TRANS-PACIFIC PARTNERSHIP TRADE GOALS TO ENHANCE ACCESS TO MEDICINES

President Obama announced in November 2009 the United States' intention to participate in the Trans-Pacific Partnership (TPP) negotiations in order to conclude an ambitious, 21st-century Asia-Pacific trade agreement that reflects U.S. priorities and values. Through this agreement, the United States is seeking to create a platform for regional integration across the Asia-Pacific that will boost trade and investment among the TPP partners, enhance economic growth and living standards, and support the creation and retention of jobs.

As part of this initiative, the Office of the United States Trade Representative (USTR) has presented a variety of trade proposals to TPP partners that are aimed at promoting access to medicines in TPP partner markets. These proposals are the product of a new strategic initiative, **Trade Enhancing Access to Medicines (TEAM)**, which is designed to deploy the tools of trade policy to promote trade in, and reduce obstacles to, access to both innovative and generic medicines, while supporting the innovation and intellectual property protection that is vital to developing new medicines and achieving other medical breakthroughs.

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.

Under the TEAM approach, the United States proposes to work with its current TPP partners – Australia, Brunei Darussalam, Chile, Malaysia, New Zealand, Peru, Singapore, and Vietnam – to achieve the following goals in the TPP:

- **Expedite access to innovative and generic medicines through a "TPP access window":** 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.

- **Enhance legal certainty for manufacturers of generic medicines:** Enhance legal certainty for producers of generic medicines throughout the TPP region by means of patent exceptions and incentives for generic medicines, while maintaining a balance of intellectual property protection for innovators.

- **Eliminate tariffs on medicines:** Immediately eliminate duties on medicines and medical devices, thereby decreasing costs for hospitals, clinics, aid organizations and consumers, among others. This includes ensuring that any existing tariffs on amoxicillin, penicillin, and anti-malarial medicines, for example, are eliminated.

- **Reduce customs obstacles to medicines:** Minimize import barriers, such as discriminatory, burdensome, and unpredictable customs procedures, that impede access to innovative and generic medicines.

- **Curb trade in counterfeit medicines:** Make customs and criminal enforcement measures available to prevent medicines bearing counterfeit trademarks from entering TPP markets, and thus support efforts of TPP countries to address the serious risks to patients posed by such counterfeits.

- **Reduce internal barriers to distribution of medicines:** Guarantee importing, exporting, and distribution rights with respect to medicines and minimize internal barriers that can stand in the way of efficiently distributing medicines to those in need.

- **Promote transparency and procedural fairness:** To ensure the fairest possible opportunity for both generic and innovative medicines to enter TPP markets, require respect for basic norms of transparency and procedural fairness in the operation of national government healthcare reimbursement programs.

- **Minimize unnecessary regulatory barriers:** Promote transparent and non-discriminatory regulatory structures to facilitate the availability of safe and efficacious medicines to the public, while also improving coherence of future rules across the region.

- **Reaffirm TPP Parties' commitment to the Doha Declaration on TRIPS and Public Health:** Incorporate important understandings on the availability of public health measures, based on the Doha Declaration on the TRIPS Agreement and Public Health.

The goals listed above demonstrate how the Obama Administration is coordinating and deploying trade policy tools to help reduce potential barriers to access to medicines, while also supporting innovation and the development of new medicines by the U.S. pharmaceutical and other health industries.

Trade policy alone cannot solve the challenges relating to access to medicines. The Obama Administration is addressing these challenges on every front: through foreign assistance and development programs, through foreign policy initiatives, and through close engagement with various countries as they work domestically on public health issues. These other Administration initiatives are coordinated by various U.S. agencies, including the U.S. Agency for International Development (USAID), and through various programs, such as the President's Emergency Plan for AIDS Relief (PEPFAR). The goals listed above reflect a commitment to work closely with trading partners to help improve access to medicines by eliminating barriers to trade in medicines and reaffirming the Doha Declaration on TRIPS and Public Health.

In addition to the goals listed above, the TEAM initiative includes new approaches to developing trade policy within the U.S. Government. USTR will convene a TEAM Task Force composed of

experts throughout the government to consider innovative trade policy approaches to promoting access to medicines. Through the TEAM Task Force and direct agency-to-agency discussions, USTR will continue to consult regularly with experts from USAID, PEPFAR and other components of the Global Health Initiative, and all other Federal departments and agencies with relevant expertise. The Task Force will report to the interagency Trade Policy Staff Committee.

Reflecting the principles underlying the TEAM initiative, the U.S. Government will continue to seek out new ideas from all sources, including from the public at large, U.S. trading partners, U.S. federal and state government representatives, and stakeholders, including innovative and generic pharmaceutical industry representatives in the relevant Industry Trade Advisory Committees, as well as health-oriented non-governmental organizations.

