Changes in the U.S. Pharmaceutical Import Mix under the Agreement on Trade in Pharmaceutical Products

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The zero-for-zero initiative on pharmaceuticals contributed to both the substantial increase in U.S. pharmaceutical imports during the past 20 years and the growing share of such imports held by formulated (dosage-form) products. Under the initiative, the United States and its major trading partners reciprocally removed tariffs on many pharmaceuticals, their derivatives, and certain chemical intermediates used to make pharmaceuticals.

The WTO Agreement on Trade in Pharmaceutical Products (or the zero-for-zero initiative on pharmaceuticals), which entered into force January 1, 1995, helped liberalize global pharmaceutical trade through reciprocal tariff elimination. U.S. imports of these goods subsequently rose from $8.6 billion in 1996 to over $113 billion in 2016.[1] Under the initiative:

- Tariffs on **formulated** (**dosage-form**) pharmaceuticals from trading partners with which the United States has normal trade relations (NTRs) were eliminated immediately upon entry into force.
- Tariffs on certain **bulk active pharmaceutical ingredients** (**APIs**) from NTR partners were also ended (APIs are further processed into formulated products):
    - Immediately upon entry into force for provitamins and vitamins, hormones, alkaloids, and antibiotics.
    - As appropriate, for products listed in the Pharmaceutical Appendix (PA) to the *Harmonized Tariff Schedule* (HTS) if classified under certain tariff lines.[2]

The U.S. pharmaceutical industry historically shipped bulk APIs between foreign production sites and the United States before formulating dosage-form products to meet national regulations and/or market access requirements.[3] Since 2000, however, the import mix has shifted towards formulated products, largely because their tariffs were eliminated in the initiative. As shown in figure 1, formulated pharmaceuticals accounted for much of the increase in U.S. pharmaceutical imports during 1996–2016, as well as for a growing share of total imports (42% in 1996 versus 84% in 2016). Several factors contributed to the growth in U.S. imports of formulated pharmaceuticals:

- **Cost Savings**. Although PA updates were intended to be negotiated and issued by initiative parties at least every three years, the intervals grew much longer, so new APIs could not be added to make them duty free. Instead, firms imported more formulations, saving nearly $32 billion in duties in 1996–2016.[4]
- **Increased Use of FTZs.** More pharmaceutical companies have been using foreign-trade zones (FTZs) to enter and process APIs, particularly for tariff inversions.[5] One source notes, "By operating in an FTZ, drug makers can avoid duties on raw materials and APIs, and elect to pay the lower or zero duty when finished drug

[1] "Zero-for-zero" is reciprocal tariff elimination on a sectoral basis; a number of sectors are covered by such initiatives.

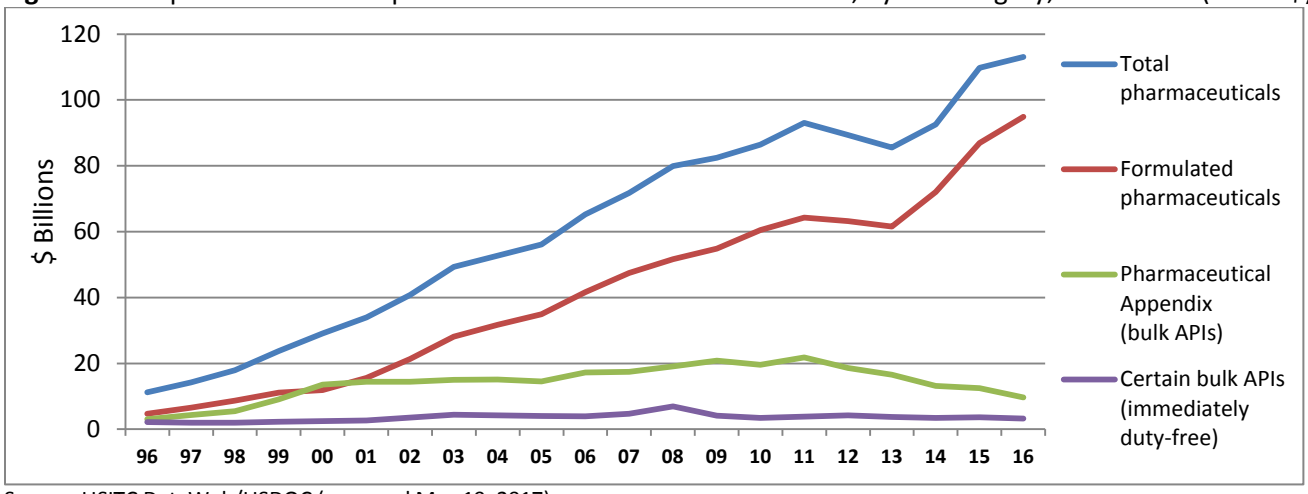
[2] The PA was updated in 1997, 1999, 2006, and 2010 through "multilateral negotiations under the auspices of the WTO," expanding coverage from about 7,000 to more than 10,000 products. (See request letter in USITC, *Pharmaceutical Products,* 2010, appendix A.) As of August 2017, parties to the Pharmaceutical Agreement have not reached consensus on next steps regarding future updates. U.S. government official, email to USITC staff, June 27, 2017. The agreement also covers certain intermediate chemicals that are immediate precursors to pharmaceuticals, but these products are not addressed in this analysis. Definitions provided are from page 1-2 of the 2010 report.

