OXFAM AMERICA ANALYSIS OF THE
USTR TRADE ENHACING ACCESS TO MEDICINES (TEAM) WHITE PAPER

I. Overview

The Office of the United States Trade Representative ("USTR") has released a White Paper outlining the Administration's plans to harmonize trade and intellectual property ("IP") policies with trading partners in order to protect and promote access to medicines.[1] According to the White Paper, the ongoing Trans-Pacific Partnership Agreement ("TPPA") negotiations provide a key opportunity for implementation by USTR of a new initiative – Trade Enhancing Access to Medicines ("TEAM") – which will "deploy the tools of trade policy in order to promote trade in, and reduce obstacles to, access to both innovative and generic medicines."

Oxfam has reviewed the USTR White Paper describing TEAM. We believe that TEAM is not an appropriate mechanism to improve access to medicines in low- and middle-income countries, and that it will in fact be harmful to access and public health.

TEAM brings nothing new to the table, as there are already mechanisms in place for addressing the nexus between trade rules and public health. Specifically, under the TRIPS Agreement and the Doha Declaration on TRIPS and Public Health, the US Government has already committed to prioritizing the promotion of public health over the protection of intellectual property for pharmaceuticals.[2] Moreover, under the May 10th 2007 Agreement, the United States re-negotiated intellectual property standards under free trade agreements ("FTA") with Peru, Panama, and Colombia, to ensure that public health was not undermined by those FTAs.

TEAM's approach is fundamentally flawed because it relies on a trade-oriented approach to address public health problems. Also, TEAM does not capture the important distinctions between availability and affordability of medicines in developing versus developed countries. And it fails to take into account fundamental differences in how originator and generic medicines are developed and commercialized, which illustrates the crucial role of generic competition in lowering prices and improving access to treatment. TEAM consists of little more than a repackaging of the demands and preferences of multinational pharmaceutical companies as pro-health policies.

Oxfam welcomes USTR's acknowledgement that intellectual property rules, together with rules affecting negotiation of pharmaceutical prices, have a direct negative impact upon the affordability of medicines and access to health care in developing countries. Oxfam also supports efforts to reduce tariffs, internal taxes, and excessive mark-ups of medicines in the

[1] See: http://www.ustr.gov/webfm_send/3059
[2] See: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

supply chain; appropriately, such efforts are being led by health experts at the World Health Organization ("WHO") rather than by US trade negotiators.

Oxfam believes that because it exacerbates rather than improves access to medicines in low- and middle-income countries, TEAM should be rejected as a new approach. This memo identifies some of the misconceptions underlying the USTR TEAM White Paper, and reviews concepts that are central to promotion of access to medicines.

II. How best to ensure access to affordable medicines

Medicines play a critical role in public health systems. In the last decades, the public health problems facing developing countries have expanded beyond infectious diseases. In large part due to changing lifestyles, a broad range of non-communicable diseases ("NCDs") are now *the* critical public health problem in developing countries. The WHO estimates that 80 per cent of all deaths from NCDs occur in low- and middle-income countries. Treatment of NCDs, such as diabetes and heart disease, relies upon long-term use of medicines. In the developing countries negotiating the Trans-Pacific Partnership Agreement – Peru, Chile, Vietnam, and Malaysia – there is a high burden of both non-communicable and infectious diseases.

Due to inadequate financial resources in the public and private sector, affordable prices for medicines are vital to ensure that governments can progressively realize universal access to health care. In particular, low-cost, quality generic medicines have played – and continue to play – a critical role in public health systems. Generics cost a fraction of originator medicine prices, and the presence of multiple generic competitors has reduced the price of treatment by as much as 80 per cent. Access to quality generic treatment is particularly important for households that lack health insurance and must therefore pay for medicines out-of-pocket. When poor households lack access to affordable generics, they must forego treatment, sell precious assets, or make difficult choices between paying for medicines and other basic necessities, such as school fees or food.

Ultimately, policies that strengthen or extend patent monopolies, which subsequently delay generic competition and the associated drop in prices, have negative impacts upon access to affordable medicines. Originator companies often note that the vast majority of medicines currently on the WHO Essential Medicines List ("EML") are off-patent, citing this as evidence that patents do not block access. However, this actually reflects the relative unaffordability of patented medicines – not the irrelevance of patent protection. The WHO EML does not include products that are too expensive, with the sole exception of medicines to treat HIV and AIDS. Otherwise, patented medicines are left off of the list due to their high price.

