

## ECL proposed amendments

Draft Report on

**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) 405 final 2020/0102 (COD)

Rapporteur: Cristian-Silviu Buşoi

### Summary

The [Association of European Cancer Leagues](#) (ECL) warmly welcomes the proposal for the EU4Health programme and the great importance it places on cancer control.

**ECL views the EU4Health programme as the driving force behind the implementation of Europe’s Beating Cancer Plan.** Therefore, it is encouraging to see the resources and objectives outlined in the proposal for the EU4Health programme are compatible with the ambitions we have [articulated for Europe’s Beating Cancer Plan](#).

The COVID-19 crisis has affected all areas of society and created profound challenges for health systems. The considerable resources allocated towards the immediate response and long-term recovery from the crisis are urgently needed and clearly demonstrates the significant value that EU action in public health can yield. Cancer leagues provided suggestions to national governments and European Commission on how to mitigate the impact of the pandemic on cancer care services [here](#).

**However, whilst the proposal can have serious and lasting impact on public health, care should be exercised to avoid diluting the focus and objectives of the programme by attempting to cover too many areas with the available resources. Steps should also be taken to include the appropriate and relevant actors in the implementation of proven evidence-based measures consistent with the programme’s objectives.**

With our amendments to the proposal, ECL would like to highlight the following key points:

- The focus of the specific objective should be to implement proven, effective practice as supported by the best available evidence;
- The general objective of programme should recognise and address health inequalities and health literacy;
- Duplication with other funding programmes at the Union level and with activities already performed by external actors and stakeholders should be avoided;
- The indicators of the programme should be aligned with those agreed upon under the Sustainable Development Goals;
- Conflicts of interest (intellectual, professional and financial) regarding the engagement of stakeholders towards the development of actions supported by the programme should be mitigated as far as is possible.

EP report page	<a href="#">European Commission Proposal</a> and its <a href="#">Annexes</a>	<a href="#">European Parliament report</a>	<b>ECL AMENDMENTS AND COMMENTS</b>
14 & 32		<p>Amendment 11</p> <p><b>(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.</b></p> <p>Amendment 37</p> <p><b>(3b) support actions to transform the health sector into a sector that comprises person-centred and outcome-based care and health systems;</b></p>	<p><b><i>ECL Comment</i></b></p> <p><i>NB. We do not support the EP draft report amendments 11 &amp; 37 as it is very vague and it lacks clarity on what is it trying to achieve. It potentially suggests restructuring of national health systems which is potentially very costly and not within the merit of the EU4Health programme.</i></p>
23-24	<p>Recital</p> <p>(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</p>	<p>Amendment 24</p> <p>(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</p>	<p><b><i>ECL Amendment</i></b></p> <p>(22) The Programme should therefore support actions to monitor, <b>prevent and manage</b> 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</p>

	<p>provide support to clinical trials so as to speed up the development, authorisation and access to innovative and effective medicines, promote incentives to <b>develop such medicinal products</b> as antimicrobials and foster the <b>digital</b> transformation of healthcare products and platforms for monitoring and collecting information on medicines.</p>	<p>and access to innovative and effective medicines <b>and treatment</b>, promote incentives to <b>boost the production capacity</b> for antimicrobials, <b>personalized treatment and vaccination</b>, and foster the <b>digital</b> transformation of healthcare products and platforms for monitoring and collecting information on medicines. <b>The programme should also strengthen decision-making on medicines by enabling access to and analysis of real-world healthcare data by regulators and health technology assessments ('HTA'), bodies.</b> The Programme should also help to ensure best use of research results and facilitate the uptake, scaling-up and deployment of health innovation in healthcare systems and clinical practice. In 2020, the Commission announced the 'Pharmaceutical strategy for Europe' with the overall goal of helping to ensure the Union's supply of safe and affordable medicines to meet patients' needs and support the European pharmaceutical industry's innovation efforts in the Union and globally. The Programme should support the implementation of the Pharmaceutical strategy for Europe.</p>	<p>provide support to <b>clinical and real world evidence generation to enable clinical trials so as to speed up</b> the development, authorisation, <b>evaluation</b> and access to <b>innovative and effective new medicines.</b>, <del>promote incentives to develop such medicinal products as antimicrobials and</del> <b>The programme should</b> foster the digital transformation of healthcare products and platforms for monitoring and collecting information on medicines. <b>The Programme should support the implementation of the new Pharmaceutical Strategy for Europe and the work of the European Medicines Agency (EMA).</b></p> <p><b>Justification:</b> <i>Rather than on 'fast' delivery of 'innovative' treatments, the programme should focus on collection and delivery of robust evidence and supporting access to high quality treatments for patients. There is evidence that many new and personalised medicines are referred to as 'innovative', yet, they fail to deliver improved outcomes for patients compared to well established more affordable interventions. The EU must ensure that new medicines coming to the market are both effective and safe. Any use of incentives should first and foremost be evaluated to prevent obstacles in terms of unaffordability and misuse of public investment (affordability and return on public investment needs to be guaranteed).</i></p>
27	<p>The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council<sup>16</sup> are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. As the Networks can improve the access to diagnosis and the provision of high-</p>	<p>Amendment 28  (27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council (16) are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. <b>ERNs are a ground-breaking platform that</b></p>	<p><b>ECL Comment</b>  <i>NB. Amendment 28 contains unclear suggestions: "The reinforcement of ERNs can play a key role in supporting the adoption of a common newly developed screening framework at Union level, starting from disease selection criteria and mechanisms, with the aim of overcoming</i></p>

