



2020/0102(COD)

4.9.2020

OPINION

of the Committee on Budgets

for the Committee on the Environment, Public Health and Food Safety

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))

Rapporteur for opinion: Nicolae Ștefănuță

PA_Legam

SHORT JUSTIFICATION

The crisis have shown that one of the lessons to draw from this Covid-19 pandemic is to build an ambitious EU Health Fund/Programme. Never again we want to experience the shortages of medical equipment. Never again should healthcare workers be put in the position to choose which patients receive life-saving equipment. The Covid-19 pandemic is the context to agree that there is a need for a stronger coordination and cooperation between the different national health systems. It is about responding to the calls of our citizens to have a more active role for the EU in the area of health.

The European Parliament has often times discussed, put this forward this issue, and only small steps were taken forward, not even using to the maximum the limited possibilities offered by the Treaties. The pandemic showed that if one national health system is fragile, or less resilient, it could have an impact for the entire EU.

The Rapporteur therefore welcomes the Commission proposal for this EU4Health Programme. It is a historic game changer, when we are looking at the ambition and the philosophy of the programme. We finally received a self-standing programme at a relevant scale. Still, according to a communication from the Commission, the Covid-19 pandemic showed a need for at least 70 billion Euro for investments in health infrastructure¹.

The Commission proposes 3 general objectives, and 10 specific objectives. Annex I indicates 50 possible type of eligible actions. The expectation is that this tool-box should strengthen the resilience of the health systems in all the Member States. The rapporteur therefore proposes a wide and balanced geographical coverage of the actions.

The size of the budget is considerably increased compared to the original health strand budget within the proposed ESF+. Nonetheless, the biggest share of financial allocation is proposed to come as external assigned revenues from the Next Generation EU (NGE) and is to be frontloaded in the first years. For the rapporteur, two things seem sure. First, the proposed overall amount is a minimum if we want to respond to the citizens expectations and to the well-known weaknesses of our health systems amplified by the pandemic. And second, the need for an ambitious EU Health programme will remain also after 2024.

Considering that the European Parliament as budgetary authority has formally no power to decide on the amount of the NGE budget, the Rapporteur therefore proposes in his draft opinion to increase the resources stemming from the MFF.

As regards the funding, governance, and implementation of the Programme, the Rapporteur understands that the Commission has worked on this proposal under extreme time pressure, he nevertheless believes that the proposed enormous flexibility should not prejudice principles of good governance, involvement of the European Parliament, transparency and accountability. He therefore proposes to strengthen the synergies and complementarity with other EU bodies, programmes and funds, notably through the creation of a reliable and efficient mechanism that would help to avoid any duplication of funding and ensure synergies. He also calls for a reinforcement of the mandates and budgets of the EU agencies dealing with health objectives. Moreover, he insists as well on the importance of the

¹https://ec.europa.eu/info/sites/info/files/economy-finance/assessment_of_economic_and_investment_needs.pdf

evaluation of this Programme and its audit. The proposed amendments seek to clarify these aspects and are intended to make the proposal also clearer and more predictable for the stakeholders as well as clearly ensure the EU added value of such a Programme.

AMENDMENTS

The Committee on Budgets calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to take into account the following amendments:

Amendment 1

Proposal for a regulation Recital 7 a (new)

Text proposed by the Commission

Amendment

(7a) The Programme should support the creation of permanent common European Medical emergency units, under the name of EU Blue Medical Corps. This new corps should be composed of medical and emergency intervention professionals from different Member States and the medical emergency units should be in charge of providing support for cross-border and pan-European medical situations or crisis. The EU Blue Medical Corps should use the positive outcomes of the voluntary mobility of medical staff financed by the EU Civil Protection Mechanism.

Amendment 2

Proposal for a regulation Recital 10

Text proposed by the Commission

Amendment

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

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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 Council¹⁰ and other relevant mechanisms and structures established at Union level. This could include strategic stockpiling of essential medical supplies or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

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

Amendment 3

Proposal for a regulation Recital 10 a (new)

Text proposed by the Commission

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 Council¹⁰ and other relevant mechanisms and structures established at Union level. This could include strategic stockpiling of essential medical supplies, ***in addition to the reactive reserve created under rescEU during the Covid-19 pandemic*** or capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the “One Health” approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention, preparedness and response.

