Free Trade Agreements

Free Trade Agreements (FTAs) are agreements between two or more countries where the countries enter into formal negotiations and agree on certain obligations that affect trade in goods and services. FTAs often address economic issues affecting trade and provide opportunities to address intellectual property rights (IPR), regulatory barriers, pricing and reimbursement, government procurement, market access, and transparency—all of which can enhance patient access to medicines globally.

Background

Free Trade Agreements (FTAs) can reduce trade barriers and create a more stable and transparent trading and investment environment, which in turn can provide benefits including increased market access and exports for industries, including the biopharmaceutical sector. Pharmaceutical manufacturers face unique market access challenges that can be addressed in FTAs including barriers related to intellectual property protection and enforcement; regulatory approval; government pricing and reimbursement; transparency; and dispute settlement. Strong provisions in FTAs, which address market access barriers for pharmaceuticals, can stimulate innovation and economic growth in FTA countries. FTA obligations are defined in the text of agreements and most FTAs are accompanied by "side letters" capturing interpretations and "understandings" contemporaneous with the negotiations.

In the United States, Congress has constitutional authority over tariff policy and final approval of an FTA, but the Office of the U.S. Trade Representative (USTR) takes the lead in negotiating FTAs. FTAs typically take several years, at a minimum, to negotiate, and require approval of Congress prior to implementation. On June 25, 2015, Congress passed Trade Promotion Authority (TPA) legislation also known as "fast track", which grants the President authority to negotiate trade deals, which Congress can approve or disapprove but cannot amend or filibuster. In Europe, negotiations are conducted by the European Commission (DG Trade), with their negotiating mandate set by the Council of the EU (Member States), and the final text approved by both the Council and the European Parliament. If the negotiated FTA includes matters falling under Member States' competence, national parliaments are asked to approve the agreement as well.

The selection of FTA partners is usually done through a calculation of economic and foreign policy considerations. Domestic political considerations also impact country selection, as certain constituencies are traditionally supportive of free trade or opposed to increased market opening.

Key Facts and Figures

- The United States currently has free trade agreements in force with twenty countries around the world. Although negotiations concluded on the Trans-Pacific Partnership Agreement (TPP) in 2015, the U.S. withdrew from the agreement, and the agreement has not yet come into force.[1]
- In August 2017, the United States, Canada, and Mexico launched negotiations to modernize the North American Free Trade Agreement (NAFTA). Key biopharmaceutical sector priorities include IP, pricing and reimbursement, market access, and transparency issues.
- The European Union (EU) has preferential trade agreements in place with over 50 countries (including Canada, South Africa, and South Korea) and a number more waiting to come into force (including Vietnam, Japan and Singapore).[2] The EU has also launched FTA talks with the Philippines, Indonesia, Australia, New Zealand, and renewing existing FTAs with Chile and Mexico.
- The 10-member Association of Southeast Asian Nations (ASEAN) has free trade agreements in place with countries including Australia, China, India, Japan and South Korea.[3]

Pfizer's Position

FTAs provide the opportunity to seek country commitments to minimum standards on a range of issues including IP and regulatory norms.

The U.S. has increasingly sought to strengthen IPR in FTAs through the inclusion of adequate regulatory data protection provisions, patent linkage, patent restoration, patent term adjustment, and IP-enforcement mechanisms. Similarly, the EU also calls out protection and enforcement of IP rights as a key element of its FTAs, often basing its approach off the EU's domestic IP regime. Intellectual property rights are designed to reward innovation and provide incentives for future innovation. Protection and enforcement of IPR can encourage future innovation, investment, and technology transfer.

Driving global regulatory norms is an increasingly important element of FTAs. FTAs usually include language referencing standards set by the WHO, ICH (International Conference on Harmonization) and other recognized international actors; they also address specific regulatory barriers. In addition a number of larger EU FTAs include Mutual Recognition Agreements on Good Manufacturing Practice (GMP); in the case of the U.S., a standalone EU-U.S. MRA was signed in March 2017 to avoid duplicative inspections of the same manufacturing sites by the U.S. FDA and EU regulators.

Encouraging FTA provisions that ensure transparency and fairness in decision-making processes for approval and pricing, reimbursement and regulation of pharmaceuticals can provide predictability and legal certainty to help sustain investment in healthcare innovation. Specifically, in FTAs negotiated by the U.S., Pfizer supports the high-level transparency and IPR commitments contained in the KORUS FTA, plus 12 years of data exclusivity for biologics. Economists have calculated that it requires at least 12 years of data protection to drive continued innovation in biologics.[4]

Depending on the market environment in a country in FTA negotiations, the scope may include other issues impacting our sector, such as procurement or investment.

How Patients, Health Care Professionals and the Health Care System Benefit

Free trade agreements that remove barriers to trade between partner countries and enshrine strong IP rights, regulatory convergence, transparency, and pricing and reimbursement provisions help create an environment for continued investment in health care innovation and ensure access to medicines for patients. Countries with established pharmaceutical industries benefit from an expanded export market and the increased global competitiveness of the industry. Countries without established pharmaceutical sectors benefit from increased investment from multinational companies, potentially helping to build a local industrial base, increase technology transfer and foreign direct investment, as well as encouraging the entry of new products to the domestic market, benefitting patients.

What It Means for Pfizer

FTAs can help reduce market access barriers so that Pfizer can deliver new medicines to patients globally. Strong IPR, regulatory, transparency, and pricing and reimbursement provisions in FTAs provide legal certainty for Pfizer when evaluating where to invest and expand R&D capabilities for the benefit of patients.

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[1] http://www.trade.gov/mas/ian/tradeagreements/fta/tg_ian_002401.asp)
[2] http://trade.ec.europa.eu/doclib/docs/2012/june/tradoc_149622.pdf
[3] http://www.aseanbriefing.com/news/2014/02/13/understanding-aseans-free-trade-agreements.html
[4] Grabowski, H., Long, G., and Mortimer, R. Data exclusivity for biologics. Nature Reviews Drug Discovery 2011(10):15.