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From Zero to 100% – New Section 232 Tariffs on Patented Drugs and the High-Stakes Onshoring and MFN Choices Ahead

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On April 2, 2026, President Donald Trump issued a proclamation titled "Adjusting Imports of Pharmaceuticals and Pharmaceutical Ingredients into the United States" (the Proclamation) under Section 232 of the Trade Expansion Act of 1962, as amended, 19 U.S.C. § 1862 (Section 232). The Proclamation follows a U.S. Department of Commerce (Commerce) investigation concluding that heavy U.S. reliance on imported patented pharmaceuticals and associated pharmaceutical ingredients, including active pharmaceutical ingredients (APIs) and key starting materials, threatens to impair U.S. national security.

The result is a new, highly targeted tariff regime. Many patented drugs and their ingredients will face up to a 100% ad valorem duty (on top of the normal "Column 1" most?favored?nation (MFN) rate under the Harmonized Tariff Schedule of the United States (HTSUS)), while some products, companies, and countries can qualify for sharply reduced or even zero additional Section 232 duties. Generics and biosimilars are excluded for now, but Commerce is directed to revisit that exclusion within a year, leaving open the prospect of future action.

In practice, the Proclamation does three things that matter most for industry:

1. **Targets patented, higher?value products:** The core 100% rate is reserved for patented, originator drugs and biologics and their ingredients.
2. **Builds in policy "off?ramps":** Companies can trade tariff relief for onshoring commitments and MFN pricing to U.S. payors, and certain critical or specialty therapies can be placed in a zero?rate bucket.
3. **Differentiates among trading partners:** Key allies receive reduced rates, the UK is given a separate path tied to a prospective deal, and some products are placed in a zero?rate "safe harbor" list for now.

Scope: What Is Covered

The new regime is anchored in U.S. note 40 to subchapter III of chapter 99 of the HTSUS, as added by Annex I to the Proclamation.

"***Patented pharmaceutical articles***" are pharmaceutical articles that: (i) are subject to a valid, unexpired U.S. patent; and (ii) are listed in the U.S. Food and Drug Administration's (FDA) Orange Book (for drugs) or Purple Book (for biologics), together with the APIs and key starting materials used to manufacture them. These "patented pharmaceutical articles" are the primary target of the new 100% Section 232 tariff in heading 9903.04.60. In effect,

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the measure is aimed squarely at higher?value, brand?name drugs and biologics that generate the bulk of originator revenues.

"***Generic pharmaceutical articles***" are FDA?approved products and associated ingredients that are off patent and off exclusivity. They are routed to heading 9903.04.67, which carries no additional Section 232 duty beyond the ordinary HTSUS rate. This distinction is central to the policy: it limits immediate consumer price impact and creates a lever for originator companies, whose tariff exposure can be reduced over time by moving products off exclusivity or accelerating generic and biosimilar strategies in particular markets.

Annex Structure: Who Is in and Who Is Out

The Proclamation's annexes define the universe of covered products and carve?outs:

- **Annex I – Positive list for Section 232 action.** Annex I (through note 40(c)) lists the HTSUS provisions under which "pharmaceutical articles" become subject to the new Chapter 99 headings 9903.04.60 through 9903.04.69. These provisions cover a broad range of Chapter 29 chemical intermediates and Chapter 30 pharmaceutical products, from APIs and intermediates to finished dosage forms and biologics.
- **Annex IV – Zero?rate "safe harbor" list.** Annex IV identifies HTSUS codes that are formally brought within the Section 232 pharmaceutical action but assigned a Section 232 tariff rate of zero. In addition, these products are carved out from the separate temporary surcharge imposed by Proclamation 11012. Annex IV therefore operates as a policy "safe harbor": these products are inside the Section 232 framework for monitoring and potential future adjustment, but, as of now, they pay only the ordinary HTSUS (Column 1) duty and do **not** bear any additional Section 232 or Proclamation 11012 surcharge.

This structure gives the administration flexibility to move products into and out of the zero?rate bucket as supply, pricing, or geopolitical conditions evolve.

