

Can We Afford the Current Model of Medical Innovation? Europe says, 'no'

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Summary

Pharmaceutical pipelines are drying up and new medicines that demonstrate any real therapeutic advantage are few and far between. At the same time, European populations are aging fast, placing greater demands on public health systems, in particular for long-term treatments for chronic diseases. To compound the situation, these changes are all occurring against the backdrop of the global financial crisis, which has triggered



major cuts in public health spending, particularly for pharmaceutical expenditure. The meeting at the European Parliament in Brussels on 18 November, provided a platform for over a hundred participants representing the full range of stakeholders to debate and discuss new models for medical innovation that can meet these challenges, which are faced by developed and developing countries, alike.

Opening

The meeting was opened by Eva Joly, the Greens MEP, who gave a resounding critique of the current intellectual property (IP) dominated model of medical research and development (R&D). Joly cited examples of the recent price cuts on medicines by EU Member States, such as Germany and Spain; and also the lack of incentive for profit-driven companies to work on R&D for neglected diseases that affect poorer countries, as clear evidence that “our current model of medical innovation does not work”.

In her introduction, Ruxandra Draghia-Akli, from the European Commission’s Directorate-General (DG) for Research talked about the changing landscape of public health, and the issue of affordability and access to treatments as a result of increased life expectancy in the EU. Dr. Draghia-Akli also spoke about the steps taken within the Commission to follow-up on the EU commitment to explore models of innovation that disassociate (de-link) the costs of R&D from medicines prices. She noted that DG Research would be exploring such models as part of the upcoming Research Framework Programme (FP) 8.

Panel One: The current model of innovation has reached its limits



The first panel of the morning, moderated by Thijs Berman MEP, served as a rather damning indictment of profit-driven, rather than needs-driven health research. Speakers presented on the structural short-comings of the IP-based business model, and its consequences for public health and public budgets.

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David Hammerstein of TransAtlantic Consumer Dialogue (TACD) opened the panel by reminding the audience that health must be viewed from the perspective of the public good; and the ability of companies to make money, while a factor, should not dictate how and if people can access safe and effective treatment. Mr. Hammerstein also pointed to recent medicines price cuts in EU States as an indication that governments are waking up to the fact that access, as well as innovation is threatened under the status quo.

IP, Competition and Access in Europe

Sophie Bloemen, Project Officer at HAI Europe, gave the first presentation; providing an overview of the relationship between competition, cost, innovation, and access in the pharmaceutical sector. The presentation showed that, under the current model, innovators have profit-driven incentives to hold on to their monopolies, which has encouraged business practices that seek to delay and deter competition from generic medicines. DG Competition’s pharmaceutical sector inquiry revealed practices by originator pharmaceutical companies, such as persistent litigation, excessive patenting, and a heavy focus on marketing and promotion of their products. Ms. Bloemen also pointed out that steps to curb such practices, for example through Anti-Trust cases and fine-tuning of the regulatory frameworks, do not address the underlying profit-driven incentive system: “we don’t need more of the same, clever marketing, good lawyers, and strategic patenting. What we do need is new R&D models that reward health impacts and real innovation.”

How the Current Model is Failing Europe

Jorg Schaaber, President of the International Society of Drug Bulletins (ISDB), started his presentation with the remarkable statistic from Prescrire International that, out of the 984 new medicines and indications over the period of 2000 – 2009, only 2% represented a real therapeutic advance for patients. The message to participants was very much: don’t be fooled – ‘new’ does not mean better. His presentation also included data that raised questions about the quality of evidence used



in the medicines authorisation process, in particular the issue of suppression of scientific evidence and the large advertising budgets employed to create blockbuster products.

Access to Medicines in Eastern Europe

Raminta Stuikyte, representing the European AIDS Treatment Group (EATG), offered an informative perspective on the issue of poor drug access for Eastern European countries both within and outside of the EU. With regard to the new EU member states whose incomes have not reached western EU levels, there are major inequalities compared with the rest of the EU. In Lithuania, up to 66% of costs for medicines supplies are paid out of pocket. In Latvia, only 15% of those in need of HIV/AIDS treatment receive it, while Latvia together with Estonia has the highest rate of new infections. Ms. Stuikyte told the meeting that pricing in non-EU Eastern European countries is better than within the EU, where new members have to adopt the EU’s IP rights regime. In Ukraine, treatment costs are approximately 2000 per year, whereas in Latvia and Estonia, patients pay 19 times more. Yet, the EU’s regulations on data exclusivity prevent the import of more affordable medicines from the Ukraine. She stated, “access and innovation are both important. Too few of us receive treatment in Latvia, too many experience stock outs in Romania. There is a need to support innovation in a better way so new EU countries can also get the treatments they need. We should not export our policies to other countries.”

