

## THE IMPACT OF TARIFF AND NON-TARIFF BARRIERS ON ACCESS TO ESSENTIAL DRUGS FOR THE POOREST PEOPLE

Despite an enormous global supply of pharmaceuticals, regular access to medicines has not been realized in much of the world. Drugs are widely available in only 28 percent of countries, with many factors, including pharmaceutical costs, affecting access.<sup>1</sup> On a national health system level, pharmaceutical costs are the largest health expenditure after staffing.<sup>2,3</sup> For individuals in developing countries, the price of essential medicines may be burdensome; these costs are usually borne by families.<sup>2</sup>

Most developing countries are net importers of pharmaceutical products and many impose tariffs and non-tariff barriers (NTBs) on finished drugs, active pharmaceutical ingredients (APIs), and excipients (inactive substances that contain the active ingredients). Tariffs and NTBs contribute to pharmaceutical costs by increasing the final price of essential drugs, limiting access for the poorest people. Although some developing countries (e.g., China, India and Brazil) have established pharmaceutical industries, they continue to import some products.<sup>4,5</sup>

This policy brief describes tariffs and NTBs and the relationship between these trade-related barriers and access to essential drugs. It explores current efforts to reduce these barriers and proposes policy and advocacy recommendations.

### Trade Negotiations

Since 1947, the General Agreement on Tariffs and Trade (GATT) and subsequent World Trade Organization (WTO) accords have facilitated the negotiation of lower tariff rates among member countries.<sup>6</sup> In addition, bilateral agreements, such as the Israel-U.S. free trade agreement (FTA),<sup>7</sup> regional trade agreements, and other trade agreements between groups of countries have resulted in drug tariff reductions.

Multilateral work continues on tariff reductions in the Doha Round, the ongoing WTO negotiations on new trade rules and implementation of the 2001 Doha Development Agenda rules.<sup>6,8</sup> Current negotiations are stalled, primarily because developed countries are reluctant to relinquish agricultural subsidies and developing countries are unwilling to reduce general import tariffs. The stalled negotiations have delayed additional pharmaceutical tariff reductions.

Public health and access to pharmaceuticals have achieved a special place in trade negotiations, as codified in GATT 1947 Article XX(b),<sup>9</sup> the Pharmaceutical Tariff Elimination Agreement,<sup>10</sup> and the Doha Declaration.<sup>11</sup> Therefore, the public health community has a key role to play in maintaining and advancing pharmaceutical trade negotiations.

### Definitions

*Tariffs* are customs duties or taxes imposed by governments when goods enter a country. They are simple rates applied to the value of imported goods. For example, when Drug A has a factory price of \$1.00 and enters a country that imposes a 10 percent tariff, the cost of Drug A is now \$1.10 – with \$0.10 going to the country.

*Non-tariff barriers* are any trade measures (other than tariffs) imposed by governments to restrict or prohibit imports. NTBs take numerous forms, such as preferences for domestic bidders in government procurement or complex language requirements on packaging.

Both tariffs and NTB rules and regulations must be managed before a product can enter a country. These measures may be designed to promote the development of locally produced goods, so that they have an advantage over imported ones. Tariffs and NTBs are the subject of attention in international organizations, such as the World Trade Organization (WTO), the World Health Organization (WHO), and the United Nations Conference on Trade and Development (UNCTAD).

## Tariffs

Although countries may impose tariffs to protect local industry, raise revenue, or retaliate against trade rule violations by another country, the global trend has been to reduce or eliminate tariffs. The goal of lower tariffs is to stimulate trade, competition, and price reductions.<sup>12</sup> Yet, some local industries may see this scenario as non-beneficial, as lower tariffs force them to compete with foreign producers who may offer better quality or lower priced goods.

From the health sector perspective, minimizing tariffs may increase purchasing power for the public and private sectors, so long as sales tax and other drug price components are controlled. Optimally, this will lead to greater availability of essential medicines for the health system. There are strong arguments in favor of tariff removal on essential pharmaceutical products, as revenue from these tariffs is low and imposing tariffs on APIs and excipients used by local producers ultimately increases the price of their products.

