



OPEN-EU | EU4Health Amendments

The 10 leading EU organisations that make up the multistakeholder Obesity Policy Engagement Network - EU (OPEN-EU) welcome the European Commission's 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 (EU4Health Programme). We are particularly encouraged by the emphasis on doing as much as possible to **forge resilient health systems across the EU, with a focus on better health outcomes across major chronic diseases and by leveraging EU regional expertise, infrastructure and competences.**

However, we are increasingly concerned that a significant realignment between scientific evidence, **person-centric infrastructure**, and related policy-making is urgently needed in order for the EU to successfully meet its obligations and aspirations under the EU4Health Programme and more broadly under the Sustainable Development Goals; particularly Goal 3.4 which aims to:

"By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being."¹

Although it comes at a time of public health crisis where obesity has emerged as one of the high risk pre-existing chronic diseases which can negatively impact COVID-19 prognosis, we very much welcome the growing trend at EU Member State level to **recognize obesity as a chronic relapsing disease and enact legislation and National Plans to this effect.** The added value of the **EU adopting a framework harmonisation role** moving forwards cannot be emphasised enough.

Portugal in 2000, **Italy** in 2019 and most recently **Germany in July 2020** have all brought in legislative packages to treat obesity as a chronic relapsing disease with related legal status and all that it entails for better health outcomes for the 80 million Europeans currently living with obesity. The European Parliament submitted three Motions for either a Written Declaration or Resolution during the 2014-2019 Mandate calling for increased action.²

¹ <https://www.who.int/sdg/targets/en/>

² The Motion for a European Parliament resolution on obesity as a health problem and a chronic disorder (B8-0681/2016) as well as the Written Declaration submitted under Rule 136 of the Rules of Procedure on the recognition of obesity as a chronic disease (P8_DCL(2016)0037) and Written declaration on obesity as a health problem (P8_DCL(2015)0051)

Now is the time to act. Germany provides the most forward-thinking and “joined up approach” to date by placing effective treatment of obesity as a gateway chronic disease as a bedrock of tertiary prevention in their comprehensive type 2 diabetes national strategy for prevention and treatment.

Now is the time to take decisive action to stem the tide of obesity, the **4th biggest direct cause of premature mortality in the EU every year** and a gateway chronic relapsing disease to 80% of Type 2 Diabetes and onset of 20% of cancers. Now is the time to act to spread the financial burden of chronic disease in Europe.

Obesity is a chronic relapsing disease defined as “dysfunctional or excess adiposity that impairs health. The underlying causes of obesity onset range from genetics, mental health disorders and how external environments impact the biology of people living with obesity. Obesity is recognized as a chronic relapsing disease by both the World Health Organisation³ and the European Medicines Agency.⁴

Our combined recommendations, as encapsulated in the OPEN-EU Policy Position Paper in addendum to this document, demonstrate that with very few adjustments, the EU4Health Programme can be a powerful tool to convincingly address the prevention of Type 2 Diabetes, certain cancers and over 200 other complications of obesity. By including obesity in the list of chronic relapsing diseases, the obesity pandemic can finally be properly addressed. As such, we have made some suggestions in existing amendments as to how this can be achieved from a practical perspective and by leveraging already identified instruments and approaches for the other named chronic diseases.

In light of national developments, we have also suggested a precise new amendment which specifically aligns the science with Public Health Policies at EU level and would provide a legal basis for sustained action at EU, National and regional levels.

From a practical perspective, to stand a chance of properly addressing obesity OPEN-EU partners advocate as follows:

In the short term and for COVID-19 Preparedness Plans:

1. In light of the current COVID-19 crisis, consideration should be taken into account for appropriate **supplies suitable for diagnosing and treating high risk groups such as those who have severe obesity (ICU equipment, PPE, bariatric medical devices).**
2. In addition, the EU could consider releasing **guidance on the safe and secure reopening of obesity treatment centres**, in order to begin addressing the backlog for vital preventative surgeries and to provide people living with the care and support that they need.

In the medium and longer term:

3. In order to preserve the long-term resilience of EU population health and healthcare systems, there needs to be a clear care pathway for people living with obesity, focusing on primary, secondary and tertiary prevention. **The EU should support national plans on Obesity** in order to tackle this ongoing obesity pandemic as a matter of priority.

³ WHO. World Health Organ Tech Rep Ser. 2000;894:i-xii, 1-253

⁴ European Medicines Agency.