	<p>quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider the extension of <b>ERNs beyond rare diseases to</b> communicable and noncommunicable diseases <b>such as</b> cancer</p> <hr/> <p>16 Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).</p>	<p><b>represents a unique opportunity and which, based on the innovative use and sharing of knowledge and health data across borders, aims to improve diagnosis and care for people living with a rare or complex disease. Therefore, the Programme should provide adequate funding to support the coordination and collaborative activities of both existing and future ERNs through grants or other instruments that are fit for purpose. It should upscale current funding to ensure that that ERNs fulfil the objectives set out in their mission.</b> As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should <b>also</b> contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider <b>reinforcing ERNs, supporting the creation of new ERNs to cover infectious diseases, complex pregnancies and rare and complex mental health diseases. The Programme should also consider the extension of the ERNs in form of excellence networks in the field of</b> communicable and non-communicable diseases, <b>including cancer and paediatric cancer. The reinforcement of ERNs can play a key role in supporting the adoption of a common newly developed screening framework at Union level, starting from disease selection criteria and mechanisms, with the aim of overcoming existing inequalities in terms of screening coverage across Member States. The Programme should support the implementation of actions that drive the development and delivery of treatments, screening programmes and European patient registries for rare diseases</b></p> <hr/> <p>16 Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in <b>cross-border healthcare (OJ L 88, 4.4.2011, p. 45).</b></p>	<p><b><i>existing inequalities in terms of screening coverage across Member States."</i></b></p> <p><i>What is referred to by a newly developed screening framework is not defined or understandable. The programme should support on an institutional footing the networking of established cancer organised cancer screening programmes as recommended by the Council recommendation (2003).</i></p> <p><i>Moreover, the EU should evaluate the financial impact of the ERN on the EU4Health programme (how much will it cost) and consider a separated more sustainable funding channel.</i></p>
--	--	--	---

31	<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>(1) protect people in the Union from serious cross-border threats to health;</p> <p>(2) improve the availability in the Union of medicines, medical devices <b>and other crisis relevant products</b>, contribute to their affordability, <b>and</b> support innovation;</p> <p>(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.</p>	<p>Amendment 31 <b>(1) support health promotion and disease prevention, reduce health inequalities, improve physical and mental health</b>, protect people in the Union from serious cross-border threats to health;</p> <p>Amendment 32 <b>(2) support existing and future Union health legislation</b>, improve the availability in the Union of medicines, <b>treatments and</b> medical devices, contribute to their <b>accessibility and</b> affordability, support <b>safe and effective use, and boost research</b> and innovation in healthcare;</p> <p>Amendment 33 (3) strengthen health systems and the healthcare workforce, including by digital transformation, <b>harmonized education and training</b>, and by increased integrated and coordinated work among the Member States, sustained implementation of best practice and <b>comparable</b> data sharing, to increase the general level of public health;</p> <p>Amendment 34 <b>(3a) strengthen health systems so that they become resilient in crises and pandemics, and develop a preparedness plan.</b></p>	<p><b>ECL Amendment</b> <b>(1) support health promotion, health literacy, and disease prevention, reduce health inequalities, improve physical and mental health</b>, protect people in the Union from serious cross-border threats to health;</p> <p><b>Justification:</b> <i>Health literacy is the ability to obtain, read, understand, and use healthcare information in order to make appropriate health decisions. Considering the importance of these factors, the term health literacy should be more explicitly referenced in the text.</i></p>
33-36	<p>Article 4 Specific objectives</p> <p>The general objectives referred to in Article 3 shall be pursued through the following specific objectives, in keeping with the “One Health” approach where relevant:</p> <p>(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</p>	<p>Amendment 35 (2) ensure the availability in the Union of reserves of crisis relevant products, and a reserve of medical, healthcare and support staff to be mobilised in case of a crisis;</p> <p>Amendment 36 <b>(3a) support actions to increase research and development, including through clinical trials, in the Union of crisis-relevant products, and access to and analysis of data from the use of such products in healthcare systems;</b></p>	<p><b>ECL Amendment</b> <b>(5) support actions aimed at addressing health inequalities and strengthening health system’s ability to foster disease prevention, early diagnosis and screening, and implement health promotion, including through the promotion of physical activity, health education-literacy, patient rights and cross-border healthcare;</b></p> <p><b>(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of</b></p>

