Human Rights and Medicines
Patients, patents and big pharma

Background

The High Level Panel (HLP) on Access to Medicines released its report and recommendations today ahead of the United Nations General Assembly in New York. The panel’s critical report recognizes the incoherence between the human rights of all people to affordable medicines and the intellectual property rules that govern the global research and development system.

Oxfam is calling on the UN Secretary General to work with all governments to implement the report’s recommendations without delay. During the Panel’s deliberations, the US State Department and pharmaceutical industry criticized the report and expert group, politicizing the process and putting the Panel’s crucial recommendations at risk.

Oxfam also calls on the UN to explore further bold recommendations – including a ban on intellectual property rules in trade agreements – to protect patients’ access to medicines.

The High Level Panel

The HLP is a unique venture set up by the UN Secretary General, Ban Ki-moon, in December 2015 to address the incoherence between the intellectual property rules that govern research and development (R&D) and the human rights to life and health, including access to medicines and health technologies.

The HLP report on Access to Medicines recognizes that the current IP based system for R&D has put many medicines out of the reach of ordinary people and proposes new ways to incentivise R&D based on human rights principles. The report’s recommendations cover all diseases and all countries. This is important given the lack of R&D for many health conditions affecting or threatening people in poorer countries and the increasingly unaffordable prices of medicines for diseases such as cancer and hepatitis C in both rich and poor countries.

Winnie Byanyima, Executive Director of Oxfam International was a member of the 15 strong HLP, which also included experts from governments, the pharmaceutical industry, development economists, academics and health experts.
**The rising cost of medicines**

“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 are the words of Tobeka Daki from South Africa who cannot access a lifesaving medicine – Herceptin – because it costs US$35,049 per patient per year.

The prices of cancer medicines have doubled in one decade in the United States. 11 of the 12 medicines approved in 2012 in the US cost more than US$100,000 per year now. For example, Eli Lilly said its new lung cancer drug, Portrazza, would cost about $11,430 a month in the US, six times the $1,870 price that leading oncologists said in a recent journal article would be a fair reflection of the benefit the drug offers compared with older therapies.

Sorafenib – a drug developed by Bayer to treat kidney cancer – costs $5,551 per month and must be given over a period of 5 years. After the government of India issued a compulsory license, an Indian company produced a generic equivalent costing US $175 per month.

The Netherlands government’s submission to the HLP highlighted the problems associated with the high cost of hepatitis C medicines, which can be as much as €96,000 for one course of treatment. Their submission said: “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 medicines to treat all people with hepatitis C would exceed the annual budget of the public hospitals in Paris.

At a cost of US$67 per pill, Linezolid, a treatment for drug resistant Tuberculosis (TB) was unaffordable for the majority of people in South Africa where drug resistant TB is a huge problem. When the patents expired, the government was able to provide a generic equivalent at $6.86 per pill.

Recently, it was discovered that Mylan pharmaceutical company has been steadily increasing the price of EpiPen, an auto-injector which delivers a life-saving dose of epinephrine to patients suffering from severe allergy, from $56 to $317 in the United States - a 461 percent increase since 2007. During the same period, its CEO’s pay rose by 671 percent to over US$18 million.

**Opposition to the High Level Panel**

During the Panel’s deliberations, the US State Department and pharmaceutical industry criticized the report and expert group, politicizing the process and putting the Panel’s crucial recommendations at risk.

The pharmaceutical industries’ criticism emerges from their strong support for the current system of IP protection – from which pharmaceutical companies benefit enormously - and their desire to maintain control over decisions on R&D and pricing. Taking a human rights approach threatens the current system of IP protections and hence the industry’s monopoly on new drugs.

The pharmaceutical industries’ chief arguments are:

*The current IP-based system works and that the industry takes steps to address any issues that do arise in relation to access to medicines (through for example tiered pricing, donations, voluntary licenses, and product partnerships).*

The high prices set by drug companies do mean that people who need the drugs can’t access them and the companies’ piecemeal solutions do not work because they don’t address the systemic failure of the current intellectual property-based system to create a R&D pipeline that is dictated by public health and not commercial interests. For example, Novartis’ donation program of Imatinib in India is approximately 3 times more costly than the price of the generic equivalent.
New medicines are expensive because R&D into new medicines is expensive – and much of the cost is borne by the pharmaceutical industry.

Unfortunately it is very difficult to get a reliable figure on the cost of R&D. Estimates of the average cost of producing new medicines – currently standing at $2.6 billion – are based on studies funded by the pharmaceutical industry and use data that is not open to public scrutiny. Independent studies suggest the figure is likely to be much lower – one study by the University of Victoria in Canada put the figure around $56 million per drug. A significant proportion of this money also comes through public funding – estimates suggest the government contributes 40 percent of the funds needed to develop general medicines and 60 percent of the funds needed to develop medicines aimed at the treatment of neglected diseases.

Organizations such as the World Health Organisation are dealing with issues relating to IP and medicines and there is need for no new initiative.

While it is true other organizations are working on this issue and they have not made a great deal of progress; they do not take a global view of the systemic problems facing all countries but instead tend to focus on specific diseases in developing countries.

**Oxfam analysis of the report’s key recommendations**

The report calls for:

- Governments to begin negotiations on a new global agreement on R&D. This agreement should prioritize human rights to health above intellectual property rules and should separate the cost of R&D from the final cost of the resulting product.

- All countries to have the power to use all the flexibilities available under international trade rules to protect access to medicines – specifically under the rules on trade related intellectual property rights (TRIPS)

- All countries to have the power to protect access to medicines under free trade agreements – these agreements often include very strict rules governing intellectual property (known as TRIPS +)

- Governments to implement legislation to enable a quick, fair, implementable and predictable process for compulsory licensing, especially for essential medicines. These licences enable the production of cheaper generic versions of vital medicines that are still under patent.

- Increased transparency on the cost of R&D, pricing, clinical trials results and patent information.

- UN to follow up on the implementation of the recommendations through an independent review body established by the Secretary General and a special session of the UNGA.

Oxfam welcomes these recommendations but calls on the UN to take further steps to explore more bold recommendations including:

- A new intellectual property regime for pharmaceutical products consistent with international human rights law and public health requirements.

- Introduction of bold punitive actions against governments making threats of retaliation against governments using the flexibilities available under world trade rules (TRIPS agreement) to protect access to medicines.
• An immediate ban on intellectual property rules in trade agreements.

• Exclude medicines on national lists or on the WHO Model List for Essential Medicines from intellectual property rules. As a starting point, governments should be allowed to issue automatic compulsory licensing for these medicines.