

U.S. Imposes New Section 232 Tariffs on Patented Pharmaceuticals and APIs

A stethoscope and a clipboard with a pen are positioned in the upper right corner of the page, partially overlapping the title area.

A significant new trade development for Israeli life sciences companies with U.S. market exposure

Dear Clients,

On April 2, 2026, US President Trump issued a Presidential Proclamation titled “Adjusting Imports of Pharmaceuticals and Pharmaceutical Ingredients into the United States,” introducing a new tariff regime on imported patented pharmaceuticals and active pharmaceutical ingredients (APIs) under Section 232 of the Trade Expansion Act of 1962.

The measure represents a significant change in the U.S. trade framework applicable to the life sciences sector. In broad terms, it moves patented pharmaceutical imports from a largely duty-free environment to a high-tariff regime designed to encourage U.S. onshoring, support U.S. manufacturing, and increase U.S. leverage over pharmaceutical pricing arrangements.

For Israeli pharmaceutical and life sciences companies with U.S. market exposure, the Proclamation may have substantial implications for cost structure, supply chain planning, and strategic manufacturing decisions. Companies exporting patented drugs, APIs, intermediates, or certain other pharmaceutical-related components to the United States should assess their exposure promptly.

Key Takeaways

- The Proclamation introduces a default 100% ad valorem tariff on covered patented pharmaceuticals and associated pharmaceutical ingredients, scheduled to take effect as of July 31, 2026 (and in certain cases as of September 29, 2026).

- Reduced-rate pathways are available in certain cases, including for companies with approved U.S. onshoring plans and for imports from certain specified jurisdictions.
- Israel does not appear to be included among the jurisdictions benefiting from country-specific reduced rates, absent a company-specific exemption or alternative qualifying pathway.
- Generic pharmaceuticals and associated ingredients are currently exempt, but that exemption is expressly subject to re-evaluation within one year.
- Several categories may qualify for zero tariff treatment or other favorable treatment in specified circumstances, including certain orphan drugs, nuclear medicines, plasma derived therapies, fertility treatments, cell and gene therapies, antibody drug conjugates, certain medical countermeasures, certain specialty pharmaceutical products, and animal health products.

Background

This new tariff regime is being instituted in response to the U.S. government's stated concern that the United States has become overly dependent on foreign manufacturing for patented drugs and APIs, thereby weakening domestic industrial resilience and limiting the country's ability to respond effectively in times of public health emergency or broader geopolitical disruption.

Main Elements of the New Tariff Regime

1. Default 100% tariff

The Proclamation establishes a 100% ad valorem duty on covered patented pharmaceuticals and associated pharmaceutical ingredients for companies that do not qualify for a lower-rate or zero-rate pathway. Companies qualify for the onshoring pathway and that have entered into qualifying "Most-Favored-Nation" ("MFN") pricing arrangements with the U.S. government may be eligible for a zero tariff rate through January 20, 2029, subject to the terms of the Proclamation and any applicable implementing measures.

2. Reduced 20% rate for approved onshoring plans

Companies that commit to transitioning production to the United States and obtain approval for a qualifying onshoring plan may be eligible for a 20% tariff rate. However, this reduced rate is temporary and is scheduled to increase to 100% on April 2, 2030, effectively creating a limited window for relocation of manufacturing to the United States.

3. Country-specific lower rates

The Proclamation provides lower tariff rates for imports from certain jurisdictions that have entered into relevant arrangements with the United States. These include:

- 15% for the European Union, Japan, South Korea, Switzerland, and Liechtenstein
- 10% for the United Kingdom, with a possible pathway to 0% depending on a future bilateral pricing agreement

At present, **Israel does not appear on this list.**

4. Generic, orphan drug, specialty product and other exemptions

The Proclamation includes several carve-outs and exemptions, including:

- potential zero tariff treatment for drugs and associated ingredients where all approved indications are designated as orphan drug exemption in certain circumstances;
- potential zero tariff treatment in specified circumstances for nuclear medicines, plasma derived therapies, fertility treatments, cell and gene therapies, antibody drug conjugates, certain medical countermeasures, certain specialty pharmaceutical products, and animal health products;
- a current exemption for generic pharmaceuticals and associated ingredients;
- preferential treatment tied to qualifying MFN pricing and onshoring arrangements with U.S. agencies; and
- additional product-specific exclusions set out in the annexes.

Why This Matters for Israeli Pharma Companies

For Israeli pharmaceutical companies, the core issue is not only whether finished products are manufactured outside the United States, but whether the relevant product, ingredient, or starting material falls within the substantive scope of the Proclamation. Companies should assume that the analysis will be product-specific and may require a detailed review of, among other things:

- product classification;
- patent status;
- FDA listing status;
- the role of the imported substance in the supply chain; and
- the identity and location of the manufacturing entity.

In practical terms, the tariffs may materially increase the landed cost of products imported into the United States. This could affect margins, pricing strategy, U.S. distribution structures, transfer-pricing positions, and broader supply-chain planning.

Companies with a significant U.S. commercial footprint may therefore face a strategic choice: absorb a substantial cost increase, pursue an onshoring pathway, or revisit their manufacturing and group structuring models.

What Companies Should Do Now

Israeli pharmaceutical and life sciences companies with current or anticipated U.S. market exposure should consider the following immediate steps:

- determine whether any finished product, API, intermediate, or key starting material may fall within the scope of the Proclamation or its annexes;
- map the relevant manufacturing and supply chain, including origin, production, testing, packaging, and other key inputs;

- assess whether any exemption, reduced rate pathway, or company specific arrangement may be available; and
- evaluate the commercial and contractual impact, including pricing, customs treatment, supply commitments, and tariff risk allocation

What Remains Unclear

A few important implementation points may remain subject to further clarification, including the precise product coverage under the annexes, the criteria for qualifying onshoring plans, the mechanics for obtaining reduced-rate or zero-rate treatment, and the manner in which U.S. authorities will administer and enforce the new regime. Companies should therefore monitor closely for annex publication, Federal Register notices, and additional agency guidance.

Disclaimer

This client update is provided for general information purposes only and does not constitute legal advice.

As always, the team at Agmon with Tulchinsky remains at your disposal.



Adv. Yifat Tsafrir, Partner
Head of the Commercial Law
Department

Yifatt@agmon-law.co.il



Adv. Lana Tavor, Partner
High-Tech, Technology and Venture
Capital Department

Lanat@agmon-law.co.il



Jerusalem

Hebrew Campus, Bld. 2,
Yeshayahu Leibovitz 30
T. +972-2-5607607
F. +972-2-5639948

Tel-Aviv

Electra Tower, 98 Yigal Alon St.
T. +972-3-6078607
F. +972-3-6078666

Be'er Sheva

Gav Yam Bld. 77 Ha'energia st.
T. +972-3-6071450
F. +972-8-6155780

Sydney, Australia

50 Carrington st. NSW 2000
T. +61-2-90606206