DON'T SHUT THE PHARMACY OF THE DEVELOPING WORLD!

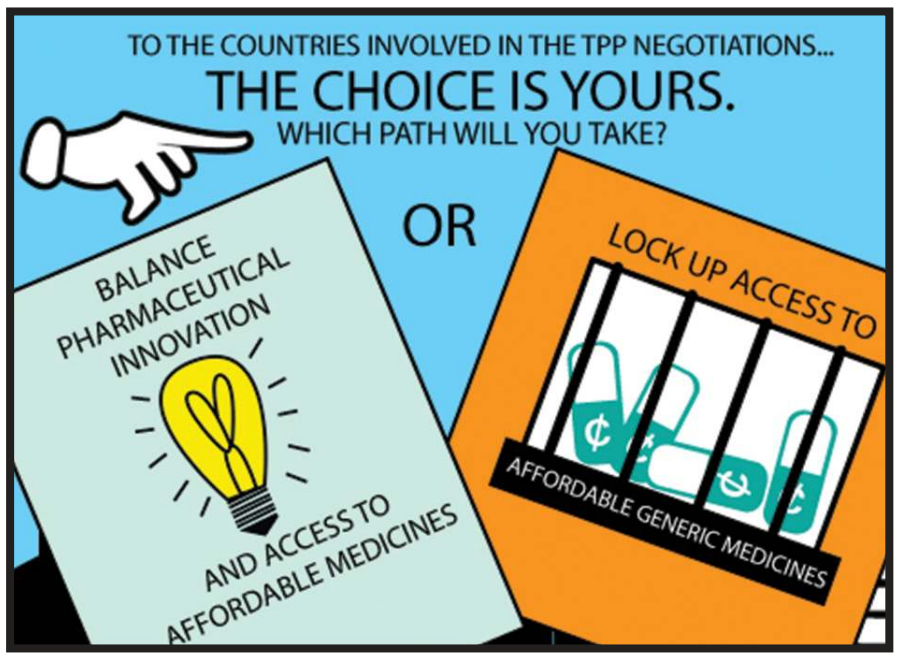
ACCESS

#HandsOffOurMeds

Issue January- March,2016

TPP: A BAD DEAL FOR MEDICINE

WHY INDIA SHOULD BE CONCERNED?



The Transpacific Partnership (TPP) Agreement is a regional trade agreement that has been recently concluded by the United States and 11 other Pacific Rim countries (Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, Vietnam). After more than five years of negotiations the official text was publicly released in November 2015 and is now publically available. The text confirms that the TPP will be the most harmful trade pact ever for access to medicines.

Analysis of the TPP text reveals that it contains intellectual property (IP) provisions that will create new and longer monopolies for multinational pharmaceutical companies, restricting price-lowering generic competition, thereby raising drug prices for millions of people and treatment providers like MSF and Ministries of Health globally. Examples of these new obligations include protecting 'ever-greening' practices and extended patent terms for the pharmaceutical industry. TPP patent rules will accelerate the trend to strengthen and extend IP barriers for medicines that have high commercial returns. These rules will also block R&D reform that would address the needs of millions of people in developing countries. There is a pressing need for reform in the way medicines, vaccines and diagnostics are researched, developed and commercialised.

The TPP reinforces the current broken system of medical research and development (R&D) that relies on high prices to pay for innovation and neglects numerous essential health needs, including for example much needed R&D for new antibiotics to address TB and other drug resistant infections.

Today, 12 TPP countries account for more than 800 million people who will be affected by harmful intellectual property provisions that undermine access to affordable generic medicines. However, if countries like India and Indonesia join the TPP, the impact will be significantly broader.

MSF urges India to lead an effort to counter the expansion of the TPP in the region as it limits production, access and trade in generic medicines. Generic competition has been one of the most reliable and powerful forces to reduce drug prices systematically, thereby making essential, life-saving medicines such as antiretrovirals (ARVs) for the treatment of HIV/AIDS more affordable for individuals and the health systems that serve them.

