

20 YEARS AFTER THE TRIPS AGREEMENT, U.S. GOVERNMENT SCORES MASSIVE VICTORY FOR BIG PHARMA IN TPP DEAL

ASIA-PACIFIC AIDS GROUPS EXPRESS DEEP DISMAY AT CONCLUSION OF SECRETLY NEGOTIATED TRANS-PACIFIC PARTNERSHIP AGREEMENT THAT THREATENS FUTURE ACCESS TO AFFORDABLE GENERIC MEDICINES AND SUSTAINABLE DEVELOPMENT GOALS

Call on Countries and Parliaments to reject ratification of TPP

6 October 2015, Bangkok, Hanoi and Kuala Lumpur – The Asia Pacific Network of People living with HIV/AIDS (APN+), Positive Malaysian Treatment Access & Advocacy Group (MTAAG+) and the Vietnam Network of People living with HIV (VNP+) are expressing deep dismay at news of the conclusion of the Trans-Pacific Partnership Agreement (TPP) led by the United States with 11 countries including seven in the Asia-Pacific region i.e. Vietnam, Malaysia, Japan, Australia, New Zealand, Singapore and Brunei. The TPPA text that was hurriedly wrapped up over the weekend in Atlanta still remains secret as details trickle out through the media of vastly expanded monopolies on medicines through extended patent and exclusivity provisions that will endanger the lives and health of hundreds of thousands of patients in these countries.

"Today, in the Asia-Pacific region, 2nd and 3rd line AIDS medicines are exorbitantly priced. US multinational pharmaceutical company Gilead is playing games with the lives of people living with Hepatitis C by creating a complex pathway of licenses, price negotiations and collection of personal data before patients can access sofosbuvir. Cancer treatment prices have skyrocketed. We are directly seeing these impacts of the US-promoted patent rules in the WTO's TRIPS Agreement that require 20 year monopolies on medicines in Malaysia. Now, 20 years after TRIPS, the next generation of international intellectual property obligations pushed by the US through the TPP would keep even more medicines unaffordable for longer periods of time," said Edward Low of MTAAG+.

The final TPP text is likely to contain intellectual property provisions pushed by the US on behalf of the multinational pharmaceutical industry that are far in excess of what developing countries like Vietnam and Malaysia have agreed to in the World Trade Organization's (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). Known as 'TRIPS-plus,' these measures are contrary to the WTO's Doha Declaration which re-affirmed the right of countries to use TRIPS flexibilities stating that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO member's right to protect public health and, in particular, to promote access to medicines for all." But the TPP likely does away with many of these TRIPS flexibilities by requiring longer patent terms, data and marketing exclusivity, patents on new forms and new uses of known medicines, harsh patent enforcement provisions and investment provisions that will allow MNCs to sue governments for pro-health policies.

"In recent days the reporting around the TPP has focussed only on an exclusivity period for biological medicines with a reported push back on the 12 year period

proposed by the US being presented as a victory for developed countries in the TPP like Australia," noted Shiba Phurailatpam of APN+. "But even a mandatory 5-year period of exclusivity along with the several other restrictive conditions imposed by the US, will have a massive adverse impact in countries like Malaysia and Vietnam as will the other damaging provisions in the intellectual property chapter. The conclusion of this trade deal makes a mockery of the Sustainable Development Goals and the new WHO HIV treatment guidelines that call for immediate initiation of treatment." he added.

The Sustainable Development Goals that all UN members including TPPA countries signed in September include ambitious health goals and call on countries to make use of the Doha Declaration to ensure access to treatment for communicable and non-communicable diseases. More recently the WHO released new HIV treatment guidelines recommending that everyone who tests positive for HIV should be put on treatment immediately instead of waiting for a lowered CD4 count. Under the latest guidelines millions more need HIV treatment including people living with HIV in TPP countries.

"In Vietnam, we are already concerned by announcements from international aid agencies including the US' PEPFAR programme of their withdrawal of funds and treatment programmes from our country," said Do Dang Dong of VNP+. "Estimates suggest that under our current budget, if Vietnam was forced to agree to all of the US' demands on patents and intellectual property in the TPP, only 30% of people living with HIV who need treatment would receive it. With the new HIV treatment guidelines from the WHO, the TPP's impact for people living with HIV will be even more severe. This is an unthinkable scenario for us."

