

39 EPHA Amendments to the EU4Health Programme proposal:

[2020/0102\(COD\) Programme for the Union's action in the field of health for the period 2021-2027 \("EU4Health Programme"\)](#)

EPHA Amendment Number	European Commission Proposal and its Annexes Draft European Parliament ENVI report	EPHA Amendments
EPHA AM 1.	European Commission 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	<p>European Commission 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 public health –for the period 2021-2027</p> <p>Justification: The EU4 programme goes beyond healthcare systems, it includes wider health prevention and promotion and as such can be the coordinating piece for a comprehensive public health approach of the European Commission</p>
EPHA AM 2.	(5) On 11 March 2020 the World Health Organization (WHO) declared the novel coronavirus (COVID-19) outbreak a global pandemic. That pandemic has caused an unprecedented worldwide health crisis with severe socio-economic consequences and human suffering.	<p>(5) On 11 March 2020 the World Health Organization (WHO) declared the novel SARS-CoV-2 coronavirus and associated respiratory disease (COVID19) outbreak a global pandemic. That pandemic, and more specifically the severe acute respiratory disease causing both premature death and chronic lung conditions that it involves, has caused an unprecedented worldwide health crisis with severe socio-economic consequences and human suffering, <i>particularly affecting people with chronic conditions and hitting the most vulnerable, patients, women, carers and the elderly the hardest.</i> The severity of the crisis demonstrates also the importance of Union action on the management of respiratory <i>and communicable</i> diseases..</p> <p>EPHA analysis and justification: Specifying the respiratory aspects of SARS-CoV2 in the draft report is helpful. However, another helpful addition would be necessary as almost all COVID-19 fatalities had an underlying, other chronic health conditions, and older people were particularly affected.</p>
EPHA AM 3.	(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity (8) . Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States in order to improve the prevention and control of the spread of severe human diseases across borders, to develop and make available products for the prevention and treatment of diseases, to combat other serious cross border threats to health and to safeguard the health and well-being of people in the Union.	(6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity (8) . Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States to support rights- and evidence-based approaches that produce high impact in order to improve the prevention and control of the spread of severe human diseases across borders, to develop and guarantee the availability and accessibility of products for the prevention and treatment of diseases, to combat other serious cross border threats to health and to safeguard the

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		health and well-being of people in the Union.
EPHA AM 4.		<p>NEW (6 a) While the Union's action in the field of health is limited, the Union shall follow a coherent public health strategy in order to flexibly respond to existing epidemics taking into consideration local specificities and have the capacity to face future worrying realities and health threats, such as pandemics and cross-border threats, including antimicrobial resistance and the health impacts of the climate crisis. The Union shall support Member States in reducing health inequalities and in achieving universal health coverage, addressing the challenges of an ageing population, of chronic diseases, or disease prevention, in promoting a healthy lifestyle, equ from a sex, gender and perspective to health and prevention services and preparing their health systems for emerging technologies,₂</p> <p>EPHA analysis:</p> <p>The EU shall go beyond pure crisis management and shall be able to address the underlying causes of poor health outcomes with a strategic approach while not forgetting reducing inequalities.</p>
EPHA AM 5.	(7) It is therefore appropriate to establish a new Programme for the Union's action in the field of health, called EU4Health Programme ('the Programme') for the period 2021 - 2027. In line with the goals of the Union action and its competences in the area of public health the Programme should place emphasis on actions in relation to which there are advantages and efficiency gains from collaboration and cooperation at Union level and actions with an impact on the internal market.	<p>(7) It is therefore appropriate to establish a new Programme for the Union's action in the field of public health, called EU4Health Programme ('the Programme') for the period 2021 - 2027. In line with the goals of the Union action and its competences in the area of public health the Programme should place emphasis on actions in relation to which there are advantages and efficiency gains from collaboration and cooperation at Union level and actions with an impact on the internal market.</p> <p>Justification:</p> <p>The EU4 programme goes beyond healthcare systems, it includes wider health prevention and promotion and as such can be the coordinating piece for a comprehensive public health approach of the European Commission</p>
EPHA AM 6.	(9) In accordance with Regulation [European Union Recovery Instrument] PE653.803v01-00 8/65 PR\1207580EN.docx EN and within the limits of resources allocated therein, recovery and	(9) In accordance with Regulation [European Union Recovery Instrument] and within the limits of resources allocated therein, recovery and resilience measures under the Programme should be

