Network for safe use of medicines in pregnancy and lactation.*

Or. en

#### Amendment 384

Pascal Arimont, Cindy Franssen, Esther de Lange

#### Proposal for a regulation

##### Recital 26

###### *Text proposed by the Commission*

(26) Cross-border cooperation in the provision of healthcare to patients moving between Member States, collaboration on health technology assessments (HTA), and European Reference Networks (ERNs) are examples of areas where integrated work among Member States has shown to have strong added value and great potential to increase the efficiency of health systems and thus health in general. The Programme should therefore support activities to enable such integrated and coordinated work, which also serves to foster the

###### *Amendment*

(26) Cross-border cooperation in the provision of healthcare to patients moving between Member States *or living in border regions*, collaboration on health technology assessments (HTA), and European Reference Networks (ERNs) are examples of areas where integrated work among Member States has shown to have strong added value and great potential to increase the efficiency of health systems and thus health in general. The Programme should therefore support activities to enable such integrated and coordinated work, which

implementation of high-impact practices that are aimed at distributing in the most effective way the available resources to the concerned population and areas so as to maximise their impact.

also serves to foster the implementation of high-impact practices that are aimed at distributing in the most effective way the available resources to the concerned population and areas so as to maximise their impact.

Or. en

**Amendment 385**  
**Joanna Kopcińska**

**Proposal for a regulation**  
**Recital 26 a (new)**

*Text proposed by the Commission*

*Amendment*

***(26a) Cross-border cooperation in the provision of healthcare to patients moving between Member States, as provided for under Directive 2011/24/EU, includes European Reference Networks ('ERN'). This is an example where integrated work among Member States has been shown to have strong added value and great potential to increase the efficiency of health systems and therefore health in general. However, it is still to be fully elaborated in terms of Union legislation, implementation and resources. The Programme should therefore aim at ensuring that such integrated and coordinated work is developed and implemented to its full potential in areas such as ERN. That work would serve to foster the implementation of high-impact practices aimed at distributing, in the most effective way, available resources to the relevant population so as to maximise their impact.***

Or. en

**Amendment 386**  
**Sara Cerdas, Tudor Ciuhodaru, César Luena, Rovana Plumb, Milan Brglez, Javi López,**

**Lukasz Kohut, Petar Vitanov, István Ujhelyi, Monika Beňová, Miroslav Číž, Robert Hajšel**

**Proposal for a regulation  
Recital 26 a (new)**

*Text proposed by the Commission*

*Amendment*

***(26a) Solidarity and unity are principles of the Union and the programme should ensure that the Union has a coherent approach to combating cross-border health-threats. Under Article 168 TFEU, the Programme should support the creation of a European Health Response Mechanism, ready to respond to public health threats, coordinated by the ECDC and led by the Commissioner for Health and the Commissioner for Crisis Management, fully articulated with the other EU health agencies. This Mechanism with its own medical resources under a strengthened Union Civil Protection Mechanism will be prepared with a pandemic emergency plan, in order to have a coordinated response and the capacity to rapidly scale up the response to future health crises, based on standardised information.***

Or. en

**Amendment 387  
Nathalie Colin-Oesterlé**

**Proposal for a regulation  
Recital 26 a (new)**

*Text proposed by the Commission*

*Amendment*

***(26a) The mobility of cross-border medical workers should be guaranteed in order to ensure the continuity of healthcare services within the European Union.***

Or. fr

## Amendment 388

Nicolae Ștefănuță, Véronique Trillet-Lenoir

### Proposal for a regulation

#### Recital 27

##### *Text proposed by the Commission*

(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council<sup>16</sup> are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider the extension of ERNs beyond rare diseases *to communicable and non-communicable diseases such as* cancer.

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

##### *Amendment*

(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council<sup>16</sup> are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider the extension of ERNs beyond rare diseases, *supporting the creation of new ERNs to cover infectious diseases, complex pregnancies and complex mental health diseases and cancer and paediatric* cancer.

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

Or. en

## Amendment 389

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

### Recital 27

#### *Text proposed by the Commission*

(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council<sup>16</sup> are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider the extension of ERNs beyond rare diseases to communicable and non-communicable diseases such as cancer.

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

#### *Amendment*

(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council<sup>16</sup> are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider the extension of ERNs beyond rare diseases to communicable and non-communicable diseases such as ***cardiovascular disease, cancer, chronic respiratory disease, diabetes and mental health conditions and other major chronic diseases, which require extensive knowledge sharing due to the complexity of cases and co-morbidities, and their increasing prevalence.***

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

Or. en

**Amendment 390**  
**Mick Wallace**

**Proposal for a regulation**  
**Recital 27**

*Text proposed by the Commission*

(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council<sup>16</sup> are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider the extension of ERNs beyond rare diseases to communicable and non-communicable diseases such as cancer.

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

*Amendment*

(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council<sup>16</sup> are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider the extension of ERNs beyond rare diseases to communicable and non-communicable diseases such as cancer, ***chronic respiratory disease, diabetes and mental health conditions and other major chronic diseases, which require extensive knowledge sharing due to the complexity of cases and co-morbidities, and their increasing prevalence.***

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

Or. en

*Justification*

*The high prevalence and mortality from chronic diseases, further increased by COVID-19, suggests that a similar approach to ERNs for rare diseases be taken for this group of diseases. It would also contribute to provide patients across Europe with the same chances of receiving high-quality medical care.*

**Amendment 391**  
**Michèle Rivasi**

**Proposal for a regulation**  
**Recital 27**

*Text proposed by the Commission*

(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council<sup>16</sup> are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider the extension of ERNs beyond rare diseases to communicable and non-communicable diseases such as cancer.

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

*Amendment*

(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council<sup>16</sup> are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider the extension of ERNs beyond rare diseases to communicable and non-communicable diseases such as ***cardiovascular disease, cancer, chronic respiratory disease, diabetes and mental health conditions and other major chronic diseases, which require extensive knowledge sharing due to the complexity of cases and co-morbidities;***

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

Or. en

**Amendment 392**  
**Frédérique Ries**

**Proposal for a regulation**  
**Recital 27**

*Text proposed by the Commission*

(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council<sup>16</sup> are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider the extension of ERNs beyond rare diseases to communicable and non-communicable diseases such as cancer.

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

*Amendment*

(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council<sup>16</sup> are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider the extension of ERNs beyond rare diseases to communicable and non-communicable diseases such as cancer, ***without impacting the efficiency of the 24 existing ERNs which are working on a range of thematic issues including bone disorders, childhood cancer and immunodeficiency.***

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

Or. en

**Amendment 393**  
**Mairead McGuinness**

**Proposal for a regulation**  
**Recital 27**

*Text proposed by the Commission*

(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council<sup>16</sup> are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider the extension of ERNs beyond rare diseases to communicable and non-communicable diseases such as cancer.

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

*Amendment*

(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council<sup>16</sup> are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider the extension of ERNs beyond rare diseases to communicable and non-communicable diseases such as cancer, ***cardiovascular disease, chronic respiratory disease, mental health conditions and other major chronic diseases.***

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

Or. en

**Amendment 394**

**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**

**Recital 27**

*Text proposed by the Commission*

(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council<sup>16</sup> are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider the extension of ERNs beyond rare diseases to communicable and non-communicable diseases such as cancer.

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

*Amendment*

(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council<sup>16</sup> are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider the extension of ERNs beyond rare diseases to **complex** communicable and non-communicable diseases such as cancer **and in the field of health crises management**.

