


Where is the 'global' in the European Union's Health Research and Innovation Agenda?

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ABSTRACT

Global Health has not featured as prominently in the European Union (EU) research agenda in recent years as it did in the first decade of the new millennium, and participation of low-income and middle-income countries (LMICs) in EU health research has declined substantially. The Horizon Europe Research and Innovation Framework adopted by the European Parliament in April 2019 for the period 2021–2027 will serve as an important funding instrument for health research, yet the proposed health research budget to be finalised towards the end of 2019 was reduced from 10% in the current framework, Horizon 2020, to 8% in Horizon Europe. Our analysis takes the evolution of Horizon Europe from the initial framework of June 2018 to the framework agreed on in April 2019 into account. It shows that despite some improvements in terms of Global Health and reference to the Sustainable Development Goals, European industrial competitiveness continues to play a paramount role, with Global Health research needs and relevant health research for LMICs being only partially addressed. We argue that the globally interconnected nature of health and the transdisciplinary nature of health research need to be fully taken into account and acted on in the new European Research and Innovation Framework. A facilitated global research collaboration through Horizon Europe could ensure that Global Health innovations and solutions benefit all parts of the world including EU countries.

INTRODUCTION

Global Health evolved from the concepts of public¹ and international health^{2–3} to form a 'system-based, ecological and transdisciplinary approach to research, education, and practice which seeks to provide innovative, integrated, and sustainable solutions to address complex health problems across national boundaries and improve health for all' (p 155).⁴ Important components of Global Health include health equity, a focus on

Summary box

- ▶ Horizon Europe, the new European Union Research and Innovation Framework for the period 2021–2027, will play an important role for health research globally.
- ▶ The overall visibility of Global Health and the participation of low-income and middle-income countries (LMICs) have declined at EU level in recent years, and Horizon Europe barely mentions Global Health and LMICs.
- ▶ Innovation is equated with industrial competitiveness of European companies rather than effective and cost-saving innovations that could benefit EU countries and LMICs alike.
- ▶ The relative budget allocated to health shows a decline from 10% in the current framework, Horizon 2020, to 8% in Horizon Europe.
- ▶ More international, transdisciplinary and equitable research collaboration and broader access to Global Health research funding is needed, especially for LMICs, to ensure that future health research is based on the Sustainable Development Goals and addresses the major health challenges the world is facing.

health issues transcending national borders, determinants of health, interdisciplinary and international collaboration and a 'health for all' approach.^{2–9}

Global Health aims to overcome the national–international divide⁹ and that between high-income countries (HICs) and low-income and middle-income countries (LMICs) through mutual exchange and partnership, including joint funding, agenda setting, planning and implementation.^{2–3 10} In doing so, Global Health aims to address the 10/90 gap,¹¹ the disparity between global health research spending and disease burden in LMICs. However, the formation of genuine

research partnerships remains a challenge,^{3 10 12} as does the prioritisation of research targeted at high disease burden populations.² These challenges are highlighted by the increasing mobility of the global population^{13 14} and the rapid rise of non-communicable diseases with complex social determinants that require transdisciplinary scientific approaches^{4 15} and innovative solutions.^{16 17}

This paper emanated from a transdisciplinary meeting of European Global Health research institutes with a non-governmental global development organisation in Brussels in July 2018. The 22 participants in this two-day meeting represented European Global Health researchers from Belgium (University of Antwerp), Germany (Ruprecht-Karls-University, Heidelberg, Ludwig-Maximilians-University, Munich), Italy (University of Milan), Spain (University of Barcelona), Sweden (Lund University), Switzerland (University of Geneva), the Netherlands (University of Amsterdam, University of Leiden, Utrecht University), the UK (Imperial College London, University College London, University of Oxford) and a non-governmental organisation (NGO) for global development, Deutsche Stiftung Weltbevölkerung (DSW). A Future Search Conference methodology^{18–20} was used to assess developments in Global Health at individual institutions, across Europe and globally. With the European Commission publishing a new European Research and Innovation (R&I) Framework, Horizon Europe, participants analysed European health R&I priorities based on Global Health challenges and with the aim to strengthen Global Health considerations in this framework. Negotiations between the Council of the European Union (EU) and the European Parliament led to modifications in the Horizon Europe Framework. The negotiating process was informed by the positions of various actors—private sector, NGOs and academic institutions—including that of the European Global Health Research Institutes Network (EGHRIN), a network formed at the Brussels meeting in July 2018, see <https://eghrin-eu>. To illustrate important text and structural changes in Horizon Europe with regard to Global Health, this paper refers to the initially proposed framework and regulation documents by the European Commission of June 2018^{21–24} as well as subsequent versions in late 2018^{25 26} leading to the documents agreed on by EU institutions and approved by the European Parliament in April 2019.^{27 28} The EU R&I Framework is analysed and appraised from a Global Health perspective and with reference to the Sustainable Development Goal (SDG) framework.²⁹