Data regarding the registration of medicines must also be interpreted with caution. While the registration of new branded medicines in developing countries theoretically should result in "availability" of new medicines in that market, it is essential to consider what portion of the population can actually obtain them. When a patent monopoly is in place, the high cost of new medicines often prevents access to those medicines except for a tiny elite that can afford them.

Thus, registration of new medicines is not a significant indicator of access. In contrast, registration of high-priced medicines may foster inequality; in many places, only a few individuals can access high-priced medicines, therefore obtaining better treatment outcomes, while the vast majority of people receive no or sub-optimal treatment. Improving the availability of, and access to, quality, low-cost generics is essential to advancing public health, particularly in developing countries.

III. Transparency in TPPA negotiations must be improved

Oxfam has been highly disappointed with this Administration's lack of commitment to transparency in the TPPA negotiations. The TPPA will have a tremendous impact upon access to health care for patients in all countries negotiating the Agreement. Nevertheless, TPPA negotiating proposals and draft negotiating texts have not been shared publicly. In the United States, they have only been made available to a limited set of stakeholders that represent narrow commercial interests – including the multinational pharmaceutical industry.

The White Paper is not an adequate substitute for release by the Administration of all of its negotiating proposals and of the current TPPA negotiating text. In lieu of resolving civil society concerns with transparency, the White Paper actually perpetuates suspicion that the United States is not upholding commitments, under either the Doha Declaration or the May 10th 2007 Agreement, to prioritize and promote access to medicines and to modify FTA proposals to support access and public health in developing countries. The White Paper should have included complete information about USTR proposals for the intellectual property and pharmaceuticals chapters of the TPPA. Instead, USTR kept its negotiating proposals secret and attempted to divert attention from the probable harmful impact of its proposals.

IV. Analysis of the USTR White Paper

The White Paper states that TEAM is "about working with trading partners to develop strong and common standards to help drive access […]".[3] Yet Oxfam's assessment is that TEAM entails, first, abandonment by USTR of important prior commitments to support access to medicines, including the May 10th 2007 Agreement, and, second, the introduction of new measures that will restrict access to treatment and harm public health. This section reviews the most worrisome aspects of the TEAM proposal.

A. The TPP "Access Window"

Under the TPPA, it appears the US Government will abandon the commitments to improving access to medicines made under the May 10th 2007 Agreement, which aimed to limit the harmful impact of data exclusivity on developing countries and which made patent linkage and patent term extensions voluntary rather than mandatory. Setting aside this agreement, under TEAM, the US Government plans instead to provide a generous window for the introduction by multinational drug companies of high-cost patented medicines in developing country markets.

[3] See FN 1.

In exchange for registering new products in developing countries during the access window, originator drug companies will benefit from several years of TRIPS-plus patent protections including data exclusivity, patent linkage, and patent term extensions. While the exact duration of the window is unknown, it is believed the window could be from two to six years. According to the White Paper, this approach aims to stimulate the entry and commercialization of originator drugs in TPPA countries, which USTR alleges will enhance access to medicines in those markets.

Oxfam disagrees with this USTR assessment and believes that the "access window" approach will actually undermine access to medicines. Irrespective of when launched, originator medicines are unaffordable for the governments of and nearly all households in low- and middle-income countries. Only generic competition, coupled with effective price negotiation by governments (when generics are not available), has been proven to lower prices thus enabling access to medicines. Yet generic competition is delayed under the USTR proposal, granting extensive TRIPS-plus patent protections in exchange for registration within the window. This proposal, together with the proposed chapter on pharmaceutical pricing (described below) would actually prevent governments in low- and middle-income countries from taking the necessary steps to ensure that patients can obtain needed medicines.

