



**2020/0102(COD)**

17.6.2020

**\*\*\*I**

## **DRAFT REPORT**

on the proposal for a regulation of the European Parliament and of the Council on the establishment of a Programme for the Union's action in the field of health –for the period 2021-2027 and repealing Regulation (EU) No 282/2014 (“EU4Health Programme”)  
(COM(2020)0405 – C9-0152/2020 – 2020/0102(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Cristian-Silviu Buşoi

### ***Symbols for procedures***

- \* Consultation procedure
- \*\*\* Consent procedure
- \*\*\*I Ordinary legislative procedure (first reading)
- \*\*\*II Ordinary legislative procedure (second reading)
- \*\*\*III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

### ***Amendments to a draft act***

#### **Amendments by Parliament set out in two columns**

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

#### **Amendments by Parliament in the form of a consolidated text**

New text is highlighted in ***bold italics***. Deletions are indicated using either the **■** symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.

By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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## DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

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

**(COM(2020)0405 – C9-0152/2020 – 2020/0102(COD))**

**(Ordinary legislative procedure: first reading)**

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2020)0405),
  - having regard to Article 294(2) and Article 168(5) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0152/2020),
  - 
  - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
  - having regard to the opinion of the European Economic and Social Committee of ... <sup>1</sup>,
  - having regard to the opinion of the Committee of the Regions of ...<sup>2</sup>,
  - having regard to Rules 59 of its Rules of Procedure,
  - having regard to the opinions of the Committee on Budgets, the Committee on Industry, Research and Energy and the Committee on the Internal Market and Consumer Protection,
  - having regard to the report of the Committee on the Environment, Public Health and Food Safety (A9-0000/2020),
1. Adopts its position at first reading hereinafter set out;
  2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
  3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

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<sup>1</sup> OJ C ... / Not yet published in the Official Journal.

<sup>2</sup> OJ C ... / Not yet published in the Official Journal.

## Amendment 1

### 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*** (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 management of respiratory diseases.***

Or. en

## Amendment 2

### 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 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***, 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.

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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 3

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

*Text proposed by the Commission*

*Amendment*

***(6 a) While the Union's action in the field of health is limited, the Union should 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, and preparing their health systems for emerging technologies.***

Or. en

### Amendment 4

#### Proposal for a regulation Recital 9

*Text proposed by the Commission*

*Amendment*

(9) In accordance with Regulation [European Union Recovery Instrument]

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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].

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***. 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 5

### 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,

#### *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 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



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.

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 6

### 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.***

Or. en

## Amendment 7

### 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. ***In times of health crises and 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.

Or. en

## Amendment 8

### 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.*

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*<sup>1a</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 9**

### **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

*Amendment*

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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).

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.

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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 10

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

*Text proposed by the Commission*

*Amendment*

***(15a) The rights of patients also extend to their right to be involved in any decision that affects their lives. Furthermore, the participation of patients and citizens is key for civil society to witness how decisions are made, as a matter of transparency and trust. In that sense, the role of patients is clearly stated in most Union legislation on pharmaceuticals. The Union legislator decided that patients are members with full rights in the Committee for Orphan***

***Medicinal Products established by Article 4 of Regulation (EC) No 141/2000 of the European Parliament and of the Council<sup>1a</sup>, in the Paediatric Committee established by Article 4 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council<sup>1b</sup>, in the Committee for Advanced Therapies established by Article 21 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council<sup>1c</sup>, in the Pharmacovigilance Committee established by Article 61a of Regulation (EC) No 726/2004 of the European Parliament and of the Council<sup>1d</sup>, and in the Management Board established by Article 65 of Regulation (EC) No 726/2004.***

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***<sup>1a</sup> Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1).***

***<sup>1b</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 (OJ L 378, 27.12.2006, p. 1).***

***<sup>1c</sup> Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).***

***<sup>1d</sup> Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136,***

## Amendment 11

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

*Text proposed by the Commission*

*Amendment*

***(15b) Health systems providing adapted healthcare services for patients with multiple conditions, from integrated healthcare, including prevention, to continuum care services, are person-centred. The Programme should therefore provide support for the transition from disease-centred healthcare to person-centred healthcare, for integration of healthcare services and continuum care, and should also support health system reforms that lead to outcome-based healthcare.***

## Amendment 12

### Proposal for a regulation Recital 16

*Text proposed by the Commission*

*Amendment*

(16) Keeping people healthy and active longer and empowering them to take an active role in managing their health will have positive effects on health, health inequalities, quality of life, productivity, competitiveness and inclusiveness, while reducing pressures on national budgets. The Commission has committed to help Member States to reach the sustainable development targets set in the 'UN 2030 Agenda for Sustainable Development' in

(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. ***Support for, and recognition of, innovation, which has an impact on health, help in taking up the challenge of achieving sustainability in the health***

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.

