INNOVATIVE HEALTH INITIATIVE

WHAT'S IN IT FOR SOCIETY?

INTRODUCTION

The EU R&I policy is one of Europe's key strategies that can help deliver both a better future for EU citizens and meet international commitments, especially the UN's Sustainable Development Goals. In this context, it is crucial to analyze the potential that the EU R&I toolbox has, in order to contribute to tackling some of the biggest societal challenges in the public health sphere, such as emergency preparedness, burden of infectious diseases including poverty-related and neglected diseases, non-communicable and rare diseases and environmental and social health determinants.

The Innovative Health Initiative is a proposed public-private partnership within the framework of the EU R&I funding programme – Horizon Europe. It will be set up as a de facto continuation of the Innovative Medicines Initiative (2007-2013) and Innovative Medicines Initiative 2 (2014-2020) and will run between 2021 and 2027. The proposed regulation covers nine Joint Undertakings, including IHI.

According to the proposed regulation, all efforts of the Joint Undertakings under Horizon Europe (with a public funding of €9.6 billion for 2021-2027) should be made with a view to deliver on global challenges and to accelerate the social, environmental and economic transition. IHI should additionally contribute towards the creation of a Union wide R&I ecosystem and foster the development of safe, effective, people-centred and cost-effective innovations that respond to strategic unmet public health needs. To assess whether IHI will be able to respond to stated challenges, public health needs and achieve its goals, we conducted a detailed assessment of the proposed regulation.

The below assessment of the legislative proposal establishing Innovative Health Initiative was made against the recommendations put forward by the Global Health Advocates and the Corporate Europe Observatory in 2020 (in the report "In the Name of Innovation - More private than public: the ways Big Pharma dominates the Innovative Medicines Initiative"), as well as the conclusions of the interim evaluation of IMI2.[1]

The main findings of the GHA and CEO report were that IMI has failed to meet the goals that justified it, including overcoming market failure and improving the development and availability of health technologies for unmet medical needs. This happened mainly because of the flawed design of the IMI. **Has the IHI proposal taken into consideration recommendations from independent evaluations of civil society and the expert group to improve the governance, transparency and accountability of this new health partnership?**

1. The interim evaluation of IMI2 provided a set of recommendations both for ongoing partnership as well as for the IHI proposal.

"In view of the EU's commitment to the SDGs, health systems, in particular, need to evolve so that they are easily accessible and affordable to all, which means concentrating on improved access to medicines, more patient-centred healthcare, and a strong focus on health promotion and disease prevention. This can be supported by innovation (...) **However, insufficient consideration of societal or user needs act as a barrier to acceptance and uptake, limiting the extent to which the full potential of novel innovative products can be realised**." [2]

TECHNICAL ANALYSIS AND ASSESSMENT OF THE PROPOSAL

Based on the assessment below, a set of recommendations was developed and it can be found in the annex.

GOVERNANCE

In order to be **transparent and accountable,** it is vital that IHI's governance structure sets the groundwork for a solid partnership. Previously, civil society has called on the IHI framework to involve civil society organisations (CSOs) in governing structures, ensure an overall balance of stakeholders within the governance, and provide provisions for transparency, such as timely publication of the Governing Board minutes. Unfortunately on those points, the proposal has not improved compared to IMI2. At the same time, IHI will significantly extend its membership of industry partners and will include the European Coordination Committee of the Radiological, Electromedical and healthcare IT Industry, the European Federation of Pharmaceutical Industries and Associations, EuropaBio, MedTech Europe and VaccinesEurope.

Under Innovative Health Initiative, the **Governing Board** remains the same as under IMI2, representing the European Commission and industry (with equal voting distribution), while other relevant stakeholders are not included. Other bodies of the IHI are the Executive Director, the States' Representatives Group and the Innovation Panel, however despite the possibility, **no stakeholder group has been foreseen**. This lowers the governance standards compared to IMI2. Despite a remark in the interim evaluation, that the "(...) *Different goals and modes of operations of industry and the public partner appeared to interfere with the efficiency of the decision making process*", no correction has been made.

A seemingly novel provision foreseen for the IHI is the **Innovation Panel**. This body will essentially serve as a Scientific Committee (fulfilling the provisions of Article 19). However, the composition of the panel is imbalanced and features **only 10% of "representatives of a scientific community"** (2 seats out of 20 in total). **Stakeholders are only represented with up to six seats**, and will be appointed by the Governing Board following an open selection process. Requirements for these six panellists are strictly defined and state that the representatives should be "involved in health care, covering notably the public sector, patients and end-users in general".

2. Study for the support of the impact assessment of potential institutionalised partnerships under Horizon Europe. It intends to assist with the preparation of the European Partnerships under Horizon Europe. Its primary objective is to support and provide inputs to the impact assessments of the 13 Candidate Institutionalised European Partnerships.

