

GLOBAL HEALTH RESEARCH AND INNOVATION

Leading European Academic Institutions’ Response to Legislative Documents for Horizon Europe

Paragraph	Text proposed by the Commission	Suggested amendment	Importance L, M, H
GENERAL INTRODUCTION TO PROGRAMME ACTIVITIES			
Proposal for a decision Annex I – paragraph 19	Greater impact will be obtained through aligning actions with other nations and regions of the world, within an international cooperation effort of unprecedented scale	Greater impact will be obtained through aligning actions with other nations and regions of the world, <i>including low and middle-income countries</i> , within an international cooperation effort of unprecedented scale. <i>This addition may help including partners from LIMCs, which has been problematic in H2020, despite its open character. We also recommend this addition at various other places, to ensure that participation of partners from low and middle income countries is actively considered.</i>	M
Proposal for a decision Annex I – paragraph 20	International joint action will ensure effective tackling of global societal challenges and Sustainable Development Goals, access to the world's best talents, expertise and resources, and enhanced supply and demand of innovative solutions.	International joint action will ensure effective tackling of global societal challenges and Sustainable Development Goals, access to the world's best talents, expertise and resources, and enhanced supply and demand of innovative solutions. <i>Global solutions to major societal challenges require a multidisciplinary, coordinated, universal effort as well captured within the framework of the Sustainable Development Goals.</i>	M

		<i>It is not just sharing talents, it is planning and executing together.</i>	
PILLAR I			
MARIE SKŁODOWSKA-CURIE ACTIONS (MSCA)			
Annex I – part I – point 2 – point 2.1 – paragraph 1	Europe needs a highly-skilled and resilient human capital base in research and innovation that can easily adapt to and find sustainable solutions for future challenges, such as major demographic changes in Europe. To ensure excellence, researchers need to be mobile, collaborate and diffuse knowledge across countries, sectors and disciplines, with the right combination of knowledge and skills to tackle societal challenges and support innovation.	Europe needs a highly-skilled and resilient human capital base in research and innovation that can easily adapt to and find sustainable solutions for future challenges, such as major demographic changes in Europe and in the world . To ensure excellence, researchers need to be mobile, collaborate and diffuse knowledge across countries, sectors and disciplines, with the right combination of knowledge and skills to tackle societal challenges and support innovation. <i>Demographic changes do not occur isolated in Europe, they are interlinked with the rest of the world, specifically emerging economies and LMIC</i>	M
Annex I – part I – point 2 – point 2.2 – paragraph 1	The EU must remain a reference for excellent research and thus attractive for the most promising researchers, European and non-European alike, at all stages of their careers. This can be achieved by enabling researchers and research-related staff to move and collaborate between countries, sectors and disciplines and thus benefit from high-quality training and career opportunities. This will facilitate career moves between the academic and nonacademic sector as	The EU must remain a reference for excellent research and thus attractive for the most promising researchers, European and non-European alike, including from low- and middle-income countries , at all stages of their careers. This can be achieved by enabling researchers and research-related staff to move and collaborate between countries, sectors and disciplines and thus benefit from high-quality training and career opportunities. This will facilitate career moves between the academic and	L

