



## Trade Tensions: India – USA trade in the Pharmaceutical Sector

Dr. Rajan Sudesh Ratna<sup>i</sup> and Ms. Huidan Xue<sup>ii</sup>

### Introduction

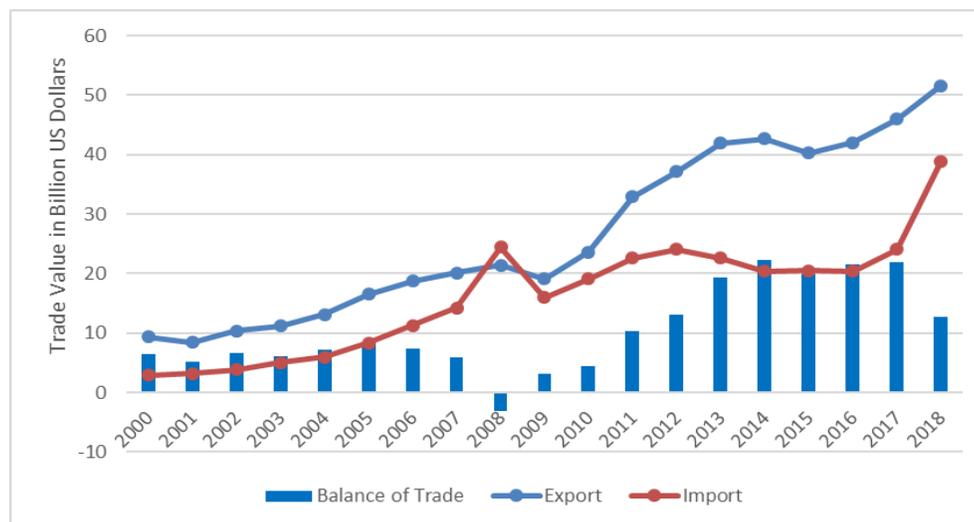
Since the rise in tariffs on aluminium and steel by the USA against its important trade partners, the entire world is debating and talking about the trade war between the United States of America (USA) and China and less attention is given to other trade tensions that are growing around with other countries as well - one such case is India. The USA president Mr. Donald Trump tweeted on 9th July 2019, “India has long had a field day putting tariffs on American products. No longer acceptable!” This was in response to India’s retaliation to USA’s imposition of tariffs on aluminum and steel imposed last year and the withdrawal of duty-free access to Indian exports under the Generalized System of Preferences (GSP) in June 2019. For the last one year, India has been restraining itself from implementing any retaliatory measure against the

USA, despite issuing a Customs Notification and keeping it in abeyance. Concerns have been raised over India-USA bilateral trade of multiple products and the possible obstacles to realizing the bilateral trade targets of 500 billion US dollars by 2025. Concerns have also been raised on the impact of Indian pharmaceutical exports to the USA

### Indo-USA Trade Characteristics

India-USA trade has been growing since 2000 with India’s exports growing at a faster pace than its imports from the USA, which leads to a favourable balance of trade of 12.7 billion US dollars in 2018, though a decline from 21.9 billion US dollars in 2017. It is this balance of trade that has worried the USA.

**Figure 1: India’s imports, export and balance of trade with the USA, 2000-2018**



Source: Compiled by authors, data taken from UN Comtrade, WITS Database: <https://wits.worldbank.org/>, accessed in July 2019.

## Pharmaceutical Trade

India is the world's third largest pharmaceutical market (in value terms) accounting for around 10 per cent of global production. It has also been recognized as the global pharmaceutical manufacturing and research hub as it is one of the largest suppliers of generic drugs, contributing to 40 per cent of generic demand in the USA and 25 per cent of all medicines in the UK. India has the highest number of USFDA approved plants for producing generic drugs outside the USA. As a major exporter of bulk drugs and formulations, the Indian pharmaceutical sector enjoys competitive advantages in various areas such as cost efficiency, large skilled workforce and supportive policies. The export of pharmaceutical products is expected to reach 20 billion US dollars by 2020 (IBEF, 2019)<sup>iii</sup>. As an emerging big pharmaceutical market as well as major global exporter, especially for the generic drug products, the pharma sector of India faces both the opportunities and the challenges.

The USA too dominates the global pharmaceutical market, both in domestic consumption and exports. It is expected that medicine spending in the USA will increase by 5 per cent every year from 2017 to 2026 and reach 5.7 trillion US dollars<sup>iv</sup>. The USA is the global leader in research and development (R&D) (with 60 billion US dollars spending on R&D annually) of pharmaceuticals and provides the most supportive domestic environments with minimal tariff barriers.

The USA has a favorable Intellectual Property (IP) system and regulatory environment that rewards and protects innovation and creates demands for patented drugs<sup>v</sup>.

In 2018, the pharmaceutical products<sup>vi</sup> export shares of India and the USA to the world were 2.69% and 8.12% respectively. In terms of bilateral trade, pharmaceutical products cover around 10 per cent of Indian's total merchandise exports to the USA. Likewise, India's imports of pharmaceutical products from the USA is around 19 per cent of its total merchandise imports from the USA. From 2000 to 2018, India's export share of pharmaceutical products to the world increased by 1.7 percentage points, while for the USA the export share declined by 3.2 percentage points during the same period.

The USA's imports from the world and India during the last decade shows that the USA's imports value of pharmaceutical products from India has been increasing over the last decades (Table 1). In 2018, the total imports of pharmaceutical products (HS 30) from India was 6.51 billion US dollars of which the medicaments (HS 3004) accounted for almost 97 per cent of total pharmaceutical products worth 6.29 billion US dollars. Over the years, India has expanded its share in the USA's market on pharmaceutical products from 1.76 per cent in 2007 to 5.64 per cent in 2018.

**Table 1: The USA Imports of Pharmaceutical Products (HS 30 and HS 3004)**

	Product Code <sup>vii</sup>	2007	2016	2017	2018
From World (US\$ billion)	HS 30	49.16	92.41	96.79	115.48
	HS 3004	40.07	67.57	65.05	71.62
From India (US\$ billion)	HS 30	0.86	7.57	6.29	6.51
	HS 3004	0.84	7.44	6.11	6.29
India's share	HS30	1.76%	8.19%	6.50%	5.64%
	HS3004	2.10%	11.02%	9.40%	8.78%

Source: Compiled by authors, data taken from UN Comtrade, WITS Database: <https://wits.worldbank.org/>, accessed in July 2019.

Compared to the USA, Indian imports of pharmaceutical products from the world are much lesser. Its total imports were only 2.48 billion US dollars. The USA's share of Indian imports of the

pharmaceutical product remains stable over the years with the total pharmaceutical products accounting for 15.72 per cent and the medicaments accounting for 18.29 per cent in 2018.

**Table 2: Indian Imports of Pharmaceutical Products (HS 30 and HS 3004)**

	Product Code	2009	2016	2017	2018
From World	HS 30	1.08	1.70	1.81	2.49
	HS3004	0.69	0.93	1.03	1.31
From the USA	HS30	0.16	0.35	0.35	0.39
	HS3004	0.08	0.21	0.22	0.24
US's share	HS30	15.14%	20.82%	19.31%	15.72%
	HS3004	11.40%	22.27%	21.49%	18.29%

Source: Compiled by authors, data taken from UN Comtrade, WITS Database: <https://wits.worldbank.org/>

With the USA's withdrawal of GSP for India, many apprehensions have been expressed by Indian pharmaceutical companies about its impact on pharma products exports to the USA. The actual situation of pharmaceutical products in the context is as follows:

- (1) Pharmaceutical products are not covered under the GSP and the USA never gave preferential market access under GSP to India or any developing country.
- (2) The applied rate of import duty on all items under chapter 30 of HSN is zero in the USA.

In views of the above, it is very clear that the withdrawal of GSP has no impact on India's exports of pharma items to the USA. The situation of tariff thus remains unchanged. In fact, what drives the flow of trade in pharmaceutical products is the non-tariff barriers (NTMs) in the form of sanitary and

phytosanitary measures (SPS)& Technical Barriers to Trade (TBT).

### Non-tariff measures and price controls

Non-tariff measures (NTMs) in WTO has various forms which include Sanitary and Phyto-sanitary (SPS) measures, Technical Barriers to Trade (TBT), Anti-Dumping, Import Licensing, Safeguard measures etc. However, to understand the nature of NTMs that can affect the trade of pharmaceutical products, we have considered the SPS and TBT measures that are notified by India and USA to WTO. These measures are in the form of standards or labelling requirements etc. which must be complied with for allowing imports. The data was taken from the WTO-ITiP database from 1995 till 30 June 2019. A summary of SPS and TBT measures that have been initiated and in force is given in Table 3 below.

**Table 3: SPS and TBT measures by India and USA (From 1995 till 30 June 2019)**

Country imposing	Total TBT in force	Total TBT initiation	Total SPS in force	Total SPS initiation	HS 30 TBT in force	HS 30 SPS in force	HS 30 TBT initiation	HS 30 SPS initiation
India	2	144	31	196	0	0	6	1
United States of America	524	1174	661	2376	40	1	87	42

Source: WTO NTM database available at <https://i-tip.wto.org/goods/Forms/GraphView.aspx>

It would be clear from the above that the total number of TBT and SPS measures in force are lesser than the those which have been initiated. On Chapter 30 items India has no SPS or TBT measures in force, the USA has 40 SPS and 1 TBT measure. It may also be

observed that the total number of SPS measures are higher than the TBT measures. It is also seen that the USA has 87 and 42 SPS and TBT measures respectively, which have been initiated on pharmaceutical products. It may also be noted that these measures are not

country specific but are applied globally for every import from any country (not only between India and the USA).

The USA has also expressed its concerns about Indian pharmaceutical industry and market for not providing fair market access for the USA including lack of protection of intellectual property rights (IPR), interpretations of intellectual property protection that favor generics and biosimilars, the goods and services tax (GST) on sourcing, manufacturing and distribution channels, as well as unpredictable and arbitrary policies and practices that negatively affect foreign companies including price ceiling or discriminations and labelling and restrictions on pricing and licensing. India has been put on the US Trade Representative's (USTR) annual "Special 301" priority watchlist which identifies countries with "serious intellectual property deficiencies", due to the USA's objects to some features of Indian patent laws<sup>viii</sup>. Besides, Indian pharma exports have been tempered out of the quality or safety concerns in the USA market. Many Indian pharma products have been rejected by the US Food and Drug Administration (USFDA) due to the lack of compliance with the evolving standards set by the USFDA<sup>ix</sup>. Indian firms received about 46 warning letters related to good manufacturing practices for "violations of regulatory significance" from the USFDA during 2013-2017<sup>x</sup>.

Both India and the USA have also been making attempts to control the over-charging of prices of pharmaceutical products by their manufacturers. 44 USA States filed a lawsuit in May 2019 in the US District Court in Connecticut against pharmaceutical manufacturers in the USA alleging that they are inflating prices for over 100 generic drugs for more than 1000 per cent and which defeats the purpose of manufacturing generic drugs and supplying to consumers at affordable price<sup>xi</sup>. Some of the names in the antitrust suit include Indian companies as well (Sun Pharmaceutical Industries Ltd., Dr Reddy's Laboratories Ltd., Aurobindo Pharma Ltd., Lupin Ltd., Wockhardt Ltd and Zydus Pharma). Lowering drug prices has been a central focus for Trump, experts, however, have questioned the usefulness of providing the list prices of medicine in ads, as most people with insurance pay far less. Recently, a USA District Judge of the District of Columbia vacated the Department of Health and Human Services' rule that would have required drug

makers to include their list prices in TV ads, saying the agency had overstepped its authority<sup>xii</sup>.

In India the National Pharmaceutical Pricing Authority (NPPA), which regulates the prices of drugs and medical devices came out with an order in February 2017 to dramatically cut the prices of Coronary Stents and Knee Implants. Till June 2019, NPPA has fixed ceiling prices of a total of 857 medicines and retail prices of 1054 medicines<sup>xiii</sup>.