*sector in the context of also addressing the challenges of demographic change. Moreover, action to reduce inequalities in health 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 13**

### **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 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

## Amendment 14

### 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 **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.

Or. en

## Amendment 15

### 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, due to its direct impact on the ability to tackle those diseases. Investments in innovative community-based approaches to tackle communicable diseases are therefore vital. The Programme should provide***



*adequate technical and financial means to provide a sustainable regional response to the fight against HIV/AIDS, tuberculosis and hepatitis in Europe, instrumental to reaching the Sustainable Development Goals.*

Or. en

## **Amendment 16**

### **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.*

Or. en

## **Amendment 17**

### **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 and behavioural** 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 **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 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 fostering 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 18**

**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, while other illnesses, for instance neurological diseases, can be managed to slow the onset if detected early, or helping patients feel their best and remain active for longer. The Union and the Member States can therefore greatly reduce the burden of Member States by working together to achieve a better and more effective management of diseases, and the Programme should support actions in this area. The Programme should support the development of specific European Diseases Management Guidelines in the area of both communicable and non-communicable diseases, such as cardiovascular diseases, neurodegenerative diseases, respiratory diseases and diabetes.*

Or. en

## **Amendment 19**

### **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

*Amendment*

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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 entire cycle of the disease starting from prevention and early diagnosis to treatment and quality of life of patients and *also improving palliative care and pain management*. The measures should benefit from the Programme and from Horizon Europe's Mission on Cancer. *The Programme should ensure the sustainability of cancer care services and cancer pain treatment across the Union.*

Or. en

## Amendment 20

### 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.*

Or. en

## Amendment 21

### Proposal for a regulation Recital 19 b (new)

*Text proposed by the Commission*

*Amendment*

***(19b) The International Agency for Research on Cancer (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<sup>1a</sup> and support cross-border research collaboration by granting appropriate allocations.***

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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 22

### Proposal for a regulation Recital 19 c (new)

*Text proposed by the Commission*

*Amendment*

***(19c) 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 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 less-developed countries 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 23

### 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 high quality healthcare products and can fully benefit from them, ***based on transparent, consistent, patient-oriented medical information. Such access could be provided by having a stable and permanent cooperation as regards health technology assessment, in support of Member State decision-making.***

Or. en

## Amendment 24

### 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 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.

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 **digital** transformation of healthcare products and platforms for monitoring and collecting information on medicines. ***The programme should also strengthen decision-making on medicines by enabling access to and analysis of real-world healthcare data by regulators and health technology assessments ('HTA'), bodies. The Programme should also help to ensure best use of research results and facilitate the uptake, scaling-up and deployment of health innovation in healthcare systems and clinical practice. 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 25

### Proposal for a regulation Recital 23 a (new)



***(23a) Health associated infections ('HAI') are infections that patients get while receiving healthcare for another condition. The European Centre for Disease Prevention and Control (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<sup>1a</sup>.***

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<sup>1a</sup> (OJ C 151, 3.7.2009, p.1)

Or. en

## **Amendment 26**

### **Proposal for a regulation Recital 25**

*Text proposed by the Commission*

*Amendment*

(25) The Union health legislation has an

(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.

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, ***including real-world healthcare data***, to underpin policymaking and monitoring.

Or. en

## Amendment 27

### Proposal for a regulation Recital 26 a (new)

*Text proposed by the Commission*

*Amendment*

***(26a) The cross-border cooperation in the provision of healthcare to patients moving between Member States, as provided for under Directive 2011/24/EU on patients' rights in cross-border healthcare, includes collaboration on HTA, and European Reference Networks ('ERN'). Those are 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 health in general. Nevertheless, those areas are not yet developed, either in terms of Union legislation, 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.*

Or. en

## Amendment 28

### 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.

*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. **ERNs are a ground-breaking platform that represents a unique opportunity and which, based on the innovative use and sharing of knowledge and health data across borders, aims to improve diagnosis and care for people living with a rare or complex disease. Therefore, the Programme should provide adequate funding to support the coordination and collaborative activities of both existing and future ERNs through grants or other instruments that are fit for purpose. It should upscale current funding to ensure that that ERNs fulfil the objectives set out in their mission.** As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should **also**

contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider **reinforcing ERNs, supporting the creation of new ERNs to cover infectious diseases, complex pregnancies and rare and complex mental health diseases. The Programme should also consider the extension of the ERNs in form of e3xcellence networks in the field of communicable and non-communicable diseases, including cancer and paediatric cancer. The reinforcement of ERNs can play a key role in supporting the adoption of a common newly developed screening framework at Union level, starting from disease selection criteria and mechanisms, with the aim of overcoming existing inequalities in terms of screening coverage across Member States. The Programme should support the implementation of actions that drive the development and delivery of treatments, screening programmes and European patient registries for rare 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).