The "access window" is based upon faulty logic including:

- *The premise that registration of originator medicines in a market translates into access*. In reality, registration does not guarantee that the medicines are available, accessible, or affordable to patients other than a tiny wealthy elite. In a previous study issued by Oxfam, the registration of 26 new medicines in Jordan, following the signature of a free trade agreement with high-levels of IP protection, resulted in nearly no sales of the medicine in the public and private sector.[4] As is often the case, high prices meant that the medicines were not accessible through the public sector or for purchase out-of-pocket by the vast majority of people. For example, Fludara, a medicine used to treat chronic myeloid leukemia, would have required a civil servant in Jordan to work 244 days to afford one unit of the medicine. Unsurprisingly, though this medicine was registered, 0 units were sold in Jordan between 2002 and 2006.[5]

- *The belief that stricter intellectual property rules will encourage companies to launch their medicines earlier in the patent term in developing countries*. In addition to effectively rewarding companies for having failed in the past to register their products in low- and middle-income countries, this approach ignores market realities. Multinational drug companies do not launch medicines in developing countries for a range of reasons that are unrelated to the level of IP protection. For example, a company may delay the launch of a medicine because it does not want to market the medicine at a low price in an emerging market, which could lead wealthier countries to demand lower prices. In

[4] See: http://www.oxfam.org/en/policy/bp102_jordan_us_fta
[5] Ibid.

the case of biologics, a company may decide not to launch the product in a market due to lack of demand, including inability to pay, or due to insufficient expertise or facilities to administer such medicines.

B. Restrictions on Pharmaceutical Pricing and Reimbursement

Based on the USTR White Paper, TEAM would address the need for better "procedural fairness" and "transparency" in the functioning of national healthcare reimbursement schemes. This is also the focus of the recently tabled US proposal for a pharmaceutical pricing chapter in the TPPA. Experts have warned that the proposed chapter, which sets forth obligations that far exceed "transparency", would tie the hands of governments – including the US Government - seeking to manage the cost of reimbursing expensive new medicines through public health programs. Where generic substitutes are not available (for instance due to patent protection), governments must effectively negotiate affordable reimbursement prices for originator drugs to avoid breaking the budget. This is especially important for developing countries, given their relative lack of resources.

C. Focus on Counterfeit Products

TEAM proposes to enhance access to medicines by fighting counterfeits. For obvious reasons, Oxfam does not support trade in counterfeit medicines, which may be of compromised quality, safety, and efficacy. However, anti-counterfeit initiatives address only a subset of the broader problem of substandard medicines because they focus only on certain trademark-infringing products. Oxfam recommends that, instead, resources be dedicated to upgrading Drug Regulatory Authorities ("DRAs") so they can effectively monitor the quality, safety, and efficacy of all medicines on the market. DRAs remove counterfeits, together with other undesirable products, through their normal registration and market surveillance activities.
Importantly, Oxfam is concerned that the United States and other countries have initiated a number of international anti-counterfeit actions that harm public health by curbing the availability of generics. Such initiatives, which use an expansive definition of "counterfeits", have resulted in the targeting of legitimate, quality generic medicines beyond products that are intended to deceive consumers. Many anti-counterfeit initiatives are fundamentally flawed in their attempt to use a trade and intellectual property framework to address a public health problem – which is also the case with TEAM.[6]

D. Additional Elements of USTR Proposal Harm Access

Throughout its White Paper, USTR promotes policies that have long been advocated by the originator pharmaceutical industry while mischaracterizing them – together with provisions in its TPPA IP proposal – as pro-access. At the same time, in its White Paper and elsewhere, USTR has failed to acknowledge that other provisions that it is seeking in the TPPA would undermine access to medicines. For instance:

[6] See: http://www.oxfam.org/en/policy/eye-ball

- In its February 2011 negotiating proposal, the United States requested that developing countries introduce new rules that would severely limit the ability of each country to define what is patentable, that is deserving of monopoly protection. In particular, the proposal would allow for the patenting of a "new form, use, or method of using" an existing product even if there is no increase in efficacy. This TRIPS-plus provision allows companies to extend the term of patent protection for existing medicines that have already received a full term of patent protection. This technique, known as "ever-greening", delays generic entry onto the market for lengthy period of times.
- In TPPA talks, USTR also seeks to eliminate pre-grant opposition, an important safeguard against undeserved patents. In many countries, including TPPA negotiating countries such as Vietnam, Australia, and New Zealand, third parties can oppose the granting of patents, a process that improves patent quality and helps to prevent abuse of the IP system. Elimination of this mechanism could facilitate use of ever-greening, which would delay generic competition.