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

Amendment

(10a) Considering that an ambitious EU4Health programme should continue in place also after Next Generation EU and after the Multiannual Financial Framework for the years(2021-2027, it would be important to go further, towards

achieving an European Health Union which could give the Union a far stronger role in the area of health by providing a European strategy and a coordinated and inclusive response to public health needs. The continuation of the Programme even after 2027 should be taken into consideration, following an assessment report approved by the European Parliament, since its continuation would help consolidate its results.

Amendment 4

Proposal for a regulation

Recital 11

Text proposed by the Commission

(11) As in the time of health crisis emergency health technology assessment as well as clinical trials can contribute to the rapid development of medical countermeasures the Programme should provide support to facilitate such actions. The Commission has adopted a proposal¹¹ on Health Technology Assessment (HTA) to support cooperation on health technology assessment at Union level.

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

Amendment

(11) As in the time of health crisis emergency health technology assessment as well as clinical trials can contribute to the rapid development of medical countermeasures the Programme should provide support to facilitate such actions. The Commission has adopted a proposal¹¹ on Health Technology Assessment (HTA) to support cooperation on health technology assessment at Union level. ***When adopted HTA should give clearance for new medical devices and medicines to enter the market once they have passed clinical trials, as well as offer guidance and support for researchers by laying down requirements for clinical trials, thereby limiting the need for a new product to undergo clinical trials in all Member States.***

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

Amendment 5

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, chronic diseases, **heart diseases, lung diseases, cancer and autism**, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups.

Amendment 6

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. ***It has highlighted, in particular, the Union's dependency on third countries for manufacturing capacity, the supply of active pharmaceutical ingredients and starting materials.*** The Programme therefore should provide support to actions which foster the production, procurement and management of crisis relevant products ensuring complementarity with other Union instruments.

Amendment 7

Proposal for a regulation Recital 14

Text proposed by the Commission

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

Amendment

(14) In order to minimise the public health consequences of serious cross-border threats to health it should be possible for actions supported under the Programme to cover coordination of the activities which strengthen the interoperability and coherence of Member States' health-systems through benchmarking, cooperation and exchange of best practices and ensure their capability to respond to health emergencies, that includes contingency planning, preparedness exercises and the upskilling of health care and public health staff and the establishment of mechanisms for the efficient monitoring and needs-driven **and equitable** distribution or allocation of goods and services needed in time of crisis. ***In order to pursue the EU4Health programme's objectives and to strengthen the synergies and complementarity between the European Centre for Disease Prevention and Control and other Union bodies, the Commission should broaden the Centre's mandate and increase its budget.***

Amendment 8

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

Amendment

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

transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide new care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs and ensure an efficient public health workforce equipped with the right skills, including digital skills. The development of a European health data space would provide health care systems, researchers and public authorities with means to improve the availability and quality of healthcare. Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006¹² 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.

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

Amendment 9

Proposal for a regulation

Recital 17

Text proposed by the Commission

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

which advance digital transformation of health services and increase their interoperability, ***implementing the EU Telematics Strategy on digitalisation of medical products and medicine***, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide new care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs and ensure an efficient public health workforce equipped with the right skills, including digital skills. The development of a European health data space would provide health care systems, researchers and public authorities with means to improve the availability and quality of healthcare. Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006¹² 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.

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

Amendment

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

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

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Amendment 10

Proposal for a regulation

Recital 18

Text proposed by the Commission

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

Amendment

(18) ***Health promotion and health prevention are vastly more cost-efficient than treatment, both in terms of money and of quality-adjusted life years.*** 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 **and in line with the Paris Agreement and the Union's climate neutrality objectives.**

Amendment 11

Proposal for a regulation

Recital 20

Text proposed by the Commission

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

Amendment

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

and funds, such as the enabling conditions under ERDF and ESF+.

Amendment 12

Proposal for a regulation

Recital 22

Text proposed by the Commission

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

Amendment

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

Amendment 13

Proposal for a regulation

Recital 23

Text proposed by the Commission

(23) As the optimal use of medicines and antimicrobials in particular yields benefits for individuals and health systems, the Programme should promote their prudent and efficient use. In line with the European One Health Action Plan against Antimicrobial Resistance¹⁴, adopted in June 2017 following the request from Member States, and given the experience with the bacterial secondary infections

Amendment

(23) As the optimal use of medicines and antimicrobials in particular yields benefits for individuals and health systems, the Programme should promote their prudent and efficient use. In line with the European One Health Action Plan against Antimicrobial Resistance¹⁴, adopted in June 2017 following the request from Member States, and given the experience with the bacterial secondary infections

related to COVID 19, it is essential that the Programme supports actions aimed at the prudent use of antimicrobials in humans, animals and crops, in the framework of an integrated policy on patient safety and prevention of medical errors.

related to COVID 19, it is essential that the Programme supports actions aimed at the prudent use of antimicrobials in humans, animals and crops, in the framework of an integrated policy on patient safety and prevention of medical errors. ***The Programme funding should be based on actions that are traceable, setting Union-wide reduction targets for antibiotics and medicine use, and should support the research and development of new antibiotics.***

¹⁴ Communication from the Commission to the Council and the European Parliament ‘A European One Health Action Plan against Antimicrobial Resistance (AMR)’, COM(2017)0339 final of 29.6.2017.

