

4 key recommendations to ensure the EU's research programmes address unmet societal needs and guarantee a public return on public investment

In December 2022, the European Commission launched the largest [public consultation](#) ever on the past, present and future of the its research programmes. This policy brief was submitted together with Global Health Advocates' (GHA) contribution to the consultation.

GHA has been and will continue to advocate for EU biomedical Research and Innovation (R&I) funding to focus on unmet societal needs and have conditions attached to ensure availability, accessibility and affordability of results outcomes. Our current biomedical R&I system, while heavily funded by public money evolved towards a market-oriented model maximising private return on public investments. As a result, the current system does not effectively respond to public health needs, with States unable to further the right to health. We need a system that maximises public returns on public investments. It is crucial to look at what has been done and achieved with Horizon 2020 and with the first two years of Horizon Europe to ensure that the future EU research programmes really delivers for people. Here are our 4 key recommendations on how this can be done.

1) Guiding principles for greater societal impact: a starting point to maximise societal impact

It is the duty of public institutions to prioritise areas where there is a public need, for example supporting areas neglected by the private sector and where there is a high societal value. CSOs have proposed a [set of 7 guiding principles that Horizon Europe should follow in order to ensure sustainable societal impact](#) of EU-funded biomedical R&I. These are:

Needs-driven: R&I priorities should be set according to priority diseases/pathogens as defined by the WHO and be set according to public health and patients' needs, defined through transparent and inclusive priority-setting processes at national, European and global levels.

Equitable: Allocations for R&I funding should be made on a fair and impartial basis. Attention should also be paid to neglected and underfunded areas and diseases, as well as to the specific needs of disadvantaged, vulnerable and marginalised groups.

Effective: R&I products should bring significant added therapeutic value and be delivered in appropriate forms for the contexts in which they need to be used.

Accessible, available and affordable: R&I should result in health technologies that are accessible and available in a timely manner and are delivered in appropriate quantities for those who need them. Such technologies should be available at a price that individuals, health systems and health providers can afford.

Efficient: Coordination and collaboration should be maximised in R&I to increase efficiency and avoid duplication or waste of resources. R&I should adopt Open Science principles and Open Knowledge approaches.

Public-interest driven ownership of results: Ownership and management of publicly funded R&I results should be driven by the public interest and explore various forms of IP management and licensing with this goal in mind. The following approaches should be considered: publication, non-exclusive licensing, donations of intellectual property and participation in public sector patent pools, among others.

Transparency: Further efforts are needed to ensure R&I, its funding processes and the prices of resulting technologies are made transparent. Beneficiaries receiving funding should make R&I costs, manufacturing costs, the costs of acquiring intellectual property rights, the patents landscape around drugs, the registration costs, the assessment of the economic value of the various exemptions and subsidies that benefit the private company, the real clinical benefits of the products for patients in comparison to existing therapeutic options, publicly available.

Compared to Horizon 2020, Horizon Europe has a few novelties to help **maximise societal impact**. For instance, for the first time Horizon Europe defines the concept of “societal impact”, linking it to sustainable development and including corresponding indicators linked to the Sustainable Development Goals (SDGs), the Paris Agreement and citizen engagement. We look forward to the publication of the societal impact dashboard, a work the Commission is currently undergoing, and to seeing them being used in the mid-term evaluation of Horizon Europe to monitor and report on the societal impact of EU-funded research.

COVID-19: a missed opportunity to put these principles into practice

When the COVID-19 pandemic started, a significant amount of public funding, including from the EU, was dedicated to R&I to quickly develop and deploy needed medical countermeasures, ranging from research through manufacturing and advanced purchase agreements. Concerned with the lack of conditions attached to these funding calls and investments, civil society organisations called on the EU institutions and national governments to incorporate collective, pro-public safeguards, such as transparency regarding public contributions, accessibility and affordability clauses and non-exclusive licenses for exploitation of end-result products.

For the first time, strong requirements in terms of access conditions and data sharing were included in calls for expression of interest for Horizon 2020 funding. The introduction of these conditions represented an important step towards safeguarding public interest in allocating public resources towards health innovations. However, it was disappointing to see that they were only applied to the call for proposal focusing on completing and deploying solutions that were already available, instead of the call focusing on developing new biomedical tools. Therefore, the potential of this paragraph has not been fully exploited when it comes to the development of COVID-19 vaccines, diagnostics and therapeutics.

