

How To Gear Up For Trump's Pharma Tariffs

By Lynn Fox, Eva Temkin and Catherine Brandon (April 29, 2026)

On April 2, President Donald Trump signed a proclamation **implementing** tariffs on certain pharmaceutical products, pursuant to Section 232 of the Trade Expansion Act of 1962.[1]

The action imposes tariffs of 100% on patented pharmaceuticals, which includes active pharmaceutical ingredients and key starting materials, as well as finished drug products.

However, there are also numerous exceptions and preferential treatment provisions, which mean that many pharmaceutical products will not be subject to tariffs or will be subject to lower tariff rates.

The new duties will go into effect on July 31 for 17 large pharmaceutical companies named in the proclamation; however, most of those companies have tariff exemptions based on agreements with the administration, per the proclamation. The tariffs are set to go into effect for all other companies on Sept. 29.

There a number of areas of ambiguity, but in general whether an imported drug or input will be subjected to tariffs — and at what rate — appears to be based on: (1) the patent status of drug product involved; (2) the specific company importing the drug; (3) the country of origin; and (4) whether an exception applies.

The proclamation begins with the blanket imposition of 100% tariffs on "patented pharmaceuticals and associated ingredients," but then sets out numerous exceptions:

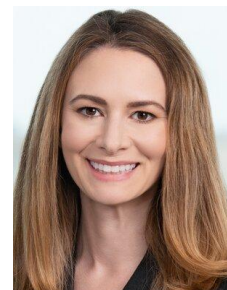
- Country-specific rates: Lower tariff rates will be imposed on imports from certain countries that have reached agreements with the U.S. on tariffs.
- Onshoring rates: Lower tariffs will be imposed on imports for companies that have plans "approved by the Secretary, to onshore production" of patented pharmaceuticals.



Lynn Fox



Eva Temkin



Catherine Brandon

- MFN exclusion: Tariffs will not be imposed on imports "for companies" that have signed agreements with the administration to onshore investments and to provide so-called most-favored-nation pricing.
- Specialty drug exclusions: Conditional exemptions may be granted for a long list of certain specialty drug products, including orphan drugs with only orphan indications, fertility treatments, cell and gene therapies, antibody drug conjugates, and other specialty pharmaceutical products as identified by the secretary of the [U.S. Department of Commerce](#), if certain conditions are met.

As a threshold question, the proclamation set out a list of tariff classifications to which the new tariffs will apply (Annex I), and a long series of tariff classifications to which a zero tariff rate will apply (Annex IV).

The Annex IV list removes some important drug products, including many antibiotics, chemical contraceptives and certain cardiovascular medicines from those covered by new tariff provisions. Thus, importers should review tariff classifications carefully in addition to use-based exclusions.

To determine correct tariff rates and avoid compliance concerns, importers should confirm tariff classifications for imported drug products, active pharmaceutical ingredients and key starting ingredients.

To ensure correct application of the new tariff provisions, importers should also be scrutinizing the country of origin, patent status and generic status, and whether the product otherwise qualifies for the specialty drug exceptions. The tariff rates on active pharmaceutical ingredients may depend on the ultimate use of the product after importation, which may create additional compliance burden for importers.

Scope of Patented Pharmaceuticals Captured by the Proclamation

New tariffs imposed by the proclamation apply only to "patented pharmaceutical articles," as defined in the proclamation.

A pharmaceutical product, as well as an ingredient for such product, will be considered a patented pharmaceutical article and so in scope for tariffs only if it is subject to a valid, unexpired U.S. patent, and listed in the [U.S. Food and Drug Administration's](#) Orange Book or Purple Book.

Thus, it appears that many drugs, and ingredients for those drugs, will fall outside the scope of the proclamation. Specifically, many older, off-patent drugs will generally not meet the patent criteria.

Similarly, drugs marketed under the OTC Monograph, which are not listed in the Orange or Purple Books, should not be subject to tariffs. And drugs should be subject to tariffs only after approval, and hence listing in the Orange Book or Purple Book, though questions remain about how products or API imported for investigational uses of approved drugs will be treated.

