AN OPPORTUNITY TO CHANGE THE EUROPEAN INNOVATION MODEL

CONTRIBUTIONS TO THE INTERIM REVIEW OF HORIZON 2020

In the midst of the crisis of access to medicine suffered by the most vulnerable populations on the planet and now also by the European citizens, Horizon 2020 cannot stay removed from the changes in science policy being demanded by society, experts and political representatives. Changes that bring science closer to the people; changes at different levels that serve the health and wellbeing of the people and to ensure that pharmaceutical products are developed for the public good. For this reason we propose; (1) to review the governing framework of the programme to give it greater transparency and a more balanced approach in decision-making and to ensure that the definition of priorities responds to the health needs of the population rather than business interests; (2) to maximize the social return on investments by including mandatory conditions for financing which will guarantee access to knowledge and affordability of pharmaceutical products; (3) to provide significant financing for alternative innovation models to the current patent system in an open and collaborative way with the goal of transitioning to a fairer, more efficient, and sustainable biomedical R&D system.

INTRODUCTION

Horizon 2020 has become one of the most important political initiatives, offering the greatest number of opportunities in the European Union. This proposal, which contains a series of recommendations, is particularly focused on the societal challenges and, in particular, biomedical research and the development of innovative health technologies.

Article 168 of the Treaty of the European Union states that it is obligatory to guarantee a high level of protection of human health(1). Moreover, it is common now to read in a great number of documents that health objectives should be cross-cutting, across all policies of the European Union(2). The best way to meet the societal challenges and protect the common good is to create public knowledge with strong civic participation and dialogue between all stakeholders. For this to occur, the societal challenges must remain a priority for two reasons. Firstly because even though great achievements have been made over the last two decades in relation to health technology R&D, many more are needed to meet the medical needs that are not being covered for the well-being of citizens in Europe and throughout the world. Secondly, much work is still to be done and it is essential, therefore, that Horizon 2020 strategically addresses real societal needs and that biomedical research is positioned to really serve the general interests of citizens. It is also necessary to create incentives and the necessary ecosystem to foster biomedical R&D for those illnesses that have been forgotten and for which research is not being carried out. Health research affects the

(2) Better research for better health. A vision for health and biomedical research from the scientific Panel for Health. The European Commission’s Scientific Panel for Health (SPH) is a science-led expert group based on the provisions of the Horizon 2020 Specific Programme that has been tasked with helping to achieve better health and wellbeing for all. https://ec.europa.eu/programmes/horizon2020/en/h2020-section/scientific-panel-health-sph
The initiatives undertaken by Horizon 2020 in the area of health technology and product R&D must add value in comparison to others that are on the market; they must also be suitable, accessible and affordable. Moreover, the environmental and societal impact of their development must be taken into account. For this reason, a fundamental review of the governing principles of Horizon 2020 and how they are transferred to member states is essential. A mandate that promotes participation, public debate and transparency between all economic, social, health, and scientific stakeholders should allow full institutional collaboration. Horizon 2020 should also extend its focus to other areas beyond the development of pharmaceutical products. The social determinants of health are numerous and it is necessary, therefore, to focus attention on other risk factors including societal factors such as health inequality, mental health, health and safety and prevention of adverse effects, guaranteed access to health services and benefits, guaranteed financial support for the maintenance of the European health system on principals such as equality in financing and progressive fiscal systems.

1) Horizon 2020 should be a policy that complements budgetary needs but it can never replace Member States’ budgets. It should be a policy that incentivizes national investment and the national budget commitments, establishing science as a State policy. One way in which it might be possible to revise Horizon 2020 would be to request that participating States increase public and private investment in R&D to at least 1.5% of GDP in order to access Horizon 2020 tenders.

2) It is also vitally important to connect Horizon 2020 with the health needs of citizens and innovation. For this it is necessary to establish an alignment of agendas that responds to the basic rights of citizens as their full integration into society and their well-being is dependent upon their health: this is the political direction in which Horizon 2020 must work.

It is also essential to take a critical look and review the objectives on the basis of which the program was created. While economic growth may be an important implication of biomedical research and medical and pharmaceutical innovation, this cannot be Horizon 2020’s primary objective. The exclusive focus on economic growth nullifies many initiatives that do not have a direct impact on the economy but rather on science itself and the lives of people and which are just as necessary. It also excludes many solutions that are not based on technology but that can contribute to reducing the incidence of mortality and morbidity among the population and promote health.

We hope that these recommendations can be useful in the current review of Horizon 2020 and the future framework programme.

1. ON THE PRIORITIES AND PRINCIPLES OF HORIZON 2020

The initiatives undertaken by Horizon 2020 in the area of health technology and product R&D must add value in comparison to others that are on the market; they must also be suitable, accessible and affordable. Moreover, the environmental and societal impact of their development must be taken into account. For this reason, a fundamental review of the governing principles of Horizon 2020 and how they are transferred to member states is essential. A mandate that promotes participation, public debate and transparency between all economic, social, health, and scientific stakeholders should allow full institutional collaboration. Horizon 2020 should also extend its focus to other areas beyond the development of pharmaceutical products. The social determinants of health are numerous and it is necessary, therefore, to focus attention on other risk factors including societal factors such as health inequality, mental health, health and safety and prevention of adverse effects, guaranteed access to health services and benefits, guaranteed financial support for the maintenance of the European health system on principals such as equality in financing and progressive fiscal systems.
social needs of the population. Provided they are part publicly funded, Horizon 2020 and national research programs should promote mutually agreed upon agendas that are oriented towards the needs of the people whose taxes are used to support them. The 2013 WHO report on Priority Medicines for Europe and the World can be a very positive instrument in better defining the agenda of Horizon 2020 in relation to health technology R&D.