¹⁴ Communication from the Commission to the Council and the European Parliament ‘A European One Health Action Plan against Antimicrobial Resistance (AMR)’, COM(2017)0339 final of 29.6.2017.

Amendment 14

Proposal for a regulation Recital 25

Text proposed by the Commission

(25) The Union health legislation has an immediate impact on public health, the lives of citizens, the efficiency and resilience of the health systems and the good functioning of the internal market. The regulatory framework for medical products and technologies (medicinal products, medical devices and substances of human origin), as well as for tobacco legislation, patients’ rights in cross-border healthcare and serious cross-border threats to health is essential to health protection in the Union. The Programme therefore should support the development, implementation and enforcement of Union health legislation and provide high quality, comparable and reliable data to underpin policymaking and monitoring.

Amendment

(25) The Union health legislation has an immediate impact on public health, the lives of citizens, the efficiency and resilience of the health systems and the good functioning of the internal market. The regulatory framework for medical products and technologies (medicinal products, medical devices and substances of human origin), as well as for tobacco legislation, patients’ rights in cross-border healthcare and serious cross-border threats to health is essential to health protection in the Union. The Programme therefore should support the development, implementation and enforcement of Union health legislation, ***working in conjunction with key partners such as the European Medicines Agency and the European Centre for Disease Prevention and Control***, and provide high quality, comparable and reliable data to underpin

policymaking and monitoring.

Amendment 15

Proposal for a regulation Recital 29

Text proposed by the Commission

(29) The types of financing and the methods of implementation under this Regulation should be chosen on the basis of their ability to achieve the specific objectives of the actions and to deliver results, taking into account, in particular, the costs of controls, the administrative burden, and the expected risk of non-compliance. This should include consideration of the use of lump sums, flat rates and unit costs, as well as financing not linked to costs as envisaged in Article 125(1) of the Financial Regulation.

Amendment

(29) The types of financing and the methods of implementation under this Regulation should be chosen on the basis of their ability to achieve the specific objectives of the actions and to deliver results, taking into account, in particular, the costs of controls, the administrative burden, and the expected risk of non-compliance. This should include consideration of the use of lump sums, flat rates and unit costs, as well as financing not linked to costs as envisaged in Article 125(1) of the Financial Regulation. ***Those details should be specified in the work programmes.***

Amendment 16

Proposal for a regulation Recital 30

Text proposed by the Commission

(30) In order to optimise the added value and impact from investments funded wholly or in part through the budget of the Union, synergies should be sought in particular between the Programme for the Union's action in the field of health and other Union programmes, including those under shared-management. To maximise those synergies, key enabling mechanisms should be ensured, including cumulative funding in an action from the Programme for the Union's action in the field of health and another Union programme, as long as such cumulative funding does not exceed

Amendment

(30) In order to optimise the added value and impact from investments funded wholly or in part through the budget of the Union, synergies should be sought in particular between the Programme for the Union's action in the field of health and other Union programmes, including those under shared-management ***and the Union agencies***. To maximise those synergies, key enabling mechanisms should be ensured, including cumulative funding in an action from the Programme for the Union's action in the field of health and another Union programme, as long as such

the total eligible costs of the action. For that purpose, this Regulation should set out appropriate rules, in particular on the possibility to declare the same cost or expenditure on a pro-rata basis to Programme for the Union's action in the field of health and another Union programme.

cumulative funding does not exceed the total eligible costs of the action. For that purpose, this Regulation should set out appropriate rules, in particular on the possibility to declare the same cost or expenditure on a pro-rata basis to Programme for the Union's action in the field of health and another Union programme ***and should require that detailed and transparent reporting be carried out.***

Amendment 17

Proposal for a regulation Recital 30 a (new)

Text proposed by the Commission

Amendment

(30 a) In order to ensure that each of these objectives is implemented at the Union level, the Commission should increase the budget and should submit a proposal to strengthen the mandates of the Union agencies, such as the European Centre for Disease Prevention and Control, the European Medicines Agency, the European Food Safety Authority, the European Chemicals Agency, and the European Agency for Safety and Health at Work, which are already pursuing some of the EU4Health objectives at their level, and should have a greater role in the governance of the EU4Health Programme.