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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 29

### Proposal for a regulation Recital 34 a (new)

*Text proposed by the Commission*

*Amendment*

**(34a) To achieve a coherent implementation of the actions included in the EU4Health programme, a EU4Health Steering Board should be established. That independent stakeholder group**

*should be responsible, inter alia, for coordination, cooperation in the implementation of the actions, and for creating synergies between the Programme and other programmes which comprise a health dimension.*

Or. en

## Amendment 30

### 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, **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 31

#### 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

### Amendment 32

#### 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 ***safe and effective use, and boost research and*** innovation ***in healthcare;***

Or. en

### Amendment 33

#### 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 ***comparable*** data sharing, to increase the general level of public health;

Or. en

**Amendment 34**

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

*Text proposed by the Commission*

*Amendment*

***(3a) strengthen health systems so that they become resilient in crises and pandemics, and develop a preparedness plan.***

Or. en

**Amendment 35**

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

*Text proposed by the Commission*

*Amendment*

(2) ensure the availability in the Union of reserves ***or stockpiles*** of crisis relevant products, and a reserve of medical, healthcare and support staff to be mobilised in case of a crisis;

(2) 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. en

## **Amendment 36**

### **Proposal for a regulation**

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

*Text proposed by the Commission*

*Amendment*

***(3a) support actions to increase research and development, including through clinical trials, in the Union of crisis-relevant products, and access to and analysis of data from the use of such products in healthcare systems;***

Or. en

## **Amendment 37**

### **Proposal for a regulation**

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

*Text proposed by the Commission*

*Amendment*

***(3b) support actions to transform the health sector into a sector that comprises person-centred and outcome-based care and health systems;***

Or. en

## **Amendment 38**

### **Proposal for a regulation**

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

*Text proposed by the Commission*

*Amendment*

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

Or. en



## Amendment 39

### Proposal for a regulation

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

*Text proposed by the Commission*

*Amendment*

***(4b) strengthen the Union’s innovation ecosystem to ensure the development and uptake of the next generation of medicines, vaccines and medical devices to meet increasing healthcare challenges and expectations that arise;***

Or. en

## Amendment 40

### Proposal for a regulation

#### Article 4 – paragraph 1 – point 4 c (new)

*Text proposed by the Commission*

*Amendment*

***(4c) enhance the equal and timely access to quality, sustainable and affordable person-centred healthcare and related care services;***

Or. en

## Amendment 41

### Proposal for a regulation

#### Article 4 – paragraph 1 – point 5

*Text proposed by the Commission*

*Amendment*

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

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

## Amendment 42

### Proposal for a regulation

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

*Text proposed by the Commission*

*Amendment*

***(5a) support the creation, development and implementation of a strategy on the health workforce in order to create an effective workforce for public health, which has the same high standards across the Union, and promote the excellence of medical and healthcare professionals;***

Or. en

## Amendment 43

### Proposal for a regulation

#### Article 4 – paragraph 1 – point 6

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

## Amendment 44

### Proposal for a regulation

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

*Text proposed by the Commission*

*Amendment*

**(6a) address the unmet needs of children and adolescents with cancer, and of survivors, through dedicated programmes and plans that enable the ERN on Paediatric Cancer and pre-existing research structures to achieve their full potential towards the required level of progress in this under-served area;**

Or. en

## **Amendment 45**

### **Proposal for a regulation**

#### **Article 4 – paragraph 1 – point 9**

*Text proposed by the Commission*

*Amendment*

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

(9) support integrated work among Member States, and in particular their health systems, including the implementation of high-impact prevention practices, **the identification of health technologies meant to benefit from a Union assessment**, and scaling up networking through the ERNs and other transnational networks;

Or. en

## **Amendment 46**

### **Proposal for a regulation**

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

*Text proposed by the Commission*

*Amendment*

**(9a) support the implementation of the ERNs registries and cancer registries;**

Or. en

## Amendment 47

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

*Text proposed by the Commission*

*Amendment*

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

Or. en

## Amendment 48

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

*Text proposed by the Commission*

*Amendment*

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

Or. en

## Amendment 49

### Proposal for a regulation Article 6 – paragraph 1

*Text proposed by the Commission*

*Amendment*

Measures referred to in Article 2 of Regulation [European Union Recovery Instrument] shall be implemented under the Programme through an amount of up to EUR 8 451 000 000 in current prices

Measures referred to in Article 2 of Regulation [European Union Recovery Instrument] shall be implemented under the Programme through an amount of up to EUR 8 451 000 000 in current prices

referred to in point (iii) of Article 3(2)(a) of that Regulation, subject to its Article 5(4) and (8).

referred to in point (iii) of Article 3(2)(a) of that Regulation, subject to its Article 4(4) and (8).