<p>coordination, provision and deployment of emergency health care capacity, data gathering and surveillance;</p> <p>(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;</p> <p>(3) support actions to ensure appropriate availability, accessibility and affordability of crisis relevant products and other necessary health supplies;</p> <p>(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;</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>(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer;</p> <p>(7) foster and support the prudent and efficient use of medicines, and in particular of antimicrobials, and more environmentally friendly production and disposal of medicines and medical devices;</p>	<p>Amendment 37 <b>(3b) support actions to transform the health sector into a sector that comprises person-centred and outcome-based care and health systems;</b></p> <p>Amendment 38 <b>(4a) support the development and implementation of a European Electronic Health Record;</b></p> <p>Amendment 39 <b>(4b) strengthen the Union's innovation ecosystem to ensure the development and uptake of the next generation of medicines, vaccines and medical devices to meet increasing healthcare challenges and expectations that arise;</b></p> <p>Amendment 40 <b>(4c) enhance the equal and timely access to quality, sustainable and affordable person-centred healthcare and related care services;</b></p> <p>Amendment 41 (5) support actions aimed at <b>addressing health inequalities and</b> strengthening health system's ability to foster disease prevention, <b>early diagnosis and screening, and implement</b> health promotion, <b>including through the promotion of physical activity, health education</b>, patient rights and cross-border healthcare;</p> <p>Amendment 42 <b>(5a) support the creation, development and implementation of a strategy on the health workforce in order to create an effective workforce for public health, which has the same high standards across the Union, and promote the excellence of medical and healthcare professionals;</b></p> <p>Amendment 43 (6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable</p>	<p><i>cancer; <b>The programme should support the implementation of Europe's Beating Cancer Plan;</b></i></p> <p><i>(9) support integrated work among Member States, and in particular their health systems, including the implementation of high-impact prevention practices, and scaling up networking through the European Reference Networks and other transnational networks <b>supporting actions outlined in Annex 1;</b></i></p> <p><b>Justification:</b> <i>Health literacy is the ability to obtain, read, understand, and use healthcare information in order to make appropriate health decisions. Considering the importance of these factors, the term health literacy should be more explicitly referenced in the text. The text should also specifically state the programme will fund the implementation of Europe's Beating Cancer Plan, a key priority of the Commission in the 2019-24 mandate.</i></p> <p><b>ECL Comment</b></p> <p><i>NB. We suggest deletion of Amendment 39 (4b) on innovation ecosystem, which should belong under the umbrella of horizon Europe rather than the health programme, to avoid duplication. In addition, the amendment refers to further support for 'new', rather than 'better quality' products which is concerning in terms of spending of public funds.</i></p> <p><i>Alternatively, we propose this amendment:</i></p> <p><b>(4b) strengthen the Union's innovation research ecosystem to ensure the development and uptake of the next generation of medicines, vaccines and medical devices to meet increasing healthcare challenges and unmet medical need. <del>expectations that arise;</del></b></p>
--	---	--

	<p>(8) support the development, implementation and enforcement of Union health legislation and provide high-quality, comparable and reliable data to underpin policy making and monitoring, and promote the use of health impact assessments of relevant policies;</p> <p>(9) support integrated work among Member States, and in particular their health systems, including the implementation of high-impact prevention practices, and scaling up networking through the European Reference Networks and other transnational networks;</p> <p>(10) support the Union’s contribution to international and global health initiatives.</p>	<p>diseases, <b>including</b> of cancer, <b>cardiovascular disease, chronic respiratory disease, diabetes and mental health conditions, with the aim of improving the quality of life</b></p> <p>Amendment 44 <b>(6a) address the unmet needs of children and adolescents with cancer, and of survivors, through dedicated programmes and plans that enable the ERN on Paediatric Cancer and preexisting research structures to achieve their full potential towards the required level of progress in this under-served area;</b></p> <p>Amendment 45 (9) support integrated work among Member States, and in particular their health systems, including the implementation of high-impact prevention practices, <b>the identification of health technologies meant to benefit from a Union assessment</b>, and scaling up networking through the <b>ERNs</b> and other transnational networks;</p> <p>Amendment 46 <b>(9a) support the implementation of the ERNs registries and cancer registries;</b></p> <p>Amendment 47 <b>(9b) support the creation of excellence networks in the field of communicable and non-communicable diseases;</b></p> <p>Amendment 48 <b>(9c) support the development of specific European diseases management guidelines in the area of both communicable and non-communicable diseases, such as cancer, paediatric cancer, cardiovascular diseases, neurodegenerative diseases, respiratory diseases and diabetes, by excellence networks</b></p>	<p><i>Amendment 48 concerns ongoing activities performed by professional societies so it must be clear that the programme will reinforce or compliment ongoing activities rather than produce duplication or potentially unhelpful competition.</i></p>
37	<p>CHAPTER IV GOVERNANCE Article 16 Joint policy implementation</p>	<p>Amendment 52</p> <p>The Commission shall consult the health authorities of the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of Non-</p>	<p><b><i>ECL Comment</i></b></p> <p><i>NB. We do not support the EP draft report amendments 52 &amp; 53. The establishment of a steering board adds a layer of unnecessary</i></p>