V. PEPFAR, the Global Health Initiative, and the Medicines Patent Pool

Oxfam acknowledges the numerous measures put in place by the United States to improve access to medicines, including PEPFAR, the Global Health Initiative, and, more recently, political support for the Medicines Patent Pool.

Yet instead of building upon these measures, by ensuring that trade policies do not undermine these and other pro-health initiatives of the US Government, USTR cites these measures in its White Paper in order to justify a trade policy that will undermine access to treatment in developing countries. This is a classic case of giving with one hand while taking with the other. Oxfam believes that, instead, each successful initiative should encourage the US Government to do more to improve access to medicines.

The President's Emergency Plan for AIDS Relief relies almost exclusively on generic medicines. At present, over 90 per cent of all medicines used under PEPFAR are generic anti-retroviral medicines manufactured in India. Without the use of generics, the US Government would not have been able to provide treatment to over 3 million people with HIV and AIDS. Yet the TPPA would undermine the effectiveness of PEPFAR by extending patent monopolies and delaying the availability of generic medicines. Vietnam, which is negotiating the TPPA with the United States, is one of the recipient countries under PEPFAR. Between 2004 and 2009, Vietnam received USD 323.6 million for HIV/AIDS prevention, treatment, and care programs. A significant portion of that money has been spent to purchase antiretroviral medicines and medicines for opportunistic infections. Although in 2005, no generics were available to Vietnam under PEPFAR, by 2008, generics comprised 97 per cent of medicines purchased by Vietnam using PEPFAR funds. This shift to generics under PEPFAR (undertaken not only by Vietnam, but also fifteen other PEPFAR countries) is calculated to have saved USD 323 million between 2005 and 2008, plus another USD 380 million in 2010.
The Global Health Initiative is one part of the Administration's broader Global Development Policy. As part of the Global Development Policy, the Administration promised to ensure

greater coherence between aid policies and other policies that impact developing countries. However, USTR negotiating proposals in the TPPA, which would introduce strict levels of IP protection and place restrictions on pharmaceutical price negotiations, contradict the objectives of the Global Health Initiative. The US Government appears to be unable or unwilling to ensure coherence between its trade and aid policies.

Oxfam, alongside many other civil society organizations, welcomed the commitment by the United States to support the Medicines Patent Pool. The Medicines Patent Pool was conceived as an effort to ensure that the unaffordable costs of new anti-retroviral medicines could be sustainably reduced, while also ensuring that new forms of innovation could be promoted, particularly new fixed-dose combinations. The underlying theory of the Medicines Patent Pool is that flexible intellectual property systems can best improve affordability and innovation. In TPPA talks, USTR has shirked this approach and instead introduced new, strict IP rules that will both undermine access to medicines and discourage innovation, since the proposed new rules would enable pharmaceutical companies to pursue additional patent protection through ever-greening.

VI. Conclusion and Recommendations

The TEAM initiative will not improve access to affordable medicines in developing countries. Its implementation would constitute a giant step backwards after a slow but positive evolution in US trade policy in recent years. In lieu of searching for an appropriate balance between the protection of intellectual property and the promotion of public health, TEAM repackages the stringent IP protections and other policies long sought by the originator pharmaceutical industry, marketing them as pro-health. If accepted by US trading partners, this approach – particularly the proposal for an "access window" – will drastically undermine access to medicines in developing countries while doing little to stimulate innovation. Together with US IP and pharmaceutical pricing proposals for TPPA, TEAM should be rejected by trading partners.

In addition, Oxfam believes the following elements must be included in the TPPA IP chapter to mitigate its probable negative impact on access to medicines and public health:

- In line with public health concerns, and the May 10th 2007 Agreement, any provisions providing for patent linkage and patent extension should be voluntary for developing countries;
- Data exclusivity provisions should include public health-related flexibilities;
- Provisions setting out an expanded scope of patentability should be voluntary for developing countries;
- There should be no TRIPS-plus IP enforcement provisions in the TPPA;
- There should be no pharmaceuticals chapter in the TPPA; and
- The TPPA negotiations should be conducted with full transparency.