Or. en

## Amendment 50

### Proposal for a regulation Article 14 – paragraph 6

#### *Text proposed by the Commission*

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

#### *Amendment*

6. Under the Programme, direct grants **shall** be awarded without a call for proposals to ERNs **and with a simplified financial and technical reporting system**. Direct grants may also be awarded to other transnational networks set out in accordance with **Union law including the participation of decentralised Union agencies**.

Or. en

## Amendment 51

### Proposal for a regulation Article 14 – paragraph 7 – point i

#### *Text proposed by the Commission*

(i) they are non-governmental, non-profit-making and independent of industry, commercial and business or other conflicting interests;

#### *Amendment*

(i) they are non-governmental **or** non-profit-making and independent of industry, commercial and business or other conflicting interests;

Or. en

## Amendment 52

### Proposal for a regulation Article 16 – paragraph 1

*Text proposed by the Commission*

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

*Amendment*

The Commission shall consult the health authorities of the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases, ***as well as relevant Union decentralised agencies, the EU4Health Steering Board and other relevant stakeholders, such as representatives of civil society organisations, in particular patients' organisations,*** on the work plans established for the Programme and its priorities and strategic orientations and its implementation.

Or. en

**Amendment 53**

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

*Text proposed by the Commission*

*Amendment*

***Article 16a***

***EU4Health Steering Board***

- 1. The Commission shall establish a EU4Health Steering Board ('the Steering Board') to advise it, in a consultative capacity, in steering the implementation of the Programme, as well as its monitoring and evaluation.***
- 2. The Steering Board shall focus on creating synergies between the Programme and other Programmes which comprise a health dimension , through coordination, cooperation and synergies, promoting engagement with patients and society , and providing scientific advice and recommendations to the Commission. In exercising its role, the Steering Board shall provide value oriented health actions, sustainability, better health***

*solutions, and shall foster access and reduce health inequalities.*

*3. The Steering Board shall be an independent stakeholder group, composed of actors from relevant sectors in the field of public health, wellbeing and social protection, with participation of representatives of regions and local health authorities, patient representatives and citizens.*

*4. The Steering Board shall be composed of 15 to 20 highly qualified individuals drawn from the fields referred to in paragraph 3. The members of the Steering Board shall be appointed by the Commission in consultation with the Parliament, following an open call for nominations or for expression of interests or both.*

*5. The members of the Steering Board shall be appointed for the period referred to in the second paragraph of Article 1.*

*6. The Steering Board shall have a chair who shall be appointed by the Commission from among its members. The Steering Board shall meet at least four times per year.*

*7. The Steering Board shall:*

*i. provide input, in the form of a comprehensive strategy, for developing annual work plans for the Programme, following a proposal from the Commission;*

*ii. elaborate a plan for steering coordination, cooperation and synergies between the Programme and other Programmes which comprise a health dimension;*

*iii. advise the Commission with regard to monitoring and evaluating the Programme, as set out in Articles 19 and 20 respectively.*

*The plan for steering coordination, cooperation and synergies shall facilitate*

*action or efforts to ensure that all the existing financial mechanisms relevant to health are visible and coordinated, and shall help to steer coordination and cooperation.*

**8. The Commission may consult the Steering Board on matters other than those referred to in paragraph 7.**

Or. en

## **Amendment 54**

### **Proposal for a regulation Article 19 – paragraph 1**

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

## **Amendment 55**

### **Proposal for a regulation Article 19 – paragraph 2**

*Text proposed by the Commission*

2. The Commission is empowered to adopt delegated acts in accordance with Article 24 concerning amendments to Annex II to amend and supplement the indicators where considered necessary.

*Amendment*

2. The Commission is empowered to adopt delegated acts in accordance with Article 24 concerning amendments to Annex II to amend and supplement the indicators, ***including programme- and action-specific ones***, where considered necessary.

Or. en



## Amendment 56

### Proposal for a regulation Article 24 – paragraph 2

*Text proposed by the Commission*

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

*Amendment*

2. The power to adopt delegated acts referred to in Article 19(2) shall be conferred on the Commission ***for a period of three years from [date of entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the three-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

Or. en

## Amendment 57

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

*Text proposed by the Commission*

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

*Amendment*

(ii) Critical health infrastructure relevant in the context of health crises, tools, structures, processes, production and laboratory capacity, including tools for surveillance, modelling, forecast, prevention and management of outbreaks ***and other relevant crisis products.***

Or. en

## Amendment 58

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

*Text proposed by the Commission*

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

*Amendment*

(iv) Development and operation of databases and digital tools and their interoperability, including where appropriate with other sensing technologies, such as space-based, ***and to support access to and analysis of data from real world healthcare settings; ;***

Or. en

## Amendment 59

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

*Text proposed by the Commission*

*Amendment*

***(xi a) Union decentralised agencies through increased resources, including staffing, for implementing eligible actions under the Programme.***

