

8 March, 2018

Drafting of Framework Programme 9

This contribution to the discussion around the drafting of Framework Programme 9 (FP9) is informed partly by discussions that took place at the event [Open Science for Health: Shaping the New Framework Programme](#), organised by Health Action International (HAI) on 31 January 2018 at the European Parliament. The event was attended by a variety of stakeholders, including academia, civil society organisations and members of European Union (EU) institutions.

Recommendations:

- FP9 shall explore patent sharing and promote licensing policies as mechanisms to improve access conditions to medical technologies; this would include a European patent pool of products developed with EU funds.
- Ensuring that public investment in research and innovation (R&I) is transparent, with the price of the end product taking into account the public contribution.
- Measurement of the social impact of public funding for R&I by developing SMART indicators that assess the impact on health-related Sustainable Development Goals (SDGs), particularly SDG 3.8.
- Funding biomedical R&I initiatives that focus on unmet public health needs and lead to biomedical products with added therapeutic value should be prioritised.
- Linking mandatory open access and open data requirements to publicly funded research to ensure that knowledge gained with the support of public funding is openly available/enjoyable/accessible to researchers and the wider public.
- FP9 shall support early publication clauses—instead of patenting—on EU-funded experimental processes in order to stimulate cooperation between research teams.
- As H2020 has, shown, it is critical that cooperation between public and private partners is guided by public interest and developed in an open and accountable way during the whole research process.
- Involvement of civil society in the drafting and implementation of FP9 will not only ensure a more participatory process, but also guarantee that other voices are heard, widening the impact and benefits of public funded research initiatives.

HAI also endorses the following demands for transparency, public return on public investment and a health needs-driven research agenda put forward by a number of civil society

organisations—for background information, see [Joint Submission to European Commission Public Consultation on Horizon 2020](#) sent in February 2017.

1. More public investments in biomedical R&I

- The EU should avoid budget cuts to the next EU Research Framework Programme (FP9) and consider increasing funds, as proposed in the European Commission (EC) communication to the Council¹.
- Within the FP9 budget, the EU should increase its investment in biomedical R&I.

2. Biomedical R&I priority setting determined by public health needs

- The EU should fund biomedical R&I initiatives that focus on unmet public health needs and lead to biomedical products with added therapeutic value.
- Biomedical R&I priorities should be set according to priority diseases/pathogens as defined by the WHO², and be set according to public health and patient needs, defined through transparent and inclusive priority-setting processes at national, European and global levels.
- The EU should adapt priority setting procedures under FP9 and its joint undertakings (such as future Innovative Medicines Initiatives and European & Developing Countries Clinical Trials Partnership) to ensure balanced stakeholder involvement and greater transparency on the decision-making processes.
- The EU should increase consistency and cooperation between FP9 and other national and European initiatives in the field of biomedical R&I.
- The EU should keep its Societal Challenge pillar as one of the key cornerstones of its research policies and funding.

3. Ensure public return on public investment & safeguard equitable access to publicly funded biomedical R&I

- The EU should attach equitable access conditions to public funding in health R&I to ensure public return on public investment and affordable access to health technologies resulting from EU R&I funds.
- Parties receiving EU biomedical R&I funding should agree on provisions to tackle the affordability, accessibility, availability and efficiency of the end product, along all the R&I stages.

¹ “A new, modern Multiannual Financial Framework for a European Union that delivers efficiently on its priorities post-2020”
https://ec.europa.eu/commission/sites/beta-political/files/communication-new-modern-multiannual-financial-framework_en.pdf

² In particular the WHO List of Priority Pathogens: http://www.who.int/medicines/publications/WHO-PPL-Short_Summary_25Feb-ET_NM_WHO.pdf

the WHO Blueprint List of Priority Diseases: <http://www.who.int/blueprint/priority-diseases/en/> and in the future the recommendations of the WHO Global Observatory on Health R&D

- Ownership and management of publicly funded R&I results should be driven by public interest and explore various forms of intellectual property (IP) management and licensing, including equitable licensing.
- The EU should do more to explore the use of milestone prizes and market entry rewards in the field of biomedical R&I, and promote models to de-link the cost of R&I from product price. (Box 2)
- FP9 should include indicators for measuring the societal impact of EU investment.

4. Increase transparency

- The EU should ensure complete transparency regarding the costs of R&I of medicinal products, so that the price of the end product takes into account the public contribution.
- The EU should make research consortium agreements under FP9—including those of its joint undertakings—available through publication. This should include the public (EU and, ideally, national public support) and private shares (in-cash and in-kind) of the contribution to the research consortium.
- Where such publication is not practicable, governance may be accomplished by committees with balanced stakeholder representation (including academia, industry and patient, civil society, and consumer groups).

5. Mandate open access publishing and open data

- The EU should mandate open access and open data requirements to publicly funded research to ensure that knowledge gained with the support of public funding is openly available to researchers and the wider public.
- The EU should limit and further specify the grounds for derogations of open data requirements allowed under the FP9.
- The EU should consider funding 'open source dividends' to incentivise open data and sharing of knowledge.

