# Public return on public investment: Ensuring sustainable societal impact of EU-funded biomedical research & innovation

## CIVIL SOCIETY'S PROPOSAL FOR HORIZON EUROPE, THE NEXT EU RESEARCH FRAMEWORK PROGRAMME

High prices of new drugs for cancer, hepatitis C and rare diseases in Europe have attracted great media and public attention and have brought the debate about access to medicines into the political spotlight in the EU and globally. Considerable public investments have been made and are being made by European taxpayers to finance scientific excellence and address key societal challenges with a robust EU research programme and budget. However, the EU research and innovation (R&I) programme currently does not attach sufficient upstream safeguards or conditions to public funding to ensure the accessibility, availability and affordability of medical products that result from public investment.[1]

The European Parliament and the European Council have repeatedly called for new approaches. In 2016, the European Parliament (EP) report on EU options for improving access to medicines and the Council Conclusions on strengthening the balance in the pharmaceutical systems urged the need to find alternative and sustainable models that guarantee better health outcomes for everyone. In 2017, Council Conclusions on the interim evaluation of Horizon 2020 towards FP9 acknowledged that EU R&I *"has a crucial role in boosting impact and transparency of R&I, and bringing science and society closer together".* In addition, the EP report on the assessment of Horizon 2020 implementation in view of its interim evaluation and the FP9 proposal stresses the *"need for sufficient transparency, traceability and a fair level of public return on investment of Horizon 2020 in terms of affordability, availability and the suitability of end products, and particularly in some sensitive areas such as health, safeguarding the public interest and equitable social impact"*.

The role of public funding in biomedical R&I and the need for maximising the results of publicly-funded research are issues discussed in several fora both at European and global levels. In May 2017, the Netherlands hosted the World Health Organisation (WHO) Fair Pricing Forum, the outcome report of which suggested that *"governments should attach conditions to research funding so that the public funding is explicitly taken account of in pricing discussions and the results are made publicly available".* A number of innovative sustainable solutions are already being piloted by a relatively small number of organisations, and deliver accessible, available and affordable health technologies for those in need. Guiding principles have been outlined in multilateral initiatives that characterise public-interest driven R&I. In the political declaration of the High Level Meeting of the UN General Assembly on Antimicrobial Resistance, 2016[2] Member States underlined that *"all research and development efforts should be needs-driven, evidence based and guided by the principles of affordability, effectiveness and efficiency and equity, and should be considered as a shared responsibility".* They acknowledged the importance of delinkage - delinking financing of R&D from the price of medicines - in facilitating equitable and affordable access to new medicines, diagnostic tools, vaccines and other results to be gained through research and development. Both the WHO Global Strategy on Public Health, Innovation and Intellectual Property (GSPOA), and the report of the Consultative Expert Working Group on Research and Development (CEWG) include these principles that should guide biomedical public interest-driven R&I.

The EU research programme is an important vehicle to implement these political recommendations. By doing so, EU R&I funding policies would also align more closely with the commitments of EU Member States in multilateral instruments to which the EU subscribes, such as WHO resolutions[3], and the Sustainable Development Goals (SDG3.8), which call for "access to safe, effective, quality and affordable essential medicines".

The proposal for Horizon Europe is the first EU Research Framework Programme to include societal impact as a key impact pathway. This represents an opportunity to implement needs-driven policies which increase the public return on investment of EU-funded biomedical R&I. This will be key to reinforce EU citizens' confidence and show that investments into health R&I result in accessible and affordable products and more effective and equitable health systems.

## KEY PRINCIPLES
## FOR SOCIETAL IMPACT-DRIVEN R&I

In order to maximise the public return and societal impact of EU biomedical R&I policies, we recommend the introduction of a set of Access Principles in Horizon Europe, to which future beneficiaries of EU R&I funding should commit to and be guided by during the implementation of the projects. Those principles are:

- **Needs-driven:** R&I priorities should be set according to priority diseases/pathogens as defined by the WHO[4] 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 on 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.

## IMPLEMENTATION IN PRACTICE:
## ACCESS PLANS AND REQUIREMENTS

In order to translate the above Access Principles into practice, we propose **the introduction of a new requirement in Horizon Europe legal documents and procedures** mandating applicants to set out in their applications how the project results and potential products will be made accessible, available and affordable. This could be done through a requirement for applicants to produce an "Access Plan", similar to already existing "Dissemination and Exploitation Plans" in the current research framework programme; as well as expanding on the information requested in the "Template for essential information to be provided for proposals including clinical trials" or other similar documents in line with the principles outlined above.

**The Work Programmes**, through which the implementation of R&I projects is ensured, **should elaborate further which elements those Access Plans may include**, depending on the type of the project and on the stage of the R&I pipeline (See Table 1 and 2). Access policy requirements should apply to proposals for biomedical R&I for treatment, prevention or diagnosis of seriously debilitating diseases or life-threatening diseases.

