



**Centre for WTO Studies**  
Centre for Research in International Trade  
Indian Institute of Foreign Trade

# Policy Brief

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### U.S. Drug Pricing Reforms and Section 232 Investigations:

### Implications for India's Pharmaceutical Sector

*Authors:*

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### Executive Summary

The Pharmaceutical sector is the cornerstone of India's export economy, accounting for USD 28.55 billion<sup>1</sup>, and amounting to 8.37% share of its exports to the world<sup>2</sup> in 2024. There have been policy interventions in the US in recent times, which seek to control domestic drug prices and enhance national security in medical supply chains. If, as a consequence of such policy changes, restrictions are imposed, Indian pharmaceutical sectors may have to face uncertainty. The proposed reintroduction of the Most-Favored-Nation (MFN) pricing model in the second term of the Trump presidency intends to align U.S. drug prices with those in other developed countries, and this could potentially depress the profit margins for the Indian exporters. Simultaneously, the discussions around the invoking of Section 232 of the U.S. Trade Expansion Act for pharmaceutical imports raise the possibility of tariff barriers and other trade restrictions ostensibly for the sake of national security, as in the cases of its applications in the steel and aluminium sectors.

The United States constitutes India's biggest pharmaceutical export market, with a share of 33.24% in India's global pharma exports. Therefore, the actions intended by the U.S. can disrupt access and pricing flexibility for Indian firms. The implications include increased compliance costs, lower market shares, and the risk of tariff retaliations.

This policy brief assesses the impact of these developments and recommends a proactive policy response. India's focus on strengthening the bilateral trade dialogue alongside a diversified export portfolio beyond the U.S. is the need of the hour. Therefore, coordinated actions

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<sup>1</sup> This also include exports of APIs, which constitute approximately 25% of India's total exports under HS Chapter 29 (Organic Chemicals) to the world and around 17% in case of exports to USA.

<sup>2</sup> India's non-oil exports to the world covering merchandise excluding petroleum, gems, and jewellery

between the Indian government and industry stakeholders are crucial to safeguard India's long-term competitiveness.

## **I. Introduction**

India is a leading supplier of affordable generic medicines, with pharmaceuticals constituting a critical component of its export basket. The United States accounts for 33.24% of India's pharma exports. It is the largest and most lucrative market for India, particularly for generic and Active Pharmaceutical Ingredients (API). However, this trade relation is now under threat on account of contemporary shifts in U.S. domestic policy in favour of curbing rising drug prices and strengthening the security of supply chains. U.S. administration in recent times have started to explore pricing reforms in a bid to reduce the cost of prescription drugs. Serious consideration is being given to the so-called Most-Favored-Nation (MFN) pricing model, which seeks to cap the U.S. drug prices to the lowest charged in comparable OECD countries. This policy would reduce the sales margin of pharmaceutical products, and thereby indirectly impact Indian pharmaceutical exports from India, including that of generics, especially for products where there is close price competition. Alongside drug pricing proposals, the U.S. is also considering the use of Section 232 of the Trade Expansion Act to restrict imports for reasons of national security, citing the criticality of pharmaceutical supplies in ensuring the health and human safety of its citizens. Application of Section 232, like in the case of steel, aluminum, and automobiles, where it has already been applied, would lead to significantly higher tariffs which might put a downward pressure on margins. If the tariffs are high enough, might even make domestic production more competitive compared to producing pharmaceuticals for the US market outside the US including in low-cost production hubs like India.

## **II. Understanding the Threat to India's Pharmaceutical Export Competitiveness**

India's Pharmaceutical sector, often called the "pharmacy of the world" due to its highly competitive production ecosystem in pharmaceuticals, is likely to face impediments to business from the evolving U.S. trade and health policies. The potential implementation of the MFN pricing of drugs and the application of Section 232, pose a dual challenge to Indian pharmaceutical exports.

Though these two U.S. policy measures are contradictory in their stated intent, with MFN aiming to lower prices through international benchmarking and Section 232 potentially raising costs through protectionist trade actions, they are convergent in their impact for Indian exporters to the US; both threaten the viability and stability of Indian pharmaceutical exports to the United States. In essence, India is confronted with the possibility of reduced competitiveness, constrained market access, and greater trade friction with its most important export destination for pharmaceuticals.

