REPORT OF THE UN SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON HUMAN RIGHTS AND MEDICINES

Oxfam's response

In December 2015, the UN Secretary-General set up a High-Level Panel on Access to Medicines to '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'. Oxfam International Executive Director Winnie Byanyima is one of the 16 HLP members.

As the HLP issues its report, we commend the UN Development Programme secretariat, whose staff worked tirelessly to support the Panel's work. Oxfam calls on the UN Secretary-General and all governments to start implementing the HLP's recommendations without delay, and to ensure that gaps not fully addressed by the HLP should be discussed further.

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BACKGROUND

In December 2015, the UN Secretary-General (SG) set up a High-Level Panel (HLP) on Access to Medicines to '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'. Oxfam International Executive Director Winnie Byanyima is one of the 16 HLP members. As the HLP issues its report today, we commend the UN Development Programme secretariat, whose staff worked tirelessly to support the HLP's work. Oxfam calls on the UN SG and all governments to start implementing the HLP's recommendations without delay, and ensure that gaps not fully addressed by the HLP should be discussed further.

WHY THE HLP AND ITS REPORT ARE IMPORTANT

The starting point for the HLP was the pledge by all world leaders, through the UN-led Sustainable Development Goals, to 'leave no one behind'. This pledge includes the recognition that human rights, including the right to life and health, are universal irrespective of where a person is born – whether in a rich or poor country. Thus, the HLP's mandate was to address the needs of all people in all countries to access health technologies, including treatment for communicable and non-communicable diseases, neglected tropical diseases and rare diseases. This is important given the lack of research and development (R&D) for many health conditions, and the increasingly unaffordable price of medicines for diseases such as cancer and hepatitis C in all countries.

Over the last 10 years, the World Health Organization (WHO) has sought to address the joint challenges of R&D, intellectual property (IP) and access to medicines, focusing on developing countries. For the following reasons, the HLP is a unique venture, intended to make significant recommendations to amend a failing R&D and access system:

1. It is an initiative convened directly at the highest level of the UN system by the Secretary-General. It could be seen as a legacy for Ban Ki-moon.

2. Its mandate recognizes and aims to remedy the incoherence between human rights and IP rules. It is a unique forum to propose a new global R&D system founded on human rights principles.

3. Its mandate to address all diseases for all people in the world requires systemic solutions, instead of narrowly focusing on neglected diseases in developing countries. The lack of R&D for therapies needed for public health and the high price of new medicines are problems that affect all healthcare payers (public and private) for all diseases, in both rich and poor countries.

4. The HLP report and its recommendations are to be launched at the time of the UN General Assembly, thus attracting the attention of world leaders.

WHY HAS THE GLOBAL SYSTEM FAILED?

The global system has failed for two reasons:

1. The R&D agenda is dictated by commercial interest, not public health.

2. Products are priced as high as the market can bear, making new medicines unaffordable.

R&D agenda dictated by commercial interest

The situation is well illustrated by the fact that only 10% of R&D spending is directed to the health problems that account for 90% of the global disease burden – the so-called '10/90 Gap'.[1] Despite progress on treatments for diseases like cancer and hepatitis C, there are still general innovation gaps in health technologies, including diagnostics, vaccines and medicines.

- WHO has declared tuberculosis (TB) a global emergency, yet its total R&D funding (mainly public) was $674m, leaving a gap of $1.3bn against the $2bn annual investment estimated in the global plan to 'Stop TB'.
- There has been a lack of diagnostics for diseases such as Ebola that are suitable for poor settings.
- No new classes of antibiotics have been brought onto the market in 40 years, despite the rise in antimicrobial resistance. Most pharmaceutical companies withdraw from antibiotics research.
- There is no cure or satisfactory treatment for many diseases such as multiple sclerosis.

Products are priced high and are unaffordable

The high price of medicines has long been seen as a problem only for developing countries. Now it is recognized that all countries and all payers (public or private) are suffering from the problems of high prices.

'I was diagnosed with breast cancer in 2013. My insurance refused to cover my Herceptin treatment because of the high price. Now the cancer has spread all over my body. I need Herceptin so that I can live and bring up my two boys.'

