BRIEFING NOTE

MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN

TRADING AWAY HEALTH: THE TRANS-PACIFIC PARTNERSHIP AGREEMENT (TPP)

The TPP trade agreement could become the worst trade pact ever for access to medicines and biomedical research and development.

After years of negotiations without appropriate public input, the US-led TPP negotiations concluded in October 2015. The deal was signed by the current 12 TPP countries in February 2016: Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States and Vietnam. The agreed text is now publicly available[1].

The TPP agreement includes several new protections for pharmaceutical companies that, if implemented, would restrict access to affordable, life-saving medicines for millions of people. Proposed by US negotiators, the intellectual property (IP) rules lengthen, strengthen and create new patent and data protections for pharmaceuticals, keeping drug prices high, dismantling public health safeguards enshrined in international law and obstructing price-lowering generic competition for medicines. As a medical humanitarian organisation working in nearly 70 countries, Médecins Sans Frontières (MSF) is concerned about the impact these provisions will have on public health in developing countries where most of MSF's operations are and beyond.

Governments have a responsibility to ensure that public health interests are not trampled and must resist pressure to erode hard-won legal safeguards for access to medicines that represent a lifeline for millions of people.

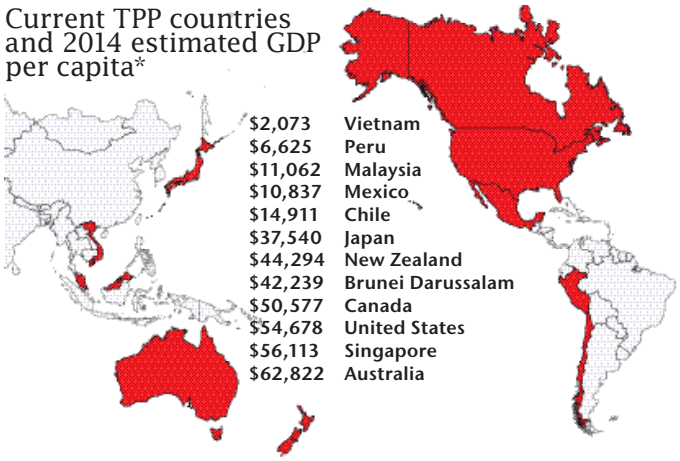
It is still possible to prevent the agreement from entering into force. MSF urges all TPP countries to reject provisions that will harm access to medicines, and to refrain from ratifying or implementing the agreement in its current form.

A DANGEROUS NEW GLOBAL NORM?

The TPP could become one of the largest trade pacts ever. It includes 12 countries today and affects more than 800 million people, however additional countries are expected to be invited to join – in particular Asia-Pacific Economic Cooperation (APEC) and Association of Southeast Asian Nations (ASEAN) countries, but with no right to amend the text.

At least South Korea, Indonesia, Taiwan, Thailand, Colombia, Argentina and the Philippines have been suggested or expressed interest in joining the TPP. The TPP is also being billed as a model for future US-led trade agreements and would set a damaging precedent for many more countries.

Current TPP countries and 2014 estimated GDP per capita*



$2,073	Vietnam
$6,625	Peru
$11,062	Malaysia
$10,837	Mexico
$14,911	Chile
$37,540	Japan
$44,294	New Zealand
$42,239	Brunei Darussalam
$50,577	Canada
$54,678	United States
$56,113	Singapore
$62,822	Australia

The TPP will ultimately impose the same standards on all member countries, even though the public health needs and capacity of governments and people to afford medicines ranges widely.

*International Monetary Fund, World Economic Outlook Database, October 2014.