**Table 1: Key Challenges and Economic Impacts of U.S. Drug Pricing Reforms and Section 232 Investigations on India's Pharma Sector**

<b>Key Challenges</b>	<b>Description</b>	<b>Potential Economic Impacts on India</b>
<b>1. Most-Favoured-Nation (MFN) Pricing</b>	U.S. prices capped to match low-price OECD countries, impacting import margins.	<ul style="list-style-type: none"> <li>➤ Reduced sales margin leading to revenue pressure on Indian exporters</li> <li>➤ Less incentive for Indian companies to invest in new or advanced medicines.</li> </ul>
<b>2. Reciprocal Tariff</b>	Section 232 may lead to the imposition of reciprocal tariffs on Indian pharma exports, ostensibly on grounds of national security.	<ul style="list-style-type: none"> <li>➤ Increased landed cost of Indian drugs in the U.S. market</li> <li>➤ Indian generic drugs may lose their price advantage vis-à-vis domestic US producers</li> </ul>
<b>3. Import Substitution</b>	The U.S. may incentivize domestic manufacturing of generics and APIs.	<ul style="list-style-type: none"> <li>➤ Loss of market share for Indian manufacturers</li> <li>➤ Long-term erosion of US import demand for pharmaceuticals</li> </ul>
<b>4. Challenge to U.S.</b>	U.S. insurers may face higher costs due to reduced competition and unstable	<ul style="list-style-type: none"> <li>➤ Indian exporters may be forced to lower prices to help</li> </ul>

<b>Key Challenges</b>	<b>Description</b>	<b>Potential Economic Impacts on India</b>
<b>Insurance Companies</b>	supply from abroad, driven by MFN pricing rules.	U.S. insurers manage rising costs. ➤ Profit margins may shrink due to tough price negotiations during reimbursements.
<b>5. Cost Shifting by U.S. Insurers to Suppliers</b>	To cope with their cost pressures, insurers and Pharmacy Benefit Managers may renegotiate contracts or increase patient premiums.	➤ Indian pharma firms might face demands for even higher discounts or see contracts revised thereby reducing earnings even further.
<b>6. Public Program Constraints</b>	U.S. public health schemes like Medicare/Medicaid have limits on how much price hikes they can absorb. Hospitals might bear the burden temporarily.	➤ Indian exporters could see delayed purchases and stricter pricing rules in government tenders, affecting the overall volume of sales.
<b>7. Non-Tariff Barriers</b>	Tighter FDA audits, new certifications, Intellectual Property restrictions	➤ Increased compliance costs, market entry delays, and reduced SME participation from India due such SME inability to effectively meet complex regulatory burden and associated costs

### **III. How Important the Pharmaceutical Sector is for USA and India?**

Pharmaceutical products represent one of the most important areas of US imports. In the year 2024, pharmaceutical products which includes APIs as well as unfinished and finished/packaged medicinal products, accounted for 7.6% of USA's global non-oil imports. Given the increasingly ageing population, demand for pharmaceuticals, including imports, are

likely to increase in importance in terms of their share of their overall share of the import basket.

Given that the US has also targeted derivative products under the ambit of sector tariffs on Steel and Aluminium, if it were to extend tariffs to the pharmaceutical sector the domains of derivative packaging products as well as machinery used to produce pharma products are likely to get impacted as well.

