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Trump Administration Expands Section 232 Tariffs to Patented Pharmaceuticals and APIs

Key Takeaways

- Covered patented pharmaceuticals, APIs and key starting materials face a default 100% ad valorem duty, subject to express carveouts and alternative tariff pathways. The tariffs will take effect on July 31, 2026 for companies listed in Annex III, and on Sept. 29, 2026 for other companies.
- Companies with U.S. Department of Commerce-approved onshoring plans may qualify for a 20% rate, which rises to 100% on April 2, 2030. Companies that enter into MFN-pricing agreements with the U.S. Department of Health and Human Services (HHS) and onshoring agreements with Commerce may qualify for a zero-duty tariff through Jan. 20, 2029.
- Products from the European Union, Japan, South Korea and Switzerland/Liechtenstein are subject to a 15% rate, while products from the United Kingdom receive a lower tariff tied to the recently concluded U.S.-U.K. arrangement on pharmaceutical pricing.
- Generic pharmaceuticals, biosimilars and associated ingredients are excluded at this time. Similarly, certain specialty products, including orphan drugs, animal-health drugs and other specified specialty products, are exempt if they come from trade-deal countries or meet an urgent public health need.

On April 2, 2026, President Trump issued a proclamation under Section 232 of the Trade Expansion Act of 1962 concluding that imports of patented pharmaceuticals and related ingredients threaten to impair U.S. national security. The White House fact sheet clarifies timing, enforcement and policy objectives. The Administration is using Section 232 not merely to raise duties, but to force a reordering of pharmaceutical sourcing, pricing and manufacturing strategy.

What the Proclamation Does

The proclamation establishes a 100% *ad valorem* duty as the default rule for imports of patented pharmaceuticals and associated pharmaceutical ingredients listed in Annex I, unless another pathway applies. It then details three principal caveats.

Related People

- Deanna Okun
- Lydia C. Pardini
- Dominic L. Bianchi
- Jane C. Dempsey

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First, imports produced by companies with Secretary-approved onshoring plans may qualify for a reduced 20% *ad valorem* rate, which rises to 100% on April 2, 2030. The tariff regime takes effect on July 31, 2026 for companies listed in Annex III and on September 29, 2026 for other companies. The White House fact sheet describes that timing as 120 days for certain large companies and 180 days for smaller companies.

Second, the Administration has established a reduced-rate pathway for certain trade-partner products. According to the White House fact sheet, products from the European Union, Japan, Korea and Switzerland/Liechtenstein are subject to a 15% tariff, while products from the United Kingdom receive a lower tariff tied to the recently concluded U.S.-U.K. pharmaceutical arrangement. The proclamation separately identifies the pharmaceutical-related trade commitments underlying that treatment. The annexes should be consulted for the operative rate treatment reflected in the tariff structure.

Third, imports produced by companies that have fully executed agreements, or are negotiating agreements with Commerce and HHS regarding MFN pricing and the onshoring of production and R&D, may qualify for zero-tariff treatment. The proclamation also gives Commerce substantial authority to approve onshoring plans and to negotiate and administer company-specific tariff arrangements.

Exemptions

The measure does not currently extend to generic pharmaceuticals, biosimilars and associated ingredients, but the White House states that this treatment will be reassessed in one year.

The proclamation also preserves zero-duty treatment for specified specialty categories, including orphan drugs, drugs for animal health and other specialty products that either originate in trade-deal countries or meet an urgent public health need.

Trade-Focused Practical Implications

For importers, manufacturers and distributors, the immediate issue is not just tariff exposure. The structure of the proclamation creates a classification, sourcing and compliance challenge. Companies will need to determine whether imported products are covered by Annex I, whether any inputs fall within carveouts, whether country-of-origin determinations support reduced-rate treatment, and whether contractual arrangements can absorb or reallocate duty risk.

Enforcement will be a priority. Importers should expect audits and requests for information related to both past and future imports. In particular, importers claiming preferential treatment should expect heightened scrutiny of their documentation supporting declarations of origin, valuation and preferential treatment qualification. Importers should review their designations of classification, valuation, origin, transfer-pricing alignment, drawback strategy and supply agreements with that enforcement posture in mind.

What to Watch

Several implementation details remain unclear. These include the procedural pathway for company-specific agreements, the standards Commerce will use to approve and monitor onshoring plans and the mechanisms by which U.S. Customs and Border Protection will administer and enforce the tariffs. The White House also states that generic and biosimilar exclusions will be revisited in one year, which means importers should not view the current carveout as permanent.

The fact sheet additionally states that the impending tariffs have already generated

approximately $400 billion in new pharmaceutical investment commitments in the United States. Whether those commitments translate into actionable sourcing shifts, qualifying onshoring plans or revised trade flows will likely determine how impactful this new regime becomes in practice.

What Companies Should Be Doing Now

Map coverage	Identify patented finished products, APIs and starting materials that may fall within Annex I or related implementation notices.
Test preferences	Evaluate whether trade-deal country treatment, specialty-product treatment or agreement-based treatment may reduce the applicable rate.
Review contracts	Check tariff-allocation clauses, price-adjustment provisions, change-in-law clauses and sourcing flexibility in supply and distribution agreements.
Validate customs positions	Reassess tariff classification, origin, valuation and recordkeeping for any product that may be affected.
Assess onshoring strategy	Determine whether the company can credibly pursue Commerce-approved onshoring commitments or Commerce/HHS pricing agreements.
Prepare for enforcement	Develop an internal substantiation file for preferential treatment claims, including sourcing records, agreement status and compliance governance.

Pharmaceutical importers and downstream customers should treat the proclamation and fact sheet as the beginning of a broader compliance and restructuring cycle. Impacts and practical legal exposure will turn on coverage, qualification for reduced-rate treatment and the adequacy of the company's documentation and implementation strategy.

If your business needs strategic legal guidance or anticipates potential impacts resulting from these announcements, contact Deanna Okun, Lydia Pardini, Dominic Bianchi, Polsinelli's Executive Action Working Group or your Polsinelli contact.