The Innovative Medicines Initiative (IMI2)

IMI2 is a Joint Technology Initiative (JTI) bringing together the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA) to "pave the way for breakthrough vaccines, medicines and treatments to tackle Europe's growing health challenges". In other words, IMI2 is a public-private partnership aiming to finance precompetitive pharmaceutical research and development.

The proposal for a Council regulation for IMI2 was presented by the European Commission on 10 July 2013. The draft Strategic Research Agenda is not part of the proposal though it is crucial as it indicates the research priorities for the next 10 years (2014-2024). The EU indicative contribution to IMI2 is EUR 1.725 billion while EFPIA will contribute EUR 1.5 billion in-kind.

Challenges and opportunities with IMI2

Priority setting

The preamble to the new IMI 2 proposal states that "*Research related to the future of medicine shall be undertaken in areas where combination of societal, public health and biomedical industry competitiveness goals requires pooling of resources and fostering collaboration between the public and private sectors* […]. *The areas* [of investments] *would be of public health interest, as identified by the World Health Organisation report on priority medicines for Europe and the World, which is currently being updated with the new version expected to be released in 2013*."

In spite of the European Commission contributing financially in a substantial way, priority setting within IMI2 remains largely industry-driven. While industry makes its choice on the basis of future market and opportunity to profit, addressing existing public health needs at EU level and globally requires enhanced EU leadership and strategizing. A more active participation of the European Commission in the definition of research priorities would also increase IMI2's consistency and cooperation with other national and European initiatives in the field of health R&D, which so far have been limited (see IMI Second interim evaluation p. 31).

- **Given that IMI2 is largely financed by EU taxpayers' money, we call for enhanced EU leadership and strategizing in order to prioritise public health needs, especially with regard to global health R&D. This is essential to increase IMI2's consistency and cooperation with other national and European initiatives in the field of health R&D.**

Addressing health R&D gaps

Existing pharmaceutical gaps and medicines development needs have been identified in the WHO Report on Priority Medicines for Europe and the World 2013, commissioned by the European Commission as a resource to be used in planning the Horizon 2020 research programme. Among the main priority areas identified, the Report recommends increased research effort on R&D for Poverty-Related and Neglected Diseases (PRNDs), which have not been sufficiently addressed in the first phase of IMI and remains marginal in the current research agenda.

There is not only a moral imperative to consider this field, but also a strong business case to include PRNDs in the scope of IMI2. Excellent expertise and knowledge within European pharmaceutical companies and academia as well as Product Development Partnerships provide a lot of potential to boost innovation in this field. By including poverty-related and neglected diseases in the scope of this PPP, members of the pharmaceutical industry who get involved in projects are able to expand and underline their commitment to neglected diseases, as stated in the London Declaration on Neglected Tropical Diseases (www.unitingtocombatntds.org), for example.

Investing in PRNDs R&D has the potential to optimise health outcomes globally, reduce poverty and foster growth, while meeting existing EU commitments to address global health needs such as the "*2010 Commission Communication and Council Conclusions on the EU role in Global Health*". Furthermore, some PRNDs are endemic in the European region and might become more prevalent in the future as a result of climate change and/or migrations. Tuberculosis (TB), for instance, is already a major public health threat to Europe, especially due to the increasing incidence of multidrug-resistant TB and the emergence of extensively drug-resistant TB. Other challenges include HIV, visceral leishmaniasis (present in patients co-infected with HIV), helminthic diseases and Chagas disease (also as a result of mother-to-child transmission).

- **Existing research gaps can only be filled if public funders take on leadership and use initiatives such as IMI2 to support research in those fields. R&D for PRNDs should therefore feature in IMI2 as recommended by the Priority Medicine Report 2013 and the IMI2 stakeholders' consultation.**

Governance

The Second Interim Evaluation of IMI called for increased transparency and clearer rules of governance for IMI2. The Scientific Committee, which should ensure science-based recommendations, expressed concerns for not having been sufficiently involved in the procedure of drafting and updating the Strategic Research Agenda (IMI Second Interim Evaluation p. 30). Some representatives of the other advisory board, the States Representative Group, which represents the interface to the relevant stakeholders in EU countries, stressed that they had a limited impact on the management of IMI (IMI Second Interim Evaluation p. 30-31). We believe that relevant public stakeholders have not been adequately involved in the activity of IMI despite the existence of mechanisms, such as consultations and the Stakeholder Forum, which could have ensured that.

- **The definition of priorities and the overall management of IMI2 should be more inclusive and transparent. Relevant public stakeholders should be consulted about the definition of research priorities and regularly informed about IMI2 developments.**

Open access to research data and access to the end product

While IMI is established to ensure that public money contributes towards more efficient and needs-driven R&D, benefits resulting from this research are mainly privatised and there are no clear conditions laid down in regards to access to research data and affordable access to the end products. Participants in previous IMI projects have complained over industry refusing to provide access to patient outcome data of clinical trials and the "inappropriate level of control and secrecy" (BMJ 2013;347:f5354).

Non-disclosure of essential R&D health data means additional delays, bottlenecks and wasteful and – in the case of clinical trials – unethical repetition in the development of life-saving medicines. Broad sharing of data resulting from IMI2 projects is therefore essential to reinforce collaborative and cumulative processes to increase scientific knowledge. Sharing data can also increase the transparency and accountability of research and bolster its reliability by enabling other investigators to repeat or extend analyses. Horizon 2020 Rules of Participation require mandatory open access to research publications and the promotion of open access to research data in order to maximise public return on investment. It is important that IMI2 implements and expands on these objectives.

In order to facilitate broad uptake and return on public investment, Intellectual Property deriving from IMI2-funded research is in principle to be licensed on non-exclusive terms. In accordance with IMI2 goals of open innovation and broad dissemination of knowledge this would benefit the scientific ecosystem and maximise societal benefits of EU funded research.

- **IMI2 should develop binding guidelines for ensuring open access to research results after the conclusion of the project.**
- **IMI2 should develop binding guidelines on Intellectual Property management and licensing (exploitation) of results, designed in a manner that ensures broad and affordable access to the end product.**

Alignment with the WHO Consultative Expert Working Group

Following the launch of the WHO Consultative Expert Working Group on Research and Development's report, at the World Health Assembly (WHA) of May 2013, WHO Member States adopted a resolution, which includes a process for rapidly identifying R&D demonstration projects. The purpose of these demonstration projects is to test new approaches to R&D that enhance needs-driven R&D and access to results. The EU has recognized the need for new bio-medical innovation models in Horizon 2020. The recent update of the report on Priority Medicines for Europe and the World 2013 also points out the need for alternative business models to address persisting market failure in global health R&D. The WHO demonstration projects provide a chance to embrace these new approaches to biomedical R&D. Lessons learned through demonstration projects can benefit European innovation projects and new models will provide incentives for new EU players (biotech, research institutes) to enter the playing field.

- **IMI2 should align and coordinate its initiatives with future initiatives resulting from the WHO CEWG process.**