These were Tobeka Daki's words to the audience at the International AIDS Conference in Durban in 2016. Tobeka is deprived of the medicine that can save her life because Herceptin costs half a million rand ($35,049) per patient per year in South Africa. Meanwhile, Roche, the company that produces Herceptin, is celebrating strong financial results for June 2016:[2]

In the UK, NICE recommended that the NHS does not pay for Kadcyla, a new medicine for breast cancer, because of its cost.[3] The medicine costs £102,405 – roughly 3.9 times the UK's 2014 per capita income of £26,350.[4]

The cost of new medicines such as those for treating cancer has escalated rapidly all over the world. Eli Lilly's new lung cancer drug, Portrazza, costs about $11,430 a month in the US – six times the $1,870 price that leading oncologists said would reflect the medicine's benefit compared with older therapies. Pfizer set the list price for Ibrance, to treat a form of advanced breast cancer, at $9,850 a month. This is high even after the 20% discount demanded by insurers.

A study of 115 medicines for diseases such as cancer, rheumatoid arthritis and multiple sclerosis illustrates that prices have now exceeded the median household income in the US. In 2013, the average annual retail price for a single medicine was $53,384, which is more than the median US household income, double the median income of Medicare beneficiaries, and more than three times as much as the average Social Security benefit in the same year.[5]

Of the 12 medicines approved in the US in 2012, 11 cost more than US $100,000 per year.[6] The average price for Bayer's kidney cancer medicine, Sorafenib, is $96,000 per year. It needs to be taken for five years. However, after issuing a compulsory licence, the price of the generic equivalent in India is around $175; a 97 percent price cut compared with Bayer's price of $5,551 for one month's course.[7]

Imatinib (Glivec) is an effective medicine to treat chronic myeloid leukaemia. The drug's originator, Novartis, challenged an Indian law which refused the patenting of the medicine. However, the Indian High Court upheld the government's decision. The price of the Indian generic equivalent of imatinib is $170 per month, compared with Novartis's price of $2,200 per month.[8] Thailand issued a compulsory licence to allow the import of the Indian generic version of imatinib, at $1.59–$2.23 for a 100mg tablet compared to Novartis's price of $29.30. A government assessment of the effect of the compulsory licence concluded that by 2009, the availability of imatinib in the Thai health care system had led to 2,435 quality-adjusted life years (QALYs) gained.[9]

High drug prices also affect communicable diseases, as illustrated by the pricing of the latest medicines for the treatment of hepatitis C. At $1,000 per day, all payers are affected. The Netherlands government's submission to the HLP highlighted the problem facing the public purse for the treatment, which costs €48,000-96,000:

'We have an estimated 20,000 patients with this disease. Such costs make our healthcare unaffordable. If we continue in this way, it will become nearly impossible to reimburse patients for these medications.'

In France, it was calculated that providing medicine to treat all people with hepatitis C would exceed the annual budget of the public hospitals in Paris.[10] In Romania, a woman with hepatitis C considered selling her house to buy the €50,000 drug that could cure her. In the UK and Sweden, the governments provided the medication only to patients with a particular degree of liver disease.

Linezolid is a treatment for drug-resistant TB. South Africa is considered one of the 22 high burden countries for TB. At $67 per pill, Linezolid was unaffordable. When the patents expired, the government was able to provide the generic equivalent at $6.86.

Pharmaceutical companies are also hiking prices of old medicines. Last year, Turing Pharmaceuticals created a scandal when it increased the price of a 62-year-old drug to treat a devastating parasitic infection from $13.50 to $750 per pill.

The pharmaceutical company Mylan has been steadily increasing the price of EpiPen, an auto-injector that delivers a life-saving epinephrine to patients suffering from severe allergy. Since 2007, the price has risen from $56.64 to $317.82, a 461% increase. During the same period, the salary of Mylan's CEO rose by $2,453,456 to $18,931,068 – a 671% increase.[11]

Orphan drugs (medicines developed to treat rare diseases that affect a few thousand patients) have become a lucrative business for pharmaceutical companies. The US and EU provide particular incentives for pharmaceutical companies to invest in R&D for orphan drugs, on top of governments' own investment. For example, the annual cost of Soliris, a treatment of the rare disease paroxysmal nocturnal hemoglobinuria, is $488,000 per patient. Last year its net sale was $2.59bn. The worldwide sale of Rituxan, an orphan cancer drug, was more than $7bn last year.[12] The treatment of the rare Fabry disease costs $49m in the Netherlands.[13]

KEY STRENGTHS OF THE HLP REPORT

The HLP report provides recommendations that address the failures in the current R&D system to respond to the human rights imperatives on access to health technologies. It has several key strengths:

1. It is founded on **human rights principles**. The very nature of fundamental human rights requires that these rights outweigh private interests under national law. Human rights are individual, inalienable, universal entitlements acquired by virtue of birth while IP rules are policy tools, among many, to encourage innovation. Other strengths of the report are:

2. It recommends **remedies for R&D that can enhance the availability and affordability of health technologies**:

- SG to convene a process for governments to negotiate a global agreement on a new R&D system, based on delinking the cost of R&D from the price of resulting products, including for neglected diseases and antimicrobial resistance (AMR).