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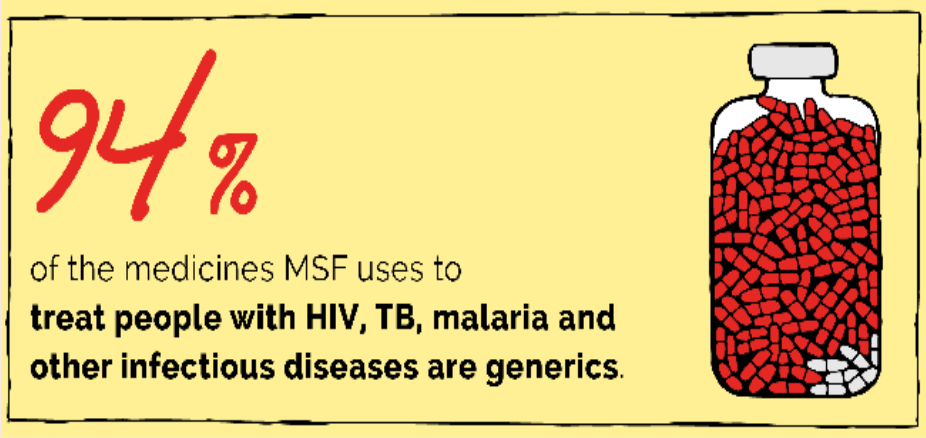
ROBUST GENERIC COMPETITION IS A CATALYST FOR AFFORDABLE MEDICINES…

In the field of health, generic competition saves lives. As a medical treatment provider, MSF relies on affordable, quality generic medicines to treat many diseases – 94% of the medicines we use to treat tuberculosis, malaria, HIV/AIDS and other infections that afflict the poorest and most vulnerable populations are generics.

Major international treatment initiatives and agencies, including the Global Fund to Fight AIDS, Tuberculosis and Malaria, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) programme, UNITAID and UNICEF, also depend heavily on affordable generic drugs to scale up urgently needed treatment programmes. For example, 97% of the antiretroviral medicines (ARVs) purchased by PEPFAR to treat HIV/AIDS are low-priced, quality-assured generic medicines[2].



Robust generic competition was instrumental in bringing down the price of the first generation of ARVs by 99% over ten years[3], a key factor that has allowed HIV/AIDS treatment to be scaled up to an estimated 17 million people in 2016[4]. But many newer medicines and vaccines are locked up by patent monopolies that protect high prices for manufacturers, and keep vitally important medicines out of reach for people.

Governments that pay for treatment programmes, either directly or by funding global health initiatives, have both an interest and a responsibility to ensure that new roadblocks are not put in the way of generic competition, or they risk jeopardising the effectiveness of the very programmes they support.

…BUT COMMITMENTS TO PUBLIC HEALTH AND MECHANISMS TO PROMOTE COMPETITION ARE CONTINUALLY ERODED BY PHARMACEUTICAL COMPANY COMMERCIAL INTERESTS

The availability of generic medicines in a particular country depends on a complex structure of laws and regulations, including those governing patents and other IP rights. Many of these regulations are influenced by trade and other types of international agreements.

In 1995, the World Trade Organization's TRIPS Agreement[5] imposed minimum IP standards across the globe for the first time, including the obligation to grant patent monopolies for pharmaceutical products. Importantly, TRIPS also includes legal safeguards that give countries some leeway in overcoming IP barriers when they hinder access to medicines, and flexibility in balancing commercial interests and public health. Subsequently, governments have made multiple commitments[6] reaffirming the importance of protecting public health over commercial interests.

Yet the legal tools and safeguards used to counterbalance commercial interests in favour of public health are continually under attack. Countries that try to promote the use of generics are frequently the target of litigation by pharmaceutical corporations[7] and are subject to diplomatic pressures, such as the threat of sanctions, by governments seeking to protect pharmaceutical companies' commercial interests[8]. These same forces seek to impose new and ever more restrictive IP rules, known as TRIPS-plus provisions, on all countries.

TRIPS-plus provisions serve to extend monopoly protection beyond what is required by international agreements and to create new kinds of monopolies, even after patent-based monopolies have expired or where they never existed. For pharmaceuticals and other health commodities, stronger IP standards mean extended patent monopolies and delayed generic competition, and that translates into higher prices for people who need medicines, for longer periods of time.

The TPP represents the most far-reaching attempt to date to impose aggressive TRIPS-plus IP standards that further tip the balance towards commercial interests and away from public health. In developing countries, where people rarely have health insurance and must pay for medicines out of pocket, high prices keep lifesaving medicines out of reach and are often a matter of life and death.

"The TPP contains a variety of new protections for pharmaceutical companies that limit the strategies governments and civil society can utilize to address high drug prices. If implemented, the TPP will have a profound negative impact on access to affordable medicines and innovation for years to come."