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2016/07/WC500209942.pdf

4. An integral element of such a harmonised framework at EU level should be the inclusion of obesity as a chronic relapsing disease defined as ***“dysfunctional or excess adiposity that impairs health. The underlying causes of obesity onset range from genetics, mental health disorders and how external environments impact the biology of people living with obesity.”***

Amendment 2	
Proposal for a regulation Recital 6	OPEN-EU's Amendment
While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States 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 crossborder threats to health and to safeguard the health and well-being of people in the Union.	While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States and regions 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 crossborder threats to health and to safeguard the health and well-being of people in the Union.
Proposal for a regulation Recital 6 a (new)	OPEN-EU's 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.	(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 such as obesity, cancer, cardiovascular diseases and diabetes , or disease prevention, in promoting a healthy lifestyle, and preparing their health systems for emerging technologies.
Amendment 5	
Proposal for a regulation Recital 10	OPEN-EU's Amendment
(10) Due to the serious nature of crossborder 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	(10) Due to the serious nature of crossborder 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

<p>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 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 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.</p>	<p>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 creating strategic reserves of essential medical Supplies, specialised nutrition 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 and particularly across all high risk pre-existing medical conditions with strong inputs from regional levels and Centres of Excellence/ ERNs</p>
Amendment 6	
Proposal for a regulation Recital 12	OPEN-EU’s Amendment
<p>(12) With a view to protect people in vulnerable situations, including those suffering from mental illnesses, noncommunicable 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. <i>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</i></p>	<p>(12) With a view to protect people in vulnerable and COVID-19 high risk situations, including those suffering from mental illnesses, noncommunicable diseases and chronic diseases, such as obesity, cancer, diabetes and cardiovascular disease, respiratory and related complications, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups. <i>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</i></p>

<p><i>ensuring that access to healthcare services is provided to chronic patients.</i> ○</p>	<p><i>telemedicine, at-home administration of medication and implementation of preventative and self-care plans, where possible and appropriate, while ensuring that access to healthcare and related community-based services is provided to chronic patients</i></p>
<p>Amendment 7</p>	
<p>Proposal for a regulation Recital 13</p>	<p>OPEN-EU's Amendment</p>
<p>(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.</p>	<p>(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.</p> <p>Consideration should also be taken into account for appropriate supplies suitable for diagnosing and treating high risk groups such as those who have severe obesity (ICU equipment, PPE, bariatric medical devices), cardiovascular or respiratory disease or diabetes</p>
<p>Proposal for a regulation Recital 14 a (new)</p>	<p>OPEN-EUs amendment</p>
<p>The evaluation by the Commission of Directive 2011/24/EU of the European Parliament and the Council 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,</p>	<p>2011/24/EU of the European Parliament and the Council 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</p>

<p>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</p>	<p>implementation of Directive 2011/24/EU, building on the example of cross-border cooperation in healthcare in border regions, guaranteeing a high level of public health protection while respecting the principle of the free movement of persons within the internal market</p>
<p>Amendment 9</p>	
<p>Proposal for a regulation Recital 15</p>	<p>OPEN-EUs amendment</p>
<p>(15) Experience from the COVID-19 crisis has indicated that there is a general need for the support to structural transformation of and systemic reforms of health systems across the Union to improve their effectiveness, accessibility and resilience. In the context of such transformation and reforms, the Programme should promote, in synergy with the Digital Europe Programme, actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide new care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs and ensure an efficient public health workforce equipped with the right skills, including digital skills. The development of a European health data space and of a European Electronic Health Record would provide health care systems, researchers and public authorities with means to improve the availability and quality of healthcare. Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of</p>	<p>(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 primary, secondary and tertiary health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention (primary, secondary and tertiary) and health promotion, to provide new outcomes based care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs and ensure an efficient public health workforce equipped with the right skills, including digital skills. The development of a European health data space and of a European Electronic Health Record would provide health care systems, researchers and public authorities with means to improve the availability and quality of healthcare. Given the fundamental right to</p>

<p>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.</p>	<p>access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006 the Programme should support actions ensuring the universality and inclusivity of health care, meaning that no one is barred access to health care, and those ensuring that patients’ rights, including on the privacy of their data, are duly respected.</p>
<p>Amendment 11</p>	
<p>Proposal for a regulation Recital 15 b</p>	<p>OPEN-EU’s amendment</p>
<p>Health systems providing adapted healthcare services for patients with multiple conditions, from integrated healthcare, including prevention, to continuum care services, are personcentred. The Programme should therefore provide support for the transition from disease-centred healthcare to personcentred healthcare, for integration of healthcare services and continuum care, and should also support health system reforms that lead to outcome-based healthcare</p>	<p>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 value-based healthcare and outcomes measurement</p>
<p>Amendment 14</p>	
<p>Proposal for a regulation Recital 17</p>	<p>OPEN-EUs Amendment</p>
<p>(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and behavioural <i>risk</i> factors. Such noncommunicable diseases as cardiovascular diseases, cancer, chronic respiratory diseases,</p>	<p>(17) The onset of Non-communicable and chronic diseases can be caused by any or a combination of genetic, physiological, external environmental and psychological factors. Such noncommunicable diseases as obesity,</p>