BACKGROUND

The challenges are significant. Many factors constrain access to safe and effective medicines of assured quality around the world. For example, poor distribution networks for medicines, rooted in a lack of basic infrastructure, transportation, hospitals, clinics and healthcare professionals, can prevent access to medicines.

Other obstacles can also limit access to medicines. For example, taxes or tariffs may be levied on donated medicines or on medicines that are supplied at cost, and the increased expense associated with those levies is then passed directly to healthcare institutions and patients. Discriminatory and non-transparent regulatory regimes, unnecessarily burdensome customs requirements and other trade barriers also hinder the provision of both innovative and generic medicines to those who urgently need them.

At the same time, counterfeit medicines impede access to real lifesaving medicines. Counterfeit and substandard medicines, often distributed by criminal networks, harm or kill sick people across the globe, with the developing world disproportionately affected. In fact, the World Health Organization (WHO) estimates that "in over 50 percent of cases, medicines purchased over the Internet from illegal websites that conceal their physical address have been found to be counterfeit."

Intellectual property plays an important role in providing the incentives necessary for the development and marketing of new medicines. An effective, transparent, and predictable intellectual property system is necessary for both manufacturers of innovative medicines and manufacturers of generic medicines. Available evidence indicates that patent protections have expired for the vast majority of medicines on the WHO's Model List of Essential Medicines, further highlighting the large volume of important medicines that were developed under intellectual property protections and that subsequently became available in generic form upon the expiration of those intellectual property protections.

The United States is a global leader. The Obama Administration is working to promote access to medicines in many ways, including through foreign assistance and development programs, foreign policy initiatives, and trade policy. The Administration's initiatives implement methods of strengthening sustainable health systems, investing in country-led health plans, improving coordination among stakeholders, and promoting research and innovation. On September 22, 2010, President Obama announced a new U.S. global development policy – the first ever for a U.S. Administration. The Global Development Policy recognizes that development is vital to U.S. national security and is a strategic, economic and moral imperative for the United States. It provides clear policy guidance to all U.S. government agencies and enumerates the core objectives, operational model, and modern architecture needed to implement this guidance. The Administration's Global Health Initiative (GHI), announced by the President in May 2009, embodies the core tenets of the development policy. GHI is helping to build sustainable capacity in the public sectors of our partner governments and at their national and community levels so that developing countries themselves can manage their health system and provide basic services over the long term. The President's Emergency Plan for AIDS Relief, which includes HIV/AIDS, TB and the Global Fund, is the largest component of the GHI. Since its inception, PEPFAR has promoted access to medicines and other products through many means, including by improving supply chain management and procurement systems, and by training health workers. In addition to GHI, many other U.S. programs are having a positive impact on health and facilitating access to medicines.

The United States also makes significant contributions to international organizations that work to address global health challenges. In addition to direct aid, the United States tries to facilitate the discovery, development and distribution of medicines in a number of innovative ways, including through the appropriate diffusion of technology and knowledge. For example, the United States, through the National Institutes of Health, was the first patent holder to share its patents with the newly established Medicines Patent Pool Foundation, which has recently been joined by the Gilead Corporation. U.S. action catalyzed G-8 leaders to voice support for the Foundation, which in turn helped Gilead Corporation to enter into an arrangement with the Patent Pool Foundation.

The United States also recognizes the challenges faced by least developed countries. For example, the WTO adopted a U.S. proposal to extend until 2016 the transition period during which these countries may opt not to implement WTO provisions concerning patent protection for medicines. Working closely with African countries, the United States was also instrumental in reaching agreement at the WTO to create a permanent mechanism to allow countries to issue compulsory licenses when necessary to export lifesaving medicines to countries in need. U.S. trade agreements support this mechanism.

USTR's role. USTR is responsible for developing and coordinating U.S. international trade, commodity, and direct investment policy, and for overseeing trade and investment negotiations with other countries. USTR is led by the U.S. Trade Representative, a Cabinet member who

serves as the President's principal advisor, negotiator, and spokesperson on trade issues. USTR is part of the Executive Office of the President. Through an interagency structure, USTR coordinates trade policy and frames issues for presidential decision.

The Trans-Pacific Partnership. The TPP is a key initiative through which the Administration seeks to advance the United States' multi-faceted trade and investment interests in the Asia-Pacific region by negotiating an ambitious, 21st-century trade agreement along with Australia, Brunei Darussalam, Chile, Malaysia, New Zealand, Peru, Singapore, and Vietnam. This initial group of like-minded countries shares the goal of creating a platform for regional integration across the Asia-Pacific and boosting trade and investment among themselves, thereby enhancing economic growth and living standards and supporting the creation and retention of jobs. This region includes some of the world's most robust economies and accounts for more than 40 percent of global trade.