The Trans Pacific Partnership Agreement

Collection of contributions published in the HAIAP Newsletters.

Vietnam

Declaration on the Trans-Pacific Partnership Agreement and access to medicines

The following declaration was signed by representatives of 100 organisations making up the Vietnam Network of People Living with HIV (VNP+)

29 February 2012

Vietnam is negotiating a Trans-Pacific Partnership Agreement (TPPA) a ‘free trade’ agreement with the United States, Australia, New Zealand, Chile, Peru, Brunei, Singapore and Malaysia.

We, the undersigned, declare our opposition to the Trans-Pacific Partnership Agreement as it puts the profits of multinational pharmaceutical companies ahead of the people's right to health. We are aware that the United States has tabled intellectual property proposals that would require significant changes to Vietnamese law. If adopted, the U.S. intellectual property proposals to the TPPA would restrict generic competition, making medicines less affordable. Medicines for HIV, Hepatitis C and lifesaving medicines for cancer and other chronic diseases are under threat. Many people in Vietnam already lack access to lifesaving medicines and new trade barriers could make this worse.

In 2008, 94% of funding for care and treatment of HIV came from programs that rely on generic medicines to provide treatment to as many people as possible, with generics accounting for over 98% of the ARVs purchased. The high cost of some patented products already limits the ability of donor programs to expand treatment access. Heightened patent protections could make this problem worse. We stand in opposition to any and all proposals that negatively affect access to medicines in the TPPA including:

• **Expansive patent protection** for new forms, uses and methods of using known substances. These aggressive low patenting standards can extend pharmaceutical monopolies for minor variations on old products, including those that contribute nothing to efficacy.

• **Patent term extensions** that stretch the duration of a patent beyond 20 years.

• **Patent linkage** that prevents registration of generic medicines and facilitates abuse.

• **Eliminating safeguards** against patent abuse, such as pre-grant opposition.

• **Biased procedural requirements** that presume challenged patents valid and measure damages by the patent holder’s assessment of value.

• **Data Exclusivity** that prevents health authorities from relying on clinical trial data to register generic versions of medicines.

• **Border measures** that could lead to unjustified seizures of generic medicines.

• **Investment rules** that could allow multinational companies to sue governments over application of domestic health regulations and that may prevent governments from promoting local manufacturing.

We call on:

• The **Government of the United States** to immediately withdraw any and all TRIPS-plus provisions in the intellectual property chapter of the TPPA, and to immediately cease all other forms of pressure and lobbying against Vietnam and Vietnamese officials.

• **Governments of other TPPA negotiating countries** to come together and refuse to accept any further restrictions on production, registration, supply, import or export of generic medicines; to launch Asian-Pacific collaboration on an urgent basis to put in place a sustainable, affordable pipeline of generic medicines for future generations; and to call for an immediate review of TRIPS and its impact on access to medicines in developing and least developed countries.
• The Vietnamese Government to immediately end secrecy around the TPPA negotiations, make negotiation texts available for public scrutiny and to support open, transparent and public consultations, and assessments of the impact on the right to health and other rights.

• The Vietnamese Parliament and constitutional bodies to immediately review the TPPA negotiating texts, their impact on the right to health and access to medicines and refuse to endorse or ratify any Agreement that includes provisions that undermine the people's right to access affordable treatment; and to review Vietnarnse patent laws and medicine regulatory rules to ensure all aspects of the Doha Declaration are incorporated in them.

• Civil society groups, people living with HIV, all communities facing communicable, chronic and/or non-communicable diseases in the TPPA negotiating countries to join forces to halt any and all trade agreements that restrict access to generic medicines.

We stand in solidarity with all peoples whose rights to life, health, livelihood, equality, equity, food, environment, knowledge and traditional systems of life and livelihood will also be negatively affected by these free trade agreements that threaten to widen the gap between the rich and the poor not only between countries but within countries as well.

For further information, please contact: Do Dang Dong Vietnam Network of People Living with HIV (VNP+) e-mail: dongdodang@gmail.com

Update on the Trans Pacific Partnership negotiations and Public Health

Deborah Gleeson, PHM Australia, 7 August 2013

Status of the negotiations

Round 18 of the TPP negotiations, was held in Kota Kinabalu, Malaysia on 15-25 July 2013. At this negotiating round there was a strong sense that the TPP countries are attempting to conclude as many areas of the text as possible before the self-imposed deadline of October 2013. But it was also clear that some controversial areas of the text, including particularly the intellectual property, state-owned enterprises and environment chapters, will not be concluded by then. Some other chapters where there are major unresolved areas include labour, investment and government procurement. There is likely to be some technical work remaining after October, and some issues that cannot be resolved at the technical level will be pushed up to the political level for resolution.

Japan joined the negotiations for the last two days of the round. At this stage it is unclear what impact Japan’s entry will have on the timelines for completion. Japan may not be so willing to accept text that has already been agreed by the other Parties.

The next round – perhaps the last formal round - of negotiations is coming up very soon on 22-30 August in Brunei. Much of the remaining technical work may be completed via ‘intersessional’ meetings or other means before or after the next round.

Update on key public health issues of concern

Access to medicines

The extreme US proposals on intellectual property and pharmaceuticals that would severely constrain access to medicines continue to be opposed by all of the other TPP Parties. World Trade Online reported on 17 July 2013 that six countries, including Australia, Canada, Chile, Malaysia, New Zealand and Singapore had tabled a principles or discussion paper at Round 17 of the negotiations that presented an alternative to the US proposal. While this paper is likely to be far more moderate than the US proposal, Vietnam is not involved. Vietnam is the most vulnerable party in terms of access to medicines.

