GLOBAL HEALTH LAW GRONINGEN

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Joint Submission to OECD Online Consultation 'Sustainable access to innovative therapies'

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Joint submission from Global Health Law Groningen Research Centre, Faculty of Law & the Global Health Unit, Dept. of Health Sciences, University Medical Centre at the University of Groningen

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

Patterns in global financing, regulatory measures by governments, and company behaviour have influenced access to innovative medicines over the last decade.

The Global Fund to Fight AIDS, Tuberculosis and Malaria, the United States President's Emergency Plan for AIDS Relief, and Unitaid have attracted and distributed major funding to improve access to these medicines while international (donor) funding has neglected the development and provision of medicines for non-communicable diseases (NCDs) to the low-resourced nations. There is little public support and funding for patient/non-governmental movements in the NCD field, leaving a gap that is filled by industry (i.e. evidenced by the spread of industry-funded patient organisations).

A proliferation of incentives based on market exclusivity (patents, supplementary protection certificate, orphan drug legislation, data exclusivity) have resulted in high prices. Underdeveloped/ill-equipped government pricing and reimbursement mechanisms have not kept pace with the development of innovative medicines for small patient populations. Decision makers have failed to capitalise on governments' negotiating power as large volume purchasers.

Company behaviour/strategy to market drugs for narrow indications has resulted in smaller patient groups, or exploitative dominant market positions, limiting negotiating power and leading to price gouging. (1)

In the short term, these measures result in unaffordable essential medicines, leading to rationing or delayed access (2) and triggering domestic litigation for patient access (3). Recently criticism was heard from physicians, specialists, and consumers (4). The crisis in access led regulators in Italy to condone the foreign purchase and import of lower priced medicines. (5)

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

1) Advance a global R&D framework to set R&D priorities and a strategy to ensure both innovation and access, including by delinking medicines prices from R&D costs. (Please see: www.delinkage.org)

2) Optimise government regulation to achieve equitable and efficient spending to a maximum of available public resources (i.e. adequate domestic financing and international aid for medicines; regulate pooled funding, price control, IP management).

3) Fairly and equitably allocate resources as required by human rights law to provide universal access to innovative medicines according to objective and transparent criteria (i.e. evidence-based medicines prioritisation including through HTA).

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

Governments have the undeniable obligation to ensure sufficient funding, infrastructure, and regulation is in place to guarantee universal access to innovative medicines proven to be a therapeutic advance. High prices commanded by pharmaceutical manufacturers jeopardise universal access to innovative medicines and health systems have neither strong institutions and capacity to rigorously assess such medicines nor the regulation to control prices. (6) Some governments are reluctant to issue licenses when patent monopolies are abused. Patient access schemes (i.e. managed entry, pay per performance, etc.) promoted by the pharmaceutical industry can stimulate the consumption of medicines of unproven benefit and offer neither long-term solutions for access nor sustainability.

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

First, governments should embrace their legal obligation and moral responsibility to realise universal access to medicines of proven therapeutic value. The limited health impacts of many medicines do not justify their expense; however, real innovations that offer health benefits, as a matter of principle, cannot be withheld from patients in need.

Thereafter, OECD countries should:

- Demonstrate the political will to advance a global R&D framework to addresses public health challenges and respect human rights imperatives for universal access;
- Ensure adequate funding for the purchase of essential medicines by countries that lack purchasing power to do so.
- Ensure the careful and objective selection and prioritisation of medicines in universal benefits packages;
- Increase competition and negotiating power, and control medicines prices through law, policy, international cooperation, and technical assistance. This includes abandoning the IP maximalist policies advanced by a number of OECD countries vis-a-vis developing county trading partners;
- Manage IP for single sourced medicines, including through the use of TRIPS Flexibilities and the creation of an essential medicines patent pool;
- Avoid creating ad-hoc earmarked funds for expensive, innovative medicines and instead seek structural, long-term solutions to bring prices down. Resulting savings should be spent on R&D activities;
- Monitor prices and affordability domestically and in the context of aid to developing countries;
- Ensure the transparency of prices and R&D costs;
- Better stewardship of government-funded innovations to prevent the public from paying twice for innovation (i.e. through tax contributions and paying the high price);
- Apply a human rights-based approach, consistent with international law, to ensure equality, non-discrimination and attention to the vulnerable in access policies.

Our recommendations are based on:

Wirtz et al. Lancet 2016 http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(16)31599-9.pdf;

2016 submissions to the UN High Level Panel by 't Hoen et al. http://www.unsgaccessmeds.org/inbox/2016/2/22/contributionglobal-health-law-committee-of-the-international-law-association and Seuba http://www.unsgaccessmeds.org/inbox/2016/2/22/contributionxavier-seubaon-behalf-of-global-health-law-committee-of-the-international-law-association?rq=xavier;

2016 Human Rights Council Resolution (A/HRC/32/L.23/Rev.1) https://documents-dds-ny.un.org/doc/UNDOC/LTD/G16/140/37/PDF/G1614037.pdf?OpenElement;

2017 European Parliament Resolution (2016/2057(INI)) http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P8-TA-2017-0061+0+DOC+PDF+V0//EN;

Other references:

(1) https://www.finance.senate.gov/ranking-members-news/wyden-grassley-sovaldi-investigation-finds-revenue-driven-pricing-strategy-behind-84-000-hepatitis-drug

https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html?_r=0

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(2) https://www.theguardian.com/society/2015/jan/16/sofosbuvir-hepatitis-c-drug-nhs

http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)30006-5/fulltext?rss=yes

(3) *Rogers v Swindon PCT* (England/2006), *Walsh v Pharmaceutical Management Agency (*New Zealand/2010), *Role N°1118-2013* (Chile/2013)

(4) http://www.demedischspecialist.nl/onderwerp/dure-geneesmiddelen;http://www.handelsblatt.com/politik/deutschland/aerzte-attackieren-pharmakonzerne-medikamente-immer-teurer-industrie-am-pranger/19550948.html

(5) https://www.altroconsumo.it/salute/diritti-in-salute/news/epatite-c

(6) Adesina Adebiyi et al. Health Policy Plan 2013, **28**(1):1-10. Gómez-Dantés et al**.** Bull World Health Organ 2012, **90**(10):788-92.

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