Amendment 18

Proposal for a regulation Recital 31

Text proposed by the Commission

Amendment

(31) Given the specific nature of the objectives and actions covered by the Programme, the respective competent authorities of the Member States are best

(31) Given the specific nature of the objectives and actions covered by the Programme, the respective competent authorities of the Member States are best

placed in some cases to implement the related activities. Those authorities, designated by the Member States themselves, should therefore be considered **to be** identified beneficiaries for the purpose of Article 195 of the Financial Regulation and the grants be awarded to such authorities without prior publication of calls for proposals.

placed in some cases to implement the related activities **if it is well justified in the work programmes**. Those authorities, designated by the Member States themselves, should therefore be considered **to be** identified beneficiaries for the purpose of Article 195 of the Financial Regulation and the grants be awarded to such authorities without prior publication of calls for proposals.

Amendment 19

Proposal for a regulation

Recital 33

Text proposed by the Commission

(33) Given the common agreed values of solidarity towards equitable and universal coverage of quality health services as a basis for the Union's policies in this area and that the Union has a central role to play in accelerating progress on global health challenges¹⁹, the Programme should support the Union's contribution to international and global health initiatives with a view to improve health, address inequalities and increase protection against global health threats.

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

Amendment

(33) Given the common agreed values of solidarity towards equitable and universal coverage of quality health services as a basis for the Union's policies in this area and that the Union has a central role to play in accelerating progress on global health challenges¹⁹, the Programme should **in a manner that complements and achieves synergies y with other relevant Union programmes and using the potential added value of the Union and national agencies specialised in health**, support the Union's contribution to international and global health initiatives with a view to improve health, address inequalities and increase protection against global health threats.

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

Amendment 20

Proposal for a regulation

Recital 42

Text proposed by the Commission

(42) The implementation of the Programme should be such that the responsibilities of the Member States, for the definition of their health policy and for the organisation and delivery of health services and medical care, are respected.

Amendment

(42) The implementation of the Programme should be such that the responsibilities of the Member States, for the definition of their health policy and for the organisation and delivery of health services and medical care, are respected **and evidenced. In order to help with the implementation of the Programme, technical assistance should be provided to Member States in need so as to ensure adequate geographical coverage for the implementation of the Programme.**

Amendment 21

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

Amendment

(43) Given the nature and potential scale of cross-border threats to human health, the objective of protecting people **living** 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.

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 22

Proposal for a regulation

Article 3 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

The Programme shall pursue the following general objectives ***of contributing to a high level of human health protection and disease prevention***, in keeping with the “One Health” approach where relevant ***and guided by Sustainable Development Goals (SDG) to ensure that the Union and Member States reach the targets of SDG 3 "Ensure healthy lives and promote well-being for all at all ages"***:

Amendment 23

Proposal for a regulation

Article 3 – paragraph 1 – point -1 (new)

Text proposed by the Commission

Amendment

(-1) making healthcare safer, reducing health inequalities, increasing life expectancy at birth, and strengthening and supporting Union health-related legislation, including in the area of environmental health, and fostering Health in All Policies;

Amendment 24

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) ***contribute to effectiveness, accessibility and resilience of*** 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 25

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

Text proposed by the Commission

Amendment

The Programme shall maximise Union added value by focusing on objectives and actions that can only be effectively achieved by Member States if they act in cooperation as opposed to acting alone;

Amendment 26

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

Text proposed by the Commission

Amendment

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

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

Amendment 27

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(1 a) support the implementation of the European Electronic Health Record programme in all Member States in order to make health data easily transferable from one Member State to another.

Amendment 28

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 ***strategic*** reserves or stockpiles of crisis relevant products, and a reserve of medical, healthcare and support staff to be mobilised in case of a crisis;

Amendment 29

Proposal for a regulation

Article 4 – paragraph 1 – point 4

Text proposed by the Commission

Amendment

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

(4) strengthen the effectiveness, accessibility, sustainability and resilience of health systems, including by supporting digital transformation, the uptake of digital tools and services, systemic reforms, implementation of new care models and universal health coverage, and address inequalities in health ***and in access to healthcare and medicine; ensuring standardised data that can be easily transferred and shared between national health systems of Member States.***

Amendment 30

Proposal for a regulation

Article 4 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The objectives of Article 4 shall be achieved in a consistent and transparent way and in a manner that is coordinated with the actions of other Union programmes and agencies.

