

Access to Lifesaving Generic Medicines Threatened by US Trade Pact

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Public Health Safeguards Could Erode Under Trans-Pacific Partnership Agreement

New York, September 8, 2011 – Access to affordable lifesaving medicines will be threatened where they are needed most—in parts of the developing world—if the U.S. insists on implementing restrictive intellectual property policies in the Trans-Pacific Partnership (TPP) trade agreement, the international medical humanitarian organization Doctors Without Borders/Médecins Sans Frontières (MSF) warned today.

As the eighth round of closed-door TPP negotiations begins in Chicago this week, a leaked draft of the U.S. position indicates that the U.S. Trade Representative (USTR) is demanding aggressive intellectual property provisions that go beyond what international trade law requires, and is turning its back on previous commitments to safeguard public health in trade agreements.

For additional details, please view [MSF's TPP Issue Brief](#).

“Our experience around the world shows that MSF’s treatment programs – and our patients’ lives – depend on the availability of quality and affordable generic medicines,” explains Sophie Delaunay, executive director of MSF-USA. “What we’re seeing here is the U.S. and the pharmaceutical industry looking to impose some of the most stringent patent protections we’ve seen to date, significantly delaying introduction of generic medicines in the countries that sign up to the TPP and creating a fundamental contradiction between U.S. trade policy and U.S. commitments to global health.”

Encompassing nine countries to start (Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore, Vietnam, and the United States), the TPP is billed as a vehicle for economic integration across the Asia Pacific region and a template for successive future regional trade agreements. As such, if hard-line intellectual property policies are included, the TPP has the potential to greatly diminish access to affordable medicines for millions of people in developing countries where MSF works and beyond.

The leaked USTR position paper, now available to the public, reveals that the U.S. is pushing its trade partners, including developing countries, to effectively lower the bar for granting patents, limit the capacity to

challenge patents, and impose new forms of intellectual property enforcement - all measures that delay the introduction of more affordable generic drugs.

Correspondence and discussions between Congress and the USTR indicate that the U.S. will demand other harsh provisions that effectively delay the introduction of generic medicines. These could include “patent extensions” that extend monopolies beyond 20 years, “patent linkage,” which delays regulatory approval of generic drugs, and expanded “data exclusivity” terms, which further restrict access to the clinical data necessary for expedient generic drug approval.

Taken together, these provisions, if adopted, represent a major retreat from previous U.S. commitments to global health, including the 2007 bipartisan New Trade Policy, in which Congress and the Bush administration agreed to abide by important public health safeguards in future trade agreements. These safeguards give governments and patients in developing countries some relief from the most stringent intellectual property regulations when urgent public health needs are at stake.

Competition among generic manufacturers, for example, is what brought the price of the first generation of HIV medicines down by more than 99 percent over the last decade, from \$10,000 per person per year in 2000 to as low as \$60 per person per year today. This dramatic price drop has played a major role in helping scale up HIV/AIDS treatment to more than six million people in developing countries.

Stifling generic competition also has implications for the U.S. government’s own foreign aid policies. The U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) relies predominantly on the purchase of generic antiretroviral medicines, and has reported significant savings through the purchase of generic medicines. Vietnam, a TPP participant, is a PEPFAR-grant recipient.

“MSF urges the U.S. to stop chipping away at hard-won public health protections, including those enshrined in international law and the 2007 New Trade Policy, and to uphold its previous commitments to support generic competition and promote access to medicines,” said Judit Rius Sanjuan, U.S. manager of MSF’s Campaign for Access to Essential Medicines. “Policies that restrict competition thwart our ability to improve the lives of millions with affordable, lifesaving treatments.”

TPP negotiating parties are under no obligation to subject their negotiating positions to public scrutiny; only the final agreed-upon text will be made publicly available. MSF believes that regional and bilateral trade negotiations, including the TPP, should be conducted in an open and transparent manner that allows for participation by civil society and other relevant stakeholders, and ensures that public health needs are given adequate attention.

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