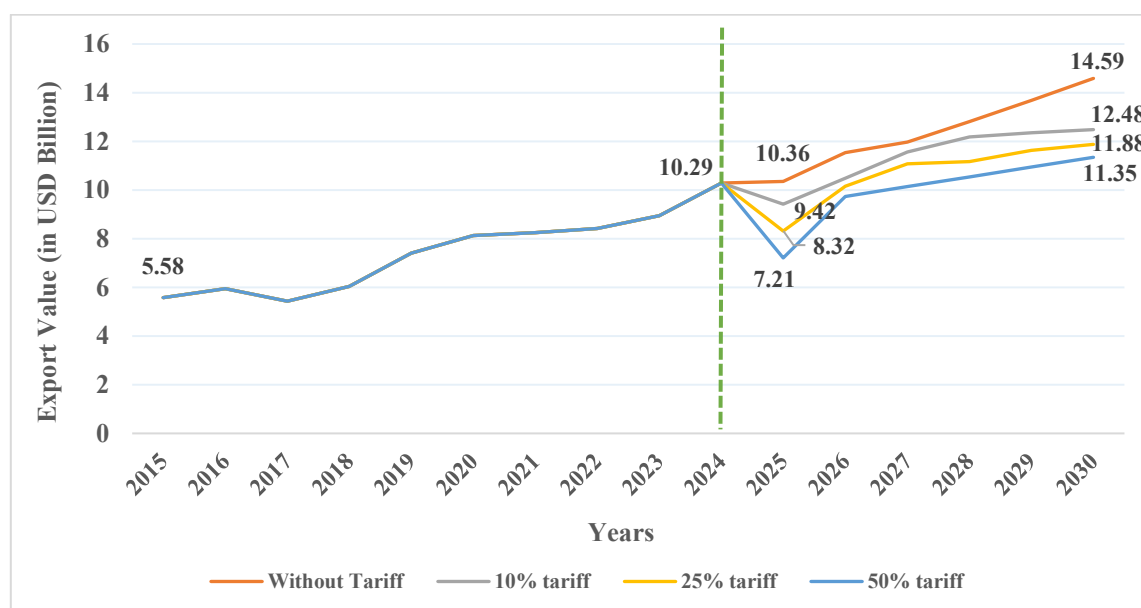
The top source countries for US pharmaceutical imports include Ireland, Switzerland, Germany, Singapore and India. These have a cumulative share of 54.31 % in the pharmaceutical products imported by the USA. India is among the top 5 source countries of US pharmaceutical imports, and accounts for 5.91% of total pharmaceutical imports of the USA. The Pharmaceuticals sector has always been a frontrunner in India's exports and accounts for 8.37% of India's total non-oil exports to the world. Of India's total pharmaceutical exports, 43.19% is directed to its top five destination countries, with the USA alone accounting for roughly one-third (33.24%). Thus, any disruption of the US market will have a significant impact on the Indian pharmaceutical industry.

#### **IV. Implications of Potential Tariffs and India's Export Exposure**

Tariffs create an immediate price hike, particularly when the shock is significant. Although the U.S. Department of Commerce initiated an investigation into pharmaceutical imports in April 2025, the subsequent announcement in July of a potential 200% tariff has raised concerns. However, given the United States' reliance on pharmaceutical imports, such a high tariff, if imposed at all, seems difficult to sustain given domestic market dependencies.

To assess the potential impact on India's pharmaceutical exports to the U.S. in the near future, given the level of tariffs imposed on other sectors in the recent past, projections have been made under three possible tariff levels at 10%, 25%, and 50%. With USA's current average Ad valorem duties, which is lower than one percent on pharmaceuticals (HS chapter 30) and around 1.6 percent in case of APIs that belongs to HS chapter 29, any sudden shift of higher tariffs in the said range will certainly further strain the finances of US consumers who are already spending way higher amounts on healthcare as compared to other developed nations.

*Figure-1: Potential Direct Impact of U.S. Tariffs on India's Exports to the U.S.*



Data Source: Author's own calculation using ITC TradeMap and UN ESCAP TINA

India's exports of pharmaceutical products (including APIs) have reached 28.55 USD billion in 2024 from 15.35 USD billion in 2015 and are projected to grow to 40.66 USD billion by 2030. The share of USA has been dominant in India's exports to the world at 10.29 USD billion in the year 2024.

Analysis shows that an imposition of 10% tariffs on pharmaceuticals could lead to a potential reduction of Indian exports to US by around USD 6 billion over the period 2025-2030. A 50% tariff could lead to reduction of exports by USD 15 billion during the same period<sup>3</sup>. The sudden drop in India's exports in the short run is expected to get offset later, as the sectoral tariffs under Section 232 apply equally to all countries. Hence, the overall impact would be significant; market forces are likely to readjust over time but at a lower level.

