HIGH PRICED MEDICINES AND LACK OF NEEDS-DRIVEN INNOVATION: A GLOBAL CRISIS THAT FUELS INEQUALITY

New opportunities and challenges one year after the landmark Report of the UN Secretary-General's High-Level Panel on Access to Medicines

Healthcare in Haiti. Photo: Toby Adamson/Oxfam

On September 14, 2016, the United Nations (UN) Secretary-General's High-Level Panel on Access to Medicines (HLP) publicly released its final report entitled 'Promoting innovation and access to health technologies'.

One year after the release of the landmark report and building upon Oxfam's September 2016 assessment, this paper provides an update on where the HLP report and its recommendations stand, assesses the level of implementation by countries and institutions – especially the UN and the World Health Organization (WHO) – and recommends ways to use the report to improve both innovation and access to medicines.[1]

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INTRODUCTION

In 2015, the UN Secretary-General established a High-Level Panel on Access to Medicines to 'review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies'. The High-Level Panel (HLP) report, released in September 2016, was welcomed by former Secretary-General Ban Ki-moon, who 'encouraged all stakeholders to review the report and its recommendations' and 'to chart a way forward in appropriate fora to ensure access to medicines and health technologies for all who need them, wherever they are.'[2]

One year later, the UN and relevant UN agencies have not taken action to move the report's recommendations forward. Direct opposition by some governments – especially the United States – and pharmaceutical companies has caused unnecessary delays. Yet many governments, experts and civil society organizations have welcomed the report, reaffirming the need for new ways to address the global crisis of high medicine prices and lack of needs-driven innovation. The current system for biomedical research and development (R&D) is driven by market dynamics, as pharmaceutical companies invest in medicines that can produce the highest profit. This model results in unaffordable prices.

The prices of new and even some old[3] medicines continue to be too high to be affordable across the world. In South Africa, a 12-month course of Herceptin, a breast cancer medicine produced by Roche, costs approximately US$38,000 or about five times the country's average household income.[4] The price of the first real cure for hepatitis C was launched at a cost of US$1,000/pill/day, which would require around US$300bn in order to treat the three million infected people in the United States.[5] The same story is repeated in other countries.[6]

Oxfam is calling on the new UN Secretary-General António Guterres and all governments to take immediate action to implement the HLP report's recommendations.

THE SIGNIFICANCE OF THE REPORT OF THE HIGH-LEVEL PANEL ON ACCESS TO MEDICINES

The HLP mandate and final report are significant for several reasons. Although the public health challenges caused by high medicine prices have been known for years, and strategies to address this problem have been negotiated in different forums including the WHO and the World Trade Organization (WTO), the UN Secretary-General went a step further. He asked the HLP to specifically address the incoherence between the obligations governments have in trade agreements that include intellectual property (IP) protections for pharmaceutical products and their human rights commitments related to access to medicines, and the new commitments that governments made as part of the UN 2030 Agenda for Sustainable Development. Of particular relevance was SDG 3 to 'ensure healthy lives and promote well-being for all', which includes a specific target on achieving Universal Health Coverage.[7]

It was the first time a UN Secretary-General (or any forum) has called for addressing the dual challenges of lack of access to affordable medicines and innovation, for ALL patients (both in developed and developing countries), for ALL diseases and for ALL medical technologies (medicines, vaccines and diagnostics).

The HLP was comprised of 15 eminent individuals, including co-chairs Ruth Dreifuss, former President of the Swiss Confederation, and Festus Mogae, former President of the Republic of Botswana. Oxfam International Executive Director, Winnie Byanyima, was one of the HLP Members, and a senior Oxfam staffer was on the HLP's Expert Advisory Group.

Following a nearly year-long process of consultation and deliberation, the HLP's final report acknowledges the global nature of the medicines crisis and the link between the lack of access to affordable medical technologies and the lack of innovation to address patients' urgent needs, and proposes concrete recommendations. The report clearly notes that while there are many important determinants of access to medicines, the HLP was asked to focus on one particular set of determinants of lack of access: medicine prices and the existence of policy incoherence between international obligations of governments, including those to protect intellectual property, to respect human rights and to meet the SDGs.

