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Trump’s 100% Pharma Tariffs: What India’s Pharmaceutical Exporters Must Know

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PUBLISHED 4 April 2026

On 2 April 2026, the United States issued a Presidential Proclamation titled “Adjusting Imports of Pharmaceuticals and Pharmaceutical Ingredients into the United States,” invoking Section 232 of the Trade Expansion Act of 1962 to impose sweeping tariffs on the import of patented pharmaceuticals and associated active pharmaceutical ingredients (APIs). The measure marks a significant shift in U.S. trade and industrial policy, positioning pharmaceutical supply chains within a national security framework rather than conventional trade regulation.

For Indian pharmaceutical companies, which are key global suppliers of active pharmaceutical ingredients (APIs) and generic formulations, this development raises critical legal, commercial, and strategic considerations.

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Key Takeaways at a Glance

- US President Trump issued a Proclamation on April 2, 2026 imposing tariffs on patented pharmaceutical imports under Section 232 of the Trade Expansion Act of 1962, citing national security.
- Standard tariff rate is 100% on patented pharmaceuticals and associated active pharmaceutical ingredients (APIs); reduced rates apply for companies with onshoring commitments.
- Generic pharmaceuticals and biosimilars are explicitly excluded from tariffs at this time, a significant reprieve for India’s generic drug sector.
- Tariffs take effect July 31, 2026 for named companies and September 29, 2026 for all others.
- India’s pharmaceutical exports to the US were valued at approximately 10.515 billion USD in 2024-25, making this the most consequential US trade action for Indian pharma in decades.
- Companies that commit to onshoring production in the US may qualify for a reduced 20% rate, with a zero-rate available for those signing Most-Favoured-Nation (MFN) pricing and onshoring agreements.

Background: The Legal Foundation

The Proclamation is issued under Section 232 of the Trade Expansion Act of 1962 (19 U.S.C. § 1862), which authorises the US President to restrict imports of any article found to threaten national security. Previously wielded against steel, aluminium, semiconductors, and automobiles, Section 232 has now been extended to the pharmaceutical sector, a dramatic escalation in the use of trade law as a lever of industrial policy.

The Secretary of Commerce conducted an investigation and advised the President that pharmaceuticals and associated active pharmaceutical ingredients (APIs), including key starting materials, are being imported in quantities and under circumstances that threaten to impair US national security. The President concurred with this finding and issued the Proclamation accordingly.

The legal architecture relies on two statutes: Section 232 provides the authority to adjust imports; Section 604 of the Trade Act of 1974 (19 U.S.C. § 2483) authorises the President to embed these changes into the Harmonized Tariff Schedule of the United States (HTSUS).

The Tariff Structure: A Tiered Regime

The Proclamation establishes a differentiated tariff regime rather than a uniform levy. Understanding which tier applies to a given product or company is the most immediate compliance priority.

The tariff tiers are as follows:

- 100% — Standard rate on all patented pharmaceuticals and associated APIs.
- 20% — Companies with approved US onshoring plans (rises to 100% by April 2, 2030).
- 15% — Products of the EU, Japan, South Korea, and Switzerland and Liechtenstein jointly.
- 10% — Products of the United Kingdom (potentially reducing to zero upon conclusion of a bilateral pharmaceutical agreement).
- 0% — Companies that have fully executed MFN pharmaceutical pricing and onshoring agreements with the US government (until January 20, 2029).

Products entirely exempt from the tariffs include: orphan drugs (all approved indications), nuclear medicines, plasma-derived therapies, fertility treatments, cell and gene therapies, antibody-drug conjugates, medical countermeasures against CBRN threats, and certain specialty pharmaceutical products designated by the Secretary of Commerce.

Critical point for Indian companies: Generic pharmaceuticals, the cornerstone of India's US pharmaceutical exports, are explicitly not subject to these tariffs at this time. The Proclamation specifically states that generic pharmaceuticals and their associated ingredients, including biosimilar products, shall not be subject to Section 232 tariffs. However, the Secretary of Commerce is required to report within one year on whether circumstances warrant imposing tariffs on generics as well.

The Onshoring Pathway

The Proclamation creates an explicit incentive structure: companies that commit to relocating manufacturing to the United States can access significantly lower tariff rates. The Secretary of Commerce is authorised to approve onshoring plans and to enter into agreements with pharmaceutical companies. Companies already listed in Annex II of the Proclamation, those that entered agreements prior to its issuance, are ratified under the new framework.

The 20% rate for onshoring companies is not permanent: it escalates to 100% on April 2, 2030, underscoring that the regime is designed as a transitional mechanism to drive domestic manufacturing, not a permanent concessional rate.