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

Or. en

**Amendment 395**  
**Joanna Kopcińska**

**Proposal for a regulation**  
**Recital 27**

*Text proposed by the Commission*

(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council<sup>16</sup> are virtual networks involving healthcare providers

*Amendment*

(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council<sup>16</sup> are virtual networks involving healthcare providers

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

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

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

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

Or. en

#### **Amendment 396**

**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 Recital 27 a (new)**

*Text proposed by the Commission*

*Amendment*

***(27a) The programme should support the EU-wide mobility of healthcare professionals, during both their education and professional careers through Erasmus + fundings, and of their particular role in improving knowledge and expertise on health threats. The programme should also facilitate the implementation of the Professional Qualifications Directive to ensure better***

*mutual recognition of qualifications of health professionals within the Union.*

Or. en

**Amendment 397**  
**Frédérique Ries**

**Proposal for a regulation**  
**Recital 27 a (new)**

*Text proposed by the Commission*

*Amendment*

*(27a) The ERNs face significant challenges to ensure they are financially sustainable and are able to operate effectively within and across national healthcare systems, as highlighted by the European Court of Auditors, in their “Special report no 07/2019: EU actions for cross-border healthcare”.*

Or. en

**Amendment 398**  
**Margarita de la Pisa Carrión**

**Proposal for a regulation**  
**Recital 27 a (new)**

*Text proposed by the Commission*

*Amendment*

*(27a) Priority should be given to clinical genomics and disease prediction programmes based on the genetic make-up of individuals (personalised or precision medicine), and the EU should lead this initiative.*

Or. es

**Amendment 399**  
**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  
Recital 27 b (new)**

*Text proposed by the Commission*

*Amendment*

**(27b) *The programme should facilitate the coordination and pooling of European multicentre clinical trials and promote the research and training actions of future European universities networks.***

Or. en

**Amendment 400**

**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  
Recital 27 c (new)**

*Text proposed by the Commission*

*Amendment*

**(27c) *The programme should guarantee the sustainable funding of European research consortia on medicines, vaccines and biological tests designed for specific infectious and transmissible diseases.***

Or. en

**Amendment 401**

**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  
Recital 27 d (new)**

*Text proposed by the Commission*

*Amendment*

**(27d) *The Programme should take***

*concrete actions against rare, complex and low-prevalence diseases. Early detection must be facilitated and projects such as “Rare 2030” encouraging with the objective to set up concrete and innovative policies for developing research and improving the lives of patients.*

Or. en

**Amendment 402**

**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  
Recital 27 e (new)**

*Text proposed by the Commission*

*Amendment*

*(27e) The programme should facilitate the revision of the EU-OSHA’s mandate to promote healthy and safe workplaces across the Union and to support the Agency’s activities and analysis on occupational safety and health. The Commission should propose a new EU Strategic Framework on Occupational Safety and Health for the period 2021 – 2027 and continue updating the directive on the protection of workers from the risks related to carcinogens or mutagens at work. The programme should also support actions to facilitate people’s return to the workplace after long-term sick leave and to better include people who are chronically sick or have a disability in the workforce.*

Or. en

**Amendment 403**

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

Susana Solís Pérez, Linea Søgaard-Lidell, Chrysoula Zacharopoulou, María Soraya Rodríguez Ramos

**Proposal for a regulation**  
**Recital 27 f (new)**

*Text proposed by the Commission*

*Amendment*

**(27f) The programme should effectively guarantee safe and timely access to sexual and reproductive health and rights (SRHR), goods (e.g. medicines, contraceptives) and services (e.g. sex education, safe abortions).**

Or. en

**Amendment 404**  
**Pascal Arimont, Cindy Franssen, Esther de Lange**

**Proposal for a regulation**  
**Recital 30**

*Text proposed by the Commission*

*Amendment*

(30) In order to optimise the added value and impact from investments funded wholly or in part through the budget of the Union, synergies should be sought in particular between the Programme for the Union's action in the field of health and other Union programmes, including those under shared-management. To maximise those synergies, key enabling mechanisms should be ensured, including cumulative funding in an action from the Programme for the Union's action in the field of health and another Union programme, as long as such cumulative funding does not exceed the total eligible costs of the action. For that purpose, this Regulation should set out appropriate rules, in particular on the possibility to declare the same cost or expenditure on a pro-rata basis to Programme for the Union's action in the field of health and another Union

(30) In order to optimise the added value and impact from investments funded wholly or in part through the budget of the Union, synergies should be sought in particular between the Programme for the Union's action in the field of health and other Union programmes, including those under shared-management, ***notably the Interreg programme which already addresses cross-border cooperation in the field of health and helps to facilitate the cross-border mobility of patients and health professionals, and to develop access to high quality healthcare through the use of common equipment, shared services and joint facilities in cross-border areas.*** To maximise those synergies, key enabling mechanisms should be ensured, including cumulative funding in an action from the Programme for the Union's action in the field of health and another Union programme, as long as such cumulative

programme.

funding does not exceed the total eligible costs of the action. For that purpose, this Regulation should set out appropriate rules, in particular on the possibility to declare the same cost or expenditure on a pro-rata basis to Programme for the Union's action in the field of health and another Union programme.

Or. en

#### **Amendment 405**

**Nicolae Ștefănuță, Véronique Trillet-Lenoir**

#### **Proposal for a regulation**

#### **Recital 30**

##### *Text proposed by the Commission*

(30) In order to optimise the added value and impact from investments funded wholly or in part through the budget of the Union, synergies should be sought in particular between the Programme for the Union's action in the field of health and other Union programmes, including those under shared-management. To maximise those synergies, key enabling mechanisms should be ensured, including cumulative funding in an action from the Programme for the Union's action in the field of health and another Union programme, as long as such cumulative funding does not exceed the total eligible costs of the action. For that purpose, this Regulation should set out appropriate rules, in particular on the possibility to declare the same cost or expenditure on a pro-rata basis to Programme for the Union's action in the field of health and another Union programme.

##### *Amendment*

(30) In order to optimise the added value and impact from investments funded wholly or in part through the budget of the Union, synergies should be sought in particular between the Programme for the Union's action in the field of health and other Union programmes, including those under shared-management ***and the Union Agencies***. To maximise those synergies, key enabling mechanisms should be ensured, including cumulative funding in an action from the Programme for the Union's action in the field of health and another Union programme, as long as such cumulative funding does not exceed the total eligible costs of the action. For that purpose, this Regulation should set out appropriate rules, in particular on the possibility to declare the same cost or expenditure on a pro-rata basis to Programme for the Union's action in the field of health and another Union programme ***guaranteeing detailed and transparent reporting***.

Or. en

## Amendment 406

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

#### Recital 30

*Text proposed by the Commission*

(30) In order to optimise the added value and impact from investments funded wholly or in part through the budget of the Union, synergies should be sought in particular between the Programme for the Union's action in the field of health and other Union programmes, including those under shared-management. To maximise those synergies, key enabling mechanisms should be ensured, including cumulative funding in an action from the Programme for the Union's action in the field of health and another Union programme, as long as such cumulative funding does not exceed the total eligible costs of the action. For that purpose, this Regulation should set out appropriate rules, in particular on the possibility to declare the same cost or expenditure on a pro-rata basis to Programme for the Union's action in the field of health and another Union programme.

*Amendment*

(30) In order to optimise the added value and impact from investments funded wholly or in part through the budget of the Union, synergies should be sought in particular between the Programme for the Union's action in the field of health and other Union programmes, including those under shared-management **and the EU agencies**. To maximise those synergies **and avoid duplications**, key enabling mechanisms should be ensured, including cumulative funding in an action from the Programme for the Union's action in the field of health and another Union programme, as long as such cumulative funding does not exceed the total eligible costs of the action. For that purpose, this Regulation should set out appropriate rules, in particular on the possibility to declare the same cost or expenditure on a pro-rata basis to Programme for the Union's action in the field of health and another Union programme.

Or. en

## Amendment 407

Edina Tóth

### Proposal for a regulation

#### Recital 31

*Text proposed by the Commission*

(31) Given the specific nature of the objectives and actions covered by the Programme, the respective competent

*Amendment*

(31) Given the specific nature of the objectives and actions covered by the Programme, the respective competent

authorities of the Member States are best placed in some cases to implement the related activities. Those authorities, designated by the Member States themselves, should therefore be considered to be identified beneficiaries for the purpose of Article 195 of the Financial Regulation and the grants be awarded to such authorities without prior publication of calls for proposals.

authorities of the Member States are best placed in some cases to implement the related activities. Those authorities, designated by the Member States themselves, should therefore be considered to be identified beneficiaries for the purpose of Article 195 of the Financial Regulation and the grants be awarded to such authorities without prior publication of calls for proposals. ***Investments from EU4Health programme should be implemented in close cooperation with Member States especially in areas falling under national competences.***

Or. en

#### **Amendment 408**

**Pascal Arimont, Cindy Franssen, Esther de Lange**

#### **Proposal for a regulation**

##### **Recital 31**

###### *Text proposed by the Commission*

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

###### *Amendment*

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

Or. en

#### **Amendment 409**

**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**  
**Recital 33**

*Text proposed by the Commission*

(33) Given the common agreed values of solidarity towards equitable and universal coverage of quality health services as a basis for the Union's policies in this area and that the Union has a central role to play in accelerating progress on global health challenges<sup>19</sup>, the Programme should support the Union's contribution to international and global health initiatives with a view to improve health, address inequalities and increase protection against global health threats.