Amendment 31

Proposal for a regulation

Article 5 – paragraph 1

Text proposed by the Commission

Amendment

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

1. The financial envelope for the implementation of the Programme for the period 2021-27 shall be EUR **10 398 000 000** in current prices (**EUR 9 370 000 000 in constant prices**).

Amendment 32

Proposal for a regulation

Article 5 – paragraph 2

Text proposed by the Commission

Amendment

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

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

Amendment 33

Proposal for a regulation

Article 6 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

These amounts shall primarily be used to support actions that can strengthen the resilience of national health systems in the regions most affected by the Covid-19 crisis and in the regions with the least resilient health systems.

Amendment 34

Proposal for a regulation

Article 7 – paragraph 1 – point 1 a (new)

Text proposed by the Commission

Amendment

(1 a) The contributions of all associated countries shall be included in the relevant parts of the Programme. The Commission shall report to the Council and the Parliament during the annual budgetary procedure the total budget of each part of the Programme, identifying each of the associated countries, individual contributions and their financial balance.

Amendment 35

Proposal for a regulation

Article 8 – paragraph 2

Text proposed by the Commission

Amendment

2. The Programme may provide funding in any of the forms laid down in Regulation (EU, Euratom) 2018/1046, in particular grants, prizes and procurement.

2. The Programme may provide funding in any of the forms laid down in Regulation (EU, Euratom) 2018/1046, in particular grants, prizes and procurement. ***The Commission shall seek to achieve effective and balanced geographical coverage across the Union, including by supporting Member States to increase the quality of the projects through capacity***

building.

Amendment 36

Proposal for a regulation Article 8 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. The resources from Next generation EU shall be targeted and benefit the Member States most affected by the Covid-19 pandemic and that have the least resilient health systems, while seeking to achieve overall balanced geographical coverage.

Amendment 37

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

Text proposed by the Commission

Amendment

4 a. The Commission shall facilitate the consistent implementation of the EU4Health Programme while seeking maximal administrative simplification. The Commission and the Member States shall, commensurate to their respective responsibilities, foster synergies and ensure effective coordination between the EU4Health programme and the other EU programmes and funds.

For that purpose, they shall:

(a) ensure that there is complementarity, synergy, coherence and consistency among different instruments at Union, national and, where appropriate, regional levels, in particular in relation to measures financed by Union funds, both in the planning phase and during implementation;

(b) optimise coordination mechanisms to

avoid duplication of effort;
(c) ensure that close cooperation exists between those responsible for implementation at Union, national and, where appropriate, regional levels to deliver coherent and streamlined support actions under the instrument.

Amendment 38

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

Text proposed by the Commission

Amendment

4b. The Commission shall develop cooperation with relevant international organisations such as the United Nations and its specialised agencies, in particular the World Health Organisation (WHO), as well as with the Council of Europe and the Organisation for Economic Co-operation and Development (OECD) when implementing the Programme, in order to maximise the effectiveness and efficiency of actions at Union and international level.

Amendment 39

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

Text proposed by the Commission

Amendment

4c. The Commission shall consult the health authorities of the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases or in other relevant Commission expert groups as well as stakeholders, in particular professional bodies in the health sector and NGOs active in the field, at all stages of the implementation of the Programme .

Amendment 40

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

Text proposed by the Commission

Amendment

2 a. Beneficiaries from countries with weak administrative capacity may request technical assistance in order to ensure that there is a fair opportunity to be awarded the grants to all the projects.

Amendment 41

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

Text proposed by the Commission

Amendment

The Commission shall create reliable and efficient mechanism in order to avoid any duplication of funding and to ensure synergies between the different Union programmes and policies that are pursuing health objectives. All the data on funding operations and actions financed under different Union programmes and funds shall be centralised under this mechanism. It shall follow the principles of transparency, traceability and accountability and shall allow better monitoring and evaluation of actions pursuing health objectives.