It appears that the tariff status of ingredients, i.e., APIs and other "key starting materials," will also depend on the patent status and Orange/Purple Book listing status of the finished drug product for which the imports will be used. In certain cases, this could mean that imports of identical API or key inputs may be subject to different tariffs based on intended use in the U.S.

Generics and Biosimilars Not Subject to Tariffs for Now

The new tariffs will not apply to "generic pharmaceuticals and their associated ingredients, including biosimilar products, at this time."

The proclamation defines "generic pharmaceutical articles" as "FDA-approved pharmaceutical articles, and associated ingredients, that are not subject to a valid, unexpired U.S. patent and are off exclusivity."

Given this framing, the definition of generic drug may be read to encompass branded products that have lost patent and regulatory exclusivities — though we would not expect such products to be subject to tariffs in the first instance, as they would have no valid, unexpired U.S. patents and so would fall outside the definition of captured patented pharmaceutical products.

As further defined, however, generic pharmaceutical articles also refers to pharmaceutical products and their ingredients as approved in a "qualifying application," meaning an application submitted under: (1) Section 505(j) of the Federal Food, Drug and Cosmetic Act for generic drugs; (2) Section 505(b)(2) of the FDCA for follow-on drugs that are not generics; (3) Section 351(k) of the Public Health Service Act for biosimilars; or (4) Section 505(t) for the FDCA and Title 42 of the U.S. Code, Section 1320f-1(e)(2)(B)(ii), for authorized

generic drug or biological products.

It appears the tariff relief with respect to this last category, authorized generics, applies only to goods that are imported by a generic or biosimilar manufacturer. While the proclamation appears to contemplate that all pharmaceutical articles would fall into either the generic or patented category, the definitions leave some ambiguities that will likely need to be resolved by future agency guidance.

In addition, the relief offered to generics and biosimilars may be time-limited. The proclamation directs the secretary of commerce to provide a report within one year with an opinion as to whether the president should take action to adjust imports of generic products.

Thus, the risk of tariffs on generics and biosimilars in the future remains a possibility. The Trump administration may rely on the threat of tariffs on generic products to leverage future negotiations with generic drugmakers, as well as countries that export significant volumes of generic drugs, such as India.

Lower Tariff Rates for Countries With Agreements

Consistent with previously announced deals with the [European Union](#), Japan, Korea, Switzerland and Liechtenstein, the tariff rate on products from those countries will be 15%.

The proclamation states that the tariff rate on U.K.-origin products is 10%, but will be reduced to zero when the U.K. completes a drug pricing agreement with the U.S.

On April 2, the U.S. Trade Representative issued a statement announcing that the U.K. deal had been finalized. However, the zero tariff rate provision will only be implemented once "all major United Kingdom pharmaceutical companies" enter into most-favored-nation and tariff agreements with the U.S.

Other countries are in the process of negotiating deals with the Trump administration. Many of those deals include commitments to zero tariffs on generic drugs but do not include provisions related to patented drugs.

For example, the recently announced framework for a deal with India provides that India will "receive negotiated outcomes with respect to generic pharmaceuticals and ingredients." Thus, it appears that patented products from India and other countries may be

subject to the higher 100% tariff rate.

Preferential Treatment for Companies With Most-Favored-Nation and Onshoring Agreements

The proclamation provides significant tariff benefits to companies that sign agreements with the administration to onshore investments and to provide so-called most-favored-nation pricing for certain products.

The products of companies that agree to onshoring plans approved by the secretary of commerce will be subject to a 20% tariff rate until April 2, 2030. The proclamation provides for the secretary of commerce to establish criteria for onshoring plans, and the Department of Commerce will provide a pathway through which companies can seek approval for such plans to secure future tariff benefits.

The plans are subject to monitoring and reporting and may be subject to retroactive tariff increases if terms are not met.

Companies that enter into onshoring plans and also sign most-favored-nation agreements with the Trump administration receive a zero tariff rate for "pharmaceuticals and associated ingredients until January 20, 2029." [The White House](#) fact sheet accompanying the proclamation indicated that the [U.S. Department of Health and Human Services](#) would provide a pathway for additional companies to enter into most-favored-nation pricing deals.