Oxfam[8] welcomed the creation of the HLP by the former UN Secretary General: the mandate asked the right question, and the final report provides useful recommendations for governments, civil society, research and development, funders and innovators.

The HLP report recognized what Oxfam has long seen in its work, that the current system of R&D for biomedical technologies is ill-suited to meet the needs of millions around the world. Too often, medical tools that could meet essential health needs are simply not developed, such as with urgently needed new antibiotics; whereas those medicines and vaccines that do emerge are unaffordable or not suitable for many. The HLP report recognizes that the innovation and access challenges are part of a common and systemic problem and that the solutions need to be global and driven by government action.

A YEAR IN REVIEW: WHAT HAS HAPPENED SINCE THE LAUNCH OF THE REPORT IN SEPTEMBER 2016?

The year following the report's release has seen new momentum generated in support of the important mandate of the HLP. There is now broad recognition of the global scope of the challenges caused by rising medicine prices and the powerful lobby of the pharmaceutical industry, as well as of the potential for the creation of new strategies, synergies and alliances for change.

But the strong opposition of governments like the US, Switzerland, Germany, Japan and the UK is derailing progress.[9]

High medicine prices and lack of innovation for neglected and infectious diseases have historically been seen as a 'developing country' or 'poor people's' problem. It has also been a source of contention between developed and developing country policies,

for example regarding inclusion of protections for pharmaceutical companies in trade agreements as pursued by the United States, European and other developed countries. But access to medicines is no longer a North versus South issue. It has become a high priority for many high-income economies, including OECD and G7 countries, as it has long been for many developing countries.

In the United States and in Europe, Members of Congress, patients, insurance companies and government payers of healthcare are raising the challenges caused by high medicine prices to the political arena. Increasingly, reforms, including many recommended by the UN High-Level Panel, are being proposed. In the United States, for example, numerous bills have been introduced at the State and Federal levels to increase transparency[10] and create government strategies to deal with high medicine prices.[11] The promise to deal with pharmaceutical company abuse and medicine pricing became a bi-partisan issue during last year's US presidential election.

Since the release of the UN HLP report, the public health challenges caused by skyrocketing drug prices have been increasingly reported and recognized. At the end of August 2017, Novartis announced a new record US price of $475,000 per treatment for the first FDA-approved gene therapy for leukaemia.[12]

Across the globe high prices for many vital medicines are crippling public health services, denying people the treatments they need and pushing many into debt. The price of insulin, which is used to treat diabetes, has increased by over seven percent in the US over the last year.[13] Diabetes is the seventh biggest killer in the US, with almost one in ten Americans suffering from the disease.[14]

In the past 15 years, the average cost of new anti-cancer treatments in Europe has more than quadrupled.[15] Without effective low-priced medicines, it is very difficult for many women in developing countries to seek treatment for diseases that cast stigma, such as HIV, tuberculosis, hepatitis C and cancer. Cancer incidence, including of the cervix and breast cancers, is increasing in lower-middle-income countries.[16] Yet the price of the cervical cancer vaccine makes it difficult for these countries to roll out the vaccine for all young women, even at the current low price offered by GAVI, the Vaccine Alliance, of US$14 per vaccination.[17] More than 3,000 women die of breast cancer every year in South Africa, and although effective treatment is available, the cost makes it prohibitive for governments, private insurers and patients to afford.[18] Both the lack of effective medicines and the high price of available medicines result in a particularly high burden on women as care-givers, although the cost of care is not economically calculated.

The recognition of the global innovation gaps and the need to search for alternative innovation systems highlighted in the HLP report were also a major priority during the negotiation of the UN High-Level Political Declaration on Antimicrobial Resistance (AMR). All UN Member States have now committed to public return on the public investment in urgently needed new antibiotics by de-linking the financing of R&D from the sales and prices of the resulting medicines. In this regard, the UN Political Declaration on AMR is in close alignment with the recommendations included in the HLP report.

The HLP report recommendations have been the subject of discussions in different national, regional and international forums and processes. The HLP report has been welcomed by most developing countries and several OECD and European governments,[19] including Austria, Brazil, Colombia, Malaysia, Netherlands, Portugal,

India and South Africa.