- Greater and more sustainable financing for R&D from public and private sources.

- Encouraging open source innovation.

- Publicly funded research to prioritise R&D for public health needs rather than commercial interests.

3. It emphasizes the right of countries to use **TRIPS flexibilities**, including compulsory licensing and pro-health patentability criteria. It recommends that WTO members log the commercial and political pressure that they face when intending to use these flexibilities, and that WTO implements punitive measures for the offending countries. This is significant because of the huge impact of such pressure on inhibiting countries from fulfilling their human rights obligations to public health.

4. It acknowledges that **FTAs include 'TRIPS plus' provisions** that increase IP protection and enforcement, thus severely restricting governments' ability to use laws and policies to fulfil their human rights obligations. The report recommends that governments entering FTA negotiations should not adopt measures that impede the realization of human rights, and should perform impact assessments of the proposed FTA measures on access to health technologies. The UN and multilateral organizations should support governments to negotiate FTAs based on human rights principles.

5. It calls on governments to implement legislation to enable a quick, fair, implementable and predictable process for **compulsory licensing**, especially for essential medicines (but falls short of recommending automatic compulsory licensing for essential medicines).

6. It acknowledges the negative impact of a lack of **transparency and accountability** in the field of health technology. To remedy this, it recommends:

- Ensuring transparency with regard to the cost of R&D, including information on other costs such as marketing and public financing.

- Expansion of the WHO price monitoring mechanism (currently focused on technologies for specific diseases).

- Making information on clinical trials publicly available, irrespective of the results of the trial (positive, negative, failed, abandoned, neutral). WHO has already set up a website

for this purpose, but it has no records. The recommendation requires companies to share the trials information that is published on the WHO website as well as in peer-reviewed journals.

- Making patent information available. The report acknowledged that the lack of information on patents in different countries has a chilling effect on generic entry to the market. Multiple patents (patent thickets) make it difficult to negotiate with patent holders for licences, whether for further research or to manufacture a generic equivalent. For example, Ritonavir (for HIV treatment) has 805 patents. The report recommends that companies make detailed information available and that the World Intellectual Property Organization (WIPO) should keep a public database on patents.

7. It calls on **governments to play their role in promoting R&D and enabling access**, including through financing R&D and using TRIPS flexibilities. The report also recognizes the **role of civil society** in promoting access to medicines and calls for support to enhance that role.

8. It recommends three mechanisms for **follow-up on implementation of the recommendations, as well as for monitoring progress on access to health technologies**:

- An independent review body established by the SG.

- A special session of the UNGA in 2018 to discuss progress in access to health technologies, encouraging and financially supporting reports from civil society.

- An inter-organizational coordination mechanism between relevant UN agencies to harmonize their country support based on human rights.

AREAS OF THE HLP REPORT THAT OXFAM WANTED TO BE STRONGER

The report made recommendations to remedy policy incoherence but was not bold enough on a number of issues. We regret that it lacked the following:

1. An acknowledgment that the current **R&D system has intrinsic systemic failure because it is based on monopoly protection of IP**, enshrined in the TRIPS Agreement and exacerbated by FTAs. The system is not based on human rights or public health needs, and the report was not bold in recommending systemic changes to ensure that human rights dictate innovation and access to health technologies for all. There should be a call for a new IP regime for pharmaceutical products consistent with international human rights law and public health requirements. This issue should be pursued in other UN fora.

2. A call for **bold punitive actions against governments making threats of retaliation against other governments' use or intention to use TRIPS flexibilities**, including compulsory licensing and pro-health patentability criteria. UN member states should reaffirm their commitment to the anti-retaliation principle and sovereignty of WTO members in complying with TRIPS. Unilateral retaliation against countries using or intending to use TRIPS flexibilities should be deemed a violation of the TRIPS Agreement. The WTO must take immediate punitive actions against such violations. The UN Human Rights Council (HRC) should also receive and investigate complaints (by governments, civil society or other stakeholders and by the HRC on its own accord) of violation of human rights treaties as a result of retaliation. The HRC should recommend appropriate actions including through the Universal Periodic Reviews of UN members. India is a case in point where pharmaceutical companies challenged the part

of India's patent law that defines patentability criteria. Although the Indian Supreme Court upheld the strict application of this law, pressure from other countries continues in order to change the law. There is also ongoing litigation filed by multinational pharmaceutical companies against the strict patentability criteria and examination processes in Argentina and Brazil. Such pressure, and these cases, must immediately stop.