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

*Amendment*

(33) Given the common agreed values of solidarity towards equitable and universal coverage of quality health services as a basis for the Union's policies in this area and that the Union has a central role to play in accelerating progress on global health challenges<sup>19</sup>, the Programme should support the Union's contribution to international and global health initiatives with a view to improve health, **including sexual and reproductive health**, address inequalities, **in particular gender inequalities**, and increase protection against global health threats.

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

Or. en

**Amendment 410**  
**Nicolae Ștefănuță, Véronique Trillet-Lenoir**

**Proposal for a regulation**  
**Recital 33**

*Text proposed by the Commission*

(33) Given the common agreed values of solidarity towards equitable and universal coverage of quality health services as a basis for the Union's policies in this area and that the Union has a central role to play in accelerating progress on global health challenges<sup>19</sup>, the Programme should support the Union's contribution to international and global health initiatives

with a view to improve health, address inequalities and increase protection against global health threats.

Union's contribution to international and global health initiatives with a view to improve health, address inequalities and increase protection against global health threats.

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

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

Or. en

### **Amendment 411**

**Pascal Arimont, Cindy Franssen, Esther de Lange**

#### **Proposal for a regulation**

##### **Recital 33**

*Text proposed by the Commission*

(33) Given the common agreed values of solidarity towards equitable and universal coverage of quality health services as a basis for the Union's policies in this area and that the Union has a central role to play in accelerating progress on global health challenges<sup>19</sup>, the Programme should support the Union's contribution to international and global health initiatives with a view to improve health, address inequalities and increase protection against global health threats.

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

*Amendment*

(33) Given the common agreed values of solidarity towards **accessible**, equitable and universal coverage of quality health services, **including in a cross-border context**, as a basis for the Union's policies in this area and that the Union has a central role to play in accelerating progress on global health challenges<sup>19</sup>, the Programme should support the Union's contribution to international and global health initiatives with a view to improve health, address inequalities and increase protection against global health threats.

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

Or. en

### **Amendment 412**

**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**  
**Recital 34**

*Text proposed by the Commission*

(34) In order to maximise the effectiveness and efficiency of actions at Union and international level, cooperation should be developed with relevant international organisations such as the United Nations and its specialised agencies, in particular the WHO, the World Bank, as well as with the Council of Europe and the Organisation for Economic Co-operation and Development (OECD) to implement the Programme. Pursuant to Article 94 of Council Decision 2013/755/EU<sup>20</sup>, persons and entities established in Overseas Countries and Territories (OCTs) are eligible for funding subject to the rules and objectives of the Programme and possible arrangements applicable to the Member State to which the relevant OCTs are linked.

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<sup>20</sup> Council Decision 2013/755/EU of 25 November 2013 on the association of the overseas countries and territories with the European Union ( ‘Overseas Association Decision’ ) (OJ L 344, 19.12.2013, p. 1).

*Amendment*

(34) In order to maximise the effectiveness and efficiency of actions at Union and international level, cooperation should be developed **with the Member States and** with relevant international organisations such as the United Nations and its specialised agencies, in particular the WHO, the World Bank, as well as with the Council of Europe and the Organisation for Economic Co-operation and Development (OECD) to implement the Programme. Pursuant to Article 94 of Council Decision 2013/755/EU<sup>20</sup>, persons and entities established in Overseas Countries and Territories (OCTs) are eligible for funding subject to the rules and objectives of the Programme and possible arrangements applicable to the Member State to which the relevant OCTs are linked.

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<sup>20</sup> Council Decision 2013/755/EU of 25 November 2013 on the association of the overseas countries and territories with the European Union ( ‘Overseas Association Decision’ ) (OJ L 344, 19.12.2013, p. 1).

Or. en

**Amendment 413**

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

**Proposal for a regulation**  
**Recital 36**

*Text proposed by the Commission*

(36) Cooperation with third countries should be strengthened on the exchange of knowledge and best practices in health systems preparedness and response.

*Amendment*

(36) Cooperation with third countries should be strengthened on the exchange of knowledge and best practices in health systems preparedness and response. ***The programme should help building a strong and effective partnership between the Union and Africa and prioritise health systems strengthening, universal access to health services and global health research and development in the framework of the EU-Africa Strategy.***

Or. en

#### **Amendment 414**

**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  
Recital 39 a (new)**

*Text proposed by the Commission*

*Amendment*

***(39a) The preamble to the Paris Agreement acknowledges the “right to health” as a key right; the article 4(1)(f) of the UNFCCC states that all Parties thereto should employ “appropriate methods, for example impacts assessments, formulated and determined nationally with a view to minimising adverse effects on the economy, on public health and on the quality of the environment, of projects or measures undertaken by them to mitigate or adapt climate change”.***

Or. en

#### **Amendment 415**

**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  
Recital 39 b (new)**

*Text proposed by the Commission*

*Amendment*

***(39b) According to the WHO, climate change affects the social and environmental determinants of health—clean air, safe drinking water, sufficient food and secure shelter—and that 250 000 additional deaths, from malnutrition, malaria, diarrhoea and heat stress, are expected every year between 2030 and 2050, with extreme high air temperatures contributing directly to deaths particularly amongst the elderly and vulnerable individuals. Through flood, heatwaves, drought and fires, climate change has a considerable impact on human health, including under nutrition, cardiovascular and respiratory diseases, and vector-borne infections.***

Or. en

**Amendment 416  
Rob Rooker**

**Proposal for a regulation  
Recital 40**

*Text proposed by the Commission*

*Amendment*

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

*deleted*

*Programme's preparation and implementation, and reassessed in the context of its mid-term evaluation.*

Or. nl

**Amendment 417**  
**Margarita de la Pisa Carrión**

**Proposal for a regulation**  
**Recital 40**

*Text proposed by the Commission*

*Amendment*

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

*deleted*

Or. es

**Amendment 418**  
**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**  
**Recital 40**

*Text proposed by the Commission*

*Amendment*

**(40) Reflecting the importance of tackling climate change in line with the Union's commitments to implement the Paris Agreement and the United Nations**

**(40) Reflecting the importance of tackling climate change in line with the Union's commitments to implement the Paris Agreement and the United Nations**

Sustainable Development Goals, this Programme will contribute to mainstream climate action in the Union's policies and to the achievement of an overall target of **25 %** of the EU budget expenditures supporting climate objectives. Relevant actions will be identified during the Programme's preparation and implementation, and reassessed in the context of its mid-term evaluation.

Sustainable Development Goals, this Programme will contribute to mainstream climate action in the Union's policies and to the achievement of an overall target of **30 %** of the EU budget expenditures supporting climate objectives. Relevant actions will be identified during the Programme's preparation and implementation, and reassessed in the context of its mid-term evaluation.

Or. en

#### **Amendment 419**

**Pascal Arimont, Cindy Franssen, Esther de Lange**

#### **Proposal for a regulation**

##### **Recital 42**

*Text proposed by the Commission*

(42) The implementation of the Programme should be such that the responsibilities of the Member States, for the definition of their health policy and for the organisation and delivery of health services and medical care, are respected.