"We are shocked that the secret deal has been concluded without public consultation or a proper health and human rights review. Even now the text is being kept secret. APN+ members are in 6 of the TPPA countries - Malaysia, Vietnam, Singapore, Australia, New Zealand and Japan - and will be among the first to face the consequences of the TPP on their health and lives. We are therefore calling on all TPP countries and their Parliaments to reject the secretly negotiated TPP text," said Shiba Phurailatpam of APN+. "Any trade agreement that further strengthens the hands of the multinational pharmaceutical industry to play games with the lives and health of millions of patients in the Asia-Pacific region is immoral and unacceptable," he added.

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Notes for Editors:

1. **Sustainable Development Goals, September 2015:** Goal 3.b: “Support the research and development of vaccines and medicines for the communicable and noncommunicable 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 [TRIPS] regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.” <https://sustainabledevelopment.un.org/?menu=1300>

2. **WHO Guidelines on when to start antiretroviral therapy 2015:** “...antiretroviral therapy (ART) should be initiated in everyone living with HIV at any CD4 cell count...recommendations is based on evidence from clinical trials and observational studies released since 2013 showing that earlier use of ART results in better clinical outcomes for people living with HIV compared with delayed treatment.” <http://www.who.int/hiv/pub/guidelines/earlyrelease-arv/en/>

3. **TRIPS-plus provisions likely to feature in the TPP :**

- DATA EXCLUSIVITY that prevents governments from relying on clinical trial data to register generic versions of medicines even if they are off-patent, their patents have expired or are revoked & complicates the issuance of compulsory licences. Reports suggest that 5 to 8 years of exclusivity for biological medicines may have been agreed to in the TPP.
- PATENT TERM EXTENSION that will extend patent life beyond 20 years.
- INCREASING PATENT SCOPE that significantly increases the number of medicines under patent by forcing governments to give 20-year monopolies on new uses & new forms of old medicines thus allowing the extension of monopolies on these medicines through minor changes in medicine formulation or process.
- PATENT LINKAGE that prevents the registration of generic versions of patented medicines and undermines the early working & research exceptions thus delaying generic entry even when a compulsory licence is issued, the patent expires or is revoked.
- INVESTMENT RULES that allow foreign companies to sue governments in private international arbitration over domestic health policies like compulsory licences, health safeguards in patent laws, price reduction measures & may prevent governments from promoting local production. Reports suggest that there may be a carve out for tobacco related investment disputes but concerns remain that other public health laws, policies and government actions would still be open to investment disputes by MNCs.
- BORDER MEASURES that will deny medicines to patients in other developing countries with custom officials seizing generic medicines being imported, in transit or that are being exported.
- INJUNCTIONS that undermine the independence of the judiciary in developing countries to place the right to health of patients over profits of multinational companies.
- OTHER IP ENFORCEMENT MEASURES that put third parties like treatment providers at risk of government actions & court cases and may draw the whole manufacturing, distribution & supply chain for generic medicines into litigation.

For an in-depth analysis of the leaked TPP proposals that may adversely impact access to medicines and public health see UNITAID's report on the TPP:
<http://www.unitaid.eu/en/rss-unitaid/1339-the-trans-pacific-partnership-agreement-implications-for-access-to-medicines-and-public-health>

4. Study on the Impact of the TPP on access to HIV treatment in Vietnam:

In 2014, an impact assessment of the provisions being negotiated in the TPP on intellectual property on access to HIV treatment in Vietnam was published.

Highlights from the study titled, "Assessing the impact of alternative patent systems on the cost of health care: Vietnam, the TPP and HIV treatment in Vietnam", include:

- Official estimates suggest that in 2014 Vietnam had around 256,000 people living with HIV. By the end of 2013 antiretroviral (ARV) therapy was provided to 82,687 people – 68% of those meeting the clinical criteria for such medicines.
- Using the current Vietnamese patent regime as our base case, we analyse the potential impact of alternative patent regimes on access to ARVs in Vietnam. The two other scenarios investigated are a patent regime making full use of TRIPS flexibilities, and a regime based on the US proposals in the 2014 leaked draft of the TPP intellectual property chapter.
- Our results indicate 82% of the HIV population eligible for treatment would receive ARVs under a full TRIPS flexibility scenario, while only 30% of Vietnam's eligible HIV patients would have access to ARVs under the US 2014 TPP proposals – more than halving the proportion treated compared to the current 68%. Similar price impacts can be expected for other countries participating in the TPP, though these are less economically vulnerable than Vietnam.

The complete study is available here:

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2536254

5. The Bangkok Declaration on Free Trade Agreements and Access to Medicines:

<http://www.bilaterals.org/?the-bangkok-declaration-on-free&lang=fr>