[3] The U.S. pharmaceutical industry generally includes all companies operating in the United States, including those with foreign parents. Intra-firm transfers (or "related-party trade") accounted for 84% of the imports in 2014 (latest available data).

[4] Industry representative, telephone interviews by USITC staff, October 22, 2015, and May 25, 2017. These duty savings are calculated using a trade-weighted rate of duty of 3.65% for 1994 (the year before entry into force) for formulated pharmaceutical subheadings in HTS chapter 30. The rate is based on calculated duties of about $126 million and customs value of about $3.46 billion. USITC DataWeb/USDOC (accessed June 29, 2017).

[5] Industry representative, telephone interview by USITC staff, July 18, 2017. Tariff inversion occurs when the tariff on an imported input is higher than the tariff on the corresponding finished good imported for U.S. consumption.

Figure 1: U.S. pharmaceutical imports under the zero-for-zero initiative, by subcategory, 1996–2016 (billion $)



Source: USITC DataWeb/USDOC (accessed May 19, 2017).

products leave the zone for sale in U.S. commerce."[6] The value of pharmaceuticals entering through FTZs for further processing grew from $2.4 billion in 2007 to a peak of $7.1 billion in 2011, and then fell to $3.5 billion in 2013 before rebounding to $6.4 billion in 2015.[7] The decline in use of FTZs for processing during 2012–13 was attributed largely to increased use of the PA again following the addition of new products during the 2010 update.[8]

- **The Effect of Outsourcing.** More pharmaceutical companies are outsourcing pharmaceutical formulation activities, including to overseas sources.[9] This trend, too, is driven by several factors:[10]
  - ***At the industry level:*** ongoing consolidation in the number of firms and U.S. production capacity.
  - ***At the firm level:*** changes in business models and supply chains, coupled with robust drug pipelines and the expertise needed for the growing number of complex specialty pharmaceuticals.
  - ***At the regulatory/market level:*** the ability of firms to import formulated products (but not bulk APIs) before U.S. market approval under the U.S. Food and Drug Administration's (FDA) guidance for Pre-Launch Activities Importation Requests. This way firms can prepare for upcoming market launches based on pending applications (both regular and abbreviated) for new drugs.[11]

Sources: References listed in footnotes, as well as USITC, *Pharmaceutical Products and Chemical Intermediates, Fourth Review*, September 2010; USITC, *Shifts in U.S. Merchandise Trade, 2014*, special topic chapter, June 2015; USITC, *Economic Impact of Trade Agreements Implemented under Trade Authorities Procedures*, June 2016; USTR, "Pharmaceuticals" (accessed April 29, 2016); USDOC, ITA, "2016 Top Markets Report: Pharmaceuticals," May 2016; U.S. Bureau of Labor Statistics, "The Pharmaceutical Industry: An Overview of CPI, PPI, and IPP Methodology," October 2011; U.S. Census Bureau, "Related Party Trade Database," NAICS 3254; *Drug Development and Delivery*, "Outsourcing Formulation Development and Manufacturing: Early-Stage Partnerships Are on the Rise," April 2, 2014; *Pharmaceutical Processing*, "CMO Report: Two-Thirds of Pharma Manufacturing Is Outsourced," November 15, 2016.

[6] Griswold, "US Drug Makers Maintain Competitive Edge through FTZ Program," *Journal of Commerce,* September 3, 2012, 54.
[7] U.S. Foreign-Trade Zones Board, *Annual Report of the Foreign-Trade Zones Board to the Congress of the United States*, 2012–15. Pharmaceuticals entering FTZs for further processing account for the majority of FTZ pharmaceutical imports (versus pharmaceuticals imported into FTZs for non-processing activities such as warehousing and distribution).
[8] Industry representative, telephone interview by USITC staff, July 18, 2017.
[9] Industry representatives, telephone interviews by USITC staff, July 11, 2017, and July 18, 2017. See also source list.
[10] Industry representative, telephone interview by USITC staff, July 18, 2017; *Drug Development and Delivery*, "Outsourcing Formulation Development & Manufacturing: Using a Single Provider Reduces Costs & Risk," March 30, 2016.
[11] FDA, "Draft Guidance for Industry, Pre-Launch Importation Requests (PLAIR)," July 2013.