*Amendment*

(42) The implementation of the Programme should be such that the responsibilities of the Member States, for the definition of their health policy and for the organisation and delivery of health services and medical care, are respected. ***However, with a view to improving the complementarity of their health services and their conditions of mobility for patients and healthcare professionals in cross-border areas.***

Or. en

#### **Amendment 420**

**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**

##### **Recital 43**

*Text proposed by the Commission*

(43) Given the nature and potential scale of cross-border threats to human health, the objective of protecting people in the Union from such threats and to increase crisis prevention and preparedness cannot be sufficiently achieved by the Member States acting alone. In accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union, action at Union level can also be taken to support Member States' efforts in the pursuit of a high level of protection of public health, to improve the availability and affordability in the Union of medicines, medical devices and other *crisis* relevant products, to support innovation and to support integrated and coordinated work and implementation of best practices among Member States, and to address inequalities in access to health throughout the EU in a manner that creates efficiency gains and value-added impacts that could not be generated by action taken at national level while respecting the Member States' competence and responsibility in the areas covered by the Programme. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

*Amendment*

(43) Given the nature and potential scale of cross-border threats to human health, the objective of protecting people in the Union from such threats and to increase crisis prevention and preparedness cannot be sufficiently achieved by the Member States acting alone. In accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union, action at Union level can also be taken to support Member States' efforts in the pursuit of a high level of protection of public health, to improve the availability, *sustainability, acceptability, accessibility* and affordability in the Union of medicines, medical devices and other *health* relevant products, to support innovation and to support integrated and coordinated work and implementation of best practices among Member States, and to address inequalities *and inequities* in access to health throughout the EU in a manner that creates efficiency gains and value-added impacts that could not be generated by action taken at national level while respecting the Member States' competence and responsibility in the areas covered by the Programme. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

Or. en

**Amendment 421**

**Pascal Arimont, Cindy Franssen, Esther de Lange**

**Proposal for a regulation**

**Recital 43**

*Text proposed by the Commission*

(43) Given the nature and potential scale

*Amendment*

(43) Given the nature and potential scale

of cross-border threats to human health, the objective of protecting people in the Union from such threats and to increase crisis prevention and preparedness cannot be sufficiently achieved by the Member States acting alone. In accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union, action at Union level *can* also be taken to support Member States' efforts in the pursuit of a high level of protection of public health, to improve the availability and affordability in the Union of medicines, medical devices and other crisis relevant products, to support innovation and to support integrated and coordinated work and implementation of best practices among Member States, and to address inequalities in access to health throughout the EU in a manner that creates efficiency gains and value-added impacts that could not be generated by action taken at national level while respecting the Member States' competence and responsibility in the areas covered by the Programme. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

of cross-border threats to human health, the objective of protecting people in the Union from such threats and to increase crisis prevention and preparedness cannot be sufficiently achieved by the Member States acting alone. In accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union, action at Union level *should* also be taken to support Member States' efforts in the pursuit of a high level of protection of public health, to improve the availability and affordability in the Union of medicines, medical devices and other crisis relevant products *and services*, to support innovation and to support integrated and coordinated work and implementation of best practices among Member States *and among their regions*, and to address inequalities in access to health throughout the EU in a manner that creates efficiency gains and value-added impacts that could not be generated by action taken at national level while respecting the Member States' competence and responsibility in the areas covered by the Programme. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

Or. en

**Amendment 422**  
**Michèle Rivasi**

**Proposal for a regulation**  
**Recital 43**

*Text proposed by the Commission*

(43) Given the nature and potential scale of cross-border threats to human health, the objective of protecting people in the Union from such threats and to increase crisis prevention and preparedness cannot be sufficiently achieved by the Member States

*Amendment*

(43) Given the nature and potential scale of cross-border threats to human health, the objective of protecting people in the Union from such threats and to increase crisis prevention and preparedness cannot be sufficiently achieved by the Member States

acting alone. In accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union, action at Union level can also be taken to support Member States' efforts in the pursuit of a high level of protection of public health, to improve the availability and affordability in the Union of medicines, medical devices and other crisis relevant products, to support innovation and to support integrated and coordinated work and implementation of best practices among Member States, and to address inequalities in access to health throughout the EU in a manner that creates efficiency gains and value-added impacts that could not be generated by action taken at national level while respecting the Member States' competence and responsibility in the areas covered by the Programme. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

acting alone. In accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union, action at Union level can also be taken to support Member States' efforts in the pursuit of a high level of protection of public health, to improve the availability, **accessibility, safety** and affordability in the Union of medicines, medical devices and other crisis relevant products, to support innovation and to support integrated and coordinated work and implementation of best practices among Member States, and to address inequalities in access to health throughout the EU in a manner that creates efficiency gains and value-added impacts that could not be generated by action taken at national level while respecting the Member States' competence and responsibility in the areas covered by the Programme. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

Or. en

## **Amendment 423**

**Jessica Polfjärd**

### **Proposal for a regulation**

#### **Recital 43**

*Text proposed by the Commission*

(43) Given the nature and potential scale of cross-border threats to human health, the objective of protecting people in the Union from such threats and to increase crisis prevention and preparedness cannot be sufficiently achieved by the Member States acting alone. In accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union, action at Union level can also be taken to support Member States' efforts in

*Amendment*

(43) Given the nature and potential scale of cross-border threats to human health, the objective of protecting people in the Union from such threats and to increase crisis prevention and preparedness cannot be sufficiently achieved by the Member States acting alone. In accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union, action at Union level can also be taken to support Member States' efforts in

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

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

Or. en

#### **Amendment 424**

**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 2 – paragraph 1 – point 3**

##### *Text proposed by the Commission*

(3) 'health crisis' means any crisis or serious incident arising from a threat of human, animal, plant, food **or environment** origin, having a health dimension and which requires urgent action by authorities;

##### *Amendment*

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

Or. en

#### **Amendment 425**

**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 2 – paragraph 1 – point 3**

*Text proposed by the Commission*

(3) ‘health crisis’ means any crisis or serious incident arising from a threat of human, animal, plant, food *or* environment origin, having a health dimension and which requires urgent action by authorities;

*Amendment*

(3) ‘health crisis’ means any crisis or serious incident arising from a threat of human, animal, plant, food, environment, ***biological, chemical and nuclear origin and a threat of unknown*** origin, having a health dimension and which requires urgent ***and coordinated*** action by authorities;

Or. en

**Amendment 426**

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

**Proposal for a regulation**

**Article 2 – paragraph 1 – point 4**

*Text proposed by the Commission*

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

*Amendment*

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

*increase the availability of data;*

Or. en

**Amendment 427**

**Mick Wallace, Clare Daly**

**Proposal for a regulation**

**Article 2 – paragraph 1 – point 4**

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 428**

**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 2 – paragraph 1 – point 4**

*Text proposed by the Commission*

(4) ‘crisis relevant products’ means products and substances necessary, in the

*Amendment*

(4) ‘crisis relevant products’ means products and substances necessary, in the

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

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

Or. en

#### **Amendment 429**

**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 2 – paragraph 1 – point 5**

##### *Text proposed by the Commission*

(5) ‘One Health approach’ means an approach which recognises **that human and animal health are interconnected**, that diseases may be transmitted from **humans to animals and vice versa** and must therefore be tackled in **both, and that the environment links humans and animals**;

##### *Amendment*

(5) ‘One Health approach’ means an approach which recognises **the interconnection between the human, animal and environmental spheres**, that diseases may be transmitted from **one pillar to another** and must therefore be tackled in **a holistic approach**;

Or. en

#### **Amendment 430**

**Rob Rooker**

#### **Proposal for a regulation**

#### **Article 2 – paragraph 1 – point 5**

*Text proposed by the Commission*

(5) ‘One Health approach’ means an approach which recognises ***that human and animal health are interconnected***, that diseases may be transmitted from humans to animals and vice versa and must therefore be tackled in both, ***and that the environment links humans and animals***;

*Amendment*

(5) ‘One Health approach’ means an approach which recognises that diseases may be transmitted from humans to animals and vice versa and must therefore be tackled in both;

Or. nl

### **Amendment 431**

**Margarita de la Pisa Carrión**

#### **Proposal for a regulation**

**Article 2 – paragraph 1 – point 5 a (new)**

*Text proposed by the Commission*

*Amendment*

***(5a) The concept of ‘human health’ encompasses absolute respect for life in all its integral dimensions: physical, psychological, emotional and spiritual aspects that are all interconnected, unlike animal health. Such inclusion requires a holistic vision of an approach to comprehensive personal health, which preserves the freedom and dignity intrinsic to the human condition in all phases of life.***