	well as stimulate entrepreneurial activity.	nonacademic sector as well as stimulate entrepreneurial activity.	
Annex I – part I – point 2 – point 2.2 – point 2.2.3 – paragraph 2 – indent 2	Cooperation, production and diffusion of knowledge within the EU and with third countries.	Cooperation, production and diffusion of knowledge within the EU and with third countries, <i>including low and middle-income countries.</i>	M
PILLAR II			
GLOBAL CHALLENGES AND INDUSTRIAL COMPETITIVENESS			
Annex I – part II – paragraph 2	Greater impact can be obtained through aligning actions with other nations and regions of the world within an unprecedented international cooperation along the lines indicated by the Sustainable Development Goals and the Paris climate agreement. Based on mutual benefit, partners from across the world will be invited to join EU efforts as an integral part of research and innovation for sustainability.	Greater impact can be obtained through aligning actions with other nations and regions of the world, <i>including low and middle-income countries,</i> within an unprecedented international cooperation along the lines indicated by the Sustainable Development Goals and the Paris climate agreement. Based on mutual benefit, partners from across the world will be invited to join EU efforts as an integral part of research and innovation for sustainability.	M
CLUSTER ‘HEALTH’			
Annex I – part II – point 1 – point 1.1 – paragraph	Health research and innovation research and innovation have played a significant part in this achievement but also in improving productivity and quality in the health and care industry. However, the EU continues to face novel, newly emerging or persisting challenges that are	Health research and innovation research and innovation have played a significant part in this achievement but also in improving productivity and quality in the health and care industry. However, the EU continues to face novel, newly emerging or persisting challenges that are threatening its citizens and public health, the sustainability of its	M

	<p>threatening its citizens and public health, the sustainability of its health care and social protection systems, as well as the competitiveness of its health and care industry. Major health challenges in the EU include: the lack of effective health promotion and disease prevention; the rise of non-communicable diseases; the spread of antimicrobial drug resistance and the emergence of infectious epidemics; increased environmental pollution; the persistence of health inequalities among and within countries affecting disproportionately people that are disadvantaged or in vulnerable stages of life; the detection, understanding, control, prevention and mitigation of health risks in a rapidly changing social, urban and natural environment; the increasing costs for European health care systems and the progressive introduction of personalised medicine approaches and digitalisation in health and care; and the increasing pressure on the European health and care industry to remain competitive in and by developing health innovation vis-a-vis new and emerging global players.</p>	<p>health care and social protection systems, as well as the competitiveness of its health and care industry. Major health challenges in the EU include: the lack of effective health promotion and disease prevention; the rise of non-communicable diseases; the spread of antimicrobial drug resistance and the emergence of infectious epidemics; increased environmental pollution; the persistence of health inequalities among and within countries affecting disproportionately people that are disadvantaged or in vulnerable stages of life; the detection, understanding, control, prevention and mitigation of health risks in a rapidly changing social, urban and natural environment; high prices of some innovative health tools and technologies; increased interdependence of EU on other regions as a consequence of globalization calling for a global health approach; the increasing costs for European health care systems and the progressive introduction of personalised medicine approaches and digitalisation in health and care; and the increasing pressure on the European health and care industry to remain competitive in and by developing health innovation vis-a-vis new and emerging global players.</p>	
<p>Annex I – part II – point 1 – point 1.1 – paragraph 4</p>	<p>These health challenges are complex, interlinked and global in nature and require multidisciplinary, cross-sectorial and transnational collaborations. Research and innovation activities will build close linkages between discovery, clinical, epidemiological, environmental and socio-economic research as well as with regulatory sciences. They will</p>	<p>These health challenges are complex, interlinked and global in nature and require multidisciplinary, cross-sectorial and transnational collaborations, including with low- and middle-income countries. Research and innovation activities will build close linkages between discovery, clinical, epidemiological, environmental and socio-economic research as well as with regulatory</p>	<p>M</p>