US residents spent around 4.8 USD trillion<sup>4</sup> on health care in the year 2023, out of which expenditure on pharmaceuticals accounts for about 12%, which in absolute terms is much too high compared to any other country<sup>5</sup>. Given the comparatively lower price elasticity of the

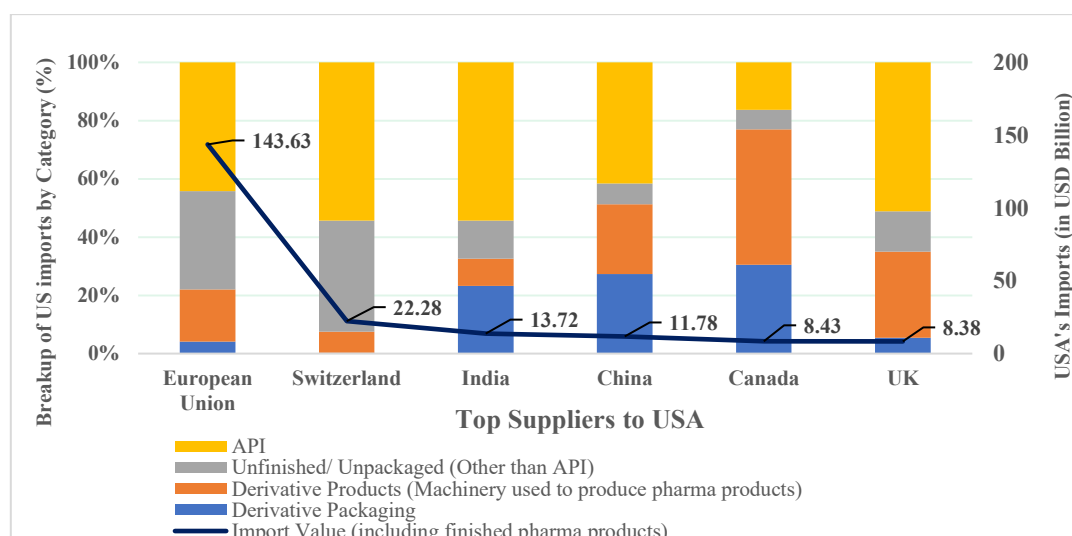
<sup>3</sup> Estimates are based on the partial equilibrium model using TINA UN ESCAP, exponentially forecasted to project potential export reductions over the 2025–2030 period

<sup>4</sup> <https://www.statista.com/topics/6701/health-expenditures-in-the-us/#topicOverview>

<sup>5</sup> IVAMA-BRUMMELL, A. M., & OSORIO-DE-CASTRO, C. S. (2022). Pharmaceutical Pricing and Reimbursement Policies: lessons learnt and perspectives for Brazil. *Revista Brasileira de Farmácia Hospitalar e Serviços de Saúde*, 13(4), 897. <https://doi.org/10.30968/rbfhss.2022.134.0897>

sector, this undoubtedly impacts the US consumers, and will increase the already high per capita cost of acquiring healthcare facilities.

*Figure-2: USA Import Sources of Pharma Products by Type (including derivative products)*



*Data Source: Author's Own Calculation using ITC TradeMap*

USA is a major importer of API and generic medicines. India's primary competitors, mainly the EU, Switzerland, and China, also export heavily in these categories. Although the volume of pharmaceutical exports to the U.S. varies across its major exporting partners, Figure 2 indicates diversification among different categories of pharmaceuticals, with the EU holding the highest export value. Ireland is in the top position among EU exporters, followed by Germany that together accounting for roughly 32-33 % of EU's exports in this sector. India's finished pharmaceutical exports to the U.S. accounts for approximately USD 12 billion out of a total of USD 13.72 billion. These exports comprise of generic and branded medicines, which constitute about 70 to 90 percent of total pharmaceutical imports by the U.S. from its major partners. Any potential imposition of tariffs by the USA is expected to hit categories such as unfinished/unpackaged (other than API), finished, derivative machinery and packaging products.