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	<p>resilience measures under the Programme should be carried out to address the unprecedented impact of the COVID-19 crisis. Such additional resources should be used in such a way as to ensure compliance with the time limits provided for in Regulation [European Union Recovery Instrument].</p>	<p>carried out to address the unprecedented impact of the COVID-19 crisis <u>and ensure that resilient and responsive healthcare and public health systems are in place in preparation for future pandemics and other health crises..</u></p> <p>Such additional resources should be used in such a way as to ensure compliance with the time limits provided for in Regulation [European Union Recovery Instrument].</p> <p>Justification: The EU4Health programme goes beyond healthcare systems, it includes wider health prevention and promotion and as such can be the coordinating piece for a comprehensive public health approach of the European Commission.</p>
EPHA AM 7.	<p>(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.</p>	<p>(12) With a view to protect people in vulnerable situations, including those suffering from mental illnesses, living with or most affected by communicable or noncommunicable diseases and chronic diseases, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to vulnerable groups. With a view to guaranteeing continued high standards of essential healthcare services, including prevention, the Programme should, in particular in times of crisis and pandemics, encourage a transition to accessible and affordable telemedicine, at-home administration of medication and implementation of preventative and self-care plans, where possible and appropriate, while ensuring that access to healthcare and prevention services is provided to chronic patients and patients at risk.</p> <p>Justification: The EU4Health programme shall support those in most need to reduce inequalities. The front-line experience of the Wide EPHA membership from the ground suggested those specifications to better target the unmet needs</p>
EPHA AM 8.	<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</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, affordability and resilience. In the context of such transformation and reforms, the Programme should promote,</p>

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	<p>synergy with the Digital Europe Programme, actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide new care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs and ensure an efficient public health workforce equipped with the right skills, including digital skills. The development of a European health data space would provide health care systems, researchers and public authorities with means to improve the availability and quality of healthcare. Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006 (12) the Programme should support actions ensuring the universality and inclusivity of health care, meaning that noone is barred access to health care, and those ensuring that patients' rights, including on the privacy of their data, are duly respected.</p> <p>12 Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).</p>	<p>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 accessibility, availability, affordability 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 noone is barred access to health care, and those ensuring that patients' rights, including on the privacy of their data, are duly respected.</p> <p>Justification: In addition to the draft report, mentioning accessability and affordability is needed to tackle inequalities in access to healthcare.</p>
EPHA AM 9.	<p>Draft EP report:</p> <p>(15b) 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>EPHA analysis:</p> <p>EPHA can not support this addition as a comprehensive public health approach and providing healthcare for all shall be the overall principle which prevails over personalised healthcare.</p>
EPHA AM 10.	<p>Draft EP report:</p> <p>(16) Keeping people healthy and active longer and empowering them to take an active role in managing their health will have positive effects on health, health inequalities, quality of life, productivity, competitiveness and inclusiveness, while reducing pressures on</p>	<p>EPHA analysis:</p> <p>EPHA can not support this addition as the focus shall be on health and not on innovation which itself is not a guarantee of better health outcomes.</p>

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	<p>national budgets. Support for, and recognition of, innovation, which has an impact on health, help in taking up the challenge of achieving sustainability in the health sector in the context of also addressing the challenges of demographic change. Moreover, action to reduce inequalities in health is important for the purposes of achieving 'inclusive growth'. The Commission has committed to help Member States to reach the sustainable development targets set in the 'UN 2030 Agenda for Sustainable Development' in particular Sustainable Development Goal 3 "Ensure healthy lives and promote wellbeing for all at all ages".(13) The Programme therefore should contribute to the actions taken towards reaching these goals.</p> <p>13 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Next steps for a sustainable European future. European action for sustainability COM (2016) 739 final of 22.11.2016.</p>	
EPHA AM 11	<p>(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental and behavioural factors. Such noncommunicable 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 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>(17) Non-communicable diseases are a result of commercial determinants of health, a combination of genetic, physiological, environmental, social and behavioural factors. Such noncommunicable 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 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>Justification: Useful approach to use the WHO on commercial determinants of health terminology here.</p>
EPHA AM 12.		<p>(17a) The role of primary prevention and health promotion is key to address long term, common European challenges such as non-communicable and communicable diseases, ageing and cross-border health threats such as future pandemics, and</p>