EU EFFORTS ON GLOBAL HEALTH IN THE LAST DECADE

Global Health came to prominence on the European agenda with the EU's first health strategy and policy framework in 2007 and Council Conclusions on Global Health in 2010.³⁰ The 2010 Council Conclusions set out to advance a visionary Global Health agenda focused on strengthening collaborative research capacity; developing

affordable medical products; dissociating Research & Development (R&D) costs from intellectual property considerations; ensuring that access to knowledge and tools form part of the R&D agenda; and strengthening health systems to measure progress on the social determinants of health.³¹ Yet, instead of being the starting point for greater Global Health research engagement, the EU Communication and Council Conclusions largely remained a statement rather than a plan for action³⁰ and few member states developed their own Global Health policies.³²

The EU Communication on its role in Global Health³³ emphasised the aspect of 'protection against Global Health threats' (p 2). Protection was, however, mainly defined in terms of strengthening 'global and third countries' national capacities of early prediction, detection and response to Global Health threats' (p 8) rather than focusing on cross-border health threats, which became more prominent in recent publications of the EU.^{27 34} This led to the question of whom health security is for^{35 36} or even what it should entail³⁷ or how 'security' should be defined and specified.³⁸ Global Health strategies with a self-interested security concern can also be perceived in the policies of member states such as the UK, Germany and France.³² Security concerns relate to a regionalisation of local epidemic outbreaks, the threat of terrorism from impoverished regions, and conflict over resources due to climate change, to name a few.³⁹ The heightened concern for security and the persistent after-effects of the 2008 financial crisis led to Europe's 2020 strategy, which focused primarily on job creation and economic growth.⁴⁰

Germany used its presidencies of the G7 and G20 summits in 2015 and 2017 to give more prominence to Global Health.^{41 42} Yet, Global Health has largely fallen off the EU research agenda.^{22 27 28}

NEW EUROPEAN R&I FRAMEWORK—HORIZON EUROPE

Horizon Europe lists health as one of six clusters in 'Global Challenges and European Industrial Competitiveness',²⁷ the second pillar of the programme. The other two pillars are 'Excellent Science' and 'Innovative Europe',²⁷ see [figure 1](#). The health cluster is divided into six priority areas: health throughout the life course; environmental and social health determinants; non-communicable and rare diseases; infectious diseases, including poverty-related and neglected diseases (PRND); tools, technologies and digital solutions for health and care, including personalised medicine, and healthcare systems.²⁸

Horizon 2020 is the EU's current R&I Framework Programme (2014–2020) with a budget of €80 billion^{34 43} with 10% earmarked for health.³⁴ The European Commission proposed the successor programme Horizon Europe in 2018, with a budget of €94.1 billion for 2021–2027 including €7.7 billion, or 8%, earmarked for health.²³ The draft documents were discussed by the Council of the EU and the European Parliament and altered with

| Pillar 1: <i>Excellent Science</i> | Pillar 2: Global Challenges and <i>European Industrial Competitiveness</i> | Pillar 3: <i>Innovative Europe</i> | |
|--|---|---|--------------------------------|
| European Research Council | a. Health <ul style="list-style-type: none"> o Health throughout the Life Course o Environmental and Social Health Determinants o Non-Communicable and Rare Diseases o Infectious Diseases <i>including Poverty-Related and Neglected Diseases</i> o Tools, Technologies and Digital Solutions for Health and Care <i>including Personalised Medicine</i> o Health Care Systems b. <i>Culture, Creativity and Inclusive Society</i> c. <i>Civil Security for Society</i> d. <i>Digital, Industry and Space</i> e. <i>Climate, Energy and Mobility</i> f. <i>Food, Bioeconomy, Natural Resources, Agriculture and Environment</i> | Clusters | |
| Marie Skłodowska-Curie Actions | | | European Innovation Council |
| Research Infrastructures | | | European Innovation Ecosystems |
| | Joint Research Centre | European Institute of Innovation and Technology | |
| Widening Participation and Strengthening the European Research Area | | | |
| <i>Widening participation and spreading excellence</i> | | Reforming and enhancing the European R&I system | |