As a result, civil society's access to a seat at the table seems restricted. The diversity of voices in the Innovation Panel is undermined by the fact that more than half of the permanent members are already representatives of the other three IHI bodies, and the **panel will be chaired by the Executive Director**.

Under Art. 114 Additional tasks, the framework highlights the IHI's task to "*ensure all stakeholders have the possibility of proposing areas for future calls for proposals*" and that regular communication is organised. However, no clearly defined framework is put forward on how this can be achieved and, as mentioned above, **stakeholders are not sufficiently included** in the governing board or IHI's bodies. Criteria for which stakeholders and interest groups will be included are also not clearly defined.

Recommendations:

- A dedicated Stakeholder Group should be created to allow for a meaningful consultation and communication with the public and relevant groups (e.g. patients and public interest groups).
- The Innovation Panel should be composed of independent representatives of the scientific community with an obligation to declare any potential conflict of interest and should be chaired by a selected chair from among its members.

AGENDA SETTING

The interim evaluation highlighted the fact that the process of developing the Strategic Research Agenda for IMI2 and call topics was considered by many stakeholders to lack transparency and to be dominated by industry partners. Most stakeholders reported that it was unclear how to contribute to the development of the SRIA or the development of the annual work program. As a result, IMI's research agenda was imbalanced towards areas that were already profitable for industry, at the expense of research into urgently needed long-term preparedness for epidemics. It took the outbreak of the COVID-19 pandemic and huge amounts of public funding suddenly being made available for IMI to start working on this issue seriously. GHA and CEO also showed how the pharmaceutical industry had previously opposed pandemic preparedness becoming part of IMI's priorities.

Agenda-setting process of the Innovative Health Initiative, including Strategic Research and Innovation Agenda should be open, transparent, and inclusive, with a meaningful involvement of CSOs and all relevant stakeholders. Unfortunately, in its current form it does not ensure adequate levels of transparency and inclusiveness.

According to the proposal, the Governing Board is obliged to adopt the SRIA, which is a joint undertaking key document that "shall identify the partnership's targeted impact, foreseen portfolio of activities, measurable expected outcomes, resources, deliverables, and milestones within a defined timeframe".

This is the task of the Governing Board, but there is no mention in the regulation about who should prepare such an agenda and who should be consulted. Similarly, the annual work programme, already being drafted, is heavily influenced by the private partner.[3] Unfortunately, IHI seems to repeat the fundamental flaw of IMI2, where the partnership strategy was prepared by only one of its branches - industry.[4]

Another important limitation of the IHI proposal is the key focus on vaguely defined strategic **unmet public health needs**, in particular, those **currently insufficiently served by industry**. The proposal says that an unmet public health need shall be defined as "a need currently not addressed by the health care systems for availability or accessibility reasons". However, the proposal does not provide any criteria to assess these reasons.

Instead, the only health need clearly addressed in the objectives of Innovative Health Initiative is the contribution to **Europe's Beating Cancer Plan**. While being an important public health challenge, cancer cannot be necessarily seen as an unmet public health need with a funding of €4 billion set aside for the Plan alone. The IHI's predecessor refers to WHO Priority Medicines List, as a blueprint for its strategic focus. The current proposal does not refer to any recognised and evidence-based tool that could be used for needs-driven priority setting. As a result, there is no clarity when it comes to selection of the final focus of the partnership. Investments in research areas where public funding is urgently needed might be at risk. These areas include long-term preparedness for epidemics (including caused by coronaviruses), HIV/AIDS, and poverty-related and neglected tropical diseases.

Recommendations:

- The IHI should clearly prioritise challenges listed in some of the most recognised resources, such as the WHO Report on Priority Medicines for Europe and the World and WHO R&D Blueprint.
- The work of IHI should be informed by a Global Health Strategy and a Communication on Global Approach to Research and Innovation - expected to be issued in 2021 - to inform R&I priorities and ensure needs driven health R&I policies.

ACCOUNTABILITY

One way to ensure societal impact of European policies and programmes, including research, is by implementing adequate **accountability mechanisms**. Unfortunately, both IMI and IMI2 operated without any defined, planned way of measuring societal impact. This seems to be somewhat improved when it comes to IHI provisions. At the very last, the proposal provides **an obligation to monitor and assess the outputs, results and impacts** in accordance with the general Horizon Europe monitoring framework, which in a limited way, considers societal impact and provides some general indicators. The proposal includes **a commitment for all Joint Undertakings to contribute to the achievement of the Sustainable Development Goals**, which are the cross-cutting reference for the EU policy, unfortunately the monitoring framework is missing.