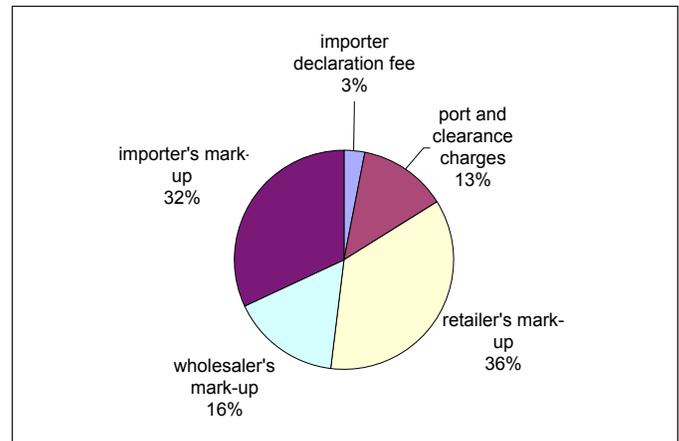
### Drug price components include:

- National pricing policies
- Market size
- Degree of competition
- Charges for port of entry clearance and freight
- Pre-shipment inspection requirements
- Pharmacy board fees
- Local drug registration
- Importer's margin
- Wholesaler and retailer mark-ups
- Non-tariff barriers

Studies examining the effect of tariff rates on access to essential pharmaceutical products and revenue indicate that:<sup>2, 12</sup>

- About 39 percent of countries do not impose tariffs on finished pharmaceuticals. Of countries that do apply tariffs, 76 percent impose rates of less than 10 percent; the overall mean rate is nearly 5 percent.<sup>2, 12</sup>
- While tariffs on all imports can represent up to one-third of all taxes, pharmaceutical tariffs generate less than 0.1 percent of gross domestic product in 92 percent of countries.<sup>2, 13</sup> Revenue losses from tariff reductions can be offset by economic gains generated by a healthier population.
- Considering the impact of other price factors, the extent to which tariffs are a barrier to access is typically modest and should not be over emphasized.<sup>2</sup> Each component should be monitored to avoid any negative impact on drug access.<sup>14</sup>

**Graph 1. Example of non-tariff price component proportions for an imported drug in Kenya<sup>15</sup>**



- Tariffs are regressive taxes, which disproportionately fall on the poor.
- Few developing countries apply their highest tariff rates; occasional rate increases occur despite potential decreases in access to essential drugs.<sup>13</sup>
- Lack of comprehensive global data complicates efforts to calculate tariff rates that are determined by WTO accords, more than 300 other trade agreements, and 930 tariff schemes applied by 132 countries. The 2007 World Tariff Profiles aggregates key data bases and should alleviate the data shortfall.<sup>16</sup>

## Non-tariff Barriers

While tariffs have been reduced, NTBs have increased dramatically.<sup>5</sup> Trade restrictions and controls asserted in a non-discriminatory manner are permissible if necessary to protect public health.<sup>9</sup> WTO documents clarify which trade restrictions and controls are permissible, such as border measures to prevent the inflow of counterfeit and pirated goods.<sup>5</sup> Ensuring that non-tariff *measures* do not become non-tariff *barriers* is critical, as NTBs reduce the quantity and variety of products entering a country – creating shortages of essential drugs and medical supplies. Reducing NTBs will facilitate product approvals and decrease costs, thereby increasing the flow of needed medications to the poor.

NTBs can take many different forms and work is needed to identify and classify those that affect access to essential medications. Given the variety of NTBs and lack of a comprehensive and uniform reference system, analysis of NTB data is complex. Formally defining NTBs, developing a protocol for collecting and disseminating data, and improving the Trade Analysis and Information System database will be undertaken by the Group of Eminent Persons on NTBs (GNTB), formed by UNCTAD.<sup>5</sup>

Because of their diversity and complexity, NTBs can complicate the efforts of both businesses and nonprofit organizations trying to import pharmaceutical products into a country. Information on procurement processes, import rules, and drug registration is hard to find for most developing countries – it is not electronically available, is not comprehensive, and may not be translated into the producer’s language. Hidden costs in the process of drug importation may take the form of:<sup>12</sup>

- Tedious and time-consuming banking procedures, particularly for remittance of foreign exchange;
- Burdensome import approval procedures that add as much as US\$7,000 and 18–36 months per product;<sup>17</sup>
- Inflated charges and additional handling fees, even on donated products;
- Lengthy approval by more than one regulatory body (e.g., by both the drug registration authority and the health insurance body).<sup>18</sup>

### Harmonizing the Standards

For WTO members, two key agreements set standards on trade measures: Sanitary and Phytosanitary Measures (SPS) addresses food safety and animal and plant health standards, and the Technical Barriers to Trade (TBT) addresses technical measures, such as testing requirements. While SPS and TBT are on point in regulating trade measures to prevent their becoming NTBs, in practice, many WTO members are slow to integrate these requirements throughout the drug supply chain. In non-WTO member countries, product approval and importation rules are not standardized; compliance with existing external international standards is not required.