JUDIT RIUS SANJUAN, US MANAGER AND LEGAL POLICY ADVISER, MSF ACCESS CAMPAIGN

SOME OF THE NEW INTELLECTUAL PROPERTY OBLIGATIONS THAT WILL KEEP DRUG PRICES HIGH

TRIPS-PLUS PROVISION	IMPACT ON ACCESS TO MEDICINES
Lowering the standards for patentability – creating new patent monopolies for existing medicines.	**The TPP requires countries to grant secondary patents on modifications of existing medicines for at least one of the following: new uses, methods of use, or processes (of a known product).** The effect will be to keep medicine prices high by delaying the availability of price-lowering generic competition. This provision is designed to prevent countries from using public health safeguards in their national patent laws and from making judicial decisions that limit abusive patent evergreening, whereby companies seek additional patents on existing medicines to prolong monopolies.
Creating data/market exclusivity – preventing drug safety regulators from using existing clinical data to give market approval to generic or biosimilar drugs and vaccines.	**The TPP requires countries to lock up the use of clinical test data by national regulatory authorities with different periods of exclusivity: at least 5 years for small molecules, at least 3 years for modifications on existing medicines, or 5 years for combinations of existing drugs, facilitating abusive data evergreening.** Furthermore, the TPP contains, for the first time in a US-led trade agreement, a data protection obligation for a class of products called biologics, which are used to treat and prevent cancer, diabetes and many other conditions, and are already expensive. The protection for biologics is at least 8 years of exclusivity or 5 years with other measures. These data obligations grant distinct and additional monopoly protection to pharmaceutical companies, even when patents no longer apply or exist, giving companies a new way to keep prices high for longer and further delay generic and biosimilar competition.
Mandating patent term extensions – extending patent terms beyond 20 years.	The TPP requires countries to create two mechanisms to extend patent terms beyond 20 years for pharmaceuticals. At present, patents on drugs in most countries last for 20 years from the date of filing. **The extra years added to the patent are extra years in which the pharmaceutical company can maintain a monopoly and continue to charge artificially high prices for the medicine, free from generic competition.**
Requiring new forms of IP enforcement – granting customs officials new powers to detain medicines in transit; requiring mandatory injunctions for alleged IP infringements; raising damages amounts.	The TPP contains a variety of obligations that increase the risk of unwarranted interruptions and delays in the flow of legitimate trade in generic medicines, and limit countries' judicial system's capacity to balance commercial and public health interests in IP disputes. These new forms of IP enforcement are reminiscent of the stalled Anti-Counterfeiting Trade Agreement (ACTA), a multinational treaty that sought to impose stringent IP rules. **These provisions strip away the ability of governments to define their own enforcement provisions as allowed by international law.**

MSF IS ALSO CONCERNED ABOUT OTHER PROVISIONS PROPOSED FOR THE TPP, INCLUDING:

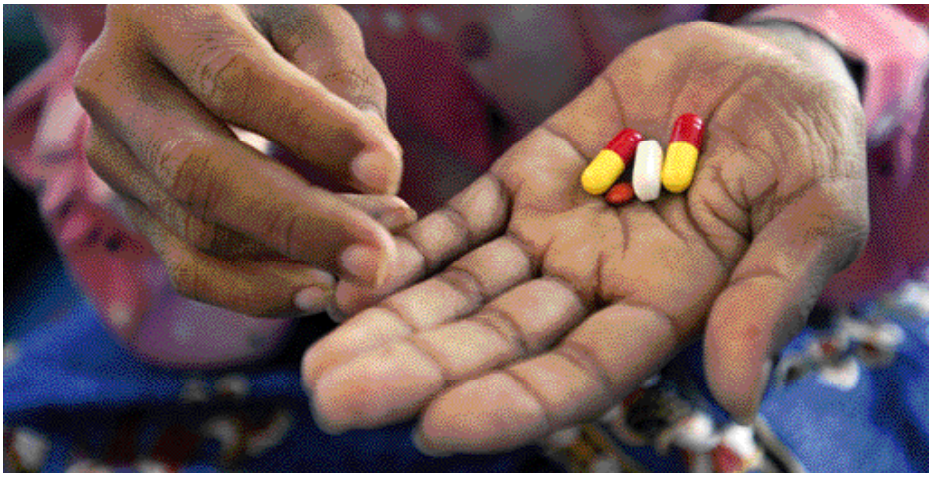
- Provisions in the Transparency and Procedural Fairness Chapter that could restrict the ability of governments to use reimbursement or price control systems to reduce healthcare costs.
- Provisions in the Technical Barriers to Trade Chapter that prohibit governments from requiring pharmaceutical companies to disclose "sale or related financial data concerning the marketing of the product" or "pricing data" as part of approval for marketing determinations.
- Provisions in the Investment Chapter that give pharmaceutical companies the right to sue governments for regulations and decisions that reduce their expected profits in private, supra-national investor-state dispute settlement (ISDS) tribunals whose decisions are usually un-appealable.