## Conclusion and way forward

Both India and the USA are global leaders in the pharma sector and big markets, not only they trade among themselves but also export to the world. While the USA is a major producer of patent pharmaceuticals, India champions the generic drugs – which are cheaper than their patented formulations. Thus, a tension between producers in competing for markets is evident and this leads at times to government interventions, especially in the USA where the pharmaceutical companies have strong say. The recent trade tension between the USA and India is not impacting the pharmaceutical industry, as both sides export to each other and at present are meeting the NTM requirements, however, in the future the possibility of using NTMs to restrict markets cannot be ruled out.

Both India and the USA are also now making efforts not only to promote their pharmaceutical sector but also ensure the benefits for consumers. One such effort is their interventions to regulate the prices of medicines and medical devices, which will benefit the consumers the most. Though these efforts have been applauded by many yet criticized by various sectors; depending on the sides they belong to. Both India and the USA must realize that under the present situation, it is time for them to seek inclusive and strategic cooperation and trade partnership in the pharmaceutical market. In both the countries R&D in pharma is strong and a collaboration in sharing the results, investing in each other and facilitating more joint venture companies will be beneficial for every segment. That way not only will they be able to allow the pharma industry to grow, but also create an enabling environment for global consumer welfare.

## Endnotes

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- i Dr. Rajan Sudesh Ratna, Economic Affairs Officer, United Nations ESCAP, South and South West Asia Office, New Delhi. The views expressed in this paper are purely personal.
- ii Huidan Xue, Intern at South and South-West Asia office, UN ESCAP and PhD candidate at University College Dublin, National University of Ireland. Email: [huidan.xue@ucdconnect.ie](mailto:huidan.xue@ucdconnect.ie)
- iii IBEF website: <https://www.ibef.org/industry/pharmaceutical-india.aspx>
- iv Cuckler, G.A., Sisko, A.M., Poisal, J.A., Keehan, S.P., Smith, S.D., Madison, A.J., Wolfe, C.J. & Hardesty, J.C. 2018, "National Health Expenditure Projections, 2017-26: Despite Uncertainty, Fundamentals Primarily Drive Spending Growth", Health affairs (Project Hope), vol. 37, no. 3, pp. 482-492.
- v Lisa Ellis, 2016. Snapshot of the American Pharmaceutical Industry. Accessed in July 2019 at: <https://www.hsph.harvard.edu/ecpe/snapshot-of-the-american-pharmaceutical-industry/>
- vi In the Harmonized System of Nomenclature, pharmaceutical products are covered under Chapter 30. For analysis we have taken the trade data from Chapter 30 of HSN.
- vii HS 30: Pharmaceutical Products; HS 3004: Medicaments (excluding goods of heading 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale.
- viii The Office of the United States Trade Representative (USTR), "2019 Special 301 Report", p. 51- p.53, April 2019. Accessed at: [https://ustr.gov/sites/default/files/2019\\_Special\\_301\\_Report.pdf](https://ustr.gov/sites/default/files/2019_Special_301_Report.pdf) on 31.07.2019
- ix <https://www.statnews.com/2019/07/22/indian-pharmaceutical-industry-drug-quality-charges/> "The Indian pharmaceutical industry is in denial over drug-quality charges" by Dinesh Thakur, July 22, 2019.
- x [https://www.usitc.gov/publications/332/executive\\_briefings/nesbitt-india\\_ebot-final.pdf](https://www.usitc.gov/publications/332/executive_briefings/nesbitt-india_ebot-final.pdf) from Barbara Unger, "An Analysis of FDA FY2017 Drug GMP Warning Letters," January 10, 2018 available at <https://www.pharmaceuticalonline.com/doc/an-analysis-of-fda-fy-drug-gmp-warning-letters-0002>
- xi <https://portal.ct.gov/AG/Press-Releases/2019-Press-Releases/TONG-LEADS-LAWSUIT-AGAINST-GENERIC-DRUG-MANUFACTURERS-IN-CONSPIRACY-TO-FIX-PRICES-FOR-OVER-100-DRUGS>
- xii <https://edition.cnn.com/2019/07/08/politics/drug-prices-tv-ads/index.html>
- xiii Monthly Summary Report, June 2019 available at [http://pharmaceuticals.gov.in/sites/default/files/Monthly%20Summary\\_0.pdf](http://pharmaceuticals.gov.in/sites/default/files/Monthly%20Summary_0.pdf)

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