Or. en

## Amendment 60

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

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

## Amendment 61

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

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

## Amendment 62

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

*Text proposed by the Commission*

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

*Amendment*

(iv) Preventive actions to protect vulnerable groups from health threats and actions to adjust the response to and management of crisis to the needs of those vulnerable groups, **such as securing basic care for chronic disease patients in need of palliative care and pain management treatment**;

Or. en

## Amendment 63

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

*Text proposed by the Commission*

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

*Amendment*

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

## Amendment 64

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

*Text proposed by the Commission*

*Amendment*

***(va) Actions to support transition to telemedicine, at-home administration of medication and implementation of preventative and self-care plans, where possible and appropriate;***

Or. en

## Amendment 65

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

*Text proposed by the Commission*

*Amendment*

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

***(ii) Support under the Strategy for the Health Workforce and in synergy with other Programmes, harmonized and standardized training and educational programmes for medical and healthcare staff, and programmes for temporary exchanges of staff, in particular with the aim of improving their curricula and digital skills;***

Or. en

## Amendment 66

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

*Text proposed by the Commission*

*Amendment*

(iii) Support *to* improve the

(iii) Support ***actions under a strategy***

geographical distribution of healthcare workforce **and avoidance** of ‘medical deserts’;

***on the health workforce to address the decision of qualified health workers to leave their Member State of origin to work elsewhere, improve the geographical distribution of healthcare workforce, avoid ‘medical deserts’ and promote and implement retention policies;***

Or. en

## **Amendment 67**

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

*Text proposed by the Commission*

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

*Amendment*

(iv) Support the establishment and coordination of Union Reference Laboratories and Centres, Centres of Excellence, **and Union disease-specific platforms for the exchange, comparison and benchmarking of best practices between Member States;**

Or. en

## **Amendment 68**

### **Proposal for a regulation Annex I – point g – point vii**

*Text proposed by the Commission*

(vii) Support capacity building for investing in and implementing health system reforms (strategic planning and access to multi-source financing);

*Amendment*

(vii) Support capacity building for investing in and implementing health system reforms, **including those leading to person-centred and outcome-based transformation** (strategic planning and access to multi-source financing);

Or. en

## **Amendment 69**

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

*Text proposed by the Commission*

*Amendment*

***(ix a) Support the establishment and functioning of excellence networks in the field of communicable and non-communicable diseases;***

Or. en

## **Amendment 70**

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

*Text proposed by the Commission*

*Amendment*

***(ix b) Support the development and the implementation of the European Disease Management Guidelines in the area of both communicable and non-communicable diseases, such as cancer, paediatric cancer, cardiovascular diseases, neurodegenerative diseases, respiratory diseases and diabetes.***

Or. en

## **Amendment 71**

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

*Text proposed by the Commission*

*Amendment*

***(xi a) Support Member States in the revision of their rare disease national plans to enact the necessary financial and organisational arrangements to integrate effectively ERNs system into national health systems;***

## Amendment 72

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

*Text proposed by the Commission*

*Amendment*

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

Or. en

## Amendment 73

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

*Text proposed by the Commission*

*Amendment*

***(xi c) Earmark funding to create effective and permanent mechanisms to build cross-ERNs collaboration to address the multi-systemic needs of rare diseases and to facilitate cross-cutting networking between different specialities and disciplines, including at the level of the European Reference Network on Paediatric Cancer ;***

Or. en

## Amendment 74

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

*Text proposed by the Commission*

*Amendment*

***(xi d) Support Member States in strengthening their centres of expertise***

*for rare diseases to build the national health systems' competencies to diagnose, treat and manage such diseases and at the same time increase the collective capacity and knowledge of ERNs, including of the ERN PaedCan;*

Or. en

## Amendment 75

### Proposal for a regulation Annex I – point g – point xiii

*Text proposed by the Commission*

(xiii) Support an Union framework *and the respective interoperable digital tools for* cooperation among Member States *and in networks, including those needed* to enable Member States to deliver joint clinical assessments *and* joint scientific consultations *to exchange outcomes of HTA cooperation.*

*Amendment*

(xiii) Support a Union framework *to strengthen health technology assessment* cooperation among Member States *in order* to enable Member States to deliver *and exchange timely, reliable and high quality* joint clinical assessments, joint scientific consultations *and other relevant activities to support decision-makers.*

Or. en

## Amendment 76

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

*Text proposed by the Commission*

*Amendment*

*(xiii a) Establish the European Electronic Health Record and support its implementation in the Member States;*

Or. en



## Amendment 77

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

*Text proposed by the Commission*

*Amendment*

***(xiii b) Support Member States to improve and further develop and implement ERN registries, cancer registries;***

Or. en

## Amendment 78

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

*Text proposed by the Commission*

*Amendment*

(h) Actions on cancer:

(h) Actions on cancer ***and paediatric cancer:***

Or. en

## Amendment 79

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

*Text proposed by the Commission*

*Amendment*

***(v a) Support equal and timely access to new medicines and new therapies , including for supportive and palliative care, for paediatric malignancies, across Europe, and foster the availability of such medicines and treatments in child-friendly doses and formulations;***