MSF URGES ALL GOVERNMENTS TO REJECT THE TPP AS LONG AS THESE DAMAGING PROVISIONS REMAIN IN THE AGREEMENT.

Countries should not agree to TRIPS-plus provisions which will severely limit access to medicines and research and development. Instead, countries must insist on protecting public health safeguards and effectively balance commercial interests and public health by fulfilling previous commitments to access to medicines, including the 2001 World Trade Organisation Doha Declaration on TRIPS and Public Health and the 2008 World Health Organisation Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property. In addition, the US government should adhere to its own May 10, 2007 New Trade Policy, which included a commitment to refrain from imposing some of the most damaging provisions.

> *"Generic production has enabled steep price reductions for HIV drugs over the past decade. But prices for newer lifesaving medicines–including second-line HIV drugs and treatments for hepatitis, tuberculosis, cancer and many other diseases–are climbing rapidly.*
>
> *If pharmaceutical companies are allowed to create patent thickets and extend monopolies unchecked, generic competition will be further delayed–and access to treatment blocked–for millions in developing countries."*

DR. MANICA BALASEGARAM, EXECUTIVE DIRECTOR, MSF ACCESS CAMPAIGN, APRIL 2013



MORE INFORMATION

Visit msfaccess.org/tpp for more information on the TPP's impact on access to medicines.

1. See the publicly released text of the TPP available from the New Zealand Ministry of Foreign Affairs and Trade: http://www.tpp. mfat.govt.nz/.
2. US Department of State. PEPFAR Blueprint: creating an AIDS-free generation, 2012: http://www.pepfar.gov/documents/organization/201386. pdf.
3. MSF. Untangling the Web of Antiretroviral Price Reductions, 16th edition, July 2013: http://www.msfaccess.org/sites/default/files/AIDS_Report_UTW16_ENG_2013.pdf.
4. UNAIDS. UNAIDS announces 2 million more people living with HIV on treatment in 2015, bringing new total to 17 million, 2016: http://www.unaids.org/en/resources/presscentre/ pressreleaseandstatementarchive/2016/may/20160531_ Global-AIDS-Update-2016.
5. The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights.
6. For example: the 2001 WTO Doha Declaration on TRIPS and Public Health; 2008 WHO Global Strategy and Plan of action on Public Health, Innovation and Intellectual Property; 2016 UN Political Declaration on HIV/AIDS: Political Declaration on HIV and AIDS: On the Fast-Track to Accelerate the Fight against HIV and to End the AIDS Epidemic by 2030. In addition, the US May 10, 2007 New Trade Policy scaled back harsh US government IP trade demands for developing countries, including patent linkage, patent term extensions and data exclusivity. See also, the 2016 CEWG Resolution from 68th WHA and the 2016 Human Rights Council Resolution.
7. For example: MSF. Novartis, Drop the Case! 2013: http://www.msfaccess.org/novartis-drop-the-case and MSF. Bayer attempts block on affordable patented drugs in India, 2012: http://www. msfaccess.org/resources/press-releases/1892.
8. For example: MSF. Doctors Without Borders Responds to Release of 2016 US Trade 301 Watch List Report, 2016: http:// www.msfaccess.org/about-us/media-room/press-releases/ doctors-without-borders-responds-release-2016-us-trade- 301-watch-.

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