	harness the combined skills of academia and industry and foster their collaboration with health services, patients, policy-makers and citizens in order to leverage on public funding and ensure the uptake of results in clinical practice as well as in health care systems. They will foster strategic collaboration at EU and international level in order to pool the expertise, capacities and resources needed to create economies of scale, scope and speed as well as to share the expected benefits and financial risks involved.	sciences. They will harness the combined skills of academia and industry and foster their collaboration with health services, patients, policy-makers and citizens in order to leverage on public funding and ensure the uptake of results in clinical practice as well as in health care systems. They will foster strategic collaboration at EU and international level in order to pool the expertise, capacities and resources needed to create economies of scale, scope and speed as well as to share the expected benefits and financial risks involved.	
Annex I – part II – point 1 – point 1.2 – point 1.2.1. - paragraph 2 – indent 2	–Maternal, paternal, infant and child health as well as the role of parents;	–Maternal, paternal, infant and child health as well as the role of parents; <i>child and maternal survival</i> <i>Given the still high infant and maternal mortality rates in large parts of the world survival should be a priority topic in addition to health since that only relates to those who survive childbirth/delivery.</i>	H
Annex I – part II – point 1 – point 1.2 – point 1.2.2. - paragraph 1	Improved understanding of health drivers and risk factors determined by the social, economic and physical environment in people’s everyday life and at the workplace, including the health impact of digitalisation, pollution, climate change and other environmental issues, will contribute to identify and mitigate health risks and threats; to reducing death and illness from exposure to chemicals and environmental pollution; to supporting environmental-friendly, healthy, resilient and sustainable living and working environments; to promoting healthy lifestyles and consumption behaviour; and to	Improved understanding of health drivers and risk factors determined by the social, economic and physical environment in people’s everyday life and at the workplace, including the health impact of digitalisation, pollution, <i>rapid urbanization</i> , climate change and other <i>national and transnational</i> environmental issues, will contribute to identify and mitigate health risks and threats; to reducing death and illness from exposure to chemicals and environmental pollution; to supporting environmental-friendly, healthy, resilient and sustainable living and working environments; to promoting healthy lifestyles and	M

	developing an equitable, inclusive and trusted society.	consumption behaviour; and to developing an equitable, inclusive and trusted society.	
Annex I – part II – point 1 – point 1.2 – point 1.2.2. – paragraph 2 – indents 1, 2, and 4	<p>–Technologies, including for assessing hazards, exposures and health impact of chemicals, pollutants and other stressors, including climate-related and environmental stressors, and combined effects of several stressors;</p> <p>–Environmental, occupational, social and behavioural factors impacting physical and mental health and well-being of people and their interaction, with special attention to vulnerable and disadvantaged people;</p> <p>–Capacity and infrastructures to collect, share and combine data on all health determinants, including exposure, health and diseases at EU and international level</p>	<p>–Technologies, <i>including low-cost technologies</i>, for assessing hazards, exposures and health impact of chemicals, pollutants and other stressors, including climate-related and environmental stressors, and combined effects of several stressors;</p> <p><i>Recognition of cost as a driver, that might be addressed through research in LMIC</i></p> <p>–Environmental, occupational, <i>economic, political</i>, social and behavioural factors impacting physical and mental health and well-being of people and their interaction, with special attention to vulnerable and disadvantaged people;</p> <p><i>Socio-economic status is a major determinant of health and should be included as such – again this indirectly opens up opportunities for collaboration with LMIC</i></p> <p>–Capacity and infrastructures to collect, share and combine data on all health determinants, including exposure, health and diseases at EU and international level, <i>including low and middle-income countries</i></p> <p><i>Data from these countries has the potential to maximize the highest quality science.</i></p>	M