Or. en

## Amendment 80

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

*Text proposed by the Commission*

*Amendment*

***(v b) Support implementing policies, national programmes and guidelines to overcome inequalities in access to essential therapies and medicines, supportive and palliative care of paediatric cancers across Europe;***

Or. en

## Amendment 81

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

*Text proposed by the Commission*

*Amendment*

***(vi a) Establishment and implementation of personalised screening programmes for cancer survivors, in particular for paediatric cancer survivors;***

Or. en

## Amendment 82

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

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

## Amendment 83

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

*Text proposed by the Commission*

(viii) Actions supporting the quality of life of cancer survivors and care givers;

*Amendment*

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

Or. en

## Amendment 84

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

*Text proposed by the Commission*

(ix) Support to the implementation of the Union's tobacco control policy and legislation;

*Amendment*

(ix) Support to the implementation of the Union's tobacco control policy and legislation, ***and other related legislation in the area of prevention;***

Or. en

## Amendment 85

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

*Text proposed by the Commission*

*Amendment*

***(ix a) Actions to support a coordinated, multi-disciplinary and patient-centred approach regarding cancer patients and survivors, in particular in the area of paediatric cancer;***

Or. en

## Amendment 86

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

*Text proposed by the Commission*

(x) Establishment and support of a mechanisms for cross-specialty capacity building and continuous education in the area of cancer care.

*Amendment*

(x) Establishment and support of a mechanisms for cross-specialty capacity building and continuous education ***of healthcare professionals and informal carers*** in the area of cancer care, ***in particular to improve the quality of care.***

Or. en

## Amendment 87

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

*Text proposed by the Commission*

*Amendment*

***(x a) Establishment and support of a mechanism for cross-specialty capacity building and continuous education and training of healthcare professionals in the area of cancer screening and early diagnosis, in particular in the area of paediatric cancer;***

Or. en

## Amendment 88

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

*Text proposed by the Commission*

*Amendment*

***(x b) Actions that promote complementary therapies in oncology exercised by authorised professionals.***

Or. en

## Amendment 89

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

*Text proposed by the Commission*

(ii) Support actions to fight vaccine hesitancy;

*Amendment*

(ii) Support actions to fight vaccine hesitancy **and promote immunization across the lifespan of people**;

Or. en

## Amendment 90

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

*Text proposed by the Commission*

*Amendment*

**(ii a) Support tools and platforms to collect real-world evidence on the safety, effectiveness and impact of vaccines after use;**

Or. en

## Amendment 91

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

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

## Amendment 92

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

*Text proposed by the Commission*

*Amendment*

***(iv a) Support action to strengthen the regulatory framework in the Union to encourage the discovery and development of innovative medicines and vaccines to meet increasing healthcare challenges, including new therapies and medicines for cancer, paediatric cancer and related supportive and palliative care;***

Or. en

## Amendment 93

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

*Text proposed by the Commission*

*Amendment*

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

***(v) Action to address market failures with regard to antibiotics and encourage sustainable investments for the discovery and development of new antimicrobials;***

Or. en

## Amendment 94

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

*Text proposed by the Commission*

*Amendment*

***(v a) Action to sustain a strong intellectual property framework, incentives and reward mechanisms for R&D, in order to attract investments in the Union for the development of the next***

*generation of medicines, vaccines and medical devices;*

Or. en

#### **Amendment 95**

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

*Text proposed by the Commission*

(x) Support action to foster international regulatory convergence on medicines and medical devices.

*Amendment*

(x) Support action to foster international regulatory convergence on medicines, ***vaccines*** and medical devices.

Or. en

#### **Amendment 96**

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

*Text proposed by the Commission*

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

*Amendment*

(ii) Support ***investments for*** the digital transformation of health care and health systems including through benchmarking and capacity building for the uptake of innovative tools and technologies; ***support and implement*** digital upskilling of health care ***professionals as part of a strategy on the health workforce***;

Or. en

#### **Amendment 97**

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

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 98**

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

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 99**

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

*Text proposed by the Commission*

*Amendment*

**(iv) Communication aimed at addressing fake news regarding medical therapies, or causes of diseases**

Or. en



## Amendment 100

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

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

## Amendment 101

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

*Text proposed by the Commission*

*Amendment*

***II a. Implementation of new procedures for accelerated development and assessment of medicines for major public health needs, taking into account novel technologies***

Or. en

## Amendment 102

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

*Text proposed by the Commission*

*Amendment*

***II b. Number of new orphan authorisations, Advanced Therapy Medicinal Products, Paediatric Use Medicinal Products or vaccines, for unmet needs***