	<p>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.</p>	<p>Communicable Diseases, <b>as well as relevant Union decentralised agencies, the EU4Health Steering Board and other relevant stakeholders, such as representatives of civil society organisations, in particular patients' organisations</b>, on the work plans established for the Programme and its priorities and strategic orientations and its implementation.</p> <p>Amendment 53</p> <p><b>Article 16a EU4Health Steering Board</b></p> <p><b>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.</b></p> <p><b>2. The Steering Board shall focus on creating synergies between the Programme and other Programmes which comprise a health dimension , through coordination, cooperation and synergies, promoting engagement with patients and society , and providing scientific advice and recommendations to the Commission. In exercising its role, the Steering Board shall provide value oriented health actions, sustainability, better health solutions, and shall foster access and reduce health inequalities.</b></p> <p><b>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.</b></p> <p><b>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</b></p>	<p><i>bureaucracy and questionable oversight of the programme with no clear and justifiable benefits for society in what concerns the implementation of actions supported by the programme.</i></p> <p><i>We have great concern about the potential conflicts of interest that could be generated by this proposal and have doubts about the extent to which it is compatible with Union legislation.</i></p> <p><i>Regular, transparent reporting to the European Parliament and continuous open stakeholder engagement, using existing channels, would be sufficient to ensure interaction between civil society, the European Institutions and member states.</i></p>
--	---	---	--

		<p>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:</p> <ul style="list-style-type: none"> <li>i. provide input, in the form of a comprehensive strategy, for developing annual work plans for the Programme, following a proposal from the Commission;</li> <li>ii. elaborate a plan for steering coordination, cooperation and synergies between the Programme and other Programmes which comprise a health dimension;</li> <li>iii. advise the Commission with regard to monitoring and evaluating the Programme, as set out in Articles 19 and 20 respectively.</li> </ul> <p>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><b>ANNEXES</b></p> <p><b>to the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL</b></p> <p><b>on the establishment of a Programme for the Union's action in the field of health –for the period 2021-2027</b></p> <p><b>and repealing Regulation (EU) No 282/2014 (“EU4Health Programme”)</b></p>			
	(g) Strengthen national health systems:	Amendment 65	<b><i>ECL Amendment:</i></b>

<p>(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;</p> <p>(ii) Training programmes for medical and healthcare staff, and programmes for temporary exchanges of staff;</p> <p>(iii) Support to improve the geographical distribution of healthcare workforce and avoidance of ‘medical deserts’;</p> <p>(iv) Support the establishment and coordination of Union Reference Laboratories and Centres, and of Centres of excellence;</p> <p>(v) Audit of Member States preparedness and response arrangements (such as crisis management, antimicrobial resistance, vaccination);</p> <p>(vi) Support upwards convergence of national systems’ performance through indicator development, analysis and knowledge brokering and the organisation of stress tests of national healthcare systems;</p> <p>(vii) Support capacity building for investing in and implementing health system reforms (strategic planning and access to multi-source financing);</p>	<p><b>(ii) Support under the Strategy for the Health Workforce and in synergy with other Programmes, harmonized and standardized training and educational programmes for medical and healthcare staff, and programmes for temporary exchanges of staff, in particular with the aim of improving their curricula and digital skills;</b></p> <p>Amendment 66</p> <p>(iii) Support actions under a strategy on the health workforce to address the decision of qualified health workers to leave their Member State of origin to work elsewhere, improve the geographical distribution of healthcare workforce, avoid ‘medical deserts’ and promote and implement retention policies;</p> <p>Amendment 66</p> <p><b>(iii) Support actions under a strategy on the health workforce to address the decision of qualified health workers to leave their Member State of origin to work elsewhere, improve the geographical distribution of healthcare workforce, avoid ‘medical deserts’ and promote and implement retention policies;</b></p> <p>Amendment 67</p> <p>(iv) Support the establishment and coordination of Union Reference Laboratories and Centres, Centres of Excellence, <b>and Union disease-specific platforms for the exchange, comparison and benchmarking of best practices between Member States;</b></p> <p>Amendment 68</p> <p>(vii) Support capacity building for investing in and implementing health system reforms, <b>including those leading to person-centred and outcome-based transformation</b> (strategic planning and access to multi-source financing);</p>	<p><i>(ix) Support the establishment and implementation of <b>evidence-based</b> programmes assisting Member States and their action to improve health promotion, <b>health literacy</b> and disease prevention (for communicable and non-communicable diseases);</i></p> <p><i>(x) Support Member States’ actions to put in place healthy and safe urban, work and school environments, to enable healthy life choices and promote healthy diets <del>taking into account</del> <b>prioritising the needs of vulnerable groups;</b></i></p> <p><b>Justification:</b> <i>Health literacy acts as a mediator between a determinant of health and the outcomes. Therefore, to reduce inequalities in health, actions can be targeted towards enhancing health literacy in order to improve outcomes.</i></p> <p><i>The programme should be more ambitious towards addressing the needs of vulnerable or excluded groups as a stated priority.</i></p>
--	---	---