3. Expanding the corporate capture of research: the new EU Joint Undertakings
4. The interim evaluation of the Innovative Medicines Initiative 2 Joint Undertaking (2014-2016) operating under Horizon 2020

In the past, IMI and IMI2 failed to ensure that health technologies developed, thanks to EU R&I funding, delivered public return on public investment. Indeed, massive sums of public funding are being invested in biomedical R&D, an important contribution which civil society believes should be considered when defining the price of medicines so that it is accessible and affordable for all. In order to ensure beneficial public health impacts, certain access conditions should apply to public funding for research projects. The Innovative Health Initiative makes an important step by committing to making *"products and services developed based or partly based on the results (...)* ***available and accessible to the public****."* However, it does not explain how this will be made possible and **does not legally commit to affordability**, despite it being mentioned in the Recitals of the proposal.

According to the Horizon Europe Regulation, specific provisions should be laid down to ensure that beneficiaries of EU funding provide open access to peer-reviewed publications. At the same time providing open access to research data follows the principle "as open as possible, as closed as necessary". Unfortunately, such provisions are not included in the regulation. The proposal does not mention any strict criteria for derogations of open data requirements. As we know, based on the evaluation of IMI2, many beneficiaries of EU public funding decided to opt-out from the obligation to provide open access to research results. To improve this, Innovative Health Initiative should include strict derogations restricted to limited and rare circumstances which should be transparently monitored and reported by the European Commission.

Additionally, the Innovative Health Initiative does not include any provision on developing a more transparent and flexible Intellectual Property Rights regime that would help facilitate translation of the project results into applications that reach society, despite it being one of the recommendations of the IMI2 interim evaluation.

Finally, the IHI proposal does not address another important recommendation from the IMI2 interim evaluation - to increase transparency of the calculation rules and composition of in-kind contributions from industry partners. The in-kind contributions were not only maintained, but also in light of proposed provisions, the audit mechanisms have not been reinforced to follow the evaluation of IMI2 and stakeholders' concerns. Furthermore, clear methodologies for quantifying additionality, leverage and competitiveness gains were not introduced.

Recommendations:

- A new requirement should be introduced according to which all beneficiaries of EU public funding for R&I for treatment, prevention or diagnosis shall commit to access, effectiveness, affordability and availability principles.
- Opting-out from the open science requirements should be restricted to limited and rare circumstances which should be transparently monitored and reported by the European Commission.
- Clear methodologies for quantifying additionality, in kind contributions, leverage and competitiveness gains should be introduced, and information should be transparent and accessible.

Annex

Review of the how civil society's recommendations on the preceding IMI initiative were incorporated into the IHI.

GOVERNANCE that ensures less industry dominance and public ownership

Recommendation	Technical Analysis	Rationale for IHI
Public interest governance NOT INCLUDED	Public interest criteria are not clearly defined in the proposal. The current mandate of the European Commission does not allow for a strong public interest guidance of the partnership and does not ensure a delivery of public interest value.	Strong representation of the public interest is essential in governance that ensures accountability, public health needs driven approach and alignment with other EU policies. The IMI2 interim evaluation showed that different goals and modes of operations of industry and the public partner appeared to interfere with the efficiency of the decision making process. The public partner should be in the driving seat, and go beyond the current obligation (Article 16) to coordinate between the activities of the JU and the Union's actions.
Balanced governance mechanisms NOT INCLUDED	All JUs are to have a Governing Board, an ED, and may have a scientific advisory body, a states' representatives group and a stakeholder group. The proposal also commits to a broad involvement of relevant stakeholders, including CSOs. Despite the possibility in general provisions, the IHI foresees neither a stakeholder group nor a meaningful involvement of a wider range of relevant stakeholders. The proposal includes a creation of the Innovation Panel, which will essentially act as a scientific advisory body. The composition of the panel is highly unbalanced - featuring only 10% of scientific community representatives and duplicating representatives of the industry and the public partner, already present in other bodies. The Panel will be chaired by the Executive Director, not an independent scientist. Advice of the Innovation Panel can be easily dismissed by the Governing Board.	Only well balanced governance can ensure real public needs driven strategic decision making. This means that CSOs and public interest groups need to be equally represented in all governance mechanisms. A dedicated Stakeholder Group should be created to allow for a meaningful consultation and communication with the public and relevant groups.The impact assessment points to the importance of breaking down barriers to cross-sectoral collaboration, including with CSOs. The Innovation Panel should be composed of independent representatives of the scientific community with an obligation to declare any potential conflict of interest and should be chaired by a selected chair from among its members (in line with Article 19 and Recital 26).

