



EPHA's response to the OECD online consultation on sustainable access to innovative therapies

Reflecting on the last 5-10 years, what do you think have been the major changes affecting access to medicines?

The chickens came home to roost. Access to affordable medicines is no longer a challenge for low and middle income countries alone, but increasingly a pertinent issue in high-income countries as well. This is the turning point in the access to medicines debate in recent years as the challenges which were up until recently observed almost exclusively in the Global South are now present in EU member states as well as the U.S. In the face of the unjustifiably high prices, policy makers are designing and imposing rigid access restriction policies in order to ration the number of patients entitled to the most expensive treatments. If they don't, the very survival and sustainability of health care systems are at risk. It is safe to say that the question of equitable access to medicines represents one of the greatest tests for cohesion and social justice. At the same time, the pharmaceutical business model is gradually shifting from the blockbuster model to the so-called niche-buster business model. The "sky is the limit" principle pursued by the drug manufacturers in pricing their products remains unchanged and is further reinforced. Furthermore, over the past decade, we have witnessed the proliferation of the bidding wars between drug manufacturers. The rising acquisition prices contribute to price hikes for medicines. In line with these developments, there has been an excessive financialisation of drug development with companies spending more on areas that boost share prices (like share buybacks) than on R&D while the "me-too" mentality leads companies to buy promising molecules on Wall Street rather than invest in real R&D.

During 2016, it became clear that the problem of high prices of medicines is systemic and here to stay. As a sign of the critical times and the gravity of the problem, the 28 EU Health Ministers signed off the most strongly worded [Council Conclusions](#) ever. They broke a series of taboos and addressed the major shortcomings of the current business model including the "holy cow", the question of the overprotection, misuse and abuse of intellectual property-related incentives for medical innovation. In addition to the [groundbreaking](#) June 2016 Council Conclusions, the Belgian and Dutch HTA agencies commissioned the 6-month "[Future Drug Pricing Scenarios](#)" project which came forward with 4 alternative models of drug development, a solid response to the "there is no alternative argument". Last but not least, last September, the UN Secretary-General's [High-Level Panel report](#) on access to medicines was published demonstrating that "[the status quo is no longer an option](#)" as The Lancet put it.

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What are the top three (3) issues that must be addressed to ensure access to innovative medicines while maintaining financial sustainability of health systems?

The number one paradox in pharmaceutical decision making is the shroud of secrecy which covers all areas. This secrecy contradicts the essence of pharmaceutical policy which is supposed to serve primarily societal and public health needs. Confidentiality, one of the pillars of the current profit-driven pharmaceutical business model creates an information asymmetry which is damaging the national public interests. There is a striking lack of transparency ranging from the cost of medical research and development to the negotiations conducted by national governments when purchasing medicines. Secrecy combined with policy fragmentation make it easier for the drug industries to play the system.

The second issue that needs to be urgently examined is the role and impact of the intellectual property-related incentives and rewards in the biomedical innovation system. Public health leadership is essential and medical innovation incentives need to be tied to public health priorities. The evidence-based analysis mandated by the EU Health Ministers Council last June on the impact of the additional forms of patent protection (namely data, market exclusivities and the supplementary protection certificate) is a step in the right direction. For example, the orphan drugs legislation put in place in Europe 17 years ago has given us some meaningful innovation but is more and more used for profit maximization by the industries to the detriment of patients. From the public health perspective, orphan drugs cannot be allowed to become the rule as they constitute an explosive mix of pared-down evaluations and the highest prices on the market guaranteed by even longer forms of patent protection.

The same applies to the various early access schemes and the overall push for accelerated approvals embodied by the controversial adaptive pathways school of thought. Faster cannot mean easier access because flexibility is important but so is patient safety. To this end, the further orphanisation of the pharmaceutical regulation, a quite likely outcome of the adaptive pathways approach with its emphasis on niches of patients must be avoided as that would hinder genuine innovation and substantial therapeutic advance. Moreover, a critical review of the impact of intellectual property rights is necessary as aggressive patenting discourages follow-on innovation and competitors do not pursue promising avenues. In addition to the above, due to stronger IPR promotion and enforcement, there is no learning from others' errors while R&D on combination of multiple compounds is substantially slowed down when medicines are owned by competing companies.

A third issue that requires attention is that of the role of public support into medical R&D. National governments in Europe and beyond need to urgently map the different ways that drug manufacturers benefit from public support. Nowadays, citizens are paying for their medicines twice or even thrice by funding research & development, by increased-co-payments, by offering significant tax breaks and incentives to companies to name just a few examples.

Why do you think there are issues in ensuring access to innovative medicines while maintaining financial sustainability of health systems?

See answer to first question.



What changes would you like to see happen to improve access to innovative therapies?

Building on the answer to the second question of the consultation, transparency at all levels should be a top priority. Member states should introduce sunshine acts in order to establish the full cost of research and development. Manufacturers should disclose detailed and independently verifiable data as to the costs of the different stages of research, development and production of their medicinal products. For governments, it is important to be aware of these costs in order to better negotiate when purchasing but also to understand how a price is set.

The role of public support into medical R&D also needs to be well documented. The definition of public support should be clarified as it covers everything from research conducted at universities and publicly-funded research centres to direct financial assistance (through grants and other sources), longer forms of patent protection, in-kind contribution and different types of flexibilities provided such as tax breaks and incentives. In addition to the above, there should be an increase in public funding going into medical funding. Public funding already plays an important role and in certain therapeutic areas, it matches or exceeds private contribution. It is therefore crucial to guarantee the appropriate transparency and governance structure to provide for a fair return on public investment. This can be achieved through open access and equitable licensing provisions. EU Horizon 2020 funding should be accompanied by public-interest provisions such as affordability and transparency conditionalities.

On the issue of intellectual property-related incentives, it is critical to review existing pieces of legislation such as the European orphan drugs regulation in order not only to tackle overprotection & abuse but also look at and test via feasibility/benefit studies and or/pilot projects alternative models such as de-linkage, innovation prizes and other forms of socially responsible licensing. New fair incentives (including but not limited to open source initiatives, public-private product development partnerships, prize funds to reward innovations, independent publicly-funded clinical trials) that promote the right to access, the sharing of medical knowledge and the protection of public health are needed so as to get useful and safe medicines. The above will serve the purpose of establishing the comparative effectiveness of a drug in a health technology assessment and will lead to real therapeutic advance.

Last but not least, it is important to guarantee a healthy and robust competition in the market to address concerns over barriers to generic competition including measures such as non-innovative patent claims or “pay to delay” deals. It is equally important to safeguard and share transparent and independent health technology assessments (HTA) to measure the effectiveness and real added therapeutic benefit of new medicinal products.