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		<p>antimicrobial resistance. The Union can bring additional added-value to offer a overall public health strategy based on identified best practices and the European dimension of identified health challenges in the area of access to healthcare, health prevention and promotion in order to reduce health inequalities and health differences in Europe.</p> <p>Justification: European answer is needed for challenges which need a common approach and joint efforts at European level.</p>
EPHA AM 13	<p><i>Amendment 17</i></p> <p><i>(18) The Programme therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health risk and behavioural risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of illicit drugs and psychoactive substances. The Programme should also contribute to the reduction of drugs-related health damage, obesity and unhealthy dietary habits, physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme therefore should contribute to a high level of human health protection and prevention, throughout the entire lifetime of an individual, including through the promotion of physical activity, nutritional care and promotion of health education. The Programme should also strengthen and support EU health related legislation, including in the area of environmental health, and fostering Health in All Policies. The Programme should also contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.</i></p>	<p>EPHA additional amendments to the draft EP report:</p> <p>18) The Programme therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing commercial determinants of health, such as the use of tobacco and related products and exposure to their emissions, alcohol use, the unhealthy food environment and the consumption of illicit drugs and psychoactive substances. The Programme should also contribute to the reduction of drugs-related health damage, obesity and unhealthy dietary habits, physical inactivity, and exposure to environmental pollution, and foster health supportive environments in order to complement Member States action in these areas. The Programme therefore should contribute to a high level of human health protection and prevention, throughout the entire lifetime of an individual, including through the promotion of physical activity, nutritional care and promotion of health education. The Programme should also strengthen and support EU health related legislation, including in the area of environmental health, and 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>Justification: commercial determinants of health, alcohol use and unhealthy food environment are cornerstones of a public health approach</p>
EPHA AM 14.		<p>NEW (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</p>

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		<p>human suffering and placed an enormous burden on health systems, as well. However, many chronic diseases, such as cardiovascular diseases, cancer, respiratory diseases and type 2 diabetes, could be prevented through access to prevention services, affordability of healthy nutrition and healthy lifestyle, while other illnesses, for instance neurological diseases, can be managed to slow the onset if detected early, or helping patients feel their best and remain active for longer. The Union and the Member States can therefore greatly reduce the burden of Member States by working together to achieve a better and more effective management of diseases, including prevention and the Programme should support actions in this area. The Programme should support the development of specific European Diseases Management Guidelines in the area of both communicable and non-communicable diseases, such as cardiovascular diseases, neurodegenerative diseases, cancer, respiratory diseases and diabetes.</p>
EPHA AM 15.		<p>NEW (18b) The International Agency for Research on Cancer (IARC) considered classified diesel engine exhaust as carcinogenic to humans. The Programm shall make sure that the health impacts and costs of air pollution are integrated into the Union action against cancer, while ensuring full coherence with the European zero emission strategy.</p>
EPHA AM 16	<p>(31) Given the common agreed values of solidarity towards equitable and universal coverage of quality health services as a basis for the Union's policies in this area and that the Union has a central role to play in accelerating progress on global health challenges (19), 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.</p> <hr/> <p>19 Council conclusions on the EU role in Global Health, 3011th Foreign Affairs Council meeting, Brussels, 10 May 2010.</p>	<p>(31) Given the common agreed values of solidarity towards equitable and universal coverage of quality health services as a basis for the Union's policies in this area and that the Union has a central role to play in accelerating progress on global health challenges (19), 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, including tackling greenhouse gas emissions responsible for the health impacts of the climate crisis as well as reducing air pollution globally.</p>
EPHA AM 17		<p>EPHA additional amendments to the EP draft report:</p> <p>(XX) To achieve a coherent implementation of the actions</p>