The report has been strongly welcomed by the European Parliamentary Working Group on innovation, access to medicines and poverty-related diseases (see full statement below), by civil society[20] and experts[21] from around the world.

European Parliament support for the HLP report [22]

'We, Members of the European Parliament Working Group on innovation, access to medicines and poverty-related diseases, would like to express our strong support for the findings and recommendations of the recently released report prepared by the High-Level Panel on Access to Health Technologies, convened by the United Nations Secretary-General.

In accordance with Article 168 of the Treaty on the Functioning of the European Union, a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities. We recognize the challenges caused by high-prices of medicines and lack of public health-driven innovation in Europe and around the world –as highlighted by the exorbitant price of hepatitis C treatments and the lack of innovation in new antibiotics– and support the need to take concrete actions at the European and global level as recommended by the UN High Level Panel report.

Specifically, we support the following concrete recommendations included in the UN report:

- Governments and the private sector must refrain from explicit or implicit pressure or other strategies that undermine the right of governments to use TRIPS flexibilities. It is imperative that governments commit, at the highest political levels, and fully respect the letter and the spirit of the Doha Declaration on TRIPS and Public Health, and refrain from any action that will limit the implementation and use of TRIPS flexibilities. The European Parliament firmly restated this recommendation in its resolution on a new strategy for trade and investment adopted on 5 July 2016.
- Governments engaged in bilateral and regional trade negotiations, including investment treaties, should ensure that these agreements do not include provisions like TRIPS-plus demands that interfere with the governments' obligations to fulfil the right to health.
- Governments, the biomedical industry, institutional funders of healthcare and R&D and civil society, should implement new models for financing and rewarding health research and development (R&D) to ensure that resulting medical technologies will be affordably available and appropriate to public health needs.
- Delinkage of the cost of R&D from product price can play an important role to reduce the costs of development, make products more affordable, and get new products to patients faster.
- Governments should require manufacturers and distributors of health technologies to disclose to drug regulatory and procurement authorities information pertaining to (i) The costs of R&D, production, marketing and distribution of health technology being procured or given marketing approval with each expense category separated; and (ii) Any public funding received in the development of the health technology, including tax credits, subsidies and grants.
- Good governance, strong and concrete accountability mechanisms and greater transparency are decisive. Transparency is necessary to hold governments, the private sector and other stakeholders accountable for the impact their actions have on access to health technologies.

We call therefore on the European Parliament initiative report on EU options for improving access to medicines and more broadly the European Union to fully welcome the UN Secretary General High Level Panel Report, acknowledge the usefulness of the recommendations above and start a process to facilitate the implementation in order to ensure both innovation and affordable and suitable access to the needed innovative medical tools, in Europe and beyond.'

The HLP report has been cited to support specific strategies to increase access to medicines at the domestic and regional levels, including efforts by the Colombian Minister of Health to reduce the price of cancer treatments. And Chile's Chamber of Deputies cited the HLP report in a resolution it passed to encourage the use of compulsory licenses to import generic versions of a patented medicine when necessary to protect and promote the health of the population.

At the global level, the report has motivated governments to agree on new processes to discuss access to medicines and challenges for innovation, and has created opportunities to increase policy coherence at the UN Human Rights Council23 and at the WTO TRIPS Council.24

Unfortunately, the UN Secretariat and the WHO are under pressure to avoid taking action, which is delaying global negotiations to address the HLP recommendations.

- **UN:** There has been little progress made on the report's recommendations for full-scale UN and member government engagement. The report urges the UN Secretary-General to establish mechanisms to ensure policy coherence, including creation of an independent review body and inter-agency taskforce, and to convene a special UN General Assembly session no later than 2018 on innovation and access to medicines under the 2030 Agenda. Yet there has been no action taken on these recommendations.
- **WHO**: Several governments attempted to have a meaningful discussion about the HLP recommendations at both the 2017 WHO Executive Board meeting and the World Health Assembly, yet their efforts have been opposed and delayed. The WHO Secretariat was reluctant to allow for that discussion to progress.[25] Only recently, the WHO agreed to include the HLP on the agenda of the upcoming January 2018 WHO Executive Board, but under a broader agenda item pushed by the US government that aims to dilute the discussions around medicine prices, trade and the need to reform the current biomedical innovation system.