### **Amendment 103**

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

*Text proposed by the Commission*

*Amendment*

***1 a. Number of Member States with improved health infrastructure***

Or. en

### **Amendment 104**

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

*Text proposed by the Commission*

*Amendment*

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

Or. en

### **Amendment 105**

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

*Text proposed by the Commission*

*Amendment*

***6 a. Age-standardised five-year net survival of paediatric cancer***

Or. en

## **Amendment 106**

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

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

## **Amendment 107**

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

*Text proposed by the Commission*

*Amendment*

**7 a. Ratio of palliative care admissions and outcome result for cancer and paediatric cancer**

Or. en

## **Amendment 108**

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

*Text proposed by the Commission*

*Amendment*

**7 b. Ratio between the number of Cancer Registries and the number of Member States reporting information on paediatric cancer stage at diagnosis**

Or. en

## Amendment 109

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

*Text proposed by the Commission*

*Amendment*

**8 a. Drug and substance use prevalence**

Or. en

## Amendment 110

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

*Text proposed by the Commission*

*Amendment*

**8 b. Obesity prevalence**

Or. en

## Amendment 111

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

*Text proposed by the Commission*

*Amendment*

**8 c. Infant mortality rate**

Or. en

## Amendment 112

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

*Text proposed by the Commission*

*Amendment*

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

9. Number of shortages of medicines in the **Member States**

**Amendment 113**

**Proposal for a regulation  
Annex II – part B – point 10 a (new)**

*Text proposed by the Commission*

*Amendment*

***10 a. Number of new antimicrobials  
authorized***

Or. en

**Amendment 114**

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

*Text proposed by the Commission*

*Amendment*

***12 a. Deaths attributable to health  
associated infections***

Or. en

## EXPLANATORY STATEMENT

### *Introduction*

On 28 May 2020, the Commission put forward a new stand-alone 9.4 billion EUR EU4Health Programme for 2021-2027 as part of the Recovery Plan, which has been a long-standing request of ENVI, to build resilient health systems in the EU by tackling cross-border health threats, making medicines available and affordable, and strengthening health systems. The Health Programme was under the initial MFF 2021-2027 proposal an integral part, as one of strands, of the European Social Fund Plus (ESF+).

The aim of the new Programme proposed by the Commission is to make sure that the EU remains the healthiest region in the world and has all possible tools available to address health challenges at national and EU level and is better prepared for any new emerging health threat that may endanger the population of the EU. The EU4Health Programme provides for new actions, which will fill in gaps that the COVID-19 pandemic has revealed in terms of the development and manufacturing of medicinal products, the adequate supply of medicines and equipment in hospitals and sufficient medical human resources, the uptake of digital tools and services that enable continuity of care, and the need to maintain access to essential goods and services in times of crisis. This will allow the EU to have more tools to take quick, decisive and coordinated action with the Member States in both preparing for and managing crises.

The Commission proposed an ambitious stand-alone EU4Health Programme to provide dedicated support for the health challenges ahead as identified in the needs assessment. Under this proposal, funding for the new Programme in the amount of EUR 9.4 billion will be a major reinforcement as compared to previous proposals under the ESF+ (EUR 413 million). The Programme will be funded from the upcoming MFF (EUR 1.7 billion) and Recovery Instrument (now called the “Next Generation EU”) (EUR 7.7 billion).

### *Rapporteur’s views*

The Rapporteur welcomes the Commission proposal for a stand-alone EU4Health Programme, with significantly increased budget, compared to its predecessor. He reiterates that only a separate and robust Programme will have the capacity to deliver on future pandemics and health threats, and very importantly, make EU health systems more resilient, able to face current weaknesses, such as medicine shortages, health inequalities and support health sector in the digital transition.

At the same time, the Rapporteur considers it important that the EU4Health Programme is more than just a response to the COVID-19 crisis. It should deliver not only on short-term crisis management but also on long-term objectives. It should be part of a common plan for action to support health policies in the EU over the next seven years. The Programme is an important element in ensuring the development of strong and resilient health systems in Member States in order to be able to cope with a possible second wave of COVID-19 and any other future health crises; at the same time, the Programme should also support Member States’ health systems and public health policies to address long-term challenges, such as antimicrobial resistance, ageing, communicable and non-communicable diseases, and at the same time prepare for emerging technologies.

Also, it should be noted that the majority of the EUR 9.4 billion health budget is frontloaded, meaning that there is a need for clear and focused objectives, thus this proposals will need to be very well structured and concrete.