Any potential imposition of tariffs on pharmaceuticals can disrupt established global supply chains. As shown in Figure 2, there is significant diversification in the types of pharmaceutical products exported by major suppliers to the U.S., and the broad U.S. import demand aligns well with India's export structure particularly in APIs and finished generic products indicating strong complementarity. Tariffs could increase cost pressure, forcing absorption of burden on



Indian exporter to remain competitive, especially given India's competitiveness alongside its peers such as the EU, Switzerland, and China. This could affect profit margins, deter future investments and can weaken India's position as a key supplier of affordable pharmaceuticals in both US and global market.

## PHARMACEUTICAL PRODUCTS

*(Type of products likely to get impacted by the imposition of tariffs)*

### Unfinished / Unpackaged (APIs and Bulk Drugs)

*Raw or base chemical compounds, used in the manufacture of final pharmaceutical products (not packaged; not in dosage form)*

**Basic chemicals:** acids, amino-acids, nitrile compounds

**Heterocyclic compounds:** with specific structures

**Vitamins & hormones:** in raw form

**Antibiotics & steroids:** penicillin, erythromycin, tetracyclines

**Gland extracts and heparin**

**Blood components and medicaments:** not processed or packaged

### Finished / Packaged

*Pharmaceutical products ready for sale, measured doses and retail-ready packaging*

**Immunological products:** like vaccines and antisera (measured doses)

**Cell cultures & toxins** for therapeutic use

**Medicaments in packaged form:**

Antibiotics, Hormones, Alkaloid-based drugs, Vitamins, antimalarial drugs, and mixed compositions

**Pharmaceutical goods:** Diagnostic reagents, Surgical materials, Chemical contraceptives, Lubricating gels, Ostomy appliances, Placebos and clinical trial kits

### Derivative Packaging

*Packaging materials used for transporting or storing pharmaceutical goods*

**Glassware:** bottles, jars

**Plastic containers:** bottles, flasks

**Aluminium foil** for blister packs or sachets

**Plastic films/sheets:** used in strip packaging

### Derivative Products (Machinery used to produce pharma products)

*Essential machinery used in production, testing, or packaging*

Filtering & purification machinery: for water and gases

Bottling and sealing machines

Packing and wrapping equipment

Machinery for extracting or preparing fats/oils

Sterilizers

Centrifuges



Given the high degree of reliance that Indian pharmaceutical exports have on the US market, particularly in the domain of generic medicines which operate on thin margins, imposition of tariffs can hamper the exports of Indian pharmaceutical companies. Some of the top Indian pharmaceutical companies that have long-established trade relations with the USA include Aurobindo Pharma, Piramal Pharma, Gland Pharma, Sun Pharma, and Dr Reddy's Laboratories and these generate an average revenue of 44.4%<sup>6</sup>.

The immediate short-term impact on these companies might stem from uncertainty around prices, but over time, it could lead to broader consequences like supply chain disruptions. Such developments could instil fear in the companies' sentiments and threaten their long-term survival. In an attempt to safeguard the company's financial health, companies may try to redirect exports to alternative markets. In the long run, the trade dynamics of this sector is also dependent on the ease with which a company can set up manufacturing bases in the US, a decision which is in turn dependent on the cost of production and the geopolitical landscape, that is, how the US structures its trade relations with other countries to facilitate exports.

Some of the major cost components that can vary significantly depending on the country of manufacturing include the cost of acquiring raw materials, manufacturing costs (land, labour, electricity, water, etc.), and packaging costs. Given the USA's high demand for bulk and low-margin generic medicines, increased manufacturing costs, particularly due to high labour costs, can result in lower-than-expected FDI in the USA. These trade adjustments are likely to affect the world by reshaping global value chains, fostering more diversified partnerships, and compelling consumers to acquire medicines at higher prices. Given that there is less elasticity in the prices of these products, they could also impact medical insurance systems and lead to higher premiums for insurers.

## **V. Conclusion**

Pharmaceuticals as a sector plays a vital role in trade between India and the USA. The export-import complementarity in this sector is strong between these two countries, with India among the top exporters of Generic medicines and APIs in the world alongside China, and the USA is among the top importers of these products, followed by the EU and Canada. China, on the other

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<sup>6</sup> <https://www.india-briefing.com/news/us-drug-price-cuts-may-hit-indian-pharma-37434.html/>

hand, also holds a key position in the global supply chain as a major supplier of raw materials for Indian manufacturers too.