New Chapter 99 Framework and Rate Tiers

Annex I introduces a set of mutually exclusive Chapter 99 headings. Every covered shipment must be assigned to exactly one of them. The headings create a tiered rate structure that reflects product type, origin country, and company?specific commitments:

Heading 9903.04.60 – Default 100% rate for patented pharmaceutical articles

- Applies to patented pharmaceutical articles.
- Imposes an additional 100 percentage points of duty on top of the Column 1 rate, except where the same shipment qualifies for a different Chapter 99 heading that provides a lower Section 232 rate (*e.g.*, allied?country, onshoring, MFN pricing, or specialty?product headings). If the Column 1 rate already exceeds 100%, no extra Section 232 duty is charged.

Heading 9903.04.61 – Transitional treatment for selected companies

- Applies to patented pharmaceutical articles imported for companies identified by Commerce, when entered before 12:01 a.m. ET on September 29, 2026.
- Duties are limited to the base HTSUS rate, with no additional Section 232 duty.
- This heading functions as interim transitional relief for firms that reached early company?specific agreements

with Commerce.

Heading 9903.04.62 – Preferential 15% rate for specified allies

- Applies to patented pharmaceutical articles from the EU, Japan, the Republic of Korea, Switzerland, and Liechtenstein.
- Adds up to 15 percentage points on top of the Column 1 duty, instead of the full 100% markup.

Heading 9903.04.63 – UK surcharge of +10 percentage points

- Applies to patented pharmaceutical articles from the UK that would otherwise fall under heading 9903.04.60.
- The additional Section 232 duty is 10%.
- The Proclamation contemplates a U.S.-UK pharmaceutical agreement that could reduce this additional duty to zero, but that has not (yet) occurred.

Heading 9903.04.64 – Onshoring plan incentive: 20% initially, then 100%

- Applies to patented pharmaceutical articles imported for companies with Commerce?approved plans to onshore production of covered pharmaceuticals and ingredients.
- Imposes an additional 20 percentage points on top of the Column 1 duty, with that additional Section 232 duty increasing to 100 percentage points on April 2, 2030.
- This creates a time?limited incentive: companies that commit to onshoring receive reduced rates in the near term, but any remaining imports under this heading face the full 100?percentage?point surcharge after April 2, 2030, unless those imports then qualify for a more favorable Chapter 99 heading (*e.g.*, MFN?pricing zero rate, specialty?therapy carve?outs, or allied?country treatment).

Heading 9903.04.65 – Onshoring plus MFN pricing: zero additional duty (through January 20, 2029)

- Applies to patented pharmaceutical articles imported for companies that both: (i) have Commerce?approved onshoring plans; and (ii) enter into MFN pricing agreements with the U.S. Department of Health and Human Services (HHS).
- Imposes no Section 232 surcharge through January 20, 2029.
- On that date, heading 9903.04.65 and the corresponding cross?reference in note 40 terminate, signaling that zero?tariff treatment is a temporary incentive to secure onshoring and pricing concessions.

Heading 9903.04.66 – Specialty therapies and animal?health products: zero additional duty

- Covers orphan drugs (for all approved indications), nuclear medicines, plasma?derived therapies, fertility treatments, cell and gene therapies, antibody?drug conjugates, medical countermeasures for chemical, biological, radiological, and nuclear threats, specified animal?health pharmaceuticals, and other specialty products designated by Commerce in consultation with HHS.
- These products pay only the base HTSUS duty, with no Section 232 surcharge.

Heading 9903.04.67 – Generic pharmaceutical articles: base duty only

- Applies to generic and biosimilar products and their ingredients, as defined in note 40(c)(iii).

- No Section 232 markup applies.

Heading 9903.04.68 – U.S.-origin APIs packaged abroad: base duty only

- Applies where the active ingredient in a dosage?form product is of U.S. origin, even if final packaging occurs abroad.
- Underscores that the measure is focused on foreign production of intellectual?property?rich drugs, not on U.S.-made ingredients shipped overseas for finishing.

Heading 9903.04.69 – Non?pharmaceutical uses of listed HTSUS codes: base duty only

- Applies to imports that enter under the listed HTSUS codes but are not “pharmaceutical articles” as defined in note 40.
- Prevents industrial or other nonpharmaceutical uses of those codes from being inadvertently swept into the pharmaceutical Section 232 tariffs.

Taken together, these headings create a powerful default 100% rate for originator products while embedding policy options (onshoring, MFN pricing, allied?country treatment, and humanitarian/specialty carve?outs) within an enforceable tariff framework overseen by U.S. Customs and Border Protection (CBP).