Transparent governance NOT INCLUDED	The proposal does not include a clear commitment to high standards of transparency at all levels, when it comes to governance.	To ensure a high level of transparency, the governing board and other bodies should publish their meeting outcomes and minutes in a timely manner. Additionally, it is recommended that the governing bodies make their rules of procedure publicly available and that the JU publishes in a timely manner all necessary information about the projects, work plans, budgets etc

AGENDA-SETTING that responds to a needs-driven research agenda

Recommendation	Technical Analysis	Rationale for IHI
Agenda setting - Strategic Research and Innovation Agenda NOT INCLUDED	The agenda setting process lacks transparency and is industry-driven. The Governing Board is responsible for adoption of the final agenda, but the proposal does not provide clarification on who is in charge of the development of the document and organising consultations.	The IMI2 evaluation is recommended to increase the transparency of the development of the strategic agenda and call topics generation to reflect European interest. **The European Commission should lead on the elaboration of the SRIA and should organise a public consultation.** The overall process should be transparent and ensure a high level of meaningful involvement of the public. Strategic research agenda and work programmes, including their draft versions, should be made public in due time.
Focus on unmet public health needs NOT INCLUDED	The proposal says that an unmet public health need shall be defined as “a need currently not addressed by the health care systems for availability or accessibility reasons”. However, it lacks additional criteria to assess these reasons. Additionally, it focuses on “diseases affecting Union’s population”, which is not clearly aligned with IHI’s planned contribution to global challenges.	**The IHI should clearly prioritise challenges listed in some of the most recognised resources, such as WHO Priority Medicines List and WHO R&D Blueprint.** The work of IHI should be also informed by a Global Health Strategy and a Communication on Global Approach to Research and Innovation - expected to be issued in 2021 - **to inform R&I priorities and ensure needs driven health R&I policies.** **The partnership should prioritise neglected areas listed including HIV/AIDS and other poverty related and neglected diseases.**

Regulatory projects NOT INCLUDED	The current proposal does not provide any safeguards or instructions for the implementation of various types of projects, including regulatory projects.	Industry partners should be restricted from leading on projects focused on regulatory issues. A dedicated ethical code of conduct should be developed by the Governing Board and consulted with the public, before the first calls for proposal start.

ACCOUNTABILITY that ensures impact for society

Recommendation	Technical Analysis	Rationale for IHI
Ensuring societal impact PARTLY INCLUDED	The proposal provides an obligation to monitor and assess the outputs, results and impacts in accordance with the general Horizon Europe rules. The proposal includes a commitment for all Joint Undertakings to contribute to the achievement of the Sustainable Development Goals.	To maximise societal impact of the IHI, in line with the Horizon Europe objectives, a set of dedicated KPIs should be elaborated. This kind of specific monitoring will help to ensure meaningful contribution of IHI towards the achievement of the SDGs.
Accessibility, availability and affordability PARTLY INCLUDED	The IHI proposal commits to making "products and services developed based or partly based on the results (...) available and accessible to the public". However, it lacks a legal commitment to affordability, despite it being mentioned in the Recitals.	In order to ensure beneficial public health impacts certain access conditions should apply to public funding for research projects. **A new requirement should be introduced according to which all beneficiaries of EU public funding for R&I for treatment, prevention or diagnosis shall commit to access, effectiveness, affordability and availability principles.**
Open access and IP regime NOT INCLUDED	The IHI proposal will follow general rules of Horizon Europe when it comes to open access policy, however it does not mention any strict criteria for derogations of open data requirements. The proposal does not include any provision on developing a more transparent and flexible Intellectual Property Rights regime that would help facilitate translation of the project results into applications that reach society.	Adequate derogations should be **restricted to limited and rare circumstances which should be transparently monitored and reported** by the European Commission. Ownership and management of publicly funded R&I results should be driven by public interest and explore various forms of intellectual property management and licensing, including equitable licensing. There should be an actionable access plan envisioned that would lay out how the end products will be made accessible.

Grant agreements NOT INCLUDED	The IHI proposal foresees publication of committed in kind contributions per participant, as it was in IMI2. It does not improve transparency when it comes to grant agreements in general.	The drafting of grant agreements should be considered a matter of public interest and have public oversight and public interest criteria attached.
"In kind" contributions NOT INCLUDED	**The IHI proposal does not include another one of the important recommendations from the IMI2 interim evaluation: to increase transparency of in-kind contributions from industry partners.** The in-kind contributions were not only maintained, but also in light of proposed provisions, the audit mechanisms have not been reinforced to follow the evaluation of IMI2 and stakeholders' concerns. Furthermore, clear methodologies for quantifying additionality, leverage and competitiveness gains were not introduced.	Contributions by industry partners should be changed to financial contributions. If maintained, clear methodologies for quantifying additionality, in kind contributions, leverage and competitiveness gains should be introduced, and information should be transparent and accessible.