Exemptions for Specialty Drugs

The proclamation provides conditional exemptions for certain categories of drugs that it terms specialty drugs. Specifically, the proclamation provides that tariff rate will be zero for:

- Drugs "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";
- 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 to be identified by the secretary of commerce in consultation with the USTR and HHS.

Many of these categories may prove hard to define, making operationalization key. This is particularly the case for categories of drugs that are not specifically defined, e.g., plasma-derived therapies, and that are use-specific, rather than product specific, e.g., fertility treatments.

In addition, these exemptions are not automatic. The exemptions will be available to imports from "jurisdictions that [have] a current or forthcoming trade and security framework agreement" with the U.S. or for products where the secretary has determined, in consultation with the HHS secretary, an urgent U.S. health need.

While the status of framework agreements with various countries is in flux, the countries with deals would appear to include all EU member states, Japan, Korea, UK and Switzerland, as well as multiple other countries.

India has signed a joint statement with the U.S., indicating that it plans to conclude an agreement, which would imply that the enumerated specialty drugs from India would also be eligible for the zero-tariff rates.

U.S.-Made Active Pharmaceutical Ingredients Further Manufactured or Packaged Abroad Not Subject to Tariffs

The proclamation provides that U.S.-origin products will be exempt from tariffs.

The specific tariff language included in the annex provides for no additional tariffs on "pharmaceutical products with an active pharmaceutical ingredient packaged in dosage form that is a product of the United States."

This language indicates that finished drug products manufactured abroad from U.S.-origin active pharmaceutical ingredients will not be subject to any additional duties if the finished

products are imported into the U.S. This may be an important provision for companies that rely on packaging or manufacturing operations outside the U.S.

Drug Products and Ingredients Not Subject to Section 232 Remain Exempt From Certain Other Special Tariff Measures

Pharmaceutical products and ingredients have been exempted from many of the other tariff measures imposed by Trump in his second term. The ingredients and drug product that had been excluded from those tariffs, including the temporary 10% tariffs recently imposed pursuant to Section 122 of the Trade Act of 1974, continue to be exempt from those other tariffs.

Thus, generic and biosimilar products that are exempted from the April 2 Section 232 action also remain exempt from the 10% Section 122 tariffs as well. However, the exemption from other tariffs could be modified in the future as the Trump administration takes actions to replace tariffs overturned by the [U.S. Supreme Court](#).

Takeaways for Affected Stakeholders

There is certainly more to come as we get closer to the effective dates of the tariffs and more ambiguities rise to the surface. In the meantime, there are a few things companies can be doing now to help identify potential tariff costs and to facilitate compliance when necessary.

For compliance and tariff mitigation purposes, companies should carefully review their imports to determine whether the proclamation applies and whether a lower tariff rate or exemption may be applicable.

This includes confirming tariff classifications and country of origin, which can affect whether tariffs apply and at what rate. It can also include ascertaining whether products fall within the exemptions for specialty products and engaging with the Department of Commerce in that process.

There are a number of issues that require further action or findings by agencies to determine how tariffs will apply. The scope of exemptions for specialty drugs will require clarification, for instance, with respect to both the scope of coverage of specialty products and covered countries. As an additional example, duplicative Harmonized Tariff Schedule code listings across Annex I and Annex IV — possibly in error — will need to be reconciled.

Some of the language in the proclamation is ambiguous or unclear. Companies should anticipate that additional government interpretative guidance is likely to emerge. Seeking out ways to influence this process now, in a fact-specific way, can be critical.

In addition, compliance reviews will be especially important because Customs and Border Protection enforcement is likely to increase generally for drug and active pharmaceutical ingredient imports.

Even companies whose products are not facially affected by these tariffs should be reviewing their custom compliance protocols and ensuring that documentation is in order to support claimed exclusions or exemptions.

[Lynn Fischer Fox](#), [Eva Temkin](#) and [Catherine A. Brandon](#) are partners at [Arnold & Porter LLP](#).

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[1] (19 U.S.C. § 1862).