Company?Specific Agreements and Staggered Effective Dates

Annexes II and III disclose extensive pre?Proclamation negotiations between Commerce and individual manufacturers:

- Annex II lists company?specific agreements related to Section 232 tariffs on pharmaceuticals and ingredients that Commerce entered into before the Proclamation. Many of the largest multinational originator companies appear here.
- Annex III lists companies whose tailored tariff treatment becomes effective 120 days after the Proclamation (July 31, 2026) rather than at the general 180?day effective date of September 29, 2026.

In practical terms, (i) Annex II and Annex III companies are likely to benefit from a mix of: (A) transitional base?duty?only treatment under heading 9903.04.61; (B) eligibility for reduced onshoring rates under heading 9903.04.64; and (C) in some cases, zero?rate treatment under heading 9903.04.65 based on MFN pricing and onshoring commitments, through January 20, 2029; and (ii) companies without such agreements face a “harder landing”: as of September 29, 2026, they default to the full 100% rate (or, where applicable, the reduced 15% rate for specified allies or the 10?percentage?point surcharge for the UK) unless and until they negotiate comparable arrangements.

Effectively, the annexes sort originator manufacturers into early movers that have aligned with the Administration’s onshoring and pricing objectives and those that may be pressured to do so by the prospect of 100% tariffs.

Key Policy Signals ‘Between the Lines’

Beyond the black?letter tariff mechanics, the Proclamation sends several strategic signals:

- Industrial policy for pharmaceuticals. Section 232 is being used as an industrial policy tool to push domestic manufacturing and research and development (R&D) for high?value patented pharmaceuticals. The onshoring incentives are central to the regime, not incidental.
- Drug pricing leverage. Zero?tariff treatment is explicitly tied to MFN pricing agreements with HHS. Originator companies are presented with a choice: accept U.S.-favorable pricing and onshoring commitments or face significant tariffs on imports.
- Differentiation among allies and others. Reduced rates for the EU, Japan, Korea, Switzerland, and Liechtenstein, a separate rate structure for the UK, and carve?outs for selected animal?health and specialty products underscore that geopolitical alignment and supply?chain resilience are as important as revenue concerns.
- Uncertainty for generics and biosimilars. While generics and biosimilars are currently shielded, Commerce is directed to reassess the treatment of these products within a year, creating uncertainty for companies and purchasers that rely heavily on offshore generic/API production.
- Enforcement and compliance posture. The Proclamation emphasizes CBP's authority to collect information, require privileged foreign status for covered nondomestic goods in foreign?trade zones (FTZs), and coordinate with Commerce and HHS. The possibility of retroactive tariff reimposition in cases of fraud or misrepresentation of onshoring commitments signals a more aggressive compliance environment for pharmaceutical importers.

Practical Steps for Pharmaceutical Companies

Pharmaceutical manufacturers, licensors, distributors, and major health care buyers should first map their portfolios to Annex I and Annex IV by identifying all products and ingredients classified under the HTSUS codes listed in note 40(c) and Annex IV, and determining for each whether it is a patented pharmaceutical article, a generic or biosimilar, a specialty therapy, or a non?pharmaceutical article. They should then quantify tariff exposure by modeling the difference between the base HTSUS rate and the applicable Section 232 surcharge rate (an additional 100% or 15% in some cases, a 10? or 20?percentage?point add?on in others, or 0% where no extra duty applies), with particular focus on high?value, patent?protected products with significant U.S. demand. At the same time, companies should evaluate whether it is commercially viable to commit to U.S. manufacturing for certain product lines and whether MFN pricing agreements with HHS make sense given their payer mix and global pricing strategy. Firms listed in Annex II or III should confirm which products receive transitional or preferential treatment and on what schedule, while those not listed should consider engaging with Commerce and HHS on potential onshoring plans, MFN pricing arrangements, or other ways to mitigate exposure to the 100% rate. Finally, companies should review customs, FTZ, and drawback strategies (ensuring accurate HTSUS classification and origin documentation, reassessing FTZ use (including privileged foreign status), and evaluating duty drawback for export flows) and closely monitor Federal Register notices and related developments on onshoring criteria, MFN pricing guidance, specialty product designations, country?specific tariff adjustments (including any U.S.-UK deal), and Commerce's one?year review of generics and biosimilars.

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