Or. es

### **Amendment 432**

**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 2 – paragraph 1 – point 5 a (new)**

*Text proposed by the Commission*

*Amendment*

**(5a) “Environmental health” means aspects of human health, such as the quality of life, which are determined by the physical, chemical, biological, social, psychosocial and aesthetic factors of our environment;**

Or. en

#### **Amendment 433**

**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 2 – paragraph 1 – point 9**

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

#### **Amendment 434**

**Antoni Comín i Oliveres**

#### **Proposal for a regulation**

#### **Article 2 – paragraph 1 – point 10 a (new)**

*Text proposed by the Commission*

*Amendment*

**(10a) "health in all policies principle":**

*policy formulation approach that systematically considers health implications of decisions in all sectors, seeking synergies and avoiding the harmful effects on health of policies outside the health sector, in order to improve population's health and health equity. It develops the capacity of health policy professionals to recognise and support the development goals of other sectors, recognising the interdependent nature of social, economic, and environmental development;*

Or. en

**Amendment 435**  
**Nicolae Ștefănuță**

**Proposal for a regulation**  
**Article 2 – paragraph 1 – point 10 a (new)**

*Text proposed by the Commission*

*Amendment*

*(10a) ‘Commercial determinant of health’ means strategies and approaches used by the private sector to promote products and choices that are detrimental to health;*

Or. en

**Amendment 436**  
**Nathalie Colin-Oesterlé**

**Proposal for a regulation**  
**Article 2 – paragraph 1 – point 10 a (new)**

*Text proposed by the Commission*

*Amendment*

*(10a) ‘shortage’ means the temporary unavailability of a medicinal product as a result of an upstream stock shortage and/or a downstream supply shortage;*

**Amendment 437**  
**Biljana Borzan**

**Proposal for a regulation**  
**Article 2 – paragraph 1 – point 10 a (new)**

*Text proposed by the Commission*

*Amendment*

***(10a) ‘Commercial determinant of health’ means commercial strategies and approaches used to promote products and choices that are detrimental to health.***

Or. en

**Amendment 438**  
**Michèle Rivasi**

**Proposal for a regulation**  
**Article 2 – paragraph 1 – point 10 a (new)**

*Text proposed by the Commission*

*Amendment*

***(10a) ‘independent from industry’ means receiving less than 20% of core funding as well as of project funding, respectively, from industry;***

Or. en

**Amendment 439**  
**Nathalie Colin-Oesterlé**

**Proposal for a regulation**  
**Article 2 – paragraph 1 – point 10 b (new)**

*Text proposed by the Commission*

*Amendment*

***(10b) ‘supply strain’ means that the manufacturer has insufficient quantities of medicines available, resulting in a***

*temporary inability to supply the usual market and a risk of disruption;*

Or. fr

**Amendment 440**

**Nathalie Colin-Oesterlé**

**Proposal for a regulation**

**Article 2 – paragraph 1 – point 10 c (new)**

*Text proposed by the Commission*

*Amendment*

*(10c) ‘supply disruption’ means the medicine is manufactured but not distributed to all pharmacies;*

Or. fr

**Amendment 441**

**Nathalie Colin-Oesterlé**

**Proposal for a regulation**

**Article 2 – paragraph 1 – point 10 d (new)**

*Text proposed by the Commission*

*Amendment*

*(10d) ‘stock shortage’ means a break in the manufacturing chain of the medicines, which may have several explanations: either the medicines cannot be manufactured or they are not allowed to enter the distribution channel because the quality of the medicines does not fully meet the required standards.*

Or. fr

**Amendment 442**

**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 3 – paragraph 1 – introductory part**

*Text proposed by the Commission*

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

*Amendment*

The Programme shall pursue the following general objectives, in keeping with the “One Health” *and “Health in all policies” approaches* where relevant:

Or. en

**Amendment 443**  
**Rob Rooken**

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

*Text proposed by the Commission*

The Programme shall pursue the following general objectives, *in keeping with the ‘One Health’ approach where relevant*:

*Amendment*

The Programme shall pursue the following general objectives, *pending the outcomes of independent, science-based impact assessments*:

Or. nl

**Amendment 444**  
**Michèle Rivasi**

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

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

*Justification*

*The "One Health" Approach is always relevant.*

**Amendment 445**  
**Michèle Rivasi**

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

*Text proposed by the Commission*

*Amendment*

**(-1) improve the health of people in the Union, including in particular by health promotion, disease prevention and by addressing health inequalities;**

*(This should be the first of the general objectives.)*

Or. en

*Justification*

*With regard to the general objectives, the EU4Health Programme should first of all have the objective to improve the health of people in the Union and to address health inequalities. These should represent an objective in their own right and not be mixed with the objective to protect people in the Union from serious cross-border threats to health. Not should general health only be mentioned in the context of health systems (Art. 3, para 1, point 3). Improving public health in general as well as addressing health inequalities are also explicitly amongst the general objectives of the current programme and should therefore also be listed here as a general objective - in their own right.*

**Amendment 446**  
**Véronique Trillet-Lenoir**

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

*Text proposed by the Commission*

*Amendment*

**(-1) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer via the establishment of a European Cancer Institute;**

Or. en

**Amendment 447**  
**Cristian-Silviu Buşoi**

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

*Text proposed by the Commission*

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

*Amendment*

(1) ***support health promotion, improve health literacy, and disease prevention, reduce health inequalities, improve physical and mental health,*** protect people in the Union from serious cross-border threats to health;

Or. en

**Amendment 448**  
**Traian Băsescu**

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

*Text proposed by the Commission*

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

*Amendment*

(1) protect people in the Union from serious cross-border threats to health, ***including by ensuring equal protection for and full access to health rights for all European Union citizens, by promoting equal opportunities for, and access to, treatment, in a non-discriminatory manner, and by reducing disparities among Member States by allocating the resources needed to achieve this goal;***

Or. ro

**Amendment 449**  
**Bartosz Arłukowicz, Jarosław Duda**

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

*Text proposed by the Commission*

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

*Amendment*

(1) protect people in the Union from serious cross-border threats to health, ***including measures to support health promotion and disease prevention, reduce health inequalities, and improve physical and mental health;***

Or. pl

**Amendment 450**  
**Joanna Kopcińska**

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

*Text proposed by the Commission*

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

*Amendment*

(1) ***support health promotion, health literacy and disease prevention, reduce health inequalities, improve physical and mental health,*** protect people in the Union from serious cross-border threats to health;

Or. en

**Amendment 451**  
**Mick Wallace**

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

*Text proposed by the Commission*

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

*Amendment*

(1) ***support health promotion and disease prevention, reduce health inequalities, improve physical and mental health,*** protect people in the Union from serious cross-border threats to health;

Or. en

### *Justification*

*In order to protect people in the Union from serious cross-border threats to health, it is necessary to ensure that the general health status in all strata of the population is good. COVID-19 has shown how people with pre-existing conditions, such as cardiovascular disease, diabetes and obesity, were affected severely by the pandemic.*

#### **Amendment 452**

**Nicolae Ștefănuță, Véronique Trillet-Lenoir**

#### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 1**

*Text proposed by the Commission*

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

*Amendment*

(1) ***support health promotion and prevention, reduce health inequalities, improve physical and mental health and*** protect people in the Union from serious cross-border threats to health;

Or. en

#### **Amendment 453**

**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 3 – paragraph 1 – point 1**

*Text proposed by the Commission*

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

*Amendment*

(1) protect people in the Union from serious cross-border threats to health;  
***implement better preparedness and coordination within and between Member States as regards health emergencies;***

Or. en

#### **Amendment 454**

**Frédérique Ries**

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

*Text proposed by the Commission*

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

*Amendment*

(1) ***support health promotion and disease prevention and*** protect people in the Union from serious cross-border threats to health;

Or. en

**Amendment 455**  
**Inese Vaidere**

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

*Text proposed by the Commission*

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

*Amendment*

(1) protect people in the Union from serious cross-border threats to health ***and reduce health inequalities among Member States;***

Or. en

**Amendment 456**  
**Mairead McGuinness**

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

*Text proposed by the Commission*

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

*Amendment*

(1) ***support and foster public health and*** protect people in the Union from serious cross-border threats to health;