<p>(viii) Support capacity building of national systems for the implementation of legislation on substances of human origin, and for the promotion of the sustainable and safe supply of such substances through networking activities;</p> <p>(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);</p> <p>(x) Support Member States' actions to put in place healthy and safe urban, work and school environments, to enable healthy life choices and promote healthy diets taking into account the needs of vulnerable groups;</p> <p>(xi) Support the functioning of the European Reference Networks and the establishment and operation of new transnational networks set out in accordance with Union health legislation, and support Member States' actions to coordinate the activities of these networks with the operation of national health systems;</p> <p>(xii) Support for Member States to strengthen the administrative capacity of their healthcare systems through benchmarking, cooperation and exchange of best practices.</p> <p>(xiii) Support an Union framework and the respective interoperable digital tools for cooperation among Member States and in networks, including those needed to enable Member States to deliver joint clinical assessments and joint scientific consultations to exchange outcomes of HTA cooperation.</p>	<p>Amendment 69</p> <p><b>(ix a) Support the establishment and functioning of excellence networks in the field of communicable and noncommunicable diseases;</b></p> <p>Amendment 70</p> <p><b>(ix b) Support the development and the implementation of the European Disease Management Guidelines in the area of both communicable and noncommunicable diseases, such as cancer, paediatric cancer, cardiovascular diseases, neurodegenerative diseases, respiratory diseases and diabetes.</b></p> <p>Amendment 71</p> <p><b>(xi a) Support Member States in the revision of their rare disease national plans to enact the necessary financial and organisational arrangements to integrate effectively ERNs system into national health systems;</b></p> <p>Amendment 72</p> <p><b>(xi b) Support the implementation of the ERNs' system for continuous assessment, monitoring, evaluation and quality improvement;</b></p> <p>Amendment 73</p> <p><b>(xi c) Earmark funding to create effective and permanent mechanisms to build cross-ERNs collaboration to address the multi-systemic needs of rare diseases and to facilitate cross-cutting networking between different specialities and disciplines, including at the level of the European Reference Network on Paediatric Cancer ;</b></p> <p>Amendment 74</p> <p><b>(xi d) Support Member States in strengthening their centres of expertise for rare diseases to build the national health systems' competencies to diagnose, treat and manage such diseases and at the same time increase</b></p>	
---	---	--

		<p><b>the collective capacity and knowledge of ERNs, including of the ERN PaedCan;</b></p> <p>Amendment 75</p> <p>(xiii) Support a Union framework <b>to strengthen health technology assessment cooperation</b> among Member States <b>in order</b> to enable Member States to deliver, <b>join and exchange timely, reliable and high quality</b> joint clinical assessments scientific consultations <b>and other relevant activities to support decision-makers</b></p> <p>Amendment 76</p> <p><b>(xiii a) Establish the European Electronic Health Record and support its implementation in the Member States;</b></p> <p>Amendment 77</p> <p>(xiii b) Support Member States to improve and further develop and implement ERN registries, cancer registries;</p>	
	<p>(h) Actions on cancer:</p> <p>(i) Support Member States and NGOs in the promotion and implementation of the recommendations of the European Code against Cancer;</p> <p>(ii) Support the establishment of quality assurance schemes for cancer centres;</p> <p>(iii) Support prevention programmes on the main cancer risk factors;</p> <p>(iv) Actions to support secondary prevention of cancer, such as early detection and diagnosis through screening;</p> <p>(v) Actions supporting access to cancer services and to innovative medicines for cancer;</p>	<p>Amendment 78</p> <p>(h) Actions on cancer <b>and paediatric cancer</b></p> <p>Amendment 79</p> <p><b>(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;</b></p> <p>Amendment 80</p> <p><b>(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;</b></p> <p>Amendment 81</p> <p><b>(vi a) Establishment and implementation of personalised</b></p>	<p><b><i>ECL Amendment:</i></b></p> <p><i>(h) Actions on cancer:</i></p> <p><i>(i.a) Support Member States, <b>the International Agency for Research on Cancer (IARC)</b> and NGOs in the promotion and implementation of the recommendations of the European Code against Cancer;</i></p> <p><i>(i.b) Support the revision and continuous update of the current edition of the European Code against Cancer accompanied by a systematic evaluation of the impact of the European Code against Cancer;</i></p>