The healthcare annex to the transparency chapter, which contains provisions directed at pharmaceutical pricing and reimbursement schemes, specifically targets national reimbursement schemes such as Australia’s PBS and New Zealand’s PHARMAC but could also

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have implications for other countries that have national formularies and/or price controls of some description. All countries appear to remain opposed to the draft text tabled by the US. Public health advocates are concerned that the US has not tabled a more acceptable proposal, as it seems likely that the annex will become a political issue towards the end of the negotiations, where trade-offs between different sectors are likely.

**Update on the Trans Pacific Partnership negotiations and Public Health – no conclusion**

December 12, 2013  From Deborah Gleeson and Brigitte Tenni

Deborah Gleeson is a member of the Public Health Association of Australia and active in the People's Health Movement. Brigitte Tenni is affiliated with Public Health Association of Australia, which has been advocating for a more just trade agreement.

HAIAP has been actively following developments of the the Trans Pacific Partnership Trade agreement with updates in HAIAP news. Countries involved in the trade negotiations include Singapore, Malaysia, the United States, Australia, New Zealand, Brunei, Peru, Chile, Japan, Canada, Mexico and Vietnam. The Agreement is in the final throes of three years of negotiations.

The Trans Pacific Partnership agreement is potentially the most damaging trade agreement covering public health ever to be signed.

Trade ministers from the negotiating countries had hoped to wrap up the three-year talks in Singapore between 7 and 12 December 2013, by making decisions on the major outstanding issues, despite significant conflicts over many of the 29 or so chapters of the agreement. They failed to meet this self-imposed deadline. A short statement issued at the end of the meeting said ministers had ‘decided to continue our intensive work in the coming weeks...’ and that they intend to meet again in January.

The countries involved have signed an agreement to keep the text confidential until after negotiations have concluded and the agreement has been signed; and to keep negotiating documents secret until four years after the agreement is concluded or the negotiations are abandoned.

**Growing secrecy**

The negotiations had always been shrouded in secrecy until mid-November when Wikileaks published the leaked text of the Intellectual Property Rights (IP) Chapter of the agreement that confirmed fears of US demands that will restrict market entry of affordable generic medicines.¹

In Singapore, stakeholders had no role as participants and no avenues for interacting with negotiators except through personal contacts and it was even more difficult than usual to get any information about what was happening. But there were reports that small groups of ministers met to hammer out compromises on the stickiest issues, and that these were then put to the rest of the countries.²

**Health and medicines**

Extremely worrying were suggestions that the group negotiating the highly sensitive IP chapter included only one of the countries advocating for a fairer proposal on medicines (it is not known which of these countries was involved).³

The draft of the IP chapter leaked to Wikileaks in November showed the United States has continued to push for expanded and extended patent protection and exclusive rights over clinical trial data, among other provisions, that could delay access to affordable medicines.⁴

Several countries have put forward a fairer counter-proposal. While Australia was reportedly involved in the early development of this counter-proposal, its current position is unclear.

The Australian government has maintained that it will not accept anything in the agreement that would undermine the Pharmaceutical Benefits Scheme or the health system. But on the third day of the Singapore talks, a leaked memo showed Australia had collaborated with the United States and Japan to revise the ‘healthcare transparency annex’, the part of the agreement that will affect the Australian Pharmaceutical Benefits Scheme (PBS).

On the final day of talks, an article in Washington Trade Daily (WTD) cast further doubt on the Australian government’s claims about protecting the nation’s health and medicines policies.
It reported that:

Australia, New Zealand and Canada, among others, dropped their objections to the high-standard disciplines in intellectual property and came on board by agreeing to the modified text. Effectively, there is consensus on the intellectual property dossier except for one developing country, WTD was told.

The ‘High-standard disciplines’ proposed refers to the extremely high level of intellectual property protection proposed by the United States. It calls for patents for new uses of existing drugs. If a new use is found for an old drug that is out of patent, the drug can be granted a new patent. Medicines like those for HIV-related disease, and cancer drugs are already priced out of reach for many people in countries like Vietnam, and the US proposals for the TPP would make this scenario much worse. Even in wealthy countries like Australia, a significant proportion of those on low incomes already postpone purchasing or go without necessary medicines due to the cost.

The US seeks clinical trial data exclusivity, which prohibits generic medicines companies from using that data to register drugs for five years. And it wants mandatory patents on most medical, surgical, and diagnostic procedures, which will increase their cost. These are only some of the US intellectual property demands, and they far exceed the World Trade Organization (WTO) rules governing patent protection enshrined in the 1994 Trade Related Aspects of Intellectual Property Rights (TRIPS).

In Australia

On the same day as the memo was leaked, the Australian government blocked an order by the Senate to reveal the Trans Pacific Partnership text before it’s signed.

In addition, 44 prominent academics and public health experts wrote to the health minister to express their concerns and to urge the government to honour the Senate order.

The Senate has passed a motion noting the letter and reiterating its call for the release of the text.

There is hope that the delay in concluding the negotiations at a time when there’s rising concern among the Australian public will mean there is time to persuade the government to take a stance that’s conducive to a healthy agreement, a healthy country and a healthy region.

It is also hoped that the Senate is successful in its efforts to make the text of the agreement available for public scrutiny before the Australian government commits to its terms.

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1 http://wikileaks.org/tpp/
3 http://www.keionline.org/node/1826
4 https://wikileaks.org/tpp/pressrelease.html
6 http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm