Appendix 10

The Study on Policies Affecting Trade in Healthcare Products in APEC (Executive Summary)

Asia-Pacific Economic Cooperation

USAID
FROM THE AMERICAN PEOPLE

POLICIES AFFECTING TRADE IN HEALTH CARE PRODUCTS IN APEC

November 2015

This publication was produced by Nathan Associates Inc. for review by the United States Agency for International Development.

EXECUTIVE SUMMARY

Improving all citizens' access to good health is an APEC priority. Such access is shaped by both the availability and cost of health care products and services. "Health care products" are defined here to include pharmaceutical and biologic drugs and other therapeutic goods, key ingredients into their manufacture, medical supplies, medical devices, and the parts, tools, and other components used to manufacture those devices. Eighty-three health care product categories, defined by four-digit Harmonized System codes, are considered in this study.

Trade in health care products takes place in a context in which there are high barriers to entry and thus limited competition; important investment and research and development expenses; high human capital skills requirements; extensive product testing to assure effectiveness and safety; significant product regulatory hurdles; exacting standards regarding good manufacturing, distribution, and labeling practices to protect product integrity; significant premiums associated with branded goods; extensive markets for generic products; high potential for fraudulent products; valuable intellectual property that needs to be protected in order to preserve incentives to invest; extensive regulatory oversight from government agencies; and intense scrutiny due to the fact that these products directly affect human well-being.

Trade can be impacted by government policies implemented at or behind the border. As is detailed in this report, products may cross borders at several points in the manufacturing and distribution stages of pharmaceutical goods and medical devices value chains as primary materials are combined, basic substances manufactured, and combination products are assembled, or as components are built and assembled and final products shipped abroad.

Global trade in health care products is dominated today by high-income economies. In 2014 APEC economies overall accounted for 16 percent of global imports and 30 percent of global exports of drugs and other therapeutic goods and about 50 percent of global imports and exports, respectively, of medical devices, as defined in this report. Within APEC, trade in drugs and other therapeutic goods represents 1.1 percent of APEC exports and 1.9 percent of APEC imports, while trade in medical devices represents 2.4 percent of APEC exports and 2.2 percent of APEC imports. However, as incomes rise and consumers' demand for improved health care expands, new markets will expand in APEC. Trade in health care products represents a dynamic segment of global merchandise trade. The most rapidly growing category of health care product trade is of formulated medicines (HS 3004), i.e., medications available in measured doses ready for consumption, trade of which grew by almost 12 percent per year for over a decade into the late 2000s.

Policies affecting trade in health care products include both tariffs and non-tariff measures (NTMs). While tariffs on health care products are low or even zero in many, especially developed, economies, applied tariff peaks as high as 30-50 percent are noted and maximum applied tariffs for selected basic health care products in selected economies are non-zero. NTMs are considered by many companies, because of the time, cost, and administrative burdens their compliance entails, to be the more trade-challenging of the two categories of trade policies.

This study presents maximum and average applied tariff rates within 4-digit Harmonized System (HS) product categories, and measures of tariff rate dispersion (standard deviations), as well as

maximum and average rates for select products at the 6-digit HS level. Data are reported for latest year available, usually 2013 or 2014. Summary observations on tariffs on average across APEC economies include the following:

- Maximum applied tariffs are highest on medical supplies (7.6 percent) and lowest on drugs and therapeutic goods (2.9 percent).
- Average tariffs are lower than maximum applied tariffs (by definition), and follow the same pattern, i.e., are highest for medical supplies (4.7 percent) and lowest on drugs and therapeutic goods (1.6 percent).
- Similarly, the largest rate dispersion occurs in medical supplies, and least dispersion is observed among tariffs on drugs and therapeutic goods.
- Within broad product categories, by APEC economy, the highest average tariffs are observed in the following economies: drug & therapeutic goods ingredients: Chile, 6.0 percent; drugs & therapeutic goods: Chile, 6.0 percent; medical supplies: Thailand, 9.1 percent; medical devices: Brunei Darussalam, 9.4 percent; and parts, tools, and components: China, 7.6 percent.
- With regard to selected products, maximum applied tariffs of 10-15 percent are observed for drugs and chemical contraceptives, while maximum rates in some economies reach as high as 30 percent for sheath contraceptives and insecticide-treated bed netting (used to prevent diseases communicated by insect bites).

