Time for the EU to lead on innovation

EU policy opportunities in biomedical innovation and the promotion of public knowledge goods.

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Health Action International (HAI) is an independent, global network working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy. www.haieurope.org

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The Trans Atlantic Consumer Dialogue (TACD) is a forum of US and EU consumer organisations which develops and agrees on joint consumer policy recommendations to the US government and European Union to promote the consumer interest in EU and US policy making. www.tacd.org

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Executive Summary

The production of knowledge that leads to innovation has always been crucial to social, political and economic development, and nowhere is this more true than in the discovery, development and production of pharmaceuticals. However, the contemporary model of biomedical research tends to enclose knowledge by means of intellectual property rights (IPRs), awarded in exchange for the results of research and development. Indeed, this model has successfully incentivised numerous key medicines in several disease areas. However, in many others it has failed, and it is becoming increasingly clear that the present model of incentives to innovation is not compatible with any vision of the economic sustainability of global healthcare and it woefully neglects the health needs of the world's poor, who enjoy very limited access to essential medicines.

One of the most critical limitations of an innovation model based on patent monopolies is the reliance on high prices of the resulting technologies. In short, it allows the innovator to recoup R&D costs through high prices while protected against competitors. In addition, the reported paucity of innovation in pharmaceutical companies' development pipelines has resulted in fewer and fewer innovative drugs of any true therapeutic value reaching the market. Originator companies have gradually shifted their focus from health-needs innovation towards marketing, wide patenting, and litigation against competitors. At the same time, the current innovation model shrouds the results of clinical trials and other health research data in secrecy, leading to a potentially unethical situation in which patients are sometimes being exposed to the harmful secondary effects of medicines where the risks are known but not revealed due to commercial confidentiality.

The globalisation of stringent intellectual property (IP) standards and the accompanying high prices have contributed to limited access to essential medicines in the Global South. Crucially, in the context of this paper, market-driven innovation, extended patents and high prices, add to the financial burden of already over-stretched European public health systems, in the midst of a global economic and public debt crisis.

For all the above reasons, debates on alternative and complementary approaches to innovation for health products have been taking place at the World Health Organization (WHO). The European Union (EU) has also committed itself to exploring alternative models, through its development and health policy objectives.

The WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPoA) of May 2008, and the EU Council Conclusions on Global Health in May 2010 both called for needs-driven innovation and for further exploration of innovation models

that de-link the cost of research and development (R&D) from the price of medicines to encourage both needs-driven research and more affordable access to essential medical technologies. The '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. Many of the new proposals in this paper have recently been recommended by a special WHO Consultative Expert Working Group on Coordination & Financing of Biomedical R&D (CEWG) that will deliver these recommendations to the World Health Assembly (WHA) in May 2012 (WHO, 2012).

In respect of publicly funded medical R&D, one of the core questions is whether knowledge generated by EU financed medical research (in other words, supported by European taxpayers) should continue to be predominantly guided by the current business models of large private actors or whether EU health research policy should contain clear social conditionality. In other words: Should the billions of Euros' worth of EU funding continue to be awarded without any strings attached such as commitments to social responsibility or openness? Should market-driven innovation be promoted by the EU to the detriment of greater access to effective and affordable health treatment?

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 public good. The EU needs to be an investor that makes sure that EU citizens reap the benefits of its investments through improved public health. It is time for the EU to be a leader in the exploration of biomedical innovation strategies that promote both affordable access to R&D outcomes, and the creation of public knowledge goods.

Various proposals and projects have been developed by governments, civil society, academics and industry which attempt to promote both access and innovation. Some are relevant to patients within the EU, while others focus entirely on developing countries and/or diseases that predominantly affect developing countries. A new paradigm of innovation in medical technologies which is gaining ground is based around the sharing of knowledge and data rather than shrouding it in IPR. While a number of these initiatives have already been implemented, others remain policy proposals. Among others, these include:

Socially Responsible Licensing (SRL) or Equitable Licensing - SRL encourages the non-exclusive or conditional licensing of patented technologies. The rationale is to generate the highest possible social benefit from publicly funded research. SRL could be the standard model for publicly funded biomedical research.

Open Source Research - Open Source mechanisms allow researchers to collaborate and share knowledge with an open approach to IPRs. A number of Open Source initiatives have been launched in the medical field over the last decade. Open Source research can be an especially useful tool for neglected diseases, antibiotic research, or for certain conditions that are not properly addressed in a purely market-driven model.

Open Access - This refers to the provision of open access to published research. The high cost of medical journals and high data access fees prevent the sharing of knowledge and wide use of crucial health-related information.

Patent Pooling - The Medicines Patent Pool (MPP) supported by UNITAID aims to simplify and improve voluntary licensing negotiations with the aim of accelerating generic competition to lower the cost of patented medicines and stimulate the development of fixed dose combinations and paediatric forms for HIV/AIDS medications. In order for this to function, companies need to license their HIV/AIDS products to the MPP.

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 usually encourage research and the development of products that target diseases which disproportionately affect developing countries.

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. Innovation prizes can function to incentivize parts of the innovation process, to reward research outcomes that are not expected to result in commercially viable products. An ambitious version of innovation prizes would include open licensing of the end products.

Biomedical R&D Treaty or Convention - Proposals would secure and enhance sustainable financing mechanisms for R&D, in order to develop and deliver health products and medical devices which address the health needs of developing countries. The R&D Convention concept is predicated upon the principles of a de-linkage of product prices and R&D costs, open-knowledge innovation, competition among suppliers of products, access to and transfer of technology to developing countries. The WHO's CEWG recommends that formal intergovernmental negotiations on a binding R&D Convention should be initiated (WHO, 2012).

Recommendations

The EU could make a real difference in supporting global calls for an improved system of biomedical innovation. The EU aims to be a leader in technological innovation, yet the EU

could and should be a leader in both innovation *and* access. For the EU to succeed, it needs to look positively at new approaches to innovation and promising developments in the area of incentives and financing of R&D. The EU should consider innovative proposals, especially proposals that de-link the R&D costs from the price of final products, and become a key player in the development of new sustainable models of biomedical innovation and public knowledge goods. The need for a new approach to innovation is even more urgent where R&D is subsidized through public funds. EU policies should be guided by the notion that knowledge goods developed by means of public funds need to be affordable and accessible to all. The Common Framework Horizon 2020 policy is an ideal opportunity for the EU to take the lead in some of the issues described above.

HAI Europe and TACD call upon the EU:

In respect of research programmes and EU internal policy, to:

- Incorporate socially responsible principles as a condition for its biomedical research grants, most notably in Horizon 2020 grants.
- Establish clear rules in Horizon 2020 to mandate open access to EU financed health related research results.
- Promote meaningful technology transfer; Horizon 2020 should increase the level of incentives and support for researchers from developing countries as compared with FP7.
- Carry out feasibility studies and pilot programmes for various innovation inducement prizes, in particular concerning HIV/AIDs, cancer research, neglected diseases and antibiotics.
- Ensure access to clinical trial data of medicines registered with the EMA or national market authorities.

In respect of international policy, to:

- Constructively engage in negotiations for a Biomedical R&D Convention as to be recommended by the WHO Consultative Expert Working Group to the 65th World Health Assembly in May 2012.
- Encourage companies to join the Medicines Patent Pool granting voluntary licences to their patented technologies for better access in all developing countries.
- Rather than extend market exclusivities through IP protection in EU Free Trade Agreements, focus on stimulating therapeutically valuable and affordable innovation.