The level of tariffs imposed by USA on the world (currently threatened at 200%) could severely disrupt the global supply chain; any retaliation or export restriction by other countries that have been announced since March 2025, has not only impacted the USA but has also started to impact, perhaps alter, global trade dynamics. India's export dependence on the USA, combined with possible retaliatory measures by other countries of the world, may alter the trade flows in the medium run.

For the USA, tariffs on imports of pharmaceuticals could result in supply shortages, increased drug prices, and delays in access to essential medicines. This may place a heavier burden on the U.S. healthcare system and disrupt treatment availability that can directly inflate the prices of medicines procured from outside US. Trade tensions can escalate with any retaliation measure by affected partners and can further weaken the U.S.'s global trade relations.

In order to diversify and mitigate the potential loss, if India seeks to redirect pharmaceutical exports away from the USA, other large importing countries may attempt to leverage the situation to negotiate lower prices. Thus, such shifts and diversification could have long-term implications for the profitability and sustainability of India's pharmaceutical industry as this could lead to downward pressure on Indian export margins and affect revenues.

Under the circumstances, India must proactively engage itself in the diversification of its export markets in order to offset overreliance on a few countries. As global trade becomes more volatile, strengthening trade relations through new or existing trade agreements can offer and ensure more secure market access.

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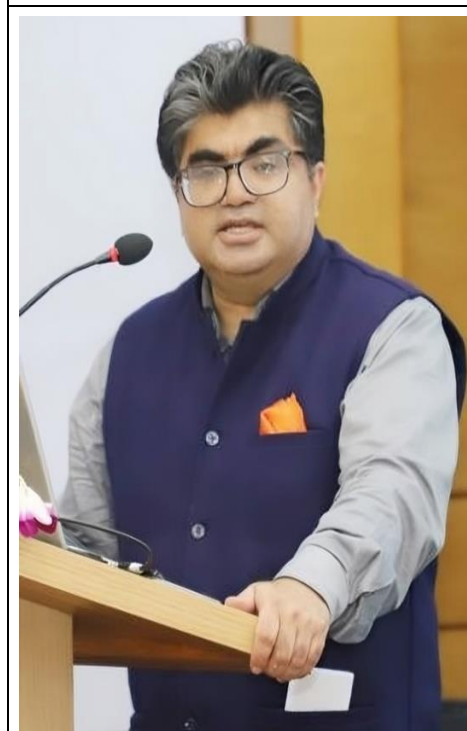
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## **ABOUT THE CENTRE**

### **About CRIT**

India's Foreign Trade Policy (FTP) Statement 2015-20 suggested a need to create an institution at the global level that can provide a counter-narrative on key trade and investment issues from the perspective of developing countries like India. To fill this vacuum, a new institute, namely the Centre for Research on International Trade (CRIT), was set up in 2016. The vision and the objective of the CRIT were to significantly deepen existing research capabilities and widen them to encompass new and specialized areas amidst the growing complexity of the process of globalization and its spill-over effects in domestic policymaking. Secondly, enhancing the capacity of government officers and other stakeholders in India and other developing countries to deepen their understanding of trade and investment agreements.

### **About CWS**

The Centre for WTO Studies which is a constituent Centre of CRIT, pre-dates the CRIT since it was created in 1999 to be a permanent repository of WTO negotiations-related knowledge and documentation. Over the years, the Centre has conducted a robust research program with a series of papers in all spheres of interest at the WTO. It has been regularly called upon by the Government of India to undertake research and provide independent analytical inputs to help it develop positions in its various trade negotiations, both at the WTO and other forums such as Free and Preferential Trade Agreements and Comprehensive Economic Cooperation Agreements. Additionally, the Centre has been actively interfacing with industry and Government units as well as other stakeholders through its Outreach and capacity-building programs by organizing seminars, workshops, subject-specific meetings, etc. The Centre thus also acts as a platform for consensus-building between stakeholders and policymakers. Furthermore, the inputs of the Centre have been sought after by various international institutions to conduct training and studies.

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