Amendment 42

Proposal for a regulation Article 13 – paragraph 1

Text proposed by the Commission

Amendment

Only actions implementing the objectives referred to in Articles 3 and 4, including those set out in Annex I, shall be eligible

Actions implementing the objectives referred to in Articles 3 and 4, including those set out in Annex I, shall be eligible

for funding.

for funding. *Actions not listed in Annex I shall only be eligible on an exceptional basis if work programmes specifically justify the need for them.*

Amendment 43

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

Text proposed by the Commission

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

Amendment

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

Amendment 44

Proposal for a regulation Article 14 – paragraph 3

Text proposed by the Commission

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

Amendment

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

Amendment 45

Proposal for a regulation Article 14 – paragraph 5

Text proposed by the Commission

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

Amendment

5. Under the Programme, direct grants may be awarded without a call for proposals to fund actions **if such grants are duly justified, if they have** a clear Union added value **and if they are** co-financed by the competent authorities that are responsible for health in the Member States or in the third countries associated to the Programme, relevant international health organisations or by public sector bodies and non-governmental bodies,

those competent authorities.

acting individually or as a network,
mandated by those competent authorities.

Amendment 46

Proposal for a regulation Article 16 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Amendment 47

Proposal for a regulation Article 18 – paragraph 1

Text proposed by the Commission

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

Amendment

The **Commission** shall **adopt delegated acts in accordance with Article 19 in order to supplement this Regulation by establishing** work programmes referred to in Article 110 of Regulation (EU, Euratom) 2018/1046. **Those** work programmes shall set out **in particular the details of the actions envisaged including the amounts provided for, the types and geographical location of the expected beneficiaries, the types of financing and the methods of implementation under this Regulation,** **and** where applicable, the overall amount reserved for blending operations.

Amendment 48

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

Text proposed by the Commission

Amendment

1 a. The Commission shall monitor continuously the management and implementation of the Programme. In order to enhance transparency, the constantly updated data on the management and implementation shall be made publicly available in an accessible manner on the Commission's website.

In particular, data for projects funded shall be included in the same database. Those data shall include:

(a) information on the types of financing and the types of beneficiaries, that allows for a transparent tracking of the financial allocations; a detailed overview of the synergies with other Union programmes, including the activities implemented by Union agencies, that allows for a proper analysis of the complementarity between different activities to be carried out.

(b) the levels of expenditure disaggregated at project level in order to allow for specific analysis, including per intervention area as defined in Article 13 and Annex I.

Amendment 49

Proposal for a regulation Article 19 – paragraph 3

Text proposed by the Commission

Amendment

3. The performance reporting system shall ensure that data for monitoring programme implementation and results are collected efficiently, effectively, and in a timely manner. To that end, proportionate reporting requirements shall be imposed on recipients of Union funds and, where

3. The performance reporting system shall ensure that data for monitoring programme implementation and results are collected efficiently, effectively, and in a timely manner **without increasing the administrative burden for beneficiaries.** To that end, proportionate reporting

relevant, on Member States.

requirements shall be imposed on recipients of Union funds and, where relevant, on Member States.

Amendment 50

Proposal for a regulation Article 20 – paragraph 2

Text proposed by the Commission

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

Amendment

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

Amendment 51

Proposal for a regulation Article 20 – paragraph 3

Text proposed by the Commission

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

Amendment

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

Amendment 52

Proposal for a regulation Article 20 – paragraph 4

Text proposed by the Commission

4. The Commission shall communicate the conclusions of the evaluations accompanied by its observations, to the European Parliament, the Council, the European Economic and Social Committee and the Committee of

Amendment

4. The Commission shall **publish and** communicate the conclusions of the evaluations accompanied by its observations **and shall present them** to the European Parliament, the Council, the European Economic and Social Committee

the Regions.

and the Committee of the Regions.

Amendment 53

Proposal for a regulation Article 20 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. The evaluation shall cover at least the following:

(a) qualitative and quantitative aspects of the implementation of the Programme;

(b) efficiency of the use of resources;

(c) the degree to which the objectives of all the measures have been achieved, specifying where possible, results and impacts;

(d) the extent to which synergies between the objectives have been reached and its complementarity with other relevant Union programmes;

(e) the Union added value and long-term impact of the Programme, with a view to taking a decision on the renewal, modification or suspension of some objectives and measures;

(f) the extent to which stakeholders have been involved;

(g) an analysis of the geographical coverage across the Union, as referred to in Article 8, and, if no such coverage is reached, an analysis of the underlying reasons.

Amendment 54

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

Text proposed by the Commission

Amendment

The audit system for the Programme shall ensure an appropriate balance between

trust and control, taking into account administrative and other costs of controls at all levels, especially for beneficiaries. Audit rules shall be clear, consistent and coherent throughout the Programme.

Amendment 55

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

Text proposed by the Commission

Amendment

The audit strategy for the Programme shall be based on the financial audit of a representative sample of expenditure across the Programme as a whole. The representative sample shall be complemented by a selection based on an assessment of the risks related to expenditure. Actions that receive joint funding from different Union programmes shall be audited only once, covering all programmes involved and their respective applicable rules.