Several initiatives are underway with regard to the development of international norms, standards and harmonization relevant to NTBs and drug access:

- The International Conference on Harmonization,<sup>19</sup>
- The World Health Organization and its regional efforts,<sup>20</sup>
- The development of pharmaceutical practice guidelines on drug registration, as has been done for manufacturing, clinical trials, and storage.<sup>21</sup>

Through such initiatives, international consensus can facilitate access to medicines while simultaneously advancing quality, safety and efficacy standards.

### The Joint Impact of Tariffs and NTBs

Estimating the impact of tariffs or NTBs on pharmaceutical product price and accessibility is complex, particularly if tariffs and NTBs are concurrently applied. Using the example of insecticide-treated bednets (ITNs), a tariff plus NTBs will increase bednet price. Eliminating the tariff may not lead to a price reduction if the indirect costs of the NTBs are retained.

In some cases, tariffs and NTBs are inextricably linked. For example, rules related to tariff exemptions and waivers in national laws may lack transparency. In this situation, the producer and/or importer may be unable to find the rules pertaining to exemptions or waivers or they may be unaware of the terms and conditions to exercise their right to exemptions or waivers. This information asymmetry leads to an increased product price.<sup>5</sup>

### The Global Health Council Supports the Following Measures

The potential benefits to minimizing tariffs and ensuring that trade measures are not barriers to essential drug access outweigh negative consequences that may arise, including short-term revenue loss to the importing country. These efforts can contribute to a healthier population by increasing access to essential drugs and other medical technologies.

Coherence between trade and health policy will be essential to accomplish the goal of minimizing tariffs and NTBs. Collaboration between the public health, trade and advocacy communities can be helpful in reducing tariffs and NTBs, and aligning trade and health policy goals. The Global Health Council recommends focusing on issues of mutual interest:

- Collecting information on waivers and exemptions and their application so that program managers have this tool at their disposal;

- Supporting the minimization of tariffs on essential drugs and medical products for the poor, particularly in multilateral, regional and national forums;
- Supporting the development of databases on NTBs and tool kits on waivers and exemptions that will facilitate efforts by organizations attempting to import drugs and medical technologies of public health significance;
- Highlighting and analyzing non-tariff barriers to essential drug access:
  - Providing input to the GNTB and the U.S. National Trade Estimate Report on Foreign Trade Barriers, published annually;<sup>22</sup>
  - Advocating for the harmonization and transparency of drug regulations;
  - Protecting the public’s health by ensuring that local standards are in compliance with international norms.