<p>(vi) Actions supporting the continuity of care (integrated care approaches for prevention, diagnosis, treatment and follow-up care);</p> <p>(vii) Actions supporting quality in cancer prevention and care including diagnosis and treatment;</p> <p>(viii) Actions supporting the quality of life of cancer survivors and care-givers;</p> <p>(ix) Support to the implementation of the Union's tobacco control policy and legislation;</p> <p>(x) Establishment and support of a mechanisms for cross-specialty capacity building and continuous education in the area of cancer care</p>	<p><b>screening programmes for cancer survivors, in particular for paediatric cancer survivors;</b></p> <p>Amendment 82</p> <p>(vii) Actions supporting quality in cancer prevention and care including diagnosis, treatment <b>and palliative care;</b></p> <p>Amendment 83</p> <p>(viii) Actions supporting the quality of life of cancer survivors and care givers, <b>including psychological support, pain management, and professional reintegration;</b></p> <p>Amendment 84</p> <p>(ix) Support to the implementation of the Union's tobacco control policy and legislation, <b>and other related legislation in the area of prevention;</b></p> <p>Amendment 85</p> <p><b>(ix a) Actions to support a coordinated, multi-disciplinary and patient-centred approach regarding cancer patients and survivors, in particular in the area of paediatric cancer;</b></p> <p>Amendment 86</p> <p>(x) Establishment and support of a mechanisms for cross-specialty capacity building and continuous education of <b>healthcare professionals and informal carers</b> in the area of cancer care, <b>in particular to improve the quality of care.</b></p> <p>Amendment 87</p> <p><b>(x a) Establishment and support of a mechanism for cross-specialty capacity building and continuous education and training of healthcare professionals in the area of cancer screening and early diagnosis, in particular in the area of paediatric cancer;</b></p>	<p><i>(iii) Support prevention programmes on the main cancer risk factors <b>that are of demonstrated effectiveness and supported by established evidence;</b></i></p> <p><i>(iv a) Actions to support secondary prevention of cancer, such as <del>early detection and diagnosis through screening;</del> <b>addressing variation of implementation of the European Guidelines for Quality Assurance in cancer screening and improving early diagnosis of cancers for which screening is not yet recommended.</b></i></p> <p><i>(iv b) <b>Ensure the continuous monitoring and evaluation of Council Recommendation on cancer screening (2003) enabling links to the European Cancer Information System and European Network of Cancer Registries.</b></i></p> <p><i>(iv c) <b>Actions to support the implementation of the WHO Global Call for the Elimination of Cervical Cancer.</b></i></p> <p><i>(v) Actions supporting access to cancer services, <b>including psycho-social support, rehabilitation and palliative care,</b> and to <b>both essential medicines and high quality innovative treatments <del>medicines</del> for cancer;</b></i></p> <p><b>Justification:</b> <i>The International Agency for Research on Cancer (IARC) was the scientific coordinator for the 4<sup>th</sup> edition and must be included in efforts to promote, implement, and evaluate the European Code against Cancer.</i></p> <p><i>All actions supported by the programme should focus on implementing proven effective methods supported by the</i></p>
--	--	--