<p>Annex I – part II – point 1 – point 1.2 – point 1.2.4. - paragraph 1</p>	<p>Protecting people against cross-border health threats is a major challenge for public health, calling for effective international cooperation at EU and global level. This will involve prevention, preparedness, early detection, treatment and cure of infectious diseases, and also tackling antimicrobial resistance (AMR) following a 'One Health approach'.</p>	<p>Protecting people against cross-border health threats is a major challenge for public health, calling for effective international cooperation at EU and global level. This will involve prevention, preparedness, early detection, treatment and cure of infectious diseases, and also tackling antimicrobial resistance (AMR) following a 'One Health approach'. <i>Poverty related and neglected diseases (PRNDs) lack private sector R&I investments due to limited commercial incentives and leave R&I into PRNDs chronically underfunded. To end these high burden epidemics, including HIV and TB and the recent threats linked to antimicrobial resistance especially important in some neighboring countries, more ambitious public investments are needed.</i></p>	<p>H</p>
<p>Annex I – part II – point 1 – point 1.2 – point 1.2.4. - paragraph 2 – indent 6</p>	<p>Trans-border aspects of infectious diseases and specific challenges in low- and middle-income countries (LMICs), such as tropical diseases.</p>	<p>Trans-border aspects of infectious diseases and <i>(new) indent 6a</i> Specific challenges in low- and middle-income countries (LMICs), <i>in particular poverty-related diseases, such as neglected tropical diseases, AIDS, tuberculosis and malaria. Poverty-related and neglected diseases need to be tackled in a comprehensive approach based on partnership with Member States and affected regions.”</i></p> <p><i>The wording tropical diseases does not capture all relevant global health problems and is line with international consensus to avoid the term tropical disease.</i></p>	<p>H</p>

Annex I – part II – point 1 – point 1.2 – point 1.2.5. - paragraph 2 – indent 5	The safety, efficacy, and quality of tools and technologies for health and care as well as their ethical legal and social impact;	The safety, efficacy, <i>cost-effectiveness</i> , <i>affordability</i> , and quality of tools and technologies for health and care as well as their ethical legal and social impact;	M
Annex I – part II – point 1 – point 1.2 – point 1.2.6. - paragraph 2 – indent 2 5	New models and approaches for health and care and their transferability or adaptation from one country/region to another	New models and approaches for health and care and their transferability or adaptation from one country/region to another, <i>including low- and middle-income countries</i> .	M
20-23 Overarching for the six areas of intervention 1.2.1 – 1.2.6		Other topics suggested: <ul style="list-style-type: none"> - <i>Equity in service access and health outcomes</i> - <i>Determinants of health, including poverty, relevant to both communicable and non-communicable diseases, which offer an opportunity to link explicitly with other Clusters</i> - <i>Mental Health as a public health priority</i> - <i>Trauma and associated physical and mental health consequences, particularly in this era of sustained conflict in many regions</i> 	M
CLUSTER 'INCLUSIVE AND SECURE SOCIETY'			
Annex I – part II – point 2. – point 2.2 – point 2,2,3. - paragraph 2 – indent 6	Human mobility in the global and local contexts for better migration governance, integration of migrants including refugees; respect of international commitments and human rights; greater, improved access to quality education, training, support services, active and inclusive	Human mobility in the global and local contexts for better migration governance, integration of migrants including refugees; respect of international commitments and human rights; greater, improved access to quality education, training, <i>healthcare</i> , support services, active and	M

	citizenship especially for the vulnerable;	inclusive citizenship especially for the vulnerable; <i>Health as central determinant of socio-economic status</i>	
CLUSTER 'FOOD AND NATURAL RESOURCES'			
Annex I – part II – point 5. – point 5.1 – paragraph 5 and 6	<p>They will also foster participatory approaches to research and innovation, including the multi-actor approach and develop knowledge and innovation systems at local, regional, national and European levels. Social innovation with citizens' engagement and trust in innovation will be crucial to encourage new governance, production and consumption patterns.</p> <p>As these challenges are complex, interlinked and global in nature, activities will follow a systemic approach, cooperating with Member States and international partners, with other funding sources and with other policy initiatives. This will involve user-driven exploitation of environmental big data sources, such as those from Copernicus, GNOS/Galileo, INSPIRE, EOSC, GEOSS, CEOS, EMODnet</p>	<p>They will also foster participatory approaches to research and innovation, including the multi-actor approach and develop knowledge and innovation systems at local, regional, national and European levels, <i>as well as globally</i>. Social innovation with citizens' engagement and trust in innovation will be crucial to encourage new governance, production and consumption patterns.</p> <p>As these challenges are complex, interlinked and global in nature, activities will follow a systemic approach, cooperating with Member States and international partners, <i>including low- and middle-income countries</i>, with other funding sources and with other policy initiatives. This will involve user-driven exploitation of environmental big data sources, such as those from Copernicus, GNOS/Galileo, INSPIRE, EOSC, GEOSS, CEOS, EMODnet</p>	M