3. **An immediate ban on 'TRIPS plus' measures in FTAs** – such measures must be halted, reversed and banned. While the report acknowledges the continuing limitations of policy space for government action because of 'TRIPS plus' measures in FTAs, it needed to have bold recommendations to stop these measures from being included in new FTAs and to delete them from already signed agreements.

4. **A mechanism to allow governments to issue effectively automatic compulsory licences for medicines on national lists, or on the WHO Model List for Essential Medicines**. Ultimately, these medicines should be exempted from IP protection.

5. **An extension of LDCs' transition periods** beyond 2021 and 2033 until an LDC ceases to be in this category of countries. All LDCs should immediately review their national and regional IP laws to ensure the full use of transition periods.

6. **Greater support for the work of civil society (CS)** to ensure access to medicines. CS work on medicines has been done in the face of massive human and financial resources limitations. UN agencies and other donors should provide funding to support it.

OPPOSITION TO THE HLP REPORT

As anticipated, both the US government and pharmaceutical companies have shown their opposition to the HLP and its work, and have attempted to undermine or water down the report. Their criticism emerges from their strong support of the current system of IP protection, and their desire to maintain control over decisions on R&D and access. Taking a human rights approach threatens the industry's monopoly power that relies on the current system of IP protections. The pharmaceutical industry is likely to attack the report's recommendations, most likely focusing on the following arguments:

1. The current IP based system works and industry actions (tiered pricing, donations, voluntary licences, product partnerships) address any issues that arise in relation to access to medicines. However, this is not accurate because:

    - High prices (as the examples above illustrate) are not solved by companies' individual, disparate and fragmented solutions. For example, Novartis's donation program of imatinib in India is approximately three times more costly than the price of the generic equivalent. Product development partnerships have a role to play for specific neglected diseases. However, it is not economically or commercially feasible to create a partnership for each product for each disease.

    - These 'initiatives' do not address the systemic failure of the current IP-based system to create R&D pipeline that is dictated by public health and not commercial interests. The system also encourages pricing at the highest price that the market can bear (see examples above).

2. New medicines are expensive because R&D into new medicines is expensive – and much of the cost is borne by the pharmaceutical industry. This is not accurate because:

    - There is a lack of transparency on the real cost of R&D. The industry claims escalating cost based on studies from Tuft's University Centre, which is funded by pharmaceutical

companies and which keeps data as commercial secrets. Their latest average cost for developing one medicine is $2.6bn.[14]

- Andrew Witty, CEO of GlaxoSmithKline, called this high cost of drug development 'one of the great myths of the industry'.[15]

- Industry figures include marketing and other management and administration costs. Industry does not make public disaggregated figures available to judge the real cost of R&D.

- An analysis of pharmaceutical R&D expenditure concluded that the median R&D cost for a company was around $56m per drug.[16]

- The cost of developing imatinib is estimated to be $38–$96m. The sales for Novartis's version of the drug in 2012 were $4.675bn, or $390m per month.[17]

- A study by the Liverpool School of Medicine concluded that a price of $100–$250 could be sufficient to meet the manufacturing costs of a 12-week course of anti-viral hepatitis C treatment.[18]

- Public funding contributes to the cost of R&D, including clinical trials. According to some estimates, public funding (especially from the US government) contributes 40% to general medicine development and 60% to the development of treatment for neglected diseases.[19]

3. Other organizations such as WHO are already dealing with issues relating to IP and medicines, so there is no need for a new initiative. It is true that other organizations are trying to address the problems, however:

    - Other organizations have focused on specific diseases in developing countries and do not take a global view of the systemic problems in all countries.

    - So far, other organizations have not made a great deal of progress.

    - The particular mandate for sorting out the incoherence between human rights and IP rules has not been negotiated by any of the other organizations.

IN CONCLUSION

The HLP report on Access to Medicines provides positive recommendations to address the incoherence between human rights and IP protection, in order to ensure access to affordable medicines for all. The UN SG and member states must start implementing the recommendations without delay. Other key issues which have not been fully addressed by the HLP should be discussed further.

NOTES

1 http://apps.who.int/medicinedocs/documents/s18767en/s18767en.pdf

2 http://www.globalhealthcheck.org/?cat=37

3 http://cancerunion.org/files/Jeremy-Hunt-1October2015-CoalitionforAffordable-TDM1-CL.pdf

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19 Report of the United Nations Secretary-General's High-Level Panel On Access To Medicines

This paper was written by Mohga Kamal-Yanni. It is part of a series of papers written to inform public debate on development and humanitarian policy issues.

For further information on the issues raised in this paper please e-mail advocacy@oxfaminternational.org

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