Amendment 56

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

Text proposed by the Commission

Amendment

The Commission or funding body may rely on combined system reviews at beneficiary level. Such combined reviews shall be optional for certain types of beneficiaries and shall consist in a systems and process audit, complemented by an audit of transactions, carried out by a competent independent auditor qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC.^{1a} They may be used by the Commission or funding body to verify overall assurance on the sound financial management of expenditure and for

reconsideration of the level of ex-post audits and certificates on financial statements.

^{1a} Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directive 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC (OJ L 157, 9.6.2006, p. 87)

Amendment 57

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

Text proposed by the Commission

Amendment

Audits may be carried out up to two years after the payment of the balance.

Amendment 58

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

Text proposed by the Commission

Amendment

The Commission shall publish audit guidelines with the aim of ensuring that there is reliable and uniform application and interpretation of the audit procedures and rules throughout the duration of the programme.

Amendment 59

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

Text proposed by the Commission

Amendment

(ii) Critical health infrastructure

(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.

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, ***in particular with investment in the least resilient national health systems;***

Amendment 60

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

Text proposed by the Commission

Amendment

(ii a) Support the building of hospitals and basic health infrastructure in the less developed regions of the Union; the Programme should participate in synergy and complementarity with the funds from the cohesion policy;

Amendment 61

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

Text proposed by the Commission

Amendment

(iva) Activities designed to monitor the cumulative health impacts of environmental risk factors, including those arising from contaminants in food, water, air and other sources as well as activities monitoring the health impacts of Union legislation, such as pharmacovigilance and similar;

Amendment 62

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

Text proposed by the Commission

Amendment

(i) Implementation, enforcement,

(i) Implementation, enforcement,

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

monitoring of Union health legislation and action; and technical support to the implementation of legal requirements ***including in the area of environmental health;***

Amendment 63

Proposal for a regulation

Annex I – point d – point i a (new)

Text proposed by the Commission

Amendment

(ia) EU policy-making to foster integrating health in all policies and in particular measures to strengthen the assessment and appropriate management of environmental risks associated with production, use and disposal of medical products;

Amendment 64

Proposal for a regulation

Annex I – point d – point viii

Text proposed by the Commission

Amendment

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

(viii) Networking by non-governmental organisations ***including European level civil society organisations*** and their involvement in projects covered by the Programme;

Amendment 65

Proposal for a regulation

Annex I – point e – point ii

Text proposed by the Commission

Amendment

(ii) Establishment and management of EU reserves and stockpiles of crisis relevant products in complementarity with

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

other Union instruments;

instruments;

Amendment 66

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, ***also including provision of adequate and appropriate information to those concerned, with particular attention being given to people with disabilities;***

Amendment 67

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 ***mitigate*** the collateral health consequences of a health crisis, in particular ***in terms of*** mental health, ***as well as the specific consequences for*** on patients suffering from chronic diseases and ***people with disabilities and*** other vulnerable groups;

Amendment 68

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

Text proposed by the Commission

(vi) Actions to strengthen surge capacity, research, development, laboratory capacity, production and deployment of

Amendment

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

crisis-relevant niche products;

ensuring product availability;

Amendment 69

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

Text proposed by the Commission

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

Amendment

(viii) Actions to support investigation, risk assessment and risk management work on the link between animal health, ***the impact of climate change and biodiversity loss, and other*** environmental factors, and human diseases, including during health crises.

Amendment 70

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

Text proposed by the Commission

(i) Support knowledge transfer actions and Union level cooperation to assist national reform processes towards improved effectiveness, accessibility, sustainability and resilience, in particular to address the challenges identified by the European Semester and to strengthen primary care, reinforce the integration of care and aim at universal health coverage and equal access to healthcare;

Amendment

(i) Support knowledge transfer actions and Union level cooperation to assist national reform processes towards improved effectiveness, accessibility, sustainability and resilience, in particular to address the challenges identified by the European Semester and to strengthen primary care, reinforce the integration of care and aim at universal health coverage and equal access to healthcare; ***in particular in the less developed regions of the Union;***

Amendment 71

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

Text proposed by the Commission

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

Amendment

(ii) Training programmes for medical and healthcare staff, ***accessibility to***

temporary exchanges of staff;

information on new care models, digital transformation, tools and services and programmes for temporary exchanges of staff;

Amendment 72

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

Text proposed by the Commission

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

Amendment

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

Amendment 73

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

Text proposed by the Commission

Amendment

(xiii a) Support cooperation and coordination between Member States for the creation of a European Network for Hospitals Excellence, improving the cross-border treatment for rare diseases and increasing access to treatment for all Union citizens.