The Commission also launched a Manifesto for EU COVID-19 research, with a set of access principles, encouraging beneficiaries of EU COVID-19 projects to guarantee a public return on public investment. It was unfortunate, however, to see the low number of relevant research organisations engaged with EU funded COVID-19 projects who actually signed the manifesto. These principles (making research results public and accessible; making data available in open access; and granting non-exclusive royalty free licences on IP resulting from public funds) should always be applied to EU-funded research, not on a voluntary basis but as binding conditions.

Engaging citizens and civil society in EU R&I: a necessary step

Civil society (NGOs and citizens) are not traditionally seen as stakeholders in R&I, unlike scientists, researchers and industry. Yet R&I is deeply relevant and important for society beyond institutional or commercial priorities. It is one of the key policy areas that can help us deliver a better future for EU and global citizens. R&I is integral to addressing the many challenges faced by society, including in health and wellbeing, food and farming systems, climate change, energy, democracy and digitalisation.

The mid-term review of Horizon 2020 noted that citizen and civil society participation in the programme was still unacceptably low and the European Commission announced Horizon Europe would be co-designed and co-created with society. CSOs have put forward key recommendations to ensure involvement of citizens in the EU R&I agenda setting. An evaluation of this engagement should be done in the framework of Horizon Europe mid-term evaluation.

2) Increasing funding for PRNDs: a precondition for tackling unmet medical needs

Existing gaps are a sad reality for many diseases that do not offer sufficient market opportunities for private sector R&D investments, such as poverty-related and neglected diseases (PRNDs), or new antimicrobials that could address the growing threat of antimicrobial resistance (AMR). This was the case, for instance, with Ebola which was identified nearly four decades earlier but R&D investments were only made following the 2014 outbreak. Still today, PRNDs are still responsible for half of all deaths in low-income countries. The lack of appropriate tools to diagnose, treat or prevent diseases can have devastating health and economic consequences.

In 2021, the EC became the second largest public funder for PRNDs, contributing a record \$202million (7.9% of the total). Although a positive trend, EU's total contribution was only 10% of the funding provided by the biggest public funder for PRNDs, the US. The EC's new position was the result of both the record funding from the EC and a sharp decline in contributions from the UK. Looking at the overall funding for PRNDs in recent years, we unfortunately see a stagnation. As the recent G-Finder report highlights, the status quo won't get us there and **sustained investment in global health innovation is critical** to develop urgently-needed solutions and to lay the groundwork for new breakthroughs.

PRNDs are the only subgroup of infectious diseases which are explicitly mentioned within the current strategic plan of Horizon Europe, also highlighted in the Horizon regulation. This level of commitment needs to be maintained by highlighting the importance of PRND R&D also in the next strategic plan. **It also needs to be reflected in the programming through specific PRND calls**, ensuring that the EU works toward Global Health, in line with the new EU Global Health Strategy. PRND-specific calls have disappeared from recent Horizon Europe work programmes. This comes as different Member States and sectors (profit/non for profit) have different capacities of engaging with programming processes and consultations, leading to an over-representation of well-funded R&D areas in contrast to neglected areas, which could pose a threat to PRND funding.

Aiming for concrete impact: prioritising TB vaccine R&D to save millions of lives

The role of vaccines in mitigating global health crises has never been clearer, nor has the need for comprehensive and sustainable funding to enable their development. Although tuberculosis (TB) is preventable and treatable, it remains one of the leading causes of death from an infectious agent. In 2021, some 10.6 million people fell sick with TB worldwide, mostly in low- and middle-income countries (LMICs), and close to 1.6 million people died.

While there is a vaccine for TB, the century-old Bacille Calmette Guérin (BCG) offers important but incomplete protection against the most severe forms of TB and it is mostly ineffective in adolescents and adults. The EU is home to many of the world's leading research institutions engaged in vaccinology and TB vaccine R&D, and even though the European and Developing Countries Clinical Trials Partnership (EDCTP) was the world's third largest funder of TB vaccine R&D in 2020, the EU still gives less than 40% of its Fair Share of TB research funding needs.