The report has been strongly opposed by pharmaceutical companies[26] as well as by the US government,[27] the European Commission, the United Kingdom, Switzerland, Japan and Germany – several of which have traditionally defended the interests of pharmaceutical companies in international negotiations. Since the formation of the HLP – and even before the final HLP report was released – pharmaceutical companies and some governments have strongly opposed it and attempted to bury its recommendations. They have been criticizing the process, particularly the core HLP mandate: recognition of policy incoherence and focus on medicine prices and pharmaceutical industry monopoly power. Those governments that seek to protect pharmaceutical industry interests insist on diluting the debate on effective measures to promote innovation and reduce medicine prices.

Figure 1: Country positioning regarding the HLP report recommendations

Source: Oxfam compilation of government statements.

WHAT NEEDS TO HAPPEN NEXT?

Strategies to deal with rising medicine prices and lack of needs-driven innovation should remain a high priority for governments. The HLP report offers opportunities to advance the implementation of urgently needed reforms in order to secure affordable health technologies that can reach the people who need them. National and global actions are needed to address this crisis and ensure equitable access to medicines across the world.

Oxfam recommends the following actions:

- **UN:** Secretary-General Guterres should work with all member governments and across all UN agencies to enable a comprehensive discussion on the implementation of the report's recommendations without delay. The challenges caused by rising medicine prices are a high political priority for many governments. The 2030 Agenda and the newly adopted SDGs are a unique opportunity for governments and UN agencies to build policy coherence. Without addressing access to medicines and innovation challenges, governments' investments and efforts in health will be incomplete, unsustainable and will leave millions behind.
- With the support of many civil society organizations around the world, Oxfam has urged the new UN Secretary-General to take action to move forward the HLP recommendations. Oxfam strongly supports the HLP report recommendation to start global negotiations among world leaders on the crisis of high medicine prices and the need for systemic reforms to the current innovation system – beyond the sphere of health ministers where discussions have mostly taken place until now.
- The HLP recommendations must be considered and fully integrated in the follow-up processes of the UN General Assembly's high-level meetings on HIV/AIDS, on Anti-Microbial Resistance (AMR), on Non-Communicable Diseases (NCDs), and in the upcoming 2018 UN High-Level Meeting on Tuberculosis. In addition, a

specific UNGA session should be created to fully discuss the global access to medicines and innovation challenges across diseases and technologies.

- **WHO:** The new Director-General should work to ensure that the WHO steps up to pursue implementation of the WHO existing mandates on access to medicines and innovation and to increase coherence and alignments among the different relevant WHO initiatives.
- There is strong coherence between the HLP report's recommendations and the WHO mandate on access to medicines. The HLP report presents a great opportunity to enhance the effectiveness and impact of the WHO work on innovation and access to medicines.
- The WHO should facilitate a comprehensive presentation of all the HLP recommendations, with indication of the alignments and opportunities for enhancing the WHO role in implementation, as well as the need and opportunities for other UN agencies and stakeholders to step up.
- **G7 and G20:** Medicine prices are threatening the sustainability and equity of all health systems, including the most advanced economies. Therefore, the HLP report should guide ongoing government negotiations on global heath priorities at the G20 and G7, starting with the upcoming G7 Health Ministerial meeting in Italy and the 2018 Canadian G7 and Argentinean G20 meetings.
- **WTO:** The December 2017 WTO Ministerial in Argentina is an important opportunity to ensure that all governments re-commit to respect the use of flexibilities included in international trade law to protect public health. It is also a forum to create processes that respond to undue pressure by pharmaceutical companies and governments on countries that take legitimate measures to increase access to affordable medicines as recommended by the HLP.

Oxfam, access to medicines and inequality

Oxfam's long history of working on medicines dates back to the 1980s when it campaigned for the pharmaceutical industry to adopt ethical marketing, through research and publication of the books 'Bitter Pills'[28] and 'The great Health Robbery'.[29] Since then, campaigning for access to medicines has been a component of Oxfam's broader program and campaigning effort for access to healthcare and for fair trade. In 2001, Oxfam launched the 'cut the cost' campaign to push pharmaceutical companies to reduce the price of medicines for diseases prevalent in developing countries, especially HIV. In the years since, Oxfam has continued advocating for affordable prices and an R&D system that is dictated by public health needs.