Figure 1 Horizon Europe R&I Framework based on the Common Understanding reached between Council and European Parliament on 27 March 2019 and the Partial General Agreement of 15 April 2019. Italicized text indicates changes in the Framework agreed upon by EU institutions in 2019.

some improvements on Global Health language and concepts^{27 28} while at the same time emphasising *European* innovations, see figure 1. The Council upheld multi-dimensionality in addressing global challenges, among others through R&I missions,^{25 28} yet did not increase the budget proposal of the European Commission of €94 billion. Contrary to the Council, the European Parliament proposed an overall research budget for Horizon Europe of €120 billion,²⁶ with the health cluster receiving 8.16% or €9.79 billion of the overall budget.⁴⁴ The budget was not part of the final Horizon Europe Framework of April 2019 and will be negotiated as part of the multiannual financial framework in 2019.⁴⁵

ANALYSIS OF EU R&I FRAMEWORK

What follows is a European Global Health institutes' analysis of Global Health issues in the current and previous Horizon Europe frameworks.^{21–24 27 28 46 47} SDGs and industrial competitiveness and innovation, which are central themes in the Horizon Europe Framework, are also considered in this analysis. Further themes such as funding, health systems, environmental and social health determinants and more detailed information on Global Health, PRND, LMICs, networking and participation are listed in the online supplementary table 1.

SDGs, Global Health, One Health and Horizon Europe

The move from the Millennium Development Goals to the SDGs calls for interdisciplinary and transdisciplinary approaches^{29 48} and thus can be seen as strengthening

Global Health endeavours. Infectious and non-communicable diseases and environmental health risks are a worldwide concern and not limited to individual countries or regions;⁴⁹ an adequate response therefore needs to be global and interconnected. The Horizon Europe Framework links the health cluster only to SDGs 3 (good health and well-being)²⁷ and 13 (climate action);²⁷ its interconnectedness with other SDGs is not specifically mentioned despite the EU's 'health in all policies' approach of 2006 which is lagging behind in implementation.⁵⁰ In the course of the negotiations of the Horizon Europe Framework, SDG references increased from 45^{22–24} to 57,^{27 28} yet the health cluster continues to be linked only to 'health' and 'climate action'.²⁷ Locating health at the centre of all other SDGs and linking health aspects with all other clusters in the Horizon Europe Framework would underscore the importance of Global Health in working towards the achievement of the SDGs and the contribution of the SDGs to Global Health⁵¹ with a view to achieving planetary health.⁶ This would incorporate a One Health approach, which is mentioned several times in the Horizon Europe Framework²⁷ in connection with antimicrobial resistance (AMR), an area for which the EU is an important global actor.⁵² While Horizon Europe acknowledges that 'health challenges are complex, interlinked and global' (p 19),²² the final framework has placed the term 'Global Health' in the context of infectious diseases.²⁷ Notwithstanding the importance of infectious diseases and the crucial addition of PRND in the final framework,²⁷ Global Health

has to be understood as a broader concept in terms of content and geographic scope.²⁴ Even in the final framework, LMICs only merit one reference,²⁷ and their participation in R&I has decreased substantially in the current Horizon 2020 programme compared with the EU Framework Programme 7.⁴⁶ This is also reflected in access to EU funding (<https://webgate.ec.europa.eu/dashboard/sense/app/93297a69-09fd-4ef5-889f-b83c4e21d33e/sheet/PbZJnb/state/analysis>) and in contrast to the EU's R&I 'open to the world policy'.⁵³ Equitable research participation is thus still a vision rather than reality.

European industrial competitiveness, innovation and Global Health

'Industrial competitiveness' is mentioned 14 times and 'industry' 67 times in the Horizon Europe Decision²⁷ as well as 13 times in the Regulation²⁸ clearly showing that the EU's paramount concern for R&I is economic. The term 'Global Health', by contrast, is only mentioned three times.^{27 28} The linking of innovation to industrial competitiveness and economic growth²⁷ is problematic, as Walsh and colleagues⁴³ pointed out with regard to the current R&I programme, Horizon 2020, criticising the 'particularly narrow interpretation of the health and wealth agenda, regarding health research as a lever for economic growth through patentable technological advances, exploitable intellectual property and the industrialisation of invention and innovation' (p 669).