		<p>Amendment 88</p> <p><b>(x b) Actions that promote complementary therapies in oncology exercised by authorised professionals.</b></p>	<p><i>best currently available evidence. Concerning secondary prevention in particular, actions should prioritise the ongoing implementation of already recommended screening programmes (namely breast, cervical and colorectal cancers) and address effective early diagnosis strategies for cancer types not yet recommended for screening, following the guidance of WHO. Horizon Europe should be used to investigate basic and pragmatic research on topics outside of this scope.</i></p> <p><i>NB. Amendment 81 of the draft EP report is of concern and requires further clarification regarding its practical implications: does this concern the return to routine screening programmes for cancer survivors, or is it concerned with long-term follow-up of survivors to identify potential new primary or secondary cancers?</i></p> <p><i>Amendment 88 is of great concern – this must be clearly reviewed to ensure that only evidence-based practice, with demonstrable clinical benefit, are to be supported. “Authorised professionals” should be clarified to ensure this refers to accredited and regulated health professionals.</i></p>
54-55	<p>(i) Actions on medicines, vaccines and medical devices:</p> <p>(i) Support to initiatives to improve vaccination coverage rates in the Member States;</p> <p>(ii) Support actions to fight vaccine hesitancy;</p> <p>(iii) Support clinical trials to speed up the development, authorisation and access to</p>	<p>Amendment 89</p> <p>(ii) Support actions to fight vaccine hesitancy <b>and promote immunization across the lifespan of people;</b></p> <p>Amendment 90</p> <p><b>(ii a) Support tools and platforms to collect real-world evidence on the safety, effectiveness and impact of vaccines after use;</b></p> <p>Amendment 91</p>	<p><b>ECL Amendment</b></p> <p>(iv a) Support action to strengthen the regulatory framework in the Union to encourage the discovery and development of <b>innovative</b> medicines and vaccines to <b>meet the patient and public health needs and guaranteed the efficacy and safety of newly approved products; increasing healthcare challenges,</b></p>

<p>innovative, safe and effective medicines and vaccines;</p> <p>(iv) Support action to ensure greater availability in the Union of medicines and medical devices and contribute to their affordability for patients and health systems;</p> <p>(v) Support action to encourage the development of innovative products and of less commercially interesting products such as antimicrobials;</p> <p>(vi) Support action to monitor shortages of medicines and medical devices occurring in hospitals and community pharmacies, to address such shortages, and to increase security of supplies;</p> <p>(vii) Support actions to encourage the development of innovative medicines and medical devices less harmful for the environment and promote greener manufacturing;</p> <p>(viii) Action to strengthen the environmental risk assessment of pharmaceuticals;</p> <p>(ix) Action to promote the prudent use and disposal of antimicrobials;</p> <p>(x) Support action to foster international regulatory convergence on medicines and medical devices.</p>	<p>(iii) Support clinical trials, <b>including those involving increased coordination at Union level and with EMA</b>, to speed up the development, authorisation and access to innovative, safe and effective medicines and vaccines;</p> <p>Amendment 92 <b>(iv a) Support action to strengthen the regulatory framework in the Union to encourage the discovery and development of innovative medicines and vaccines to meet increasing healthcare challenges, including new therapies and medicines for cancer, paediatric cancer and related supportive and palliative care;</b></p> <p>Amendment 93 (v) Action to <b>address market failures with regard to antibiotics and encourage sustainable investments for the discovery and development of new</b> antimicrobials;</p> <p>Amendment 94 <b>(v a) Action to sustain a strong intellectual property framework, incentives and reward mechanisms for R&amp;D, in order to attract investments in the Union for the development of the next generation of medicines, vaccines and medical devices;</b></p> <p>Amendment 95 (x) Support action to foster international regulatory convergence on medicines, <b>vaccines</b> and medical devices.</p>	<p><del><b>including new therapies and medicines for cancer, paediatric cancer and related supportive and palliative care;</b></del></p> <p>(vi) Support action to monitor, <b>prevent and manage</b> shortages of medicines and medical devices occurring in hospitals and community pharmacies, to address such shortages, and to increase security of supplies;</p> <p>(vii) Support actions to encourage the development of <del><b>innovative</b></del> medicines and medical devices less harmful for the environment and promote greener manufacturing;</p> <p><b>ECL Comment</b></p> <p><i>NB. ECL disagrees with amendment 93 as AMR is a complex issue which cannot be fixed by incentives and generation of new antibiotics alone, it is necessary to take a broad approach and tackle overuse of antibiotics in veterinary medicine, as suggested by point (ix) of the initial text.</i></p> <p><i>ECL further disagrees with amendment 94 and thinks EU4health should focus on improving public health in the EU rather than focus on competitiveness of European industry. There are other mechanisms that can fund such actions within the EU.</i></p>
<p><b>ANNEX II</b> <b>INDICATORS FOR THE EVALUATION OF THE PROGRAMME</b></p>		