<p>and diabetes, represent major causes of disability, ill-health, healthrelated 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 noncommunicable 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.</p>	<p>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 noncommunicable 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.</p>
<p>Amendment 16</p>	
<p>Proposal for a regulation Recital 17 b (new)</p>	<p>OPEN-EUs Amendment</p>
<p>(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 noncommunicable 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.</p>	<p>(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 noncommunicable 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, dieticians and practitioners involved in the treatment of gateway diseases such as obesity 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</p>

	healthcare services.
Amendment 17	
Proposal for a regulation Recital 18	OPEN-EUs Amendment
<p>(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 healthrelated 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.</p>	<p>(18) The Programme therefore should contribute to primary, secondary and tertiary 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, 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, personalised nutritional care and promotion of health education. The Programme should also strengthen and support EU healthrelated 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. In the case of chronic diseases such as obesity where primary prevention has been addressed, we need to focus more on secondary and tertiary prevention.</p>

Amendment 18	
Proposal for a regulation Recital 18 a new	OPEN-EUs Amendment
<p>(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 noncommunicable diseases, such as cardiovascular diseases, neurodegenerative diseases, respiratory diseases and diabetes.</p>	<p>(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 effectively treating gateway chronic disease such as obesity while other chronic conditions, 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 and Regions 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 noncommunicable diseases, such as circulatory diseases, cancer, respiratory diseases, obesity, neuro degenerative diseases and mental illness along the life course.</p>
Amendment 19	

Proposal for a regulation Recital 19	OPEN-EUs Amendment
<p>(19) Cancer is the second leading cause of mortality in the Member States after cardiovascular diseases. It is also one of non-communicable diseases that share common risk factors and the prevention and control of which would benefit the majority of citizens. In 2020 the Commission announced the ‘Europe’s Beating Cancer Plan’ which would cover the entire cycle of the disease starting from prevention and early diagnosis to treatment and quality of life of patients and 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.</p>	<p>(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 gateway diseases such as obesity for 20% of cancers and the prevention and control of which would benefit the majority of citizens. In 2020 the Commission announced the ‘Europe’s Beating Cancer Plan’ which would cover the entire cycle of the disease starting from 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.</p>
Proposal for a regulation Recital 19.d NEW	OPEN-EUs Amendment NEW
	<p>(19d) Obesity is the 4th largest direct cause of premature mortality in the EU, and a gateway chronic relapsing disease to 80% of Type 2 Diabetes and onset of 20% of cancers. Obesity affects 80 million Europeans and has been recognised as one of the high risk pre-existing chronic diseases which can negatively impact COVID-19 prognosis, demonstrating a clear threat to the resilience of European healthcare systems. Obesity must be addressed leveraging the scientific evolution for evidence-based policymaking, and in alignment with international standards and national implementation trends to recognise obesity as a chronic relapsing disease defined as dysfunctional or excess adiposity that impairs</p>

	health.
Amendment 26	
Proposal for a regulation Recital 25	OPEN-EUs Amendment
<p>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, including real-world healthcare data, to underpin policymaking and monitoring</p>	<p>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, including regional data and real-world healthcare and social data, to underpin policymaking and monitoring</p>
Amendment 32	
Proposal for a regulation Article 3 – paragraph 1 – point 2	OPEN-EUs Amendment
<p>(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;</p>	<p>(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 and social care</p>

Amendment 37	
Proposal for a regulation Article 4 – paragraph 1 – point 3 b (new)	OPEN-EU’s Amendment
3b) support actions to transform the health sector into a sector that comprises person-centred and outcome-based care and health systems;	support actions to transform the health sector into a sector that comprises person-centred, value-based health systems and outcomes measurement ;
Amendment 43	OPEN-EU’s Amendment
Proposal for a regulation Article 4 – paragraph 1 – point 6	
(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 ;	(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, including of cancer, obesity, cardiovascular disease, chronic respiratory disease, diabetes and mental health conditions, with the aim of improving the quality of life ;
Amendment 53	
Proposal for a regulation Article 16 a (new)	OPEN-EUs 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	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

<p>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.</p> <p>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.</p> <p>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.</p> <p>5. The members of the Steering Board shall be appointed for the period referred to in the second paragraph of Article 1.</p> <p>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.</p> <p>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</p>	<p>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.</p> <p>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.</p> <p>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.</p> <p>5. The members of the Steering Board shall be appointed for the period referred to in the second paragraph of Article 1.</p> <p>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.</p> <p>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</p>
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<p>synergies between the Programme and other Programmes which comprise a health dimension;</p> <p>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.</p> <p>8. The Commission may consult the Steering Board on matters other than those referred to in paragraph 7.</p>	<p>synergies between the Programme and other Programmes which comprise a health dimension;</p> <p>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.</p> <p>8. The Commission may consult the Steering Board on matters other than those referred to in paragraph 7.</p>
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