This study also examines – through a WTO database of NTM notifications, a review of governments' recent foreign trade barriers reports, and interviews with government and business representatives – the range of NTMs that affect trade in health care products. These include regulatory hurdles associated with product approval or registration to gain market access, lack of adherence to or convergence with recognized international standards, requirements that oblige foreign companies to engage with local partners in order to do business in local economies, low de minimis Customs value thresholds, regulation of trade in remanufactured medical devices, and the costs associated with these.

The study provides numerous examples of the lack of convergence with international regulatory and standards best practice benchmarks. Among the most challenging, either because of the time or cost or uncertainty involved, are: requirements by some economies that clinical trials be repeated within their borders; requirements by some economies that U.S. FDA approval be achieved even if the manufacturer does not intend to sell into the U.S. market; delays or lack of transparency in product approval processes; inconsistent application of registration or licensing requirements to domestic versus foreign companies; obligations of foreign firms to distribute through local companies; limited or lack of or non-transparent comment processes as new drug or medical device regulatory frameworks are developed; extended delays in foreign product approval by national pharmaceutical agencies, thereby denying patients access to new, innovative health care products; and bans by some economies on the importation of remanufactured health care products, a growing segment of health care product trade. Estimation of frequency and coverage of NTMs across health care products trade suggests that while low in most economies (less than 5 percent), they are significant in several.

Increases in the time or costs associated with these NTMs may be felt disproportionally by small- and medium-sized enterprises. Such firms more likely lack the legal or government affairs representation in foreign markets that large, multinational corporations can support. SMEs predominate in the health care industry (in terms of numbers of firms) and are often the ones

whose products provide cutting-edge innovations in terms of new drugs, new processes for manufacturing, and new technologies for delivering therapies to consumers. NTMs thus pose a significant deterrence to SMEs seeking to export to foreign markets.

Because of the great diversity of health care systems across APEC, it is difficult to detail the impacts of tariffs and NTMs on each economy's health care products. However, this review makes evident the great deal of variation that exists in both categories of trade policies on health care products trade within the region.

Although average tariffs may be low, maximum applied tariffs of key products are non-trivial. These tariffs are particularly burdensome in the case of medical supplies, the costs of which are typically not covered in most economies by third-party payers. Moreover, since out-of-pocket expenditures are relatively more significant in lower income economies, whose consumers are more likely to purchase health care products directly, the impacts of tariffs on prices faced by health care consumers in lower income economies, assuming that tariffs are indeed passed through in the market, are more significant. This is a form of regressive taxation on those health care consumers less able to afford the additional costs of health care.

In summary, this review has highlighted two sets of issues for consideration by APEC's life sciences and trade officials:

1. Divergent tariff rates across APEC economies are observed, highest in upper-middle income economies and lowest in high income economies; also, tariff peaks for specific products are significant, even for certain key medicines and supplies.
2. Lack of harmonization of non-tariff measures across APEC economies – particularly, lack of convergence of regulations and standards with international benchmarks and national treatment practices that discriminate against foreign firms – contradict APEC's goal of supply-chain connectivity, increase costs for companies, and, ultimately, result in decreased access and increased costs for APEC consumers of health care products.

To address these issues, APEC may wish to consider:

1. Identifying obstacles to converge, reduce, or even eliminate tariffs on the health care products identified in this study as one step to improve health care in APEC.
2. Undertaking regulatory cooperation to promote health care products' supply-chain connectivity, by working toward NTM coordination in several areas, e.g.,
    a. Support for harmonized guidelines for multi-regional clinical trials (MRCTs) being developed by ICH that will *inter alia* streamline clinical trial procedures, while considering ethnic and population characteristics in the design of MRCTs.
    b. Encouraging the adoption of ISO certification for quality management practices and eliminate need for separate certification;
    c. Reaffirmation of commitment to good regulatory practices in health care product markets to minimize time and cost and increase transparency;
    d. Promotion of the use of a common standard regarding product serialization in conformance with international proposals;
    e. Embrace the role of third-party logistics providers in health care product value-chains to maximize supply-chain connectivity;

f. Elimination of preferences for domestic firms that discriminate against foreign health care product suppliers;

g. Exploration of the possibility of complying with the Medical Device Single Audit Program as an additional step toward regulatory convergence.

More broadly, APEC members should facilitate the transit of all goods, not just health care products, across borders, including adoption of the Trade Facilitation Agreement and trusted trader concepts across the region.

Commitment to and progress in the adoption of these recommendations will help to reduce costs or margins and improve the efficiency of health care product value chains.

Further analysis is recommended to understand the impacts of these measures on accessibility and affordability of innovative health care products in pursuit of APEC's ultimate goal, i.e., improvement in health outcomes for APEC's nearly 3 billion people.