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Practical Compliance Readiness Ahead of New Pharmaceutical Tariffs

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Section 232 Investigation into Pharmaceuticals

Beginning Tuesday, September 29, 2026, all patented pharmaceuticals and associated active pharmaceutical ingredients (APIs) imported into the United States will be subject to a 100 percent tariff under Section 232 of the Trade Expansion Act of 1962 unless they qualify for specific exemptions.[1]

Notably, the tariffs established under **Proclamation 11020**[2] apply only to articles that are also products, or ingredients of products, subject to a valid and unexpired US patent and listed in publications maintained by the Food and Drug Administration (FDA) as approved for marketing in the United States. Generics and biosimilars are excluded from these tariffs at this time, but the secretary of Commerce is scheduled to reassess this treatment within one year.

Key Exemptions and Reduced Rates

Certain patented products qualify for exemptions or reduced tariff rates under the terms of Proclamation 11020.

Product-based exemptions

Certain specialty pharmaceuticals defined in recent guidance, including qualifying orphan drugs, plasma-derived therapies, and fertility treatments may receive a zero Section 232 tariff rate.[3] This guidance also establishes a zero additional Section 232 duty for products solely intended for clinical trials, research and development, or other noncommercial applications.[4] Companies may also request a product-specific determination that they meet an urgent US public-health need.[5]

Country-of-origin-based reductions

Products originating from the European Union, Japan, South Korea, Switzerland, and Liechtenstein generally qualify for a 15 percent rate, and qualifying products of the United Kingdom currently qualify for a 0 percent Section 232 rate.[6] Products made with US-origin API that is packaged abroad face only the base duty, with no Section 232 markup.[7] Absent another exclusion, covered products from other countries face the full 100 percent rate.

Importantly, the tariff rate depends on the country of origin for the product under the applicable rules, which may differ from the country it was exported from. In many pharmaceutical rulings, US Customs and Border Protection (CBP) has considered the country of origin to be where the API is manufactured, not where the finished product is manufactured or packaged.[8]

Exemptions tied to onshoring and pricing agreements

Companies that enter into an approved onshoring agreement with the federal government may receive a 20 percent rate, scheduled to rise to 100 percent in 2030. Companies with an approved onshoring agreement that also enter into a most favored nation (MFN) pricing agreement with the Department of Health and Human Services (HHS) may receive a zero rate until January 2029.

1 These tariffs took effect for specific companies listed in Annex III of Proclamation 11020 earlier this year and go into effect for all importers on September 29, 2026.

2 *Adjusting Imports of Pharmaceuticals and Pharmaceutical Ingredients Into the United States,* Proclamation 11020, 91 FR 18,183 (April 9, 2026). https://www.federalregister.gov/documents/2026/04/09/2026-06956/adjusting-imports-of-pharmaceuticals-and-pharmaceutical-ingredients-into-the-united-states.

3 *Guidance and Procedures for Implementing Tariff Adjustments for Specialty Pharmaceuticals and Associated Pharmaceutical Ingredients and Technical Corrections to the Harmonized Tariff Schedule of the United States for Duties Imposed Under Proclamation 11020,* 91 FR 60,361 (September 23, 2026). https://www.federalregister.gov/documents/2026/09/23/2026-19498/guidance-and-procedures-for-implementing-tariff-adjustments-for-specialty-pharmaceuticals-and.

4 *Guidance and Procedures for Implementing Tariff Adjustments for Specialty Pharmaceuticals,* 91 FR 60,364 (September 23, 2026).

5 *Guidance and Procedures for Implementing Tariff Adjustments for Specialty Pharmaceuticals,* 91 FR 60,362-60,363 (September 23, 2026).

6 US Department of Commerce, Bureau of Industry and Security, *Notice of Reduction of Tariffs on Patented Pharmaceuticals and Pharmaceutical Ingredients for Products of the United Kingdom Implemented by Presidential Proclamation 11020,* 91 FR 49,406 (August 4, 2026).

7 US CBP, *Guidance: Section 232 Duties on Imports of Patented Pharmaceutical Articles and Ingredients* (July 30, 2026).

8 See, e.g., HQ H342828 (US CBP, June 24, 2025).

Preparing Now for Increasing Classification and Country-of-Origin Risk

Pharmaceutical manufacturers, importers, and supply chain participants now face significantly increased financial and enforcement risk. Providing inaccurate or indefensible HTS classifications and COO data to CBP upon importation enhances this risk. One of the biggest hurdles for companies surrounding the new tariffs is not the tariff (duty) rate itself, but rather the requirement to establish and document a defensible methodology for classifying products and determining the accurate COO before the new tariff expansion takes effect September 29.

Companies cannot comply with customs requirements or effectively manage tariff exposure if they cannot quickly identify which products, APIs, suppliers, and manufacturing sites impact their applicable duty treatment. However, the supporting data required to determine tariff treatment often resides in multiple systems that may not be connected or integrated.

To manage and mitigate these risks, companies should, at a minimum, take the following steps now:

- **Validate and document the basis** for each HTS classification and COO determination. Given the potentially significant duty consequences associated with the new tariffs, companies should record their decision-making and maintain documentation that includes product specifications, manufacturing information, supplier certifications, bills of materials, relevant customs rulings, exception handling, and any internal analyses supporting the determination. Importers should maintain documentation consistent with 19 USC 1508 and 19 CFR Part 163, which require retention of customs records for five years from the date of entry or from the date of the activity that required creation of the record.[9]
- **Create a centralized inventory** of all imported products and APIs that may be impacted by the new tariffs. The inventory should contain the HTS classification, COO, manufacturing location, API source, any claimed specialty product category, whether an import is intended solely for a qualifying noncommercial use, and applicable tariff treatment. Prioritize products with high import volumes and products that will be subject to specific tariff provisions. The objective is not simply to identify tariff exposure but ensure that the company can consistently document, apply, and defend its classification and COO decisions. A centralized product master database can help companies quickly assess the impact of future tariff changes and regulatory developments.
- **Establish a governance process** for maintaining tariff-sensitive product data. Information ownership and governance—whether managed through spreadsheets, licensed customs brokers, or a trade management system—should be assigned clearly and documentation reviewed periodically to ensure classifications, COO determinations, and tariff treatments remain current.

9 19 USC 1508(a), (c); 19 CFR Part 163.4(a).

Conclusion

Given the US government's continued focus on trade policy and enforcement, pharmaceutical manufacturers should establish tariff compliance as a strategic priority. As the trade and regulatory landscape continues to evolve, companies that prepare to quickly identify affected products and produce supporting documentation will better position themselves to comply with duty requirements and respond to regulatory scrutiny, should it arise.

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