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Response to OECD Online Consultation
'Sustainable access to innovative therapies'

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Introduction

Health Action International (HAI) is the only non-governmental organisation that is dedicated to strengthening medicines policy to improve public health. HAI's staff and network of independent experts in 70 countries share information and expertise to solve medicines access and use problems around the world.

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

The last fifteen years have seen a dramatic increase in the price of new pharmaceuticals. Economic crisis and the resulting effects on health budgets has disproportionately affected certain OECD countries (Greece, Spain, Ireland) but it is safe to say that access to medicines has now become a global crisis. Even the most affluent countries struggle to make new medicines available to their populations and the medical profession is sounding the alarm.[i] [ii] [iii] [iv]

At the same time, the rate of innovation measured from a health perspective does not keep track.[v] For example, analysis of pharmaceutical innovations in Europe show that in the last fifteen years, of the 1432 new authorisations, only 29% ranked from 'possibly helpful' (20%), through 'offers and advantage' (7%) to a real advance (2%). 51% were classified as 'nothing new'.[vi] In other words, OECD societies pay more for medicines than ever, but do not get the level of therapeutic innovation one would expect in return. At the same time, there is a drive to accelerate the market authorisation for new products and accept lower evidentiary safety and efficacy requirements. [vii] [viii] New effective medicines are increasingly considered cost-effective but remain unaffordable, which leads to rationing of these proven effective medicines.[ix] [x]

Globalised norms for the protection of intellectual property affect, in particular, countries with a pharmaceutical industry based on the production of generic medicines. Global consequences of this became apparent during the HIV crisis but now affect medicines access more broadly.[xi] Some OECD countries, however, seem to lose the appetite to provide development assistance to ensure low and middle-income countries can finance the procurement of essential medicines.[xii] [xiii] The Lancet Commission on Essential Medicines Policies estimated that universal access to a basic package of essential medicines in low- and middle- income countries would require US$12.90/capita - US$25.40/capita per annum.[xiv] However, some high priced medicines are not included in this estimate.

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

1. Price of medicines need to be at the level a community can afford. If this is not the case, governments should intervene.
2. Governments should experiment with new business models for innovation that move away from a market-driven biomedical R&D agenda and market exclusivities as the predominant financing mechanism.
3. Governments need to assure adequate financing for health based on the principles of universal health coverage and the Sustainable Development Goals (SDGs).

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

- Reliance on exclusivity (patents, data exclusivity, market exclusivity, supplementary protection certificates) as the predominant way of financing R&D. These market exclusivities offer a means to prevent competitors from entering the market. Governments that attempt to negotiate the price of medicines in the face of such monopolies are near powerless.
- Misuse of the orphan medicinal products designation by industries that have adopted the ''niche-buster'' business model, in which marketing authorisation is sought for narrow therapeutic indications backed by market exclusivity and as a result exorbitant medicines prices. Subsequently, the medicines developed as an orphan drug are re-submitted for a new narrow therapeutic indication, therefore accumulating several orphan-drug designations.[xv] Seven of the ten top drugs in global sales have received an orphan indication or designation from the FDA.[xvi]
- Anti-competitive practices such as payments for the delay of generic competition (e.g. pay-for-delay agreements; patent litigation cases).[xvii]
- Lack of government stewardship with regards to priority setting and public financing of and involvement in R&D. As a result, the public pays twice: first as a taxpayer and later as a consumer of health care.
- Weak price negotiation position of governments. For example, the pharmaceutical industry has access to the EU single market while pricing issues are dealt with at the member state level. Some countries demote that role further to regional or hospital authorities that do not have the same negotiating power a government or a group of countries might have. The EU has put itself in a particularly weak position by muting the use of patent abuse remedies such as compulsory licensing (incl. public non-commercial use) through data exclusivity rules without providing waivers necessary for the registration of generic versions produced by a licensee. The weak position of governments is exacerbated by the lack of transparency with regards to R&D cost.

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

The last decade has seen the publication of a number of important reports and recommendations. The Report of the Lancet Commission on Essential Medicines Policies[xviii] offers a good overview of today's issues with pharmaceutical innovation and access that are also relevant for OECD countries.

We specifically would like to make the following recommendations:

Pricing

- More expansive use of flexibilities in patent laws by OECD countries to intervene when proven effective medicines have an unaffordable price.
    - The use of such flexibilities will also strengthen the negotiating positions of governments.
- Better use of government purchasing powers in price negotiations, including EU country level collaboration. Government procurement should allow for the public non-commercial use of patents, as and when required to provide access to lower priced medicines of importance.
- Use of competition law when medicines are priced above the level the community can afford by investigating and sanctioning anti-competitive practices. For example, the European Commission's DG competition should investigate medicines pricing practices.[xix]
- Move towards price transparency and make the real price paid for medicines publicly available (i.e. not the list price).

Research and Development

- Promote and implement "delinkage" models for innovation where the remuneration of the R&D expenditure is no longer dependent on the ability to ask high prices for medicines. For a description of delinkage models see: http://delinkage.org/.
- Explore alternative drug development models and means of production to produce lower priced medicines.
- Ensure transparency of know-how on drug development (crucial for the development of biosimilars), clinical trial and pharmacovigilance data.

Regulatory Measures

- Base decisions on medicines marketing authorisation on solid scientific evidence; take into account considerations on added therapeutic value.
- Ensure robust and independent Health Technology Assessment systems (HTA).
- Safeguard the independence of regulatory and decision-making bodies from corporate interests.
- Implement strong policies on conflicts of interest.

International Solidarity in Global Health

- OECD countries should honour their commitments to the Sustainable Development Goals and ensure adequate funding for the development and procurement of essential medicines and support the establishment of an essential medicines patent pool.[xx]

With kind regards,

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