Or. en

#### **Amendment 457**

**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 3 – paragraph 1 – point 1**

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

#### **Amendment 458**

**Cristian-Silviu Bușoi**

#### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 2**

*Text proposed by the Commission*

(2) improve the availability in the Union of medicines, medical devices **and other crisis relevant products, contribute to their affordability, and** support innovation;

*Amendment*

(2) **support existing and future Union health legislation, improve the equal availability, accessibility and affordability of health care and services in the Union, including of medicines, treatments and medical devices, support safe and effective use, and boost research and innovation in healthcare; support systematic health impact assessment of other EU policies ensuring a comprehensive, Health in All Policies approach.**

Or. en

#### **Amendment 459**

**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**  
**Article 3 – paragraph 1 – point 2**

*Text proposed by the Commission*

(2) improve the availability *in the Union* of medicines, medical devices and *other crisis relevant products*, contribute to their affordability, *and* support innovation;

*Amendment*

(2) *support existing and future Union health legislation*, improve the availability *and sustainable production capacity* of medicines, *treatments and* medical devices *in the Union* and to *ensure* their *accessibility and* affordability, support *safe and effective use*, *and boost research and innovation in healthcare without duplicating efforts under programmes, including Horizon Europe*;

Or. en

**Amendment 460**

**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 3 – paragraph 1 – point 2**

*Text proposed by the Commission*

(2) improve the availability in the Union of medicines, medical devices and other *crisis* relevant products, contribute to their affordability, and support innovation;

*Amendment*

(2) *support existing and future Union health legislation*, improve the availability in the Union of medicines, *vaccines*, medical devices and other *medical* relevant products *and e-health solutions*, contribute to their *accessibility, sustainability and* affordability, and support *research, innovation and development in health and healthcare*;

Or. en

**Amendment 461**  
**Kateřina Konečná**

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

*Text proposed by the Commission*

(2) improve the availability in the Union of medicines, medical devices **and other crisis relevant products, contribute to their affordability, and** support innovation;

*Amendment*

(2) **support existing and future Union health legislation,** improve the **equal availability, accessibility and affordability of health care and services** in the Union, **including** of medicines, **treatments and** medical devices, support **safe and effective use, and boost research and** innovation **in healthcare;**

Or. en

*Justification*

*Access to healthcare, including medicines, is a fundamental patients' right. Patients will only benefit from care and services if they are available in a timely manner, accessible and affordable to all who need them. EPF's principle of equitable access is based on needs not means.*

**Amendment 462**  
**Joanna Kopcińska**

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

*Text proposed by the Commission*

(2) improve the availability in the Union of medicines, medical devices **and other crisis relevant products,** contribute to their affordability, **and** support **innovation;**

*Amendment*

(2) **support existing and future Union health legislation,** improve the availability in the Union of medicines, **treatments and** medical devices, contribute to their **accessibility and** affordability, support **the safe and effective use of medicines, and advance research in healthcare;**

Or. en

**Amendment 463**  
**Mick Wallace**

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

*Text proposed by the Commission*

(2) improve the availability in the Union of medicines, medical devices and other **crisis** relevant products, contribute to their affordability, **and** support innovation;

*Amendment*

(2) **support existing and future Union health legislation**, improve the availability in the Union of medicines, medical devices and other relevant products, contribute to their **accessibility and** affordability, support **safe and effective use, and boost research and** innovation **in healthcare**;

Or. en

*Justification*

*The Programme should not be limited to crisis relevant products and should support innovation in care as well as products to the benefit of all patients in the Union in an equitable manner.*

**Amendment 464**  
**Michèle Rivasi**

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

*Text proposed by the Commission*

(2) improve the availability in the Union of medicines, medical devices **and other crisis relevant products**, contribute to their affordability, **and** support innovation;

*Amendment*

(2) improve the availability in the Union of medicines, **treatments and** medical devices, contribute to their **accessibility and** affordability, support **their safe and effective use, and boost research and** innovation **in healthcare with a net benefit for public health**;

Or. en

*Justification*

*Innovation is a means, not an objective. Innovation is not good per se - innovation can bring about improvements, but it can also make things worse. It is therefore important to qualify what kind of research and innovation we need - only then can it be included in the general objectives.*

#### Amendment 465

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 3 – paragraph 1 – point 2

*Text proposed by the Commission*

(2) improve the availability in the Union of medicines, medical devices and other crisis relevant products, contribute to their affordability, and support innovation;

*Amendment*

(2) ***restore pharmaceutical independence of the Union to*** improve ***ensure*** the availability in the Union of medicines, ***vaccines and diagnostic tools***, medical devices and other crisis relevant products, contribute to their affordability, and support innovation ***via the Pharmaceutical Strategy***;

Or. en

#### Amendment 466

Frédérique Ries

#### Proposal for a regulation

#### Article 3 – paragraph 1 – point 2

*Text proposed by the Commission*

(2) improve the availability in the Union of medicines, medical devices and other ***crisis*** relevant products, contribute to their affordability, ***and*** support innovation;

*Amendment*

(2) improve the availability in the Union of medicines, medical devices and other relevant products contribute to their ***accessibility and*** affordability, support ***safe and effective use, and boost research and*** innovation ***in healthcare***;

Or. en

#### Amendment 467

Véronique Trillet-Lenoir, Stéphane Bijoux

#### Proposal for a regulation

#### Article 3 – paragraph 1 – point 2

*Text proposed by the Commission*

(2) improve the availability in the Union of medicines, medical devices and other crisis relevant products, contribute to their affordability, and support innovation;

*Amendment*

(2) improve the availability in the Union, ***especially in the outermost regions and the overseas countries and territories***, of medicines, medical devices and other crisis relevant products, contribute to their affordability, and support innovation;

Or. fr

**Amendment 468**

**Mairead McGuinness**

**Proposal for a regulation**

**Article 3 – paragraph 1 – point 2**

*Text proposed by the Commission*

(2) improve the availability in the Union of medicines, medical devices and other crisis relevant products, contribute to their affordability, and support innovation;

*Amendment*

(2) improve the availability in the Union of medicines, medical devices and other crisis relevant products, contribute to their ***accessibility and affordability not only during times of crisis***, and support ***research and*** innovation;

Or. en

**Amendment 469**

**Mick Wallace, Clare Daly**

**Proposal for a regulation**

**Article 3 – paragraph 1 – point 2**

*Text proposed by the Commission*

(2) improve the availability in the Union of medicines, medical devices and other crisis relevant products, contribute to their affordability, and support innovation;

*Amendment*

(2) improve the availability in the Union of medicines, medical devices and other crisis relevant products, ***including products which remain essential in times of crisis***, contribute to their affordability, and support innovation;

Or. en

## Amendment 470

Bartosz Arłukowicz, Jarosław Duda

### Proposal for a regulation

#### Article 3 – paragraph 1 – point 2

*Text proposed by the Commission*

(2) improve the availability in the Union of medicines, medical devices and other **crisis** relevant products, contribute to their affordability, and support innovation;

*Amendment*

(2) improve the availability in the Union of medicines, medical devices and other relevant products, contribute to their affordability, **promote their safe use, and intensify** and support innovation;

Or. pl

## Amendment 471

Jessica Polfjärd

### Proposal for a regulation

#### Article 3 – paragraph 1 – point 2

*Text proposed by the Commission*

(2) improve the availability in the Union of medicines, medical devices and other crisis relevant products, contribute to their affordability, and support innovation;

*Amendment*

(2) improve the availability in the Union of medicines, medical devices and other crisis relevant products, contribute to their **accessibility and** affordability, and support innovation;

Or. en

## Amendment 472

Inese Vaidere

### Proposal for a regulation

#### Article 3 – paragraph 1 – point 2

*Text proposed by the Commission*

(2) improve the availability in the Union of medicines, medical devices and other crisis relevant products, contribute to

*Amendment*

(2) improve the availability in the Union of medicines, **treatment**, medical devices and other crisis relevant products,

their affordability, and support innovation;

contribute to their affordability, and support innovation;

Or. en

#### **Amendment 473**

**Cristian-Silviu Buşoi**

#### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 3**

##### *Text proposed by the Commission*

(3) strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, sustained implementation of best **practice and** data sharing, to increase the general level of public health.