Key Dates and Implementation Timeline

April 2, 2026: Proclamation signed. Secretary of Commerce and Secretary of Health and Human Services(HHS) directed to pursue negotiations with pharmaceutical companies and trading partners.

Within 90 days (by ~July 1, 2026): Secretary of Commerce and HHS must update the President on progress of MFN pricing and onshoring negotiations.

July 31, 2026: Tariffs take effect for companies listed in Annex III of the Proclamation (those that have existing agreements or approved plans).

September 29, 2026: Tariffs take effect for all other companies not listed in Annex III.

Within 1 year of April 2, 2026: Secretary of Commerce must report on whether action is needed on generic pharmaceutical imports, the most consequential deadline for India's generic sector.

January 20, 2029: Zero-tariff window under MFN and onshoring agreements expires. Applicable rates revert unless agreements are extended or modified.

April 2, 2030: Reduced 20% rate for onshoring companies escalates to 100%, completing the transition period.

Scope: What Is and Is Not Covered

The Proclamation applies to “patented pharmaceuticals and associated pharmaceutical ingredients” as listed in Annex I. These are innovative, typically branded pharmaceuticals, those approved under the standard approval pathway, as distinct from generic pharmaceuticals approved under the abbreviated pathway (Section 505(j) of the US Federal Food, Drug and Cosmetic Act). Annex IV lists products currently at a zero-tariff rate under Section 232.

Products of US-origin are not subject to the tariffs. Drawback, the refund of duties when goods are re-exported, is available in respect of duties imposed under the Proclamation. Goods admitted into US foreign trade zones after the effective date must be admitted as “privileged foreign status,” ensuring they bear the tariff on eventual consumption.

Note on country-specific treatment: The Proclamation establishes preferential rates for the EU (15%), Japan (15%), South Korea (15%), Switzerland and Liechtenstein jointly (15%), and the United Kingdom (10%, potentially reducing to zero upon conclusion of a bilateral pharmaceutical agreement). India is not currently among the countries accorded a preferential rate, and would be subject to the standard 100% rate on patented pharmaceutical and API exports to the US, absent an onshoring plan or MFN pricing agreement.

India’s Pharmaceutical Export Footprint: The Stakes

India’s pharmaceutical exports reached USD 30.47 billion in 2024–25, registering a growth of 9.4 percent over the previous year. The country is today the world’s third-largest pharmaceutical producer by volume and fourteenth by value, with more than 3,000 companies, 10,500 manufacturing units, and over 60,000 generic brands across 60 therapeutic areas. Indian medicines reach over 200 markets worldwide, with more than 60 percent of exports destined for stringent regulatory geographies, a testament to the quality standards Indian manufacturers have consistently demonstrated on the global stage. The United States sits at the centre of this export story, accounting for approximately 34 percent of India’s pharmaceutical exports, making it by far the single largest destination market.

India-Specific Analysis: Risks, Opportunities, and Strategic Considerations

Immediate Impact: The Generics Shield

India’s pharmaceutical exports to the United States are overwhelmingly concentrated in generic medicines and APIs for generics. The current exclusion of generics from the tariff regime shields the vast majority of Indian exports from immediate impact. This is not an oversight, the US depends heavily on Indian-manufactured generics to keep its healthcare system affordable, and disrupting that supply would be politically and economically untenable in the short term.

The Impending Generics Review: A One-Year Countdown

The most serious medium-term risk for Indian pharmaceutical companies is the mandatory one-year review of generic pharmaceutical imports. If the Commerce Secretary concludes that tariffs on generics are warranted, a follow-on proclamation could impose significant duties on the segment where India is most exposed. Companies should begin contingency planning for this scenario now.

Patented Pharmaceuticals and API Exports

For Indian companies that have expanded into the innovator segment, those manufacturing patented drugs or supplying APIs for patented products, the 100% tariff represents an immediate and severe cost escalation. Indian companies in this segment will need to evaluate their eligibility for the onshoring pathway and whether entering into an agreement with the US government is commercially viable.

The Onshoring Opportunity and Its Complexities

The Proclamation creates a pathway by which a company can reduce its tariff burden to 20% (or zero if an MFN pricing agreement is also signed) by committing to onshore production. This raises complex strategic questions for Indian pharma groups: does the cost of establishing US manufacturing facilities outweigh the tariff savings? What regulatory and contractual obligations does an onshoring plan entail? How will the Commerce Secretary define and enforce onshoring milestones?

