EU Policy Opportunities in Biomedical Innovation and the Public Good

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EXECUTIVE SUMMARY

Knowledge management is becoming more and more central to our social and economic well-being. This is especially relevant to the realm of pharmaceuticals. The current model of biomedical innovation tends to enclose knowledge using intellectual property (IP) rights that are meant to be rewarded in exchange for innovation. However, driven by today's social and economic reality this model of innovation often fails to take into account economic sustainability, does not always deliver needs-oriented innovation, and tends to neglect the least wealthy parts of the world's population including many European Union (EU) citizens. A very worrying development is that pharmaceutical companies' new production pipelines are drying up and fewer truly innovative medicines that add any real therapeutic value are reaching the markets. Moreover, the cost of biomedical innovation is one of the important factors used to justify the high price of medical products. The unsustainability of this situation in the midst of a general public debt crisis is forcing some EU governments to take difficult decisions which, to the detriment of patients and consumers, limit access to life-saving medical technologies.

The *Horizon 2020 EU Research and Innovation Framework* provides the EU with an opportunity to make socially responsible choices that lead to new sustainable models of innovation which contribute to the common good. The EU needs to be a smart investor that makes sure the health of all citizens reaps the benefits of its investments. Now is the time for the EU to be a leader in exploring alternative strategies to biomedical innovation.

In light of Horizon 2020 and the Innovation Union agenda, this Policy Brief offers an overview of the most important contemporary discussions, initiatives and proposals on biomedical innovation, and provides recommendations to European institutions on how to become leaders in exploring new and complementary models of innovation, establishing a truly innovative research agenda while implementing their commitments to Health Equity within the EU and to Global Health. Business as usual is no longer an option. There are

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moral reasons, but also economic and prudential imperatives for policy-makers to explore the proposals being developed, as these aim not only to ensure broad access to medical technologies, but also to ensure the sustainability of European health systems, by rationalising public investment, and improving innovation through efficient knowledge management.

Even worse, this system which shrouds in secrecy the results of health research data resulting from clinical trials leads to an unethical situation in which many patients are being exposed to the harmful secondary effects of drugs where the risks are already known but are not revealed due commercial confidentiality

The World Health Organization (WHO) Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA) of May 2008, and the EU Council Conclusions on Global Health in May 2010 both called for needs-driven innovation and the further exploration of innovation models that de-link the cost of R&D from the price of medicines to ensure both innovation and access to essential medical technologies. “De-linkage” of R&D costs from the price of medicines addresses three weaknesses of the current model of medical innovation: unaffordability, unavailability and unsuitability.

The core of the question we pose is whether knowledge generated by EU financed medical research (in other words, supported by European taxpayers) should continue to predominantly be guided by the generation of returns for private actors or whether EU health research should contain clear social conditionality . For example, the taxpayers who financed the development of a drug cannot obtain it for their family members because they cannot afford it. Should billions of Euros stemming from EU funding continue to be awarded without any strings attached and little consideration for public health benefit and affordability?

Various proposals and projects have been developed by governments, civil society, academics and industry which promote access and innovation. Some are relevant for patients within the EU, while others focus entirely on developing countries and/or neglected diseases, which are relevant to EU policies and commitments in Development and Global Health. While a number of these initiatives have already been implemented, others still remain policy proposals. These include:

Socially responsible IP management or Equitable licensing - The rationale behind equitable licensing is to generate the highest possible social benefit out of publicly funded research. It encourages the open or non-exclusive licensing of patented technology. It would promote R&D in the field of neglected diseases and antibiotics. We propose conditions to be attached to the participation rules of Horizon 2020, specifically to grants for biomedical research.

Open Source research - A new paradigm of innovation in medical technologies which is gaining ground and which is based around the sharing of knowledge rather than enclosing it by means of IP protection. "Open Access" usually refers to projects that provide open data once published. The current expensive medical journals, high data access fees, and the secrecy shrouding raw research data and the results of clinical trials all prevent timely and wide use of crucial health-related information. A number of open source initiatives have been launched in the medical fields over the last decade. Open source medicine can be an especially useful tool for neglected diseases, antibiotic research or for certain conditions that are not properly addressed in the pure market-driven model.

Voluntary licenses to the Medicines Patent Pool - Obtaining a licence for an existing patent can be done on a case by case basis through voluntary or non-voluntary licensing. But it is also possible to manage IP collectively through patent pooling. The Medicines Patent Pool allows producers to pay royalties to patent owners in order to manufacture patented medicines and sell them in countries well before the expiration of the patent term. The MPP is designed to reduce the price of existing medicines and speed up their availability as well as the development of fixed dose combinations and paediatric treatments.

Product Development Partnerships (PDPs) - Aimed at developing new medicines and vaccines through a combination of resources from the public sector, philanthropy, and the pharmaceutical industry. PDPs research, develop and support accessibility of new health technologies that target diseases which disproportionately affect developing countries. The R&D pipeline for neglected diseases is now beginning to show signs of life, with PDPs managing almost 150 projects in pre-clinical and clinical development.

Innovation inducement prizes - Prizes are an incentive system to induce R&D for new essential medicines, and can be implemented in a manner that ensures competition, affordability and widespread access. In the open licensing approach, cash prizes would be a substitute for exclusive rights to sell products and monopoly prices. Innovators would be awarded large monetary "prizes" based in part or in whole on the improvements to health outcomes over existing products. There already exists a variety of prize schemes relevant to medicines development.

Intergovernmental Instrument on Coordination & Financing of Biomedical R&D – Currently being considered by the WHO, this instrument would combine financial obligations for countries to contribute to R&D financing with incentives that deliver innovation and access.

RECOMMENDATIONS: The way innovation is currently being rewarded is putting the economic sustainability of EU research financing at peril. The EU cannot limit itself to "planting the seeds" of

innovation and then naively expect growth, private re-investment in socially relevant projects, and the blossoming of innovation. Thence the EU´s Horizon 2020 project should condition any release of knowledge property to a business plan that conforms to ethical, social and environmental objectives in accordance with the public interest. Furthermore, for the EU to be a leader in technological innovation, it needs to take a broader perspective and look at key developments in open source research and open medicine. We call upon the European Parliament and the European Commission to:

- Incorporate Equitable licensing as a condition for its biomedical research grants, most notably in Horizon 2020 grants.
- Engage in meaningful technology transfer; Horizon 2020 should provide at least the same level of incentives and support for researchers from developing countries as FP7.
- Engage in feasibility studies and pilots for various innovation inducement prizes, in particular concerning cancer research, HIV/AIDs and antibiotics.
- Constructively engage in negotiations for an Essential Health and R&D Treaty at the World Health Organisation as being proposed by the Expert Working Group.
- Orient receptors of EU grants to license to the Medicines Patent Pool mechanism.
- Clear rules in Horizon 2020 to mandate open access to EU financed health related research results.

Now is the time for the EU to take the lead. **The upcoming Horizon 2020 EU Research and Innovation Framework provides the EU with an opportunity to make socially responsible choices that lead to new sustainable models of innovation which contribute to the common good.** The Research program has a budget of 80 billion Euros, unequalled by research budgets globally**. Openness, knowledge sharing and de-linkage or disassociation of the R&D costs from the price of products should be the underlying principles.**

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