A recent study concluded that a **new TB vaccine would be highly impactful and cost-effective but further efforts are needed for future development.** TB vaccine R&D must be prioritised and funded by the EU throughout the different R&D stages to ensure candidates advance to full-scale development and a new TB vaccine to be brought to fruition. The EU should continue to be a champion for TB vaccine R&D and to support the WHO TB Vaccine Accelerator Council.

3) Serving public interests, not private profits with PPPs

When it comes to Public-Private Partnerships (PPPs), whose goals were to fill the gaps left by market failure, GHA and CEO report's from May 2020 investigating the Innovative Medicines Initiative (IMI) and the Bio-Based Industries (BBI) showed that they failed to deliver. For IMI, it meant not overcoming market failure and not improving the development and availability of health technologies for unmet medical needs.

IMI has been continuously criticised by the patients, consumers, doctors, payers, HTAs, and public interest organisations for the lack of inclusivity in the choice of research priorities, the governance structures, and the dominance of large industry players. Formal evaluations of the previous initiatives pointed to the imbalance in the representation of stakeholders and very low transparency standards. **GHA had proposed a series of recommendations¹** to guarantee a public interest-driven partnership. These include recommendations on its **governance** to ensure **less industry dominance and more public ownership; agenda-setting** that responds to a **needs-driven research agenda**; and **accountability** to safeguard **impact for society**.

There were some changes in new Innovative Health Initiative (IHI) compared to IMI, when it comes to its governance and accessibility of the research outputs. First, the Joint Undertakings regulation calls for all beneficiaries to ensure that results are affordable, available, and accessible to the public at fair and reasonable conditions. However, the success of including this requirement in the regulation is dimmed by the fact that IHI's primary goal will not be to deliver ready-to-use technology to citizens, but rather to conduct research that contributes to their long-term development. Nevertheless, it is an important precedent that will keep this partnership accountable for ensuring access to the results of publicly funded research. In addition, despite the claim that the IHI's Science and Innovation Panel represents "the wider healthcare community", there are no civil society organisation representatives, and barely one patient organisation out of six seats reserved for that category of representatives. This is contrast to the four seats reserved for IHI industry partners. However, it remains to be seen whether

¹ See pages 63-64.

IHI will improve its standards on transparency and accountability. So far, the timely publication of the Governing Board's meeting records has not been improved. For instance, none of the Board meeting minutes have been made public, and the most recent agenda published dates back to June 2022.

4) Tackling global challenges requires increased international cooperation

Rather than competition, international cooperation is the best way to better protect everyone, including EU citizens, from global health threats. The question is not if another pandemic will occur but whether we would be better prepared to respond to it. The world needs flexible, adaptable, and sustainable global health R&D funding, capacity, and infrastructure to successfully address existing global health challenges and future pandemics and this should be made a priority in the upcoming Horizon Europe Strategic Plan. Access inequalities and corporate capture of publicly funded innovation have been at the heart of the COVID-19 global response and we cannot allow these same mistakes to happen again in the future.

Improved alignment and coordination of European research opportunities with global health policy objectives would ensure greater effectiveness and impact of European research spending. **Horizon Europe could further improve international cooperation in the field of R&D.** The EU should recognise that there are innovations that are taking place in LMICs and in Africa and that collaboration with these partners could benefit all. This cooperation needs to prioritise health R&D in order to contribute to a strong and resilient public health system, as outlined the EC's communication on the Global Approach to Research and Innovation. CSO are key in translating R&D into societal benefits, therefore they need to be involved in the design, implementation and evaluation of R&D to ensure cooperation is driven and tailored by local demand and priorities. Horizon Europe needs to have specific mechanisms to encourage more global participation, in particular from LMICs. The Africa Initiative is an important step in the right direction and should be institutionalised for the entire duration of Horizon Europe.

Moreover, **exploiting synergies between Horizon Europe and the NDICI-Global Europe remains critical to ensure R&I is better embedded in the EU's external action.** The EU should also seek a more coherent approach between EU-funded interventions in LMICs that can contribute to a more enabling R&I environment, for instance the Team Europe Initiatives on MAV+, and the Sustainable Healthcare Industry for Resilience in Africa (SHIRA).