Labonté and Gagnon³⁹ point out the danger of health inequity through trade and intellectual property rights especially for poorer countries. The interests of industry and the needs of patients for 'affordable, cost-effective, clinically relevant, user responsive innovations' (p 1403)⁵⁴ differ, and many countries are not in a position to afford the latest health technology or innovation.^{43 54}

The pharmaceutical industry has shown little interest in developing products regarded as non-profitable, such as an investment in new antibiotics (see EU Action Plan against AMR 2011, https://ec.europa.eu/health/amr/sites/amr/files/communication_amr_2011_748_en.pdf, p 8). This has aggravated the Global Health burden in terms of AMR.^{55 56} The same holds true for PRND.^{57 58} Since 2016, more engagement by pharmaceutical and diagnostic companies on AMR research has been noticeable following an industry declaration (<https://www.ifpma.org/resource-centre/declaration-by-the-pharmaceutical-biotechnology-and-diagnostics-industries-on-combating-antimicrobial-resistance/>) and the emergence of more public-private partnerships (<https://accesstomedicinefoundation.org/amr-benchmark/about-the-benchmark/the-context>), many of them initiated by the EU⁵⁹ which has been a major funder for PRND.⁶⁰ The EU has addressed AMR in strategies and action plans since 2001 (https://www.eca.europa.eu/lists/ecadocuments/ap19_03/ap_amr_en.pdf) and supported joint African and European research for AMR and PRND through the European and Developing Countries Clinical Trials Partnership (EDCTP) for research

and product development.^{61–66} In the 2011 EU action plan on AMR, the lack of new antimicrobial agents was addressed by launching new programmes under the Innovation Medicines Initiative (https://ec.europa.eu/health/amr/sites/amr/files/communication_amr_2011_748_en.pdf page 9; <https://www.imi.europa.eu/>), the EU's largest public-private partnership. This initiative has been criticised for its industry-driven research agenda and non-transparent decision-making^{67 68} as well as its lack of support to small-sized and medium-sized enterprises⁶⁷ and for the health needs and participation of LMICs (<https://eghrin.eu/>).

The 'innovation principle' of the EU²⁷ is a case in point for the dominance of industrial concerns. This 'principle' has been lobbied for by European companies since 2013 (https://corporateeurope.org/sites/default/files/corporation_letter_on_innovation_principle.pdf) and can be seen as an attempt by European industries to weaken the 'precautionary principle' (for a definition, see https://eur-lex.europa.eu/summary/glossary/precautionary_principle.html),⁶⁹ which is mentioned as a guiding principle in Horizon Europe.²⁷ Despite the vagueness and ambiguity of this term,⁷⁰ the precautionary principle has safeguarded the health of European citizens through, for example, a ban on the export of bovine animals from the UK at the time of the BSE scandal in the late 1990s (<http://curia.europa.eu/juris/showPdf.jsf?jsessionid=9ea7d0f130d6a4ba85620a864bb1accde4ffad75ac.e34KaxiLc3eQc40LaxqMbN4PahaOe0?text=&docid=101067&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=303969>). For the first time, the industry-backed 'innovation principle' (defined as 'whenever precautionary legislation is under consideration, the impact on innovation should also be taken into full account in the policy and legislative process', see https://corporateeurope.org/sites/default/files/corporation_letter_on_innovation_principle.pdf) has been incorporated into an EU R&I Framework, Horizon Europe, despite civil society and political parties alerting to the possibility of increased risks to human health and 'thwarting long-established and settled EU environmental principles' (p 12)⁶⁹ (<https://corporateeurope.org/en/environment/2018/12/innovation-principle-trap>; <https://www.greens-efa.eu/en/article/news/the-innovation-principle-is-a-regulatory-trojan-horse-from-the-industry/>; <https://epha.org/removing-innovation-principle-from-horizon-europe/>). The decision to include the 'innovation principle' therefore raises questions about the influence of industry at EU level and whom the EU sees as beneficiaries of 'innovations'. EU initiatives to advance needed innovations should operate under the precautionary principle and fulfil responsible R&I requirements (<https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation>),^{69 71} both of which are mentioned in Horizon Europe.²⁷

