



TO: FEROX CLIENT
FROM: FEROX STRATEGIES
DATE: APRIL 3, 2026
RE: PHARMA SECTION 232 ANALYSIS

State of Play

On April 2, 2026, the Trump Administration announced the imposition of Section 232 tariffs on certain patented pharmaceutical products. The Pharmaceutical Section 232 investigation was initiated on April 1, 2025, along with other Section 232 investigations into semiconductors and critical minerals.

The Secretary of Commerce report alleged a threat to national security from the U.S.'s heavy reliance on imports of patented pharmaceuticals and APIs. The President acknowledged this threat and decided on actions under Section 232 authority to adjust these imports.

Proclamation Provisions

- Imports of patented pharmaceuticals and associated pharmaceutical ingredients listed in [Annex I](#) of the proclamation will be subject to a 100 percent *ad valorem* duty rate.
- Imports of patented pharmaceuticals and associated pharmaceutical ingredients listed in Annex I will be reduced for companies that have onshoring agreements (signed or in principle) with the Secretary of Commerce (“the Secretary”).
 - These rates will increase to 100 percent on April 2, 2030.
- Products listed in Annex I from Japan, the European Union, the Republic of Korea, and Switzerland and Liechtenstein jointly will have a tariff rate of 15 percent, unless a lower rate from other provisions applies.
 - Products of the United Kingdom shall be subject to a 10 percent tariff per its pricing agreement.
- A zero *ad valorem* tariff rate will apply for products (1) where all approved indications are designated as orphan pursuant to the Orphan Drug Act, 21 U.S.C. 360aa *et seq.*, and its implementing regulations (2) nuclear medicines (3) plasma derived therapies (4) fertility treatments (5) cell and gene therapies (6) antibody drug conjugates (7) medical countermeasures related to chemical, biological, radiological, and nuclear threats or (8) other specialty pharmaceutical products to be identified by the Secretary, as well as (9) pharmaceutical products for animal health.
 - To qualify for the zero *ad valorem* tariff rate, the products must be of a jurisdiction that has a current or forthcoming trade and security framework agreement as referenced in Executive Order 14346 (Modifying the Scope of



Reciprocal Tariffs and Establishing Procedures for Implementing Trade and Security Agreements); OR

- Meet an urgent United States health need.
 - The Secretary shall publish a Federal Register notice whenever he makes a determination related to these criteria.
- Companies with MFN pharmaceutical pricing agreements will have a zero ad valorem tariff rate on pharmaceuticals and related ingredients until January 20, 2029.
 - The Secretary retains the authority to raise tariff rates on companies with an MFN pricing agreement if they fail to meet commitments under the agreement.
- Tariffs go into effect on July 31, 2026, for larger manufacturers listed in [Annex II](#) of the proclamation, and September 29, 2026, for all other manufacturers.
 - Once in effect, the Section 232 Tariffs will remain enforceable until the Administration explicitly changes or removes them.
- Generic pharmaceuticals, in addition to biosimilars, and their ingredients are currently exempt from tariffs under section 232.
 - Within a year, the Secretary, after consulting with relevant officials, must update the President on any need to adjust imports of these products.

Impact to Rare Disease Manufacturers

The orphan drug exemption provides meaningful protection for rare disease manufacturers, but significant uncertainty remains around implementation. The zero tariff rate for orphan-designated products is conditioned on either originating from a country with a qualifying trade and security framework agreement or meeting an "urgent United States health need" standard, a term the Administration has not yet defined. Until Commerce publishes Federal Register guidance clarifying that standard, rare disease manufacturers with non-trade-deal country supply chains should not assume their products are fully insulated, and Ferox is actively engaging the Administration to ensure the exemption is interpreted as broadly as the policy's intent suggests.

[Annex language](#) relevant to the implementation of Section 232 tariffs for rare disease manufacturers includes:

- (h)(iii) **Heading 9903.04.66 applies to drugs and associated ingredients for all approved indications that are designated as orphan pursuant to the Orphan Drug Act, 21 U.S.C. 360aa et seq. and its implementing regulations;** nuclear medicines; plasma derived therapies; fertility treatments; cell and gene therapies; antibody drug conjugates; medical countermeasures related to chemical, biological, radiological and nuclear threats; or other specialty pharmaceutical products **identified by the Secretary of Commerce or pharmaceutical products for animal health imported from a jurisdiction**



that has a current or forthcoming trade and security framework or that meet an urgent U.S. health need. The Secretary shall publish a Federal Register notice when the conditions above are met and shall notify CBP of all such products.

-

Heading	Article Description	Rates of Duty		
		1		2
		General	Special	
9903.04.66	Drugs and pharmaceutical articles for the specific uses provided in subdivisions (c) and (h)(iii) of U.S. note 40 to this subchapter.....	The duty provided in the applicable subheading + 0%	The duty provided in the applicable subheading	The duty provided in the applicable subheading