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Heading off Global Action on Access to Medicines in 2018

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At the dawn of 2018, political and health leaders must seize the growing momentum and opportunities to tackle the protracted challenges of access to medicines that undermine efforts to save lives and improve health as committed under the Agenda 2030 SDG by all UN member states.

Over half of the world's population does not have access to essential health services, 3.5 billion people are excluded from getting essential medicines; they are neither available nor affordable. The misaligned incentives are the root causes hampering access as well as research and development (R&D) of new molecules which address priority diseases.

Soaring prices of EpiPens for severe allergies, cancer and Hepatitis C treatments dominated headlines in recent years and left millions behind, unable to access the

treatments and vaccines they need, even among high income countries. Death tolls of preventable or treatable diseases due to lack of access to vaccines or medicines licensed in the market are ethically and politically unacceptable. Or the cost of access results in unbearable financial hardships to patients and families and impoverishes them because of large medical bills [i]. High priced medical products are a major financial burden to health insurance funds.

The scientific communities and vaccine industry had failed to develop an effective vaccine for diseases preferentially affecting the poor; this was reflected by the 11 thousand death toll from the Ebola epidemic in Western African countries. Despite that Ebola was diagnosed since 1976, no vaccine was developed. Moreover, there have been just two new classes of antibiotics developed after 1962; though analogue development had kept pace with the emergence of resistant bacteria [ii]. The stagnation of R&D of new classes of antibiotics threatens both global human security and the human right to health; AMR will kill an estimated 10 million people every year by 2050.

Not only people in low- and middle-income countries do not have access, the treatment cost of Hepatitis C, up to US\$84,000—for a three-month course, is unaffordable even by American citizens or insurance funds[iii]. Companies' pricing decisions serve their own financial interests at the expense of patients' wellbeing [iv].

The monopoly status of patented products incentivized by the intellectual property regime is the root cause of limited access to medicines. Where there is no expectation of high profit margins or sales, such as with Ebola, neglected tropical diseases or antibiotics despite public health significance, there is no R&D. In contrast, where there is a lucrative market such as for treatments of hepatitis, cancer and other NCDs, the soaring price is the main barrier [v].

Implementing TRIPS flexibilities, a legal right by all WTO members to safeguard public health interests of their population, also faces challenges such as the use of compulsory licensing of Efavirenz for HIV by Thailand [vi], and imatinib for treatment of leukemia in Colombia. Implementing compulsory licensing, especially for countries considered Upper Middle Income economies, faces considerable retaliation and political pressures from governments in certain high-income countries and industry. As a result, a study predicts a low probability of continued implementation of compulsory licensing [vii]. Hence, further systematic assessment of global health governance on the current patent regime including TRIPS flexibilities, is required.

With growing recognition of both the challenge and the need for reform, many governments around the world agree on key ways to tackle access and biomedical innovation challenges. This includes the importance of promotion of competition, transparency and new models of innovation. For example, Malaysia promotes competition to increase access to high priced hepatitis C treatments. In 2017, Malaysia was the first country to issue a TRIPS compliant compulsory license to allow both innovation and generic competition [viii]. Generic competition has reduced prices; a three-month course of treatment in Egypt dropped from US\$ 900 in 2015 to less than US\$ 200 in 2016, and in Pakistan the same course today costs as little as US\$ 100 [ix].

There is also growing consensus on the need for increased transparency in medicines' prices, research and development costs and clinical trials. Many WHO Member States agreed [x] [xi] to the need to pursue new models for innovation for urgently needed new antibiotics that ensure a return on the public investment by delinking the cost of research and development from prices and sales to improve access to medicines.

To head off this 'perfect storm' of global health challenges, the World Health Organization's Executive Board on January 22–27, 2018 as well as the World Health Assembly in May 2018 will consider for the first time the recommendations of the 2016 UN Secretary-General's High-Level Panel on Access to Medicines [xii]. Based on recommendations of the Panel, the two platforms should find strategic solutions and concrete actions for improved access to medicines and leaving no one behind.

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