Companies that fail to meet onshoring commitments face not only prospective tariff reinstatement at 100%, but also potential retroactive tariff imposition. The Proclamation explicitly provides that if fraud or deliberate misrepresentation is found, the Secretary may reimpose tariffs retroactively. This provision warrants careful legal diligence before any agreement is entered.

Regulatory note for Indian companies: The MFN pricing agreement pathway (the zero-tariff route) requires agreement with the US Secretary of Health and Human Services on pharmaceutical pricing, a commitment that could have significant implications for global pricing strategy, licensing arrangements, and relationships with other market regulators, including in India itself. Companies must assess these implications holistically before entering any such agreement.

Impact on API Manufacturing

The Proclamation's reach extends to "key starting materials" and APIs, not just finished pharmaceutical products. India is a dominant supplier of APIs globally. Even where final drug products are generic and currently excluded, any future expansion of the tariff regime to cover APIs for generic medicines would have cascading effects across Indian API manufacturers and their downstream customers.

Legal and Compliance Action Points

- **Product Classification Audit:** Conduct an immediate audit of all products exported to the US. Determine whether each falls within "patented pharmaceuticals" (tariffed) or "generic pharmaceuticals" (currently excluded). Review Annexures I and IV of the Proclamation.
- **Onshoring Plan Eligibility:** For companies in the patented segment, evaluate eligibility for the onshoring plan approval process. Monitor Federal Register notices on criteria to be published by the Secretary of Commerce.
- **MFN Agreement Assessment:** Assess the commercial and regulatory implications of entering into MFN pharmaceutical pricing agreements with HHS. Consider impact on global pricing strategies, licensing terms, and obligations under Indian price control regulations.
- **Generics Review Monitoring:** Track the one-year review process for generic pharmaceuticals. Engage with India's Pharmaceuticals Export Promotion Council (Pharmexcil) and the Ministry of Commerce on advocacy and policy responses.
- **Supply Chain Restructuring:** Review supply chain structures to assess whether transshipment through third countries could affect origin determination and tariff applicability, while ensuring full compliance with US customs regulations on country of origin.
- **HTSUS Classification Review:** Review HTSUS classifications for all exported products, particularly as Customs and Border Protection (CBP) is authorised to take measures to administer the new tariffs, including potential reclassification actions.

Broader Trade Law Context

This Proclamation is the latest in a series of Section 232 actions under the current US administration, following earlier proclamations on steel, aluminium, copper, semiconductors, timber, and automobiles. The pattern reflects a deliberate policy of deploying national security trade law to drive domestic manufacturing across strategically significant industrial sectors.

The Proclamation also advances an MFN pharmaceutical pricing agenda, an attempt to align international pharmaceutical prices with domestic US pricing, which has long been a policy ambition of the Trump administration. The linkage of tariff relief to pricing concessions is a novel use of trade law with significant implications for intellectual property regimes, parallel import rules, and the global pharmaceutical pricing ecosystem.

Challenges to the Proclamation's legality may emerge in US courts, as earlier Section 232 actions have attracted litigation. The courts have generally upheld broad presidential discretion under Section 232, but the extension of national security reasoning to pharmaceuticals, a sector not traditionally associated with defence manufacturing, may face more rigorous judicial scrutiny. Indian companies and the Indian government should monitor such litigation closely.

At the bilateral level, the absence of India from any preferential rate category is conspicuous. India and the United States have been engaged in broader trade negotiations, and this Proclamation will inject new urgency and complexity into those discussions. Whether India can negotiate a pharmaceutical-specific arrangement, analogous to those accorded to the EU, Japan, and the UK, will depend on diplomatic engagement at the highest levels.

Conclusion

President Trump's April 2, 2026 Pharmaceutical Import Proclamation is one of the most significant US trade actions affecting the Indian pharmaceutical industry in its history. While the exclusion of generics provides critical short-term relief, the medium-term risks are substantial: the generics review, the tariffs on patented APIs, and the structural push toward US-based manufacturing

all demand urgent strategic and legal attention.

Indian pharmaceutical companies, whether they manufacture generics, APIs, or have exposure to the patented segment, should assess their specific exposure, evaluate the onshoring and MFN agreement pathways, and prepare for the regulatory and compliance requirements that will emerge as the Commerce Department issues Federal Register notices operationalising this Proclamation.

This is not a static situation. The Secretary of Commerce will issue further guidance, tariff rates may be adjusted, and the generics review will be a critical inflection point. Active monitoring and early engagement with regulatory developments will be essential over the coming months.

For more details, write to us at: contact@indialaw.in

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