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		included in the EU4Health programme, a EU4Health Steering Board should be established <i>ensuring appropriate representation of patients, public interest not-for profit public health. organisations</i> . That independent stakeholder group should be responsible, inter alia, for coordination, cooperation in the implementation of the actions, and for creating synergies between the Programme and other programmes which comprise a health dimension.
EPHA AM 18		<p>Article 2 definitions</p> <p>NEW 'Commercial determinant of health' means strategies and approaches used by the private sector to promote products and choices that are detrimental to health.</p> <p>Justification: To bring in line with the EU document with WHO terminology on this: Definition of commercial determinants of health</p> <p>WHO commercial determinants of health Kickbusch I, Allen L, Franz C. The commercial determinants of health. Lancet Glob Health. 2016;4(12):e895–e6.</p>
EPHA AM 19		<p>Article 2 definitions</p> <p>NEW (11) Planetary health: The concept of planetary health is based on the understanding that human health and human civilisation depend on flourishing natural systems and the wise stewardship of those natural systems.</p> <p>Reference: Safeguarding human health in the Anthropocene epoch: report of The Rockefeller Foundation–Lancet Commission on planetary health (2015)</p>
EPHA AM 20.	<p>Article 3 General objectives</p> <p>The Programme shall pursue the following general objectives, in keeping with the "One Health" approach where relevant:</p>	<p>Article 3</p> <p>The Programme shall pursue the following general objectives, in keeping with the "One Health" and "planetary health" approaches where relevant:</p>

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EPHA AM 21.	<p>Article 3</p> <p>Amendment 31 <i>(1) support health promotion and disease prevention, reduce health inequalities, improve physical and mental health, protect people in the Union from serious cross-border threats to health;</i></p> <p>Amendment 32 <i>(2) support existing and future Union health legislation <u>for the protection and promotion of health</u>, 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;</i></p>	<p>Article 3</p> <p>EPHA supports Amendments 31 and 32 of the EP draft report to make sure that the scope of the general objectives are not extremely narrow with some additions</p>
EPHA AM 22.		<p>Article 3</p> <p>NEW (4) To support systematic health impact assessment of other EU policies ensuring a comprehensive, Health in All Policies approach</p>
EPHA AM 23.	<p>Article 4 Specific objectives</p> <p>(5) support actions aimed at strengthening health system's ability to foster disease prevention and health promotion, patient rights and cross-border healthcare, and promote the excellence of medical and healthcare professionals;</p>	<p>(5) support actions aimed at addressing health inequalities and strengthening health system's ability to foster disease prevention, early diagnosis and screening, and implement health promotion, inclusive of mental health, including through the promotion of physical activity, health education, patient rights and cross-border healthcare;</p>
EPHA AM 24.	<p>(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer;</p>	<p>(6) support action, including policy, for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer by providing a European strategic Chronic disease framework to support Member States action addressing the commercial determinants of health;</p>
EPHA AM 25.		<p>NEW (22) Support actions to ensure the implementation of cross-cutting EU policy initiatives aimed at building a</p>

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		sustainable Europe with a high level of human health protection, such as the European Green Deal and its component strategies.
EPHA AM 26.	CHAPTER IV GOVERNANCE <i>Amendment 53</i> Article 16a EU4Health Steering Board	EPHA additional amendments to the EP draft report: <i>NEW. 3a</i> The Steering Board shall focus on creating synergies between the Programme and other Programmes which comprise a health dimension in particular Horizon Europe and its missions and partnerships, through coordination, cooperation and synergies, promoting engagement with patients, civil society organisations and citizens , 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.
EPHA AM 27.	CHAPTER IV GOVERNANCE <i>Amendment 53</i> Article 16a EU4Health Steering Board	EPHA additional amendments to the EP draft report: 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. <i>The candidate to the Steering Board should publish their conflict of interest declaration ahead of the appointment.</i>
ANNEXES to 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")		
EPHA AM 28.		