Bearing in mind the above, the Rapporteur considers that **the Commission proposal for the EU4Health Programme should be reinforced** in the following main aspects:

- More **investment into the healthcare systems** is needed, in particular in infrastructure, including at the level of primary care, to work towards the long-term strengthening of health systems, well beyond the current health challenges.
- There is a need for concrete and clear proposals for the **frontloading**, including shifting the funds to better healthcare, equal access to healthcare and resilient health systems.
- All actions of the Programme should have a **person-centred and outcome-based health approach**, with the focus on prevention, individual's specific healthcare needs taking into account the patient's own goals in treatment alongside the provider's best clinical expertise in the topic as a medical professional.
- **Health inequalities** need to be at the core of the Programme, taking into account the fact that they are avoidable inequalities in health between groups of people within countries and between countries, and that they arise from inequalities within and between societies. Inequalities in health status among population groups, countries and regions, and access to affordable, preventive and curative health care of good quality are also among major challenges in the areas of health security and health systems impeding their overall functioning.
- The Programme should have better focus on **disease prevention** throughout the lifetime of an individual and **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, the consumption of illicit drugs and psychoactive substances, obesity and unhealthy dietary habits, and physical inactivity. Disease prevention and health promotion should be the lead general objective of the Programme.
- The Programme should support investments into **early diagnosis and screening** in order to strengthen the prevention and screening for both communicable and non-communicable diseases, such as cardiovascular diseases, neurodegenerative diseases, respiratory diseases, diabetes, cancer and paediatric cancer.
- The Programme should support the development of the **Electronic European Health Record** that would provide health care systems with means to improve the availability and quality of healthcare, and patients to get access to treatment more rapidly and easily.
- The Commission should develop guidelines on patient safety, and promote investments in modernizing health systems to overcome and reduce to minimum, **Healthcare Associated Infections** (HAIs), taking into account the fact that HAIs can happen in any health care facility, including hospitals, ambulatory surgical centres, end-stage renal disease facilities, and long-term care facilities.
- There is a need for European guidelines for the **management of chronic diseases**, namely

in form of **European Diseases Management Guidelines** sectorial for each disease, communicable and non-communicable diseases, such as cancer. In addition, there is a need for the reinforcement of existing **European Reference Networks (ERNs)** and their extension in the form of **Excellence Networks in the field of communicable and non-communicable diseases**.

- It is important to reinforce the role and functioning of EU agencies, such as the European Centre for Disease Prevention and Control (**ECDC**) and the European Medicines Agency (**EMA**).
- It should be ensured that the EU4Health Programme creates synergies and complementarities with other Programmes, for the establishment and implementation of a **Strategy for the Health Workforce** with the aim of improving the curricula of health professionals and their digital skills, the health service coverage and quality of health, but also with the aim of addressing the brain drain and unbalanced mobility.
- It is also important to have a **governance mechanism to ensure complementarity, coordination and synergies** between the EU4Health Programme and other EU funding instruments and programmes, such as the Enhanced Union Civil Protection Mechanism (UCPM/rescEU), the European Regional Development Fund (ERDF), the European Social Fund Plus (ESF+), Horizon Europe, the Digital Europe programme (DEP) and the Connecting Europe Facility Programme 2 Digital (CEF Digital). The Programme should also significantly contribute to the reinforcement of **patient's rights** in the EU as rights of everyone to the enjoyment of the highest attainable standard of physical and mental health, and foster the full implementation of the **Cross-border Healthcare Directive**, guaranteeing a high level of public health protection while respecting the principle of the free movement of persons within the internal market.
- A **EU4Health Steering Board** should be created with a focus on creating synergies between the Programme and other programmes where a health dimension is integrated, through coordination and cooperation, promoting patients and society engagement, and providing scientific advice and recommendations.
- In order to ensure effective governance and active participation of Member States it is important to involve **Member States and the Steering Board better** in the implementation of the Programme, including in the adoption and implementation of annual working programmes.
- **Mental health and ageing**. Most of EU countries are currently facing a major demographic challenge. The implications are yet to be calculated – but governments and policy-makers already agree that we will soon have to make important changes in how we deal with the growing number of elderly people who ask for adequate support and demand and deserve full participation in our societies. The Programme should therefore support Member States efforts in areas such as early diagnosis, treatment, support and prevention, training of practitioners in mental health or awareness raising and ensuring that mental health issues of elderly people are better known and properly addressed.
- Finally yet importantly, **vaccine hesitancy** which, according to the ECDC, refers to delay in acceptance or refusal of vaccines despite availability of vaccination services, and which



is complex and context specific varying across time, place and vaccines, is another important challenge in health care where the Programme should focus on. The WHO declared vaccine hesitancy, including complacency and lack of confidence and convenience, one of ten threats to global health in 2019. The Programme should therefore support action aimed at ensuring equitable access to vaccines for all EU citizens, fighting disinformation, and improving vaccine confidence.

### ***Conclusion***

The Rapporteur considers that the Commission proposal for the stand-alone EU4Health Programme is a good basis for Parliament as co-legislator to work on and formulate its position in a speedy manner (the Regulation establishing the Programme will be apply as of 1 January 2021). The Rapporteur has identified, after listening attentively to the views of different stakeholders, a number of areas where the Commission proposal needs to be clarified or further reinforced in order to ensure the best possible Health Programme for European citizens.