The inclusion of the Access Plan will stimulate the applicants to think upstream about some of the challenges that will come down the research and innovation pipeline. Access Plans should be proportionate to the scale of the project and should contain access measures to be implemented both during and after the project. Access Plans will be taken into consideration during the project assessment stage (in the "Impact" section of the project proposal) and will be updated during the implementation of the project. Beneficiaries will be required to report periodically to the Commission on the concrete access activities they carry out. At the end of the project the final report must include the final version of the Access Plan and be considered for the final evaluation of the project by the European Commission. All Access Plans should be made publicly accessible in order to promote transparency.

## **TABLE 1:** Examples of applicable societal-impact driven principles for different stages of biomedical R&I and examples of how these are being implemented in practice

| Stage of R&I | Key elements to consider in protecting societal impact-driven investment | Principles | Examples of initiatives applying this in practice |
|---|---|---|---|
| **Basic medicines product research**<br>- Screening<br>- Hit-to-lead<br>- Lead optimization | The proposed R&I project addresses unmet biomedical needs | **Needs-driven**<br>**Equitable**<br>R&I proposals should focus on unmet public health needs (WHO R&D Blueprint, AMR Development and Stewardship Framework, WHO Global Health R&D Observatory) and on those health technologies and strategies that deliver a clear added therapeutic value | DNDi Drug Booster |
| | The proposed R&I project entails maximal exchange of information and knowledge | **Public-interest driven ownership of results**<br>**Transparency**<br>The research institution must reserve the right to continue using the relevant IP for research and teaching so that follow-on innovation is not inhibited. | Open source malaria<br>Pathogen box |
| Clinical trials | The proposed R&I project will contribute to medical progress | **Transparency**<br>**Efficiency**<br>To avoid duplication and research waste, and accelerate medical progress, Horizon Europe should sign up to and fully implement WHO best practices in clinical trial transparency, and require grantee institutions to do the same. Horizon Europe should annually audit grantees' compliance.[5] | Aeras (tuberculosis vaccines) |
| Technology transfer | Management of IP | **Accessible, available and affordable**<br>**Efficient**<br>**Public-interest driven ownership of results**<br>**Transparency**<br>Technology transfer agreements must include provisions to ensure future affordability. This may be achieved through the following strategies:<br>• Non-exclusive agreements to encourage competition and reduce prices of medicines.<br>• When exclusivity is necessary to attract investors, the technology transfer agreements shall include provisions securing affordable access to the technology.<br>The transferring institution maintains rights to amend or revoke the agreement should the agreement result in unsatisfactory affordable access. | Berkeley University's Socially Responsible IP Management Programme |

## TABLE 2:
How Access Plans link to TPPs

**The Access Plan should make a clear link with established target product profiles (TPPs), where they exist, in order to guarantee that financed projects align with public health needs.**

- **Indications:** Which disease?
- **Additional therapeutic value:** Does the product address biomedical gaps?
- **Population:** Which patients and where? Vulnerability of patient groups.
- **Transparency:** How are Open Science principles implemented?
- **Clinical Efficacy:** Will the product be highly effective for the indication?
- **Safety and Tolerability:** What kind and how many adverse effects the product will have? In adults? In children?
- **Stability:** How long will it be possible to store the products and under which conditions? Will the formulation be suitable for the target populations?
- **Route of Administration:** How do you envisage the product to be given to patients?
- **Dosing Frequency:** How often and how long will it have to be given?
- **Cost:** Will it be affordable to target population? What are the mechanisms by which the applicant intends to make the product affordable (for example, product price ceilings, open licensing, technology transfer, etc.). Where details on the target price are included within TPPs, the Action Plan should demonstrate how the beneficiary will meet this target price
- **Time to Availability:** How long will it take to develop?
- **Registration:** In which countries the developer will seek to have the technology marketed? Projected timeline for registration and marketing.

[1] Answer given by Commissioner Moedas on behalf of the Commission to a Parliamentary question, October 2016, stating that "the applicable rules do not foresee conditions being attached to EU-funded research projects on pricing of products" http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=P-2016-006918&language=EN

[2] https://digitallibrary.un.org/record/842813/files/A_71_L-2-EN.pdf

[3] For example, WHA resolution 61.21 on "Global strategy and plan of action on public health, innovation and intellectual property" or WHA resolution 66.22 on "Follow up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination"

[4] 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.

[5] For more details, see: Transparency International, Cochrane, TranspariMED and CRIT. 2017. Clinical Trial Transparency: A Guide for Policy Makers https://docs.wixstatic.com/ugd/01f35d_def0082121a648529220e1d56df4b50a.pdf A simple checklist of WHO best practices can be found here: https://www.transparimed.org/single-post/2018/08/22/How-strong-are-your-clinical-trial-reporting-policies-New-checklist. Please note that Horizon 2020 formally signed up to WHO best practices, but to date has not published the stipulated audit reports.

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