Responses

There were two official responses to the panel from, Bernard Pecoul of the Drugs for Neglected Diseases Initiative (DNDi), and Maria Iglesia Gomez from DG SANCO. Dr. Pecoul presented an operational example of a non-traditional R&D model, a product development partnership that included some of the features that campaigners have called for, for example: de-linkage between R&D costs and medicines prices, a needs-driven approach to research priorities, and a built-in consideration of access as an integral part of the R&D process. Dr. Pecoul stated that, “[w]hen we negotiate contracts, we have to overcome the IP barrier. We won’t sign if we’re not guaranteed that the product will be available to all people. We look to encourage open source and open publication and to support and facilitate technology transfer. If we have to go into patent and licensing terms, it is in the context of protecting the access of patients”

Mrs. Iglesia Gomez’s statement outlined DG SANCO’s commitment to developing health policies that put patients and consumers first and to a cooperative approach to the innovation challenges.

Discussion Topics from the Panel

During the discussion following Panel One, participants posed questions to the panel on the viability of public-private partnerships to address the high costs of medicines; how milestone prizes for research breakthroughs can be valued in order to be a meaningful incentive; the danger of relying on industry data; and how much the EU can and would commit to exploring alternative models of innovation.

Panel Two: New models for innovation and access to medicines

Panel two presented a range of proposals and initiatives that promote access and therapeutic benefits with real health impacts; from those that sit on the edges of the traditional IP-dominated R&D model to those completely outside it. Carl Schlyter, the Greens MEP, acted as moderator for this panel.



Judit Rius Sanjuan from Knowledge Ecology International (KEI) opened the panel with an overview of the EU’s internal and global commitments to explore models that de-link the cost of R&D from the price of medicines: the WHO’s *Global Strategy and Plan of Action (GSPA) on Public health, Innovation and Intellectual property*, the EU’s own *Council Conclusions on Global Health* (May 2010) that also call for a coordinated global framework for R&D; and the *Communication on the Innovation Union* (June 2010), which proposes a more efficient system with more value for money on R&D, cooperation between researchers and innovators, and recognition of the importance of competition.

Towards new models of innovation: Future work in the WHO



Zafar Mirza, who is the Coordinator of the Department of Public Health, Innovation and Intellectual property within the office of the Director-General of the World Health Organization (WHO), was the first presenter. Dr. Mirza gave an update on WHO’s work on implementing the GSPA, in particular on the formation of a new expert working group (EWG) on Innovative R&D Financing and on the new mandate that the EWG will operate under, following the resolution at this year’s World Health Assembly.

UNITAID & Medicines Patent Pool

The second presentation, from Ellen t’Hoen representing the Medicines Patent Pool run by UNITAID, focused on the importance of sustainable access to medicines, and financing mechanisms that support sustainable access. The presentation clearly illustrated the vital role of generic competition in bringing down the price of anti-retroviral medicines (ARVs) and improving access to ARVs in both developing and developed countries. The aim of the patent pool is not just to allow competitive generic manufacturing, but also to encourage the development of compounds or adapted formulations, such as for paediatric use. However, at the root, it was acknowledged that the initiative can only be successful if patent-holders join, and Ms. t’Hoen called governments to urge pharmaceutical companies to participate.



De-linking Research Costs from the Price of Medicines

Michelle Childs from Médecins Sans Frontières (MSF) again raised the issue of the weakness of the current market-based R&D model for meeting the particular needs of developing countries. The current system yields medicines that are unaffordable, unavailable, or unsuitable for some developing country contexts (i.e. heat stable, paediatric formulations) and the link between the cost of R&D and the prices of medicines feeds these problems. The presentation focused on the EU’s existing commitments to explore de-linkage, and set out some principles to ensure affordability and accessibility, such as; third-party competition, push funding (R&D grants) to small companies, and prizes (pull funding) to stimulate research in priority areas and reward results that meet the criteria for affordability, accessibility and real health impacts.