Rather than equating the 'precautionary principle' with thwarting progress and innovation, constraints can stimulate creative solutions as has been shown in LMICs with many advancements in health.^{72 73} EU member states could

benefit from these innovations with regard to effective and cost-efficient health products, strengthened health systems and health information as well as better service delivery.^{72–79} Cost-effectiveness is mentioned in terms of tools²⁷ and health systems^{27,28} in Horizon Europe, and one way to advance cost-effective innovations would be for the EU to strengthen partnerships between LMICs and HICs such as the EDCTP. This programme is an effective partnership between African and European health institutes in terms of planning and conducting innovative health research for PRND and in terms of collaboration and joint oversight.^{64–66} EDCTP has shown success in developing medicines, vaccines and diagnostics (http://www.edctp.org/web/app/uploads/2018/09/Tackling-infectious-disease-in-sub-Saharan-Africa_EDCTP-funded-clinical-studies-for-medical-interventions-2003-2018-4.pdf) and could benefit from a higher budget and geographic expansion. With a successor programme to the current partnership programme being negotiated, the mention of Global Health as a possible area for partnership is helpful,²⁸ however, negotiations for an EU-Africa Global Health Partnership increasingly focus on health security, which may indicate a shift in the priorities of the EDCTP successor programme (Science Business, 20 May 2019; <https://sciencebusiness.net/framework-programmes/news/more-details-emerge-44-possible-horizon-europe-partnerships>. List of candidates for European partnerships available at <https://sciencebusiness.net/sites/default/files/inline-files/HE-partnerships.pdf>).

A VISION FOR GLOBAL HEALTH RESEARCH

In a global and interlinked world, there is a need for equitable,¹⁰ well-funded innovative health research between LMICs and HICs⁷⁹ that addresses interconnected health issues: climate change; migration; access to food and water; the spread of diseases and epidemics; the development of new, needed and affordable diagnostics and medicines; and the strengthening of health systems to significantly decrease the global disease burden⁴⁹ and to improve health equity while ensuring consistency between (European) health and trade policies.^{7,39,80} Such R&I could be a catalyst for the implementation of the SDGs and a move towards a One Health and eventually a Planetary Health approach.⁶ Global Health research and cost-effective solutions would also benefit HICs, such as European member states, that increasingly struggle with high medicine prices and an overstretched work force, a problem well-known to LMICs.^{73,74,79} In order to devise global solutions to global problems, cooperation not only needs to involve LMICs but also extend beyond research institutions to civil society (eg, NGOs) and governments.⁴ This would ensure that key stakeholders have a voice in the R&I agenda and facilitate implementation at the national level while strengthening a transdisciplinary research approach. The equitable cooperation of research institutes globally is also a crucial element for advancing Global Health research, yet should take the key element of governance into account.⁸¹ This vision of equitable

research in Global Health supported by the EU is based on the Decision document, which foresees improved pan-European and regional collaboration.²⁷ Yet, further globalisation of this vision is needed to enable institutions in LMICs to better access direct funding for health R&I and to lead on much needed research in Global Health. This could also be achieved through a strengthening and widening of the EU partnership programme EDCTP as well as Global Health research networks.

CONCLUSION

The discussion and analysis of the proposed Horizon Europe R&I Framework by European researchers engaged in Global Health confirmed the importance of the EU and this framework for health R&I, yet found it wanting in terms of a genuine Global Health approach despite some improvements to the framework during the negotiating process. European industrial interests were found to dominate with regard to Global Health innovations; LMIC participation, by contrast, is hardly mentioned in the framework.

Aluttis and colleagues³⁰ in analysing Global Health in relation to the EU remark that ‘the EU remains a forceful actor in the world which can speak with a strong voice on health matters of global concern’ (p 6). In order to maintain this role, the EU will need to fully embrace the concept of Global Health in the implementation of its R&I agenda and facilitate and adequately fund joint Global Health research to ensure that health innovations benefit all parts of the world. Special Horizon Europe funding calls with an intent to increase participation of LMIC research institutes could directly benefit the EU through effective and cost-saving innovations in and from LMICs and their transfer to Europe. The EU would therefore benefit from strengthening partnership programmes such as EDCTP or by facilitating funding for global research networks that include research institutions based in LMICs and work in a transdisciplinary way with equitable governance structures.

Applying a Global Health concept and strategy to the framework would show effects beyond health, as Speakman and colleagues⁸² comment: ‘A prominent EU Global Health strategy would not only benefit Global Health. It would also show leadership from Europe, promoting the values of which the EU is justifiably proud: respect for human dignity and human rights, freedom, democracy, equality...’ (p e393). An enhanced EU strategy on Global Health could help invigorate world class health research with tangible Global Health outcomes and sustainable Global Health innovations for coming generations.

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Competing interests RvL is also chief executive officer and founder of Madam Therapeutics, a private entity that is pursuing the development of new antibiotics. All other authors declare no known conflict of interest.

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