Patient's Voice

As people living with HIV who rely on a life-long supply of quality generic medicines to stay alive, we are intimately aware that patent barriers undermine the availability of low-cost, life-saving generic medicines coming from India. After India started implementing the WTO TRIPS Agreement ten years ago, we have watched with concern as new cancer medicines that have been patented one by one are being 'merely imported' in small quantities and launched at an exorbitant monthly cost of Rs. 1 lakh to 1.5 lakh per patient. In the absence of local generic supply due to 20 years product patents, new cancer medicines are now priced out of reach of patients and publicly-funded cancer hospitals.

LOON GANGTE, an HIV Activist
Delhi Network of Positive People

How do patents impact patients?

India has the highest burden of drug-resistant TB in the world with close to 1,00,000 suspected cases. Multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB) are on the rise, and access to new antibiotics will play a key role in developing new TB regimens to address growing treatment needs and improve cure rates.

Delamanid is a new antibiotic which has been included in the World Health Organisation's (WHO) treatment guidelines since 2014. A recent study showed that up to two thirds of MDR-TB patients are likely to benefit from the new drugs, especially delamanid. Patients with an even more severe form of the disease, extensively drug-resistant TB (XDR–TB) - in desperate need of more effective drugs - need delamanid to be added to their treatment regimens.

To date, however, few 100 patients worldwide have obtained access to this drug.

The company marketing delamanid, Otsuka Pharmaceutical Ltd., has neither filed for marketing approval in India, nor is it conducting phase III trials in India, which would provide crucially important evidence about the practicalities of using delamanid alongside other anti-TB drugs.

Without local clinical trials and marketing approval, delamanid cannot be procured by the national TB programme, or other treatment providers, to treat people with the deadliest, most drug-resistant forms of the disease.

In India's pre-2005 patent system, if a company did not bring a new drug to India, companies could step in to register the new drug in India and start supply of generic versions. Today, with product patents being granted, this cannot be done easily.

The compound patent on delamanid has been granted in India to the Japanese company Otsuka Pharmaceutical Ltd. and is set to expire only in 2023.

More than three years have passed since the grant of the patent in India, and the working statement (Form 27) submitted by Otsuka to the Indian patent office reveals a startling fact: the patented medicine is neither being imported, nor has the company issued any licence to a generic manufacturer to supply the medicine to the National TB programme in India, or other developing countries for that matter.

Production of affordable generic versions of delamanid is blocked by patents, leaving Otsuka as the sole supplier of the medicine. According to the Indian Patent Act, patents are not granted "merely to enable patentees to enjoy a monopoly on a patented medicine", and the patent holder must make the drug affordable and accessible to patients. Therefore, the government must take the necessary steps to ensure that this life-saving medicine becomes available to the National TB programme.

Update on IP Policy

Do we need a national Intellectual Property Rights (IPR) Policy?

The IPR Think Tank was convened in November 2014 by the Department of Industrial Policy & Promotion (DIPP) to draft IPR policy for India amidst much controversy regarding US criticism of India's patent system. At issue, the fact that a number of weak patents had been rejected and a 'compulsory license' was issued to an Indian company to allow competition against an exorbitantly priced cancer drug patented by the German Multinational Bayer.

The first draft of the National IPR Policy by the IP Think Tank was released in December 2014 and stakeholders were asked to provide comments.

The IP Think Tank submitted its draft policy in secrecy to the government in April 2015 laying stress on several measures for a stronger enforcement of IPRs including setting up of special courts for patent cases and a taxpayer-funded "Task Force". These provisions go beyond international trade rules and incur the risk of excessive enforcement of IP in India, presenting a serious threat to price-lowering competition from Indian manufacturers of generic medicines.

The final draft of India's national intellectual property policy has been circulated for inter-ministerial consultation and will be sent to the Cabinet for approval. The policy is expected to be released soon.

