



21 September 2021

Dear Commissioner Gabriel,  
Dear Commissioner Kyriakides,

As representatives of 13 organisations including universities, students, healthcare workers, citizens and public interest organisations, we are concerned about the preparatory process of the Innovative Health Initiative. In our previous [letter](#) sent in December 2019, we insisted on the need to ensure that priority setting for the new partnership is driven by public health needs and we urged the European Commission to guarantee that the public interest is in the driving seat of the future Joint Undertaking.

Unfortunately, it is striking to once again see the private sector taking a lead on priority setting by dominating the development of the Strategic Research and Innovation Agenda. This risks further tilting the balance away from public health and public interest needs.

The evaluations of the previous health partnerships, Innovative Medicines Initiative (IMI and IMI2) pinpointed stakeholders' concerns about the lack of inclusiveness and transparency in the selection of research priorities and governance structures. The dominance of large groups of influence representing the health industry remains a serious problem. The evaluations warned that scientific advisory groups did not have a significant influence on shaping the strategic agenda and directions of the partnership.

Civil society urges the European Commission to address these imbalances and to ensure that the new partnership - Innovative Health Initiative - is properly shaped by (see more in Annex):

- **Focusing on public health priorities and societal needs**
- **Allowing independent science to guide decision making process**
- **Responsible and equitable planning and measuring of public health and societal impact**
- **Using public funding as a leverage to ensure accessibility and affordability of end products**

- **Attach strings to the use of public funding as a leverage to guarantee accessibility and affordability of end products and open access to data and know-how**
- **Ensuring it is fully transparent and equipped with strong public governance and accountability mechanisms.**

Undersigned organisations welcome a possibility of a meeting to discuss listed public concerns and to provide critical input into the future decision of the governing body of the Innovative Health Initiative.

**Supporting organisations:**

1. Global Health Advocates
2. Aurora Universities Network
3. AIDS Action Europe
4. Asociación por un Acceso Justo al Medicamento (AAJM)
5. Médecins du Monde
6. Treatment Action Group
7. Sciences Citoyennes
8. Salud por Derecho
9. Deutsche Stiftung Weltbevölkerung (DSW)
10. Health Action International
11. Universities Allied for Essential Medicines
12. Prescrire
13. NoGracias

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## How to make IHI work for society?

### 1. Societal needs should not be overshadowed by the private sector

Unfortunately, the updated version of the Strategic Research and Innovation Agenda once again is short of ensuring that patients, end-users and public interest groups are meaningfully involved in priority setting for this much needed JU. The document reads “Europe’s failure in translating research results into tangible health products can be attributed to insufficient early consideration of societal needs”. If we are to take this lesson seriously, we cannot afford once again giving a freehand to the private sector to streamline their industrial priorities without paying attention to actual societal needs. There needs to be a strong stewardship from the public authorities and meaningful involvement of citizens, patients, consumers and payers.<sup>1</sup>

### 2. Unmet public health needs should be clearly defined

The proposed strategic document does not provide information on specific public health areas in which the developed innovations are supposed to add value. The proposed definition of unmet public health needs does not clearly define how these areas will be selected, and at the same time draws attention to a very narrow range of health needs - cancer and neurodegenerative diseases. While these are important public health challenges, the health needs of the citizens are much broader.

This was reflected in IHI’s predecessors, IMI and IMI2, through the inclusion of important diseases of public health interest for some of Europe’s most vulnerable populations, such as poverty-related neglected diseases, including tuberculosis, as well as broader public health needs, like the development of effective vaccines and research and development to respond to the growing threat of antimicrobial resistance; research areas that showed promising advances throughout IMI’s tenure. Failure to maintain support for research and innovation in these areas will interrupt critical, ongoing research that has already been negatively affected by disruptions caused by the COVID-19 pandemic and curtail opportunities to build on prior European investments.

To ensure that public funds are properly invested going forward, decisions must be made in an open, transparent and public-driven process. The current Innovation Panel structure does not provide an adequate level of independent scientific advice for governing bodies, based on the three criteria outlined in the SRIA (high burden, economic impact and transformational nature), to make appropriate decisions in this regard. We welcome proposed improvements by the ITRE Committee to introduce an independent scientific advisory body to guide scientific focus for R&I activities of the JU.

### 3. Results and outcomes must be monitored and measured

The proposed SRIA claims that IHI is to foster the development of innovations and to facilitate the creation of new products and services to prevent, intercept, diagnose, treat and manage diseases. Similarly to IMI and IMI2, IHI will focus on so-called, “pre-competitive” research. While one of the biggest considerations from IMI and IMI2 was whether they achieved a meaningful societal impact, based on the previous PPP [evaluation](#) and [CSOs reports](#), we remain vigilant about foreseen outcomes of IHI. Not only the selection of appropriate priorities, but also an

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<sup>1</sup> An example of such meaningful co-creation is “[Horizon Terre](#)”.

adequate system for measuring progress is crucial in ensuring the real impact of the JU. At the moment, the draft document does not present details as to what socio-economic impact it wants to achieve and how it will be measured. It also says nothing about ownership of the results, which was another crucial problem of previous partnerships.

The experience of previous partnerships as well as recent lessons from the COVID-19 pandemic show the importance of attaching provisions to public funding to tackle affordability, accessibility, availability and efficiency along all the R&I stages. We firmly believe that the EU should include such provisions and explore various forms of IP management and licensing, including equitable licensing.

Moreover, the health partnership should include indicators for measuring the societal impact of EU investment, clearly defined in a transparent multi-stakeholder process, be linked to SDGs and have robust monitoring via targeted indicators.

#### **4. EU citizens' interest and rights must be safeguarded**

IHI is being designed to advance utilisation and uptake of digitalisation and data exchange in health care, including Artificial Intelligence, Big Data and real-world data.

Such ambitious progress in the use of technology with high privacy and security risks should only take place under the guidance of public institutions and under the solid supervision of the relevant authorities. Simple participation of patients and healthcare professionals at a later stage, once the framework is sealed, is not enough to ensure appropriate conduct. Unless the governance and accountability mechanisms of the future JU are revised, it cannot be considered an appropriate platform to address such sensitive topics.