3) Horizon 2020 must bring science and innovation closer to the people and this must be the central axis upon which the programme must be supported. Under this model, it is important to seize the opportunity to turn the products, data and discoveries that arise from public financing into public assets; that the investment made provides a return for society. This social return, accessibility and the suitability of the product should be the elements on which the Horizon 2020 program is sustained.

4) It is necessary for civil society to form an active part of Horizon 2020, participating in both the implementation and the decision making process.

2. ON THE PROPOSALS AND METHODOLOGY OF HORIZON 2020

It is fundamental that biomedical R&D investment increases if we want to respond to the health needs of many people around the world. It also key that research is productive and is not duplicated, with a real impact on society in its different dimensions. On the other hand, it must be result oriented in relation to quality, accessible and transparent research in its management and in all of its development.

5) It is necessary to increase budgets earmarked for health R&D and to establish better systems of accountability both in budgetary and methodological terms and for the results of initiatives financed by Horizon 2020.

6) A results-based approach should be the main tool on which Horizon 2020 activities are built and upon which financial initiatives are reported. The real impact should be evaluated in the same way in order to identify the scale and scope of same.

7) New public financing models such as the Tax on Financial Transitions should see revenue ring-fenced to fund global health and, in particular, biomedical R&D that complements Horizon 2020.

All investment must provide a return for society

3. ON INTELLECTUAL PROPERTY, THE PUBLIC INTEREST AND THE SOCIAL RETURN OF HORIZON 2020

The management of intellectual property is one of the fundamental pillars upon which Horizon 2020 is based. In order to change the model of patents and monopolies, steps must be taken to break the link between the price of financing R&D, promoting competition while at the same time rewarding, incentivizing, recognizing and financially compensating the effort of researchers and innovators.

8) Horizon 2020 must incorporate non-exclusive licenses within its rules and guiding principles, examining their possibilities on a case-by-case basis. This process should include clauses that safeguard all development right up to the end, including derivatives such as spin-offs.

9) Responsible licenses must be considered when negotiating intellectual property rules, even if it may take several years for the final product to come to market. If the intellectual property is transferred to a spin-off company, the public developer of the project must remain on in an advisory capacity to ensure participation during the post-development phase.

10) Horizon 2020 has had an Open Access mandate for all projects. This positive aspect brings to light the lack of access for two reasons: 1) in many cases the publication of results is biased and 2) specialized publications do not openly disclose the payments received from users who access articles arising from a publicly funded program. Horizon 2020 must add additional regulations to tackle this, and in the interests of complete accessibility, can establish binding and obligatory mechanisms to ensure the free availability of all publications financed through the programme.

11) In relation to access to data(4), additional special binding dispositions must be included to ensure access to all data from all programmes financed by Horizon 2020. These would be accessible to all persons who wish to check them and/or use them for subsequent research.

12) The European Commission must monitor public financing for R&D in new health technologies, identifying the traceability of investment made therein. All those who receive H2020 financing should sign a commitment to reveal the costs or the R&D of the products and to ensure affordable prices.

13) It is necessary to redouble efforts to further strengthen greater collaboration between Member States, research bodies

---

and all the stakeholders involved in Horizon 2020. Models of open collaboration\(^5\) can maximise and accelerate many research projects that are already underway. They can also establish the basis for future collaboration to ensure the maximum return on the economic and financial resources invested.

14) Horizon 2020 must promote alternative innovation models\(^6\) to the current system of monopolies brought about by patents. That’s why it’s necessary to upgrade innovation models, promote patent pools, rewards for innovation, initiatives for transparency in clinical trials and PDPs; measures that bring transparency to the cost of R&D while ensuring a sustainable price for the product with clear accessibility, suitability and affordability. These models must be used as a series of mechanisms to incentivize innovation and break the link between the cost of R&D and the cost of the products.

15) Initiatives that choose to use alternative formulas in technology transfers and/or collaborative models, such as responsible licenses (see recommendation 14), must be rewarded as a way to promote new models.

16) Public Public-private initiatives, such as IMI, have mainly been oriented towards the commercial interests of industry and not the general public interest. There is an imbalance that weakens the people’s right of access to health and access to medicines which makes it necessary for the European Commission to take leadership in promoting civil society participation in decision-making processes such as IMI 2. Contributions should be equal in kind and quantity, whether they are of public or private origin.

17) The IMI 2 initiative must include transparency, access to all results and data and decisive commitment to open innovation models among its guiding principles, rewarding and incentivizing the development of health products and technology that opt for licenses that guarantee universal access to the new public assets that are developed.

---