A particular area of concern for health groups is that the IP policy will impact the pharmaceutical sector, as India is a key global supplier of affordable generic versions of drugs that otherwise would be out of reach for public health programmes, treatment providers and millions of people in need. Re-opening the discussion on India's patent system could provide US pharmaceutical companies and the US Trade Representative with an opportunity to take forward their agenda to undermine public health safeguards in India's patent system with the aim of curbing the growing competition from manufacturers supplying quality affordable generic medicines across the world that are made in India.

Negotiations on trade agreement RCEP in April

People living with HIV hold a rally outside Udyog Bhawan, Office of Ministry of Commerce & Industry to protest against the dangers of RCEP on health.

The Regional Comprehensive Economic Partnership (RCEP) is a proposed free trade agreement (FTA) being negotiated between the ASEAN (Association of Southeast Asian Nations) countries and an additional six countries including India, Australia, China, Japan, New Zealand and South Korea.

A leaked draft of the IP chapter shows that Japan and South Korea are pushing for harmful intellectual property provisions aimed at blocking or delaying access to affordable generic medicines from India.

As negotiations on RCEP gain momentum in the coming year, we urge Indian parliamentarians to monitor very closely the RCEP negotiations on IP, and to make sure the terms of any trade agreement reached do not impede free trade in affordable generic medicines that so many patients, treatment providers and Ministries of Health in the developing world rely upon.

Like members of European Parliament, Indian parliamentarians should call for greater transparency, in particular on access to the negotiating documents of FTAs. The Ministry of Commerce should be required prepare additional on-line material that explains the government's negotiating positions; and to report more extensively on the outcome of negotiating rounds.

The next round of RCEP will take place in Perth, Australia, in April.

US faces exorbitant drug prices

The challenge of high prices of medicines is a global and growing problem that negatively affects millions of people globally. It is increasingly being recognized as a growing challenge in the United States as well. The prices of medicines in the United States are in fact some of the highest in the world because US law and the pharmaceutical reimbursement system is highly favourable to multinational pharmaceutical companies, thereby limiting competition and capacity to negotiate prices.

According to a Kaiser Family Foundation poll, a large majority of Americans consider the prices of prescription drugs to be unreasonable. Headlines and editorials from leading US publications have continued to highlight the issue of high priced medicines. US government reactions have included a Department of Health and Human Services forum, and several Congressional hearings and investigations. For example, in January, the US Senate Finance Committee published results of an 18-month investigation into the pricing and marketing strategies of pharmaceutical company Gilead's hepatitis C drug sofosbuvir in a bipartisan report. The report found that Gilead's pricing strategy sought to maximize profits "regardless of the human consequences" for people in need of access to sofosbuvir.

The high prices debate has also expanded into the US 2016 Presidential Candidates' campaigns, with formal proposals introduced by two leading Democratic candidates, Bernie Sanders and Hilary Clinton. Clinton's plan calls for shortened intellectual property monopolies, allowing government to negotiate prices, price caps and parallel importation. Sander's Prescription Drug Affordability Act would require companies to submit research and development costs, restricts the US Trade Representative's ability to negotiate trade deals that would raise the price of medicines, and also provides for government price negotiation and parallel importation among other measures. Several Republican candidates have similarly acknowledged issues around high drug prices in their Presidential campaign efforts.

More than two dozen US stakeholder groups including doctors, think tanks, insurers, and other stakeholders have introduced proposals to address high US drug prices, several of which are under consideration. For example, one proposal from 51 members of the US Congress authorizes the US National Institutes of Health (NIH) to make use of existing laws that allow NIH to mandate the licensing of patents to third parties of products developed from federally funded research to "discourage drug price gouging."

Published by
MSF Access Campaign,
India

For any concern or query, kindly contact:
Neha Saluja
neha.saluja@new-delhi.msf.org

ACCESS CAMPAIGN
MEDECINS SANS FRONTIERES