Prize Fund Model for Innovation and Access



The Prize fund model for innovation and access was presented by James Love of KEI. Mr. Love stressed the need to de-link the prices of medicines from the incentive mechanism and explained how prize funds for R&D would do this and support i) increased sharing and access to knowledge, ii) more efficiently-designed incentives to innovate, iii) rewards based on improvements to health outcomes, iv) reduced incentives for marketing and promotion, v) elimination of high prices for medicines, and vi) a market based on affordable (generic) manufacture of medicines.

Mr. Love also noted that prize mechanisms have been used throughout history to reward innovation, and that there are different ways to design prize mechanisms; ranging from the ‘winner takes all’ approach to a proportional award system. He called for the implementation of some test cases based, for example, on the current proposals for TB and Chagas. Mr. Love then presented two proposals:

- 1) the Donor Prize Proposal for HIV/AIDS treatment, where a certain amount of money would go into a fund for a reward and companies would have to license to the UNITAID patent pool in order to receive it. The fund would also have an innovation dividend. This voluntary approach would allow donors to buy the medicines at marginal cost.
- 2) the Cancer prize fund, which would pay out to companies based on the therapeutic and health impact value of their medicines. Generic production would reduce restrictions on access and every patient could have access to the most effective cancer treatments. The reward could include provisions for researchers that published through open access fora, shared data, or contributed to the development of the medicine in question.



Francisco Rossi from the Latin America & Caribbean - Global Alliance for Access to Medicines presented the innovation and access issues as viewed from the Latin American perspective. Mr Rossi was adamant that, while European policymakers are trying to balance their economic interests with social interests, in Latin America, without an industry, the problem is one of access. Therefore, free trade agreements, such as those negotiated with the United States and the EU bring additional cost burdens when developing countries are forced to pay the same costs for their medicines as industrialised countries. It seems the object of demanding that countries sign up to international agreements, such as the World Trade Organization's *Agreement on Trade-related Aspects of Intellectual Property (TRIPS)*, is to inhibit local lines of R&D and maintain monopoly prices.

New innovation models from the South II

Zakir Thomas presented the work of the Open Source Drug Discovery (OSDD) initiative, a collaborative research community of 4511 members across 130 countries that works on milestone challenges in the drug discovery process, such as the re-annotation of the tuberculosis genome. Mr. Thomas opened his presentation with shocking statistics on tuberculosis (TB) incidence: globally, there are 4500 deaths from TB every year, and in India, where OSDD is based, TB claims a life every 20 seconds. He sees the OSDD paradigm as a way to overcome the constraints of the IP-based model that means “if there is no golden pot at the end of the line, there is no incentive”. Based on a system of attribution and rewards for solutions to interim challenges, OSDD is free to focus on diseases that are neglected by larger market-driven pharmaceutical companies.



Responses



Robert Sebbag, Vice President Access to Medicines at sanofi-aventis, was the first respondent to the panel. He expressed a desire for a more cooperative approach from civil society organisations towards research-based pharmaceutical companies, and called for forward-looking partnerships between different research actors. But, he maintained that “health has a cost”. He recognised that drug donation by companies was not a solution to access problems and that the industry was at a crossroads. With the blockbuster model failing, companies are now looking to developing country markets for big volumes and low margins. Following Dr. Sebbag's statement, moderator Carl Shlyter MEP intervened to state that regardless of companies' intentions, they are tied to a certain business model: “the logic of the corporation is profit, you cannot change that”.

Discussion from Panel Two

A number of participants called for a focus on the necessary structural changes, rather than on the behaviour or actions of specific companies. There were also questions and comments on how to ensure that open source breakthroughs do not get co-opted by monopolies further down the line in the discovery process; the importance of exploring models of medical research that are driven by societal needs and public health priorities; while other participants voiced concerns that despite growing acknowledgment of the failures of the IP-based R&D model, the EU and other industrialised countries continue to export this model to developing countries through bilateral and international trade agreements.

Closing remarks

Carl Schlyter MEP closed the morning conference by calling for renewed attention to the concept of incentive prizes for innovation, calling it 'a very human concept'. David Co-organiser, David Hammerstein from TACD added his thanks to the panellists and participants and encouraged all participants to see the meeting as one step in an ongoing process to move us towards new more sustainable models of medical R&D that bring the access and innovation that the public needs.

To access the webstream of the event, click on the following link:

<http://www.greenmediabox.eu/archive/2010/11/18/innovation/>

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