## References

- <sup>1</sup> World Health Organization. 2004. World medicines situation. Available from: [http://whqlibdoc.who.int/hq/2004/WHO\\_EDM\\_PAR\\_2004.5.pdf](http://whqlibdoc.who.int/hq/2004/WHO_EDM_PAR_2004.5.pdf)
- <sup>2</sup> Olcay M, Laing R. 2005. Pharmaceutical tariffs: what is their effect on prices, protection of local industry, and revenue generation: Commission on Intellectual Property Rights, Innovation and Public Health. Available from: [www.who.int/intellectualproperty/studies/TariffsOnEssentialMedicines.pdf](http://www.who.int/intellectualproperty/studies/TariffsOnEssentialMedicines.pdf)
- <sup>3</sup> Perez-Casas C, Herranz E, Ford N. 2001. Pricing of drugs and donations: options for sustainable equity pricing. *Trop Med Int Health* 6(11):960-4.
- <sup>4</sup> Bale H. 2001. Consumption and trade in off-patented medicines. Working paper no. 65: Indian Council for Research on International Economic Relations. Available from: [www.icrier.org/pdf/bale65.PDF](http://www.icrier.org/pdf/bale65.PDF)
- <sup>5</sup> United Nations Commission on Trade and Development Secretariat. 2007. Market access, market entry and competitiveness, background note, February 14, 2007. Available from: [www.unctad.org/en/docs/c1d83\\_en.pdf](http://www.unctad.org/en/docs/c1d83_en.pdf)
- <sup>6</sup> Gerber J. International Economics. Third ed. Boston: Addison-Wesley; 2005.
- <sup>7</sup> US-Israel FTA. [accessed August 1, 2007], Available from: [http://www.ustr.gov/Trade\\_Agreements/Bilateral/Israel/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/Israel/Section_Index.html)
- <sup>8</sup> World Trade Organization. Doha Development Agenda: Negotiations, implementation and development. [accessed August 13, 2007], Available from: [http://www.wto.int/english/tratop\\_e/dda\\_e/dda\\_e.htm](http://www.wto.int/english/tratop_e/dda_e/dda_e.htm)
- <sup>9</sup> General Agreement on Tariffs and Trade. The general agreement. [accessed July 1, 2007], Available from: [www.wto.int/english/docs\\_e/legal\\_e/gatt47\\_e.pdf](http://www.wto.int/english/docs_e/legal_e/gatt47_e.pdf)
- <sup>10</sup> General Agreement on Tariffs and Trade. Pharmaceutical Tariff Elimination Agreement. [accessed August 1, 2007], Available from: [http://www.wto.int/gatt\\_docs/English/SULPDF/91770009.pdf](http://www.wto.int/gatt_docs/English/SULPDF/91770009.pdf)
- <sup>11</sup> World Trade Organization. 2001. Declaration on the TRIPS agreement and public health. Available from: [www.wto.int/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.int/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm)
- <sup>12</sup> Bates R, Tren R, Urbach J. 2006. Still taxed to death: an analysis of taxes and tariffs on medicines, vaccines, and medical devices. American Enterprise Institute, Brookings Joint Center for Regulatory Studies. Available from: <http://aei-brookings.org/admin/authorpdfs/page.php?id=1136>
- <sup>13</sup> European Commission. Working document on developing countries' duties and taxes on essential medicines used in the treatment of the major communicable diseases. Brussels, 10 March, 2003. [accessed July 1, 2007]. Available from: <http://trade-info.cec.eu.int/doclib/html/113184.htm>
- <sup>14</sup> World Health Organization. 2006. Public health, innovation and intellectual property rights: report to the Commission on Intellectual Property Rights, Innovation and Public Health. Available from: [www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf](http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf)
- <sup>15</sup> Kenyan Ministry of Health, Health Action International, World Health Organization. 2004. A survey of medicine prices in Kenya. Available from: <http://www.haiweb.org/medicineprices/surveys/200411KE/sdocs/kenya.pdf>
- <sup>16</sup> World Trade Organization. 2007. World Tariff Profiles 2006. Available from: [www.wto.org/english/tratop\\_e/tariffs\\_e/tariff\\_profiles\\_2006\\_e/tariff\\_profiles\\_2006\\_e.pdf](http://www.wto.org/english/tratop_e/tariffs_e/tariff_profiles_2006_e/tariff_profiles_2006_e.pdf)
- <sup>17</sup> Federation of Indian Chambers of Commerce and Industry. Non-tariff barriers stump pharma exports to China: FICCI. January 27, 2007 [accessed July 13, 2007], Available from: [www.ficci.com/press/230/press6.htm](http://www.ficci.com/press/230/press6.htm)
- <sup>18</sup> ASEAN. Frequently asked question on non tariff issues in ASEAN, in Market access: negotiations, a simple guide. [accessed August 1, 2007], Available from: [www.aseansec.org/economic/afta/faqs.htm](http://www.aseansec.org/economic/afta/faqs.htm)
- <sup>19</sup> International Conference on Harmonization. [accessed August 1, 2007], Available from: <http://www.ich.org/cache/compo/276-254-1.html>
- <sup>20</sup> World Health Organization. Norms, standards and guidance for pharmaceuticals. [accessed July 11, 2007], Available from: [www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/norms\\_standards/en/](http://www.who.int/medicines/areas/quality_safety/quality_assurance/norms_standards/en/)
- <sup>21</sup> WHO Expert Committee on Pharmaceutical Preparations. 2003. Thirty-seventh report: World Health Organization. Available from: [http://whqlibdoc.who.int/trs/WHO\\_TRS\\_908.pdf](http://whqlibdoc.who.int/trs/WHO_TRS_908.pdf)
- <sup>22</sup> Office of the U.S. Trade Representative. 2007. National trade estimate report on foreign trade barriers. Available from: [www.ustr.gov/Document\\_Library/Reports\\_Publications/2007/2007\\_NTE\\_Report/Section\\_Index.html?ht=](http://www.ustr.gov/Document_Library/Reports_Publications/2007/2007_NTE_Report/Section_Index.html?ht=)



### Global Health Council

is the world's largest membership alliance dedicated to saving lives by improving health throughout the world. The Council serves and represents thousands of public health professionals from more than 100 countries on six continents.

[www.globalhealth.org](http://www.globalhealth.org)

1111 19th Street NW, Suite 1120  
Washington, DC 20036

---

15 Railroad Row  
White River Junction, VT 05001