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	(d) Development and implementation of Union health legislation and action, in particular through support to:	(d) Development and implementation of Union legislation and action for the protection and promotion of health , in particular through support to:
EPHA AM 29.	(d) (i) Implementation, enforcement, monitoring of Union health legislation and action; and technical support to the implementation of legal requirements;	(d) (i) Development , implementation, enforcement, monitoring of Union legislation and action for the protection and promotion of health ; and technical support to the implementation of legal requirements;
EPHA AM 30.		EPHA amendment: (d) NEW(xii) Systematic health impact assessment of other EU policy actions
EPHA AM 31.	(f) Preparedness, prevention and response to cross-border health threats: (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,	(f) Preparedness, prevention and response to cross-border health threats: (iv) Preventive actions to protect vulnerable groups from health threats and actions to adjust the response to and management of crisis to the needs of those vulnerable groups, such as securing basic care for non-communicable and chronic disease; including palliative care and pain management treatment
EPHA AM 32.	<i>Amendment 79</i> <i>(v a) Support equal and timely access to new medicines and new therapies, including for supportive and palliative care, for paediatric malignancies, across Europe, and foster the availability of such medicines and treatments in child-friendly doses and formulations;</i>	EPHA additional amendments to the EP draft report: (v a) Support equal and timely access to <u>truly innovative medicines and therapies</u>
EPHA AM 33.	<i>Amendment 80</i> <i>(v b) Support implementing policies, national programmes and guidelines to overcome inequalities in access to essential</i>	EPHA additional amendments to the EP draft report:

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	<i>therapies and medicines, supportive and palliative care of paediatric cancers across Europe;</i>	(v b) Support implementing policies, national programmes and guidelines to overcome inequalities in access to essential therapies and medicines, supportive and palliative care of paediatric cancers across Europe; <u>including availability and affordability of such health care and service.</u>
EPHA AM 34.	Amendment 90 <i>(ii a) Support tools and platforms to collect real-world evidence on the safety, effectiveness and impact of vaccines after use;</i>	EPHA additional amendments to the EP draft report: <i>(ii a) Support tools and platforms to collect real-world data on the safety, effectiveness and impact of vaccines after use <u>while guaranteeing robust evidence generation in the pre-approval phase</u></i>
EPHA AM 35.	Amendment 91 <i>(iii) Support clinical trials, including those involving increased coordination at Union level and with EMA, to speed up the development, authorisation and access to innovative, safe and effective medicines and vaccines;</i>	EPHA additional amendments to the EP draft report: <i>(iii) Support clinical trials, including those involving increased coordination at Union level and with EMA, to speed up the development, authorisation and access to innovative, safe and effective medicines and vaccines; <u>Support publication of all clinical reports (including CSRs) on the day of marketing authorisation</u></i>
EPHA AM 36.	(v) Support action to encourage the development of innovative products and of less commercially interesting products such as antimicrobials, <u>to address unmet medical needs;</u>	
EPHA AM 37.	Amendment 94 <i>(v a) Action to sustain a strong intellectual property framework, incentives and reward mechanisms for R&D, in order to attract investments in the Union for the development of the next generation of medicines, vaccines and medical devices;</i>	EPHA alternative wording to the EP draft report: <i>(v a) Support actions to implement models of R&D and IP ownership and management which prioritize the public interest and guarantee societal benefit, for example by including binding safeguards to ensure availability, accessibility and affordability of medical products developed with public funds.</i>
ANNEX II INDICATORS FOR THE EVALUATION OF THE PROGRAMME		
EPHA AM 38.	Amendment 101 <i>II a. Implementation of new procedures for accelerated development and assessment of medicines for major public health needs, taking into account novel technologies</i>	EPHA alternative wording to the EP draft report: <i>IIa Review existing fast-track flexibilities in the EU approval framework and support pragmatic clinical trials</i>

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EPHA AM 39.	<i>Amendment 104</i> <i>1 b. Number of Member States that implemented the European Electronic Health Record</i>	EPHA additional amendments to the EP draft report: 1 b. Number of Member States that implemented the European Electronic Health Record <i>while providing stronger guarantees for personal data protection.</i>