Amendment 74

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

Amendment

(ii) Support to the digital transformation of health care and health systems including through benchmarking and capacity building for the uptake of

innovative tools and technologies; digital upskilling of health care professionals;

innovative tools and technologies **and the healthcare literacy of the general population**; digital upskilling of health care professionals;

Amendment 75

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 and bodies, **with full respect for the protection of individuals' data**; develop appropriate governance structures and sustainable, interoperable Union health information systems, as part of the European Health Data Space and strengthen citizens' access to, **management of** and control over their health data;

Amendment 76

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

Text proposed by the Commission

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

Amendment

(iv) Support optimal use of telemedicine/telehealth **by making use of the latest digital technologies available, such as robotics, AI and use of** satellite communication for remote areas, foster digitally-driven organisational innovation in healthcare facilities and promote digital tools supporting citizen empowerment and person-centred care **that limit health-care inequalities**.

Amendment 77

Proposal for a regulation
Annex I – point k

Text proposed by the Commission

(k) Communication and outreach to stakeholders and citizens, in particular:

Amendment

(k) Communication and outreach to stakeholders, ***including European level civil society organisations working on health and health related issues*** and citizens, in particular:

Amendment 78

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

Text proposed by the Commission

Amendment

(iiia) Communication aimed at addressing fake news regarding medical therapies or causes of disease.

PROCEDURE – COMMITTEE ASKED FOR OPINION

Title	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”)
References	COM(2020)0405 – C9-0152/2020 – 2020/0102(COD)
Committee responsible Date announced in plenary	ENVI 17.6.2020
Opinion by Date announced in plenary	BUDG 17.6.2020
Rapporteur Date appointed	Nicolae Ștefănuță 18.6.2020
Discussed in committee	13.7.2020
Date adopted	1.9.2020
Result of final vote	+: 37 –: 1 0: 2
Members present for the final vote	Rasmus Andresen, Clotilde Armand, Robert Biedroń, Anna Bonfrisco, Olivier Chastel, Lefteris Christoforou, David Cormand, Paolo De Castro, José Manuel Fernandes, Eider Gardiazabal Rubial, Alexandra Geese, Valentino Grant, Elisabetta Gualmini, Francisco Guerreiro, Valérie Hayer, Eero Heinäluoma, Niclas Herbst, Monika Hohlmeier, Mislav Kolakušić, Moritz Körner, Joachim Kuhs, Zbigniew Kuźmiuk, Hélène Laporte, Pierre Larroustourou, Janusz Lewandowski, Margarida Marques, Siegfried Mureșan, Victor Negrescu, Andrey Novakov, Jan Olbrycht, Dimitrios Papadimoulis, Karlo Ressler, Bogdan Rzońca, Nicolae Ștefănuță, Nils Torvalds, Nils Ušakovs, Johan Van Overtveldt, Rainer Wieland, Angelika Winzig
Substitutes present for the final vote	Petros Kokkalis

FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

37	+
ECR	Zbigniew KUŹMIUK, Bogdan RZOŃCA, Johan VAN OVERTVELDT
GUE/NGL	Petros KOKKALIS, Dimitrios PAPADIMOULIS
ID	Hélène LAPORTE
NI	Mislav KOLAKUŠIĆ
PPE	Lefteris CHRISTOFOROU, José Manuel FERNANDES, Niclas HERBST, Monika HOHLMEIER, Janusz LEWANDOWSKI, Siegfried MUREȘAN, Andrey NOVAKOV, Jan OLBRYCHT, Karlo RESSLER, Rainer WIELAND, Angelika WINZIG
RENEW	Clotilde ARMAND, Olivier CHASTEL, Valérie HAYER, Moritz KÖRNER, Nicolae ȘTEFĂNUȚĂ, Nils TORVALDS
S&D	Robert BIEDROŃ, Paolo DE CASTRO, Eider GARDIAZABAL RUBIAL, Elisabetta GUALMINI, Eero HEINÄLUOMA, Pierre LARROUTUROU, Margarida MARQUES, Victor NEGRESCU, Nils UŠAKOVS
VERTS/ALE	Rasmus ANDRESEN, David CORMAND, Alexandra GEESE, Francisco GUERREIRO

1	-
ID	Joachim KUHS

2	0
ID	Anna BONFRISCO, Valentino GRANT

Key to symbols:

+ : in favour

- : against

0 : abstention