Since the adoption of the WTO TRIPS Agreement that created new government obligations to protect medical technologies with patent monopolies, pressure from civil society, including Oxfam, has resulted in a number of safeguards to increase access to medicines, including the WTO Doha Declaration that established the norm that public health should take precedence over commercial interests.

Oxfam's Even It Up Campaign and 2017 report 'An economy for the 99 percent'[30] show that 1% of the world's population owns almost half of global wealth and that obligations for intellectual property protection enable pharmaceutical corporations with monopoly power to accumulate vast wealth that can be wildly disproportionate to the investment they have made in R&D, while furthering inequality by raising healthcare costs and thereby denying access to needed treatment. Oxfam has also been challenging pharmaceutical companies and the investment community to integrate access to medicines into their business models.[31]

Highlights of the UN High-Level Panel Report's recommendations

The Panel made a total of 30 recommendations in its report. The report's key message is that no one should suffer because they cannot afford medicines, diagnostics, medical devices or vaccines.

The Report provides a clear set of recommendations that build on work done by previous experts at WHO and other forums and that should provide guidance to governments, as well as civil society, private sector and UN institutions, on ways to improve policy coherence to increase needs-driven innovation and access to medicines.

The report states the following:

It recommends that governments increase their current levels of investment in health technology innovation to meet unmet needs and that they promote incentives and financing strategies that delink the costs of innovation from the end prices of health technologies to ensure its availability and affordability.

It asserts the need to enhance transparency within the current R&D system – including R&D costs, clinical trial data, registration practices and pricing and patent information.

It reiterates that obligations for intellectual property protection do not take precedence over public health needs. The report recognizes the role of voluntary licenses for patents that can be issued by pharmaceutical companies as well as their limits when, for example, they exclude middle-income countries, where the majority of the world's poor live. The report recognizes the role of flexibilities provided under the TRIPS Agreement that enable governments to fulfill their human rights obligations by taking necessary measures to secure the availability and affordability of health technologies. Governments can thereby ensure that patents are only awarded for genuine innovation and can use compulsory licenses and other TRIPS flexibilities when patents have been granted.

It says governments and pharmaceutical companies must refrain from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities as reaffirmed in the Doha Declaration on TRIPS and Public Health. WTO Members must register complaints against undue political and economic pressure, and take punitive measures against offending Members.

It recommends that the UN Secretary-General initiate a global process for governments to negotiate agreements on the coordination, financing, and development of health technologies, including a global R&D Convention or agreement.

Finally, it notes the many reasons why people do not get the healthcare they need. These include under-resourced health systems, a lack of sufficiently qualified and skilled healthcare workers, inequalities between and within countries, exclusion, stigma, discrimination and exclusive marketing rights, to name a few.

However, the Panel notes that affordability of treatment is a key concern. While fully appreciating the broader context and determinants of health technology access, the High-Level Panel's recommendations focus on its mandate to address a specific and important aspect of health technology innovation and access: medicine price affordability and the policy incoherence among various international obligations of governments, including those to protect intellectual property, respect human rights and meet the SDGs.

NOTES

1 The final HLP report and 182 submissions received from a wide range of stakeholders including governments, pharmaceutical and biotechnical companies, academics, civil society groups and multilateral organizations are available on the UN SG High-Level Panel website at: http://www.unsgaccessmeds.org/#homepage-1

2 Secretary-General's message on the report of the High-Level Panel on Access to Medicines, 'Promoting Innovation and Access to Health Technologies' (2016) https://www.un.org/sg/en/content/sg/statement/2016-11-22/secretary-generals-message-report-high-level-panel-access-medicines-

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7 Relevant targets in SDG 3 include among others: Target 3.8 Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all; and Target 3.b: Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.

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Although the UK government has not spoken out publicly against the HLP and appears to actively avoid being drawn out on the topic, it opposed the HLP in a private meeting. See http://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Commons/2016-12-01/55941/

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