USTR White Paper On Trade In Medicines Raises Questions

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The Office of the US Trade Representative this week released a position paper on medicines and trade, in the midst of a controversial negotiation for a trade agreement with Pacific-bordering nations. The USTR "white paper" was billed as trade goals to enhance access to medicines, but stirred sharp criticism from public interest groups which found its claims of promoting medicines access for the poor disingenuous.

USTR released the white paper<http://www.ustr.gov/webfm_send/3059> [1] on 12 September, the first day of the eighth round of closed-door negotiations for a Trans-Pacific Partnership trade agreement, taking place in Chicago likely through 15 September.

In its paper on Trans-Pacific Partnership Trade Goals to Enhance Access to Medicines, USTR said that clear obligations to follow intellectual property rights would boost innovation and bring legal certainty to generic drug producers and marketers. The paper says its proposals are the product of work of a little-known new strategic initiative called Trade Enhancing Access to Medicines (TEAM).

"The TEAM initiative reflects fresh thinking about trade and access to medicines. It is about more than allowing access to medicines. It is about working with trading partners to develop strong and common standards to help drive access - propelling the TPP countries to the front of the line for important innovative medicines and for generic competition, while promoting U.S. jobs and exports," the paper said.

The reaction of trading partners in the TPP negotiations was not known at press time. Partners include Australia, Brunei Darussalam, Chile, Malaysia, New Zealand, Peru, Singapore, and Vietnam. The USTR press release is here<http://www.ustr.gov/about-us/press-office/press-releases/2011/september/trade-enhancing-access-medicines> [2].

The white paper says the United States proposes to work with partners to achieve the following goals in a TPP agreement:

Expedite access to innovative and generic medicines through a "TPP access window"

Enhance legal certainty for manufacturers of generic medicines

Eliminate tariffs on medicines

Reduce customs obstacles to medicines

Curb trade in counterfeit medicines

Reduce internal barriers to distribution of medicines

Promote transparency and procedural fairness

Minimize unnecessary regulatory barriers

Reaffirm TPP Parties' commitment to the Doha Declaration on TRIPS and Public Health

The latter commitment to the Doha Declaration has been a flashpoint in this month's negotiations for a declaration on non-communicable diseases (NCDs), such as cancer, diabetes or heart disease. Developed countries have been seen as trying to keep reference to the Doha Declaration from being mentioned in the NCD declaration. In the white paper, USTR suggests it might modify the Doha Declaration language in the TPP, as it states: "Incorporate important understandings on the availability of public health measures, based on the Doha Declaration on the TRIPS Agreement and Public Health," rather than just stating that it incorporates the Doha Declaration itself.

The "access window" states that it would: "Promote the availability of life-saving and life-enhancing medicines in TPP markets and simultaneously establish a pathway for generics to enter those markets as quickly as possible by conditioning obligations to apply certain pharmaceutical-specific intellectual property protections on the requirement that innovators bring medicines to TPP markets within an agreed window of time." This likely refers to data exclusivity periods during which generic companies cannot use the patent holders' marketing data, which effectively delays low-priced generic competition.

The customs and criminal enforcement measures the US proposes to institute against counterfeit medicines will be watched closely by observers (if they are permitted to view them before final agreement), as such measures have been seen as occasionally interfering with trade in legitimate generics, including as the subject of a World Trade Organization dispute settlement case.

"The truth is, trade policy by itself can't address all the challenges of access to medicines, but we believe trade policy can be a meaningful component of the Obama Administration's broad effort to promote that access," US Trade Representative Ron Kirk said in a release. "These Trans-Pacific Partnership proposals will help to drive access to innovative and generic medicines, through tariff cuts, intellectual property provisions, and a host of other measures that will help to boost the availability of life-saving innovative and generic medicines to people throughout the Asia-Pacific region."

Critics not Persuaded

The TPP negotiations have been plagued by secrecy from the start, but it appears the new paper did little to shed light on the substance of the talks or dispel concerns from non-industry observers kept outside of the process.

"USTR seems to frame, as an access to medicine strategy, the granting of exclusive rights to rely upon regulatory test data, patent linkage and patent term extensions to innovators who register drugs within a window of time," Krista Cox, an attorney at Knowledge Ecology International, said in a KEI analysis available here<http://keionline.org/node/1262> [3]. "This is the PhRMA/BIO version of how to promote access, with the White House logo, in a large trade negotiation. This is access for people who can afford to pay monopoly prices for medicine. In developing countries, that is certainly not going to achieve access to medicine for all."

"The USTR paper on the TPP and access to medicines, released today [12 September], is misleading and puts forth the fundamentally flawed premise that speeding up market entrance of brand-name, monopoly-priced drugs will, in itself, solve the challenge of access to affordable medicines," Judit Rius Sanjuan, US manager of the Medicins Sans Frontieres Campaign for Access to Essential Medicines, said in the KEI release. "At heart, this is an issue of affordability, and USTR simply does not acknowledge that high priced brand-name drugs imposed by monopolies are a principal barrier to access to medicines."

"It is insulting that USTR has released this five-page paper on 'access to medicines' on the same day that it has tabled its most controversial and access-restricting provisions at the Trans-Pacific FTA negotiations - and then failed entirely to address those provisions, or the other access-restricting elements of its aggressive intellectual property proposal, in this paper," said Peter Maybarduk, Global Access to Medicines program director at Public Citizen. "The Obama administration is heading rapidly in the wrong direction, at the expense of global public health. This paper is primarily window dressing for USTR's pro-Big Pharma, anti-access to medicines status quo."

The Obama administration received support from US industry through a note from the Chamber of Commerce. "We urge USTR to not only seek the highest IP standards as it introduces and finalizes the remaining proposals but to also reject any efforts to weaken IP protection," it said in a note<http://www.theglobalipcenter.com/blogs/intellectual-property-rights-protection-21st-century-trade-agreement> [4] from the Chamber Global IP Center. "The [TPP] agreement should include standards similar to those in the U.S.-Korea Free Trade Agreement and ensure the standards apply to all TPP participants. In this regard, we look forward to reviewing the Administration's IPR White Paper, which has been prepared for the TPP negotiations and was released earlier today."

The Chamber also cited bipartisan letter to Kirk sent by Senators Orrin Hatch (Republican, Utah) and John Kerry (Democrat, Massachusetts), signed by 37 senators, urging that 12-year regulatory data protection for biologics be the baseline for the TPP negotiations. The Senate letter is here<http://freepdfhosting.com/e7e59cb7b6.pdf> [5] [pdf] (via Pharmalot).

Perhaps the biggest question to be raised is what is really in the text of the secret trade deal, and will the US Congress or any other elected body be given the right to weigh in on it before - or after - completion.

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