##### *Amendment*

(3) strengthen health systems and the healthcare workforce, including by digital transformation, **harmonized education and training** and by increased integrated and coordinated work among the Member States, sustained implementation of best **practices, health literacy, joint health targets, metrics and patients, and comparable** data sharing, to increase the general level of public health.

Or. en

#### **Amendment 474**

**Jessica Polfjärd**

#### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 3**

##### *Text proposed by the Commission*

(3) strengthen health systems and **the healthcare workforce**, including by digital transformation and by increased **integrated and** coordinated work among the Member States, sustained implementation of best practice and data sharing, to increase the general level of public health.

##### *Amendment*

(3) strengthen health systems and **make them more resilient and responsive to crises**, including by digital transformation and by increased coordinated work among the Member States, sustained implementation of best practice and data sharing, **in order** to increase the general level of public health.

Or. en

**Amendment 475**  
**Kateřina Konečná**

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

*Text proposed by the Commission*

(3) strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, sustained implementation of best practice **and** data sharing, to increase the general level of public health.

*Amendment*

(3) strengthen health systems and the healthcare workforce, including by digital transformation, **harmonized education and training**, and by increased integrated and coordinated work among the Member States, sustained implementation of best Practice, **improvement of health literacy for citizens and patients and comparable** data sharing, to increase the general level of public health.

Or. en

**Amendment 476**

**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 3 – paragraph 1 – point 3**

*Text proposed by the Commission*

(3) strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, sustained implementation of best practice and data sharing, to increase the general level of public health.

*Amendment*

(3) strengthen health systems and the healthcare workforce, including by digital **and green** transformation, and by increased integrated and coordinated work among the Member States, sustained implementation of best practice and **comparable** data sharing, to increase the general level of public health **and health literacy of the population**.

Or. en

**Amendment 477**  
**Michèle Rivasi**

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

*Text proposed by the Commission*

(3) strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, sustained implementation of best practice and data sharing, to increase the general level of public health.

*Amendment*

(3) strengthen health systems, ***their sustainability*** and the healthcare workforce, including by digital transformation ***that fully respects the European data protection framework, harmonized education and training,*** and by increased integrated and coordinated work among the Member States, sustained implementation of best practice and ***comparable*** data sharing, to increase the general level of public health.

Or. en

*Justification*

*We also need to strengthen the sustainability of health systems. It is of paramount importance that the digital transformation fully respects the European data protection framework (see paragraph 33 of the European Parliament Resolution of 10 July 2020 on EU public health strategy post COVID-19).*

**Amendment 478**  
**Mick Wallace, Clare Daly**

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

*Text proposed by the Commission*

(3) strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, sustained implementation of best practice and data sharing, to increase the general level of public health.

*Amendment*

(3) strengthen health systems and the healthcare workforce, including by digital transformation ***of all health care services and procedures,*** and by increased integrated and coordinated work among the Member States, sustained implementation of best practice and data sharing, to increase the general level of public health.

Or. en

#### **Amendment 479**

**Pascal Arimont, Cindy Franssen, Esther de Lange**

#### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 3**

##### *Text proposed by the Commission*

(3) strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, sustained implementation of best practice and data sharing, to increase the general level of public health.

##### *Amendment*

(3) strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States **at national, regional and local level**, sustained implementation of best practice and data sharing, to increase the general level of public health.

Or. en

#### **Amendment 480**

**Nicolae Ștefănuță, Véronique Trillet-Lenoir**

#### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 3**

##### *Text proposed by the Commission*

(3) strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, sustained implementation of best practice and data sharing, to increase the general level of public health.

##### *Amendment*

(3) strengthen health systems and the healthcare workforce, including by digital transformation **harmonized education and training** and by increased integrated and coordinated work among the Member States, sustained implementation of best practice and data sharing, to increase the general level of public health.

Or. en

#### **Amendment 481**

**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 3 – paragraph 1 – point 3**

*Text proposed by the Commission*

(3) strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, sustained implementation of best practice and data sharing, to increase the general level of public health.

*Amendment*

(3) strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, sustained implementation of best practice and ***comparable and interoperable*** data sharing, to increase the general level of public health.

Or. en

**Amendment 482**

**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**  
**Article 3 – paragraph 1 – point 3**

*Text proposed by the Commission*

(3) strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, sustained implementation of best practice and data sharing, to increase the general level of public health.

*Amendment*

(3) strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, sustained implementation of best practice and data sharing, to ***ensure interoperability of their actions and*** increase the general level of public health.

Or. en

**Amendment 483**  
**Marian-Jean Marinescu**

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

*Text proposed by the Commission*

(3) strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, sustained implementation of best practice and data sharing, to increase the general level of public health.

*Amendment*

(3) strengthen health systems, **health infrastructure** and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, sustained implementation of best practice and data sharing, to increase the general level of public health.

Or. en

**Amendment 484**  
**Nathalie Colin-Oesterlé**

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

*Text proposed by the Commission*

*Amendment*

**(3a) support and strengthen existing and future EU health legislation to improve the availability in the EU of medicines, medical devices and other products that are required in case of shortages, and contribute to their accessibility and affordability;**

Or. fr

**Amendment 485**  
**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 3 – paragraph 1 – point 3 a (new)**

*Text proposed by the Commission*

*Amendment*

**(3a) reduce health inequalities between**

*Member States and within Member States while taking into account the “health in all policies” approach;*

Or. en

**Amendment 486**

**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 3 – paragraph 1 – point 3 a (new)**

*Text proposed by the Commission*

*Amendment*

***(3a) support systematic health impact assessment of other EU policies ensuring a comprehensive, Health in All Policies approach;***

Or. en

**Amendment 487**

**Marian-Jean Marinescu**

**Proposal for a regulation**

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

*Text proposed by the Commission*

*Amendment*

***(3a) support action aimed to provide equal access to health care, innovative medical treatment, medicines and medical devices;***

Or. en

**Amendment 488**

**Michèle Rivasi**

**Proposal for a regulation**

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

*Text proposed by the Commission*

*Amendment*

**(3a) support actions on integrative, person-centred and outcome-based care and health systems;**

Or. en

**Amendment 489**

**Piernicola Pedicini, Eleonora Evi**

**Proposal for a regulation**

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

*Text proposed by the Commission*

*Amendment*

**(3a) contribute to disease prevention by addressing key environmental risk factors;**

Or. en

**Amendment 490**

**Aldo Patriciello**

**Proposal for a regulation**

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

*Text proposed by the Commission*

*Amendment*

**(3a) make health systems become resilient and better respond to health crises;**

Or. en

**Amendment 491**

**Jessica Polfjärd**

**Proposal for a regulation**

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

*Text proposed by the Commission*

*Amendment*

***(3a) support the prevention of communicable diseases within the Union;***

Or. en

**Amendment 492**

**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 3 – paragraph 1 – point 3 b (new)**

*Text proposed by the Commission*

*Amendment*

***(3b) support health promotion, health protection and disease prevention, reduce health inequalities and inequities, improve physical and mental health, addressing in particular the key lifestyle related risk factors with a focus on the Union added value and scale up to healthier and more resilient societies;***

Or. en

**Amendment 493**

**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 3 – paragraph 1 – point 3 b (new)**

*Text proposed by the Commission*

*Amendment*

***(3b) provide integrated healthcare, accessible at local or regional level, enabling patients to be better supported in their own local and social environment;***

Or. en

**Amendment 494**  
**Rob Rooken**

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

*Text proposed by the Commission*

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

*Amendment*

The general objectives referred to in Article 3 shall be pursued through the following specific objectives, ***pending the outcomes of independent, science-based impact assessments***:

Or. nl

**Amendment 495**  
**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 – introductory part**

*Text proposed by the Commission*

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

*Amendment*

The general objectives referred to in Article 3 shall be pursued through the following specific objectives, in keeping with the “One Health” ***and “Health in all policies” approaches*** where relevant:

Or. en

**Amendment 496**  
**Michèle Rivasi**

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

*Text proposed by the Commission*

*Amendment*

***(-1) address key lifestyle risk factors as***

***well as environmental risk factors and improve physical and mental health;***

Or. en

*(Linked to the amendment by the same author to Article 3(1)(-1a).)*

*Justification*

*This specific objective is inserted as a new first specific objective to reflect the element of health promotion and disease prevention of the newly introduced first general objective by the same author. Moreover, addressing key lifestyle risks is explicitly listed in the first specific objective of the current programme and should also be listed here as the first specific objective. While there have been many fatalities due to COVID-19, there are many more due to key lifestyle risk and environmental risks. The first specific objective should therefore take a broad approach to public health before cross-border health threats and crisis-related aspects.*

**Amendment 497**  
**Michèle Rivasi**

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

*Text proposed by the Commission*

*Amendment*

***(-1a) implement the right to timely access to affordable, preventive and curative health care of good quality, and promote the use of health equity impact assessments of all relevant policies;***

Or. en

*(Linked to the amendment by the same author to Article 3(1)(-1a).)*

*Justification*

*This specific objective is inserted as a new specific objective at the beginning of the specific objectives to reflect the element of reducing health inequalities in the newly introduced first general objective by the same author. The second specific objective should take a broad approach to public health before cross-border health threats and crisis-related aspects. The right to timely access to affordable, preventive and curative health care of good quality is Principle 16 of the European Pillar of Social Rights.*

**Amendment 498**  
**Michèle Rivasi**

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

*Text proposed by the Commission*

*Amendment*

***(-1b) support implementation of the zero pollution ambition for a toxic-free environment;***

Or. en

**Amendment 499**  
**Traian Băsescu**

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

*Text proposed by the Commission*

*Amendment*

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

(1) strengthen the capability of the Union for prevention, preparedness and response to serious cross-border threats to health, and the management of health crises, including through coordination, provision and deployment of emergency health care capacity, data gathering and surveillance, ***including by enhancing the capacity of all of the Member States' health systems to quickly build autonomous mobile hospitals that can treat affected patients near infection hotspots;***

Or. ro

**Amendment 500**  
**Joanna Kopcińska**

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

*Text proposed by the Commission*

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

*Amendment*

(1) ***in full accordance with Article 168(5) of the Treaty on the Functioning of the European Union***, strengthen the capability of the Union, ***including the EMA and the ECDC***, for prevention, preparedness and response to serious cross-border threats to health, and the management of health crises, including through coordination, provision and deployment of emergency health care capacity, data gathering and surveillance;

Or. en

**Amendment 501**

**Michèle Rivasi**

**Proposal for a regulation**

**Article 4 – paragraph 1 – point 1**

*Text proposed by the Commission*

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

*Amendment*

(1) strengthen the capability of the Union for prevention, preparedness and response to serious cross-border threats to health, and the management of health crises, including through coordination, provision and deployment of emergency health care capacity, data gathering and surveillance, ***and the coordination of stress testing of national healthcare systems***;

Or. en

*Justification*

*It is of crucial importance that stress tests are conducted of national health systems. Such stress tests were called for by the European Parliament in its resolution on the EU public health strategy post COVID-19 of 10 July 2020 (see paragraph 9).*

### Amendment 502

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 1

###### *Text proposed by the Commission*

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

###### *Amendment*

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

Or. en

### Amendment 503

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 1

###### *Text proposed by the Commission*

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

###### *Amendment*

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

Or. en

### Amendment 504

Margarita de la Pisa Carrión

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

*Text proposed by the Commission*

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

*Amendment*

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

Or. es

**Amendment 505**  
**Cristian-Silviu Buşoi**

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

*Text proposed by the Commission*

*Amendment*

***(1a) 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 506**  
**Véronique Trillet-Lenoir, Nicolae Ştefănuţă, 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 1 a (new)**

*Text proposed by the Commission*

*Amendment*

**(1a) Support the strengthening of the competences and resources of the European health agencies namely the ECDC and the EMA, the European Food Safety Authority (EFSA), European Chemicals Agency (ECHA) and EU-OSHA;**

Or. en

**Amendment 507**

**Adam Jarubas**

**Proposal for a regulation**

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

*Text proposed by the Commission*

*Amendment*

**(1a) create and develop 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 508**

**Nathalie Colin-Oesterlé**

**Proposal for a regulation**

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

*Text proposed by the Commission*

*Amendment*

**(1a) support the creation, development and implementation of a strategy to tackle shortages of medicines and medical**

*devices in order to ensure all patients in the European Union are able to access treatment;*

Or. fr

**Amendment 509**  
**Danilo Oscar Lancini**

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

*Text proposed by the Commission*

*Amendment*

*(1a) support actions aimed at modernise and digitalise the EU regulatory Network at European and national level;*

Or. en

**Amendment 510**  
**Margarita de la Pisa Carrión**

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

*Text proposed by the Commission*

*Amendment*

*(1a) promote online medical and health education in general;*

Or. es

**Amendment 511**  
**Cristian-Silviu Buşoi**

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

*Text proposed by the Commission*

*Amendment*

*(1b) support actions aimed at*

*modernise and digitalise the EU  
regulatory Network at European and  
national level;*

Or. en

**Amendment 512**  
**Adam Jarubas**

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

*Text proposed by the Commission*

*Amendment*

*(1b) modernise and digitalise the EU  
regulatory Network at European and  
national level;*

Or. en

**Amendment 513**  
**Nicolae Ștefănuță, Véronique Trillet-Lenoir**

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

*Text proposed by the Commission*

*Amendment*

*(1a) The objectives of Article 4 shall be  
delivered in a consistent and transparent  
way and in a manner that is coordinated  
with the actions of other Union  
programmes and agencies.*

Or. en

**Amendment 514**  
**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 2**

*Text proposed by the Commission*

(2) ensure the availability in the Union of reserves *or stockpiles* of crisis relevant products, and a reserve of medical, healthcare and support staff to be mobilised in case of a crisis;

*Amendment*

(2) ensure the availability in the Union of reserves of crisis relevant products, and a reserve of medical, healthcare and support staff to be mobilised in case of a crisis *or shortage, ensure that such a reserve is available for fair access by all Member States in the Union;*

Or. en

**Amendment 515**

**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 2**

*Text proposed by the Commission*

(2) ensure the availability in the Union of reserves or stockpiles of *crisis* relevant products, and a reserve of medical, healthcare and support staff to be mobilised in case of a crisis;

*Amendment*

(2) ensure the availability in the Union of reserves or stockpiles of *medical* relevant products, and a reserve of medical, healthcare and support staff to be mobilised in case of a crisis, *improving the training of health professionals and updating their knowledge;*

Or. en

**Amendment 516**

**Margarita de la Pisa Carrión**

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

*Text proposed by the Commission*

(2) ensure the availability in the Union of reserves or stockpiles of crisis relevant products, and a reserve of medical, healthcare and support staff to be mobilised in case of a crisis;

*Amendment*

(2) ensure the availability in the Union of reserves or stockpiles of crisis relevant products, ***as well as production capacity***, and a reserve of medical, healthcare and support staff to be mobilised in case of a crisis;

Or. es

**Amendment 517**

**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 2**

*Text proposed by the Commission*

(2) ensure the availability in the Union of reserves or stockpiles of crisis relevant products, and a reserve of medical, healthcare and support staff to be mobilised in case of a crisis;

*Amendment*

(2) ensure the availability in the Union of reserves or stockpiles of crisis relevant products, and a reserve of medical, healthcare and support staff to be mobilised in case of a crisis ***such as the European Medical Corps***;

Or. en

**Amendment 518**  
**Jessica Polfjärd**

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

*Text proposed by the Commission*

(2) ensure the availability in the Union of reserves ***or stockpiles*** of crisis relevant products, and a reserve of medical, healthcare and support staff to be

*Amendment*

(2) ensure the availability in the Union of reserves of crisis relevant products, and a reserve of medical, healthcare and support staff to be mobilised in case of a

mobilised in case of a crisis;

crisis;

Or. en

## **Amendment 519**

**Nathalie Colin-Oesterlé**

### **Proposal for a regulation**

#### **Article 4 – paragraph 1 – point 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***(2a) support the creation, development and implementation of a strategy on health personnel in order to ensure an effective public health workforce, with the same high standards across the Union, and promote the excellence of medical and healthcare professionals; to this end, simplify the rules to allow cross-border health workers effective mobility, particularly in the event of a crisis or pandemic;***

Or. fr