	<p>A Programme Indicators</p> <p>I. Quality and completeness of EU and MS preparedness and response planning for serious cross border threats to health</p> <p>II. Access to centrally authorised medicines, e.g. number of orphan authorisations, Advanced Therapy Medicinal Products, Paediatric Use Medicinal Products or vaccines, for unmet needs</p> <p>III. Number of actions and best practices directly contributing to the SDG 3.4/Member State</p> <p>IV. Implementation of best practices by EU Member States</p>	<p>Amendment 100</p> <p>II. Access to centrally authorised medicines, e.g. number of orphan authorisations, Advanced Therapy Medicinal Products, Paediatric Use Medicinal Products or vaccines</p> <p>Amendment 101</p> <p><b>II a. Implementation of new procedures for accelerated development and assessment of medicines for major public health needs, taking into account novel technologies</b></p> <p>Amendment 102</p> <p><b>II b. Number of new orphan authorisations, Advanced Therapy Medicinal Products, Paediatric Use Medicinal Products or vaccines, for unmet needs</b></p>	<p><b>ECL Amendment:</b></p> <p><i>III. Number of actions and best practices directly contributing to the SDG 3.4 &amp; SDG 10/Member State</i></p> <p><i>IV. Implementation of best practices by EU Member States addressing health inequalities [SDG 10]</i></p> <p><b>Justification:</b> <i>To reflect the focus of the programme on addressing inequalities in health supporting the implementation of SDG goals 3.4 and 10.</i></p>
	<p>B <u>The following indicators will also be used to monitor the implementation of the Programme:</u></p> <p>1. Number of Member States with improved preparedness and response planning</p> <p>2. Vaccines, medicines, medical devices and other countermeasures during crises [made available by type and by MS]</p> <p>3. Number of vaccine doses distributed</p> <p>4. Number of entities benefiting of medicines and medical devices</p> <p>5. EU Laboratory capacity index (EULabCap)</p> <p>6. Age-standardised five-year net survival of cervical, breast and colorectal cancer</p> <p>7. Ratio of Cancer Registries (CRs) and number of Member States (MSs) reporting information</p>	<p>Amendment 103</p> <p><b>1 a. Number of Member States with improved health infrastructure</b></p> <p>Amendment 104</p> <p><b>1 b. Number of Member States that implemented the European Electronic Health Record</b></p> <p>Amendment 105</p> <p><b>6 a. Age-standardised five-year net survival of paediatric cancer</b></p> <p>Amendment 106</p> <p>7. Ratio of the number of Cancer Registries (CRs) and number of Member States reporting information on cervical, breast, <b>lung</b> and colorectal cancer stage at diagnosis</p>	<p><b>ECL Amendment:</b></p> <p><i>8. Smoking prevalence among persons Age-standardized prevalence of current tobacco use among persons aged 15 years and older [SDG 3.a.1]</i></p> <p><i>8b. Percentage of adults (aged 18+) classified as overweight or obese</i></p> <p><i>15. Avoidable deaths attributed to cardiovascular disease, cancer, diabetes &amp; chronic respiratory disease for persons aged less than 75 years [SDG 3.4.1]</i></p> <p><i>16. Total alcohol per capita (age 15+ years) consumption [SDG 3.5.2]</i></p>

	<p>on cervical, breast, and colorectal cancer stage at diagnosis</p> <p>8. Smoking prevalence</p> <p>9. Number of shortages of medicines in the single point of contact network</p> <p>10. Access to centrally authorised medicines for unmet needs</p> <p>11. Number of audits conducted in the EU and in third countries to ensure good manufacturing practices and good clinical practices (Union control)</p> <p>12. Deaths attributable to antimicrobial resistant infections</p> <p>13. Number of hospital units involved in ERN and of patients diagnosed and treated by the members of ERN networks</p> <p>14. Number of Health Technology Assessment reports jointly carried out</p>	<p>Amendment 107</p> <p><b>7 a. Ratio of palliative care admissions and outcome result for cancer and paediatric cancer</b></p> <p>Amendment 108</p> <p><b>7 b. Ratio between the number of Cancer Registries and the number of Member States reporting information on paediatric cancer stage at diagnosis</b></p> <p>Amendment 109</p> <p><b>8 a. Drug and substance use prevalence</b></p> <p>Amendment 110</p> <p><b>8 b. Obesity prevalence</b></p> <p>Amendment 111</p> <p><b>8 c. Infant mortality rate</b></p> <p>Amendment 112</p> <p>9. Number of shortages of medicines <b>in the Member States</b></p> <p>Amendment 113</p> <p><b>10 a. Number of new antimicrobials authorized</b></p> <p><b>Amendment 114</b></p> <p><b>12 a. Deaths attributable to health associated infections</b></p>	<p><b>17 a. Population vaccination coverage - HPV vaccination coverage for one dose (females 12-13 years old)</b></p> <p><b>17 b. Population vaccination coverage - HPV vaccination coverage for two doses (females 13-14 years old)</b></p> <p><b>18. Screening coverage (by examination &amp; invitation) for breast, cervical and colorectal cancer screening programmes</b></p> <p><b>Justification:</b> <i>Proposed indicators correspond to those established for the SDGs and include widely accepted and routinely collected indicators at the programme level for screening and vaccination.</i></p> <p><b>NB.</b> <i>Amendment 107 is imprecise and unclear as presently drafted and possibly too difficult to register.</i></p>
--	---	---	--