PILLAR III ACTIONS TOWARDS THE JOINED RESEARCH CENTER, TOPIC HEALTH

<p>Annex I – part II – point 6 – paragraph 3</p>	<p>The JRC performs its own research and is a strategic manager of knowledge, information, data and competences to deliver high quality and relevant evidence for smarter policies. To achieve this, the JRC works together with the best organisations world-wide, and with international, national and regional stakeholders.</p>	<p>The JRC performs its own research and is a strategic manager of knowledge, information, data and competences to deliver high quality and relevant evidence for smarter policies. To achieve this, the JRC works together with the best organisations world-wide, and with international, national and regional stakeholders <i>including those from low and middle-income countries.</i></p> <p><i>This addition would ensure that partners from low and middle-income countries are welcome to join this new European Research Instrument</i></p>	<p>M</p>
<p>Annex I – part II – point 6 – point 6.2.2.1, Health - indent 1</p>	<p>Health</p> <p>–Scientific and technical policy support for improved public health and health care systems, including medical devices and health technology assessments, databases, digitisation;</p>	<p>Health</p> <p>–Scientific and technical policy support for improved, <i>accessible and affordable</i> public health and health care systems, including medical devices and health technology assessments, databases, digitisation;</p> <p>(new indent) <i>Research on newly emerging health issues and health threats, such as emerging infections and antimicrobial resistance.</i></p> <p><i>These areas are often subject to market failure, hence without public support innovation in this development space is lacking behind.</i></p>	<p>M</p>

<p>Annex I – part III – point 1.2. – point 1.1.2. – paragraph 7</p>	<p>While the EU may bear alone the initial risk of selected innovation and market deployment actions, the aim will be to de-risk these and stimulate, from the on-set and during the development of the action, co-investments from alternative sources and even substitutive investors.</p>	<p>While the EU may bear alone the initial risk of selected innovation and market deployment actions, the aim will be to de-risk these and stimulate, from the on-set and during the development of the action, co-investments from alternative sources and even substitutive investors. <i>Initial risk bearing by the EU is especially relevant for those innovation areas where there is a clear market failure, such as with the development of new antibiotics as well as specific products for poverty-related diseases.</i></p> <p><i>This addition is crucial for product innovation for poverty related diseases.</i></p>	<p>H</p>
<p>Annex I – part III – point 1.2. – point 1.2.2. – paragraph.</p>	<p>The EIC SPV will proactively leverage from the on-set co- and alternate public and private investments into individual Accelerator’s operations and the SPV, perform due diligence, and negotiate technical terms of each investment in compliance with the principles of additionality EN 67 EN and prevention of conflict of interests with other activities of the entities or counterparts. The EIC SPV will also define and implement an exit strategy for equity participation, which may include proposing to implementing partners financing under InvestEU, where appropriate and for operations whose risks have been sufficiently lowered so that they meet criteria of Article 209(2) of the Financial Regulation.</p>	<p>The EIC SPV will proactively leverage from the on-set co- and alternate public and private investments into individual Accelerator’s operations and the SPV, perform due diligence, and negotiate technical terms of each investment in compliance with the principles of additionality EN 67 EN and prevention of conflict of interests with other activities of the entities or counterparts. The EIC SPV will also define and implement an exit strategy for equity participation, which may include proposing to implementing partners financing under InvestEU, where appropriate <i>(taking into account specific issues around areas with market failure)</i> and for operations whose risks have been sufficiently lowered so that they meet criteria of Article 209(2) of the Financial Regulation.</p> <p><i>This addition is crucial to promote for product innovation for PRNDs and NCDs.</i></p>	<p>H</p>