Bora Pharmaceuticals

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U.S. Pharmaceutical Tariffs (Section 232): Implications & Actions

Overview

The U.S. government is advancing a **Section 232 pharmaceutical tariff framework** aimed at strengthening domestic manufacturing of medicines, APIs, and key starting materials.

Key confirmed elements:

- Applies to branded pharmaceuticals and APIs
- Does NOT apply to generics or biosimilars
- Designed to incentivize U.S.-based manufacturing through economic pressure and policy alignment

Tariff Structure & Pathways to Mitigation

The policy introduces a tiered tariff reduction mechanism tied to U.S. commitments:

- **Baseline tariff**: Applied to imported branded pharmaceutical products
- **Reduced to ~20%** with approved U.S. onshoring plan (via Secretary of Commerce)
- **Reduced to 0%** with approved onshoring plan AND Most-Favored-Nation (MFN) pricing agreement (via Secretary of Health and Human Services)

Strategic Implications for Pharmaceutical Companies

This policy effectively forces pharma leaders to make a strategic choice:

1. **Absorb Tariffs**
   By compressing margins on U.S. sales, this creates potential pricing pressure

2. **Restructure Supply Chain**
   If companies choose to accelerate their U.S. manufacturing footprint and reconfigure global supply chains accordingly, they must navigate regulatory and tech transfer complexity

3. **Engage in Federal Negotiation**
   Given the tiered tariff structure, companies could develop a credible onshoring roadmap and evaluate the implications of pursuing MFN pricing arrangements

What Will the U.S. Government Likely Require?

To secure tariff relief, companies will need to present a robust, evidence-based onshoring plan, including:

- U.S.-bound product portfolio (SKUs)
- Current manufacturing footprint and supply chain
- Identified U.S. manufacturing site(s)
- Tech transfer and validation (PPQ) timelines
- Capital investment (CapEx) and equipment plans
- Workforce/headcount strategy
- QA, regulatory, and compliance transition plans
- R&D transfer (if applicable)
- Milestone-driven roadmap for U.S. production ramp-up

Where Bora Pharmaceuticals Can Help

Bora is uniquely positioned to act as a strategic partner for rapid, credible onshoring execution, helping clients move from policy uncertainty to an executable onshoring plan for tariff mitigation. Bora can provide:

- Strategic onshoring guidance, translating policy into actionable manufacturing strategies to support development of government-ready onshoring plans
- Execution readiness through U.S.-based manufacturing capacity, scalable infrastructure for accelerated production ramps, and proven tech transfer and validation expertise
- Regulatory and operational support through supply chain redesign, QA/regulatory transitions, and other program management needs

Recommended Immediate Actions for Pharma Companies

The U.S. government is advancing a **Section 232 pharmaceutical tariff framework** aimed at strengthening domestic manufacturing of medicines, APIs, and key starting materials.

Assess exposure: Identify U.S.-bound branded products at risk

Scenario plan: Tariff vs. onshoring vs. hybrid strategies

Initiate feasibility assessments: Evaluate onshoring options

Engage early: Work with partners to build credible, government-aligned plans

This policy represents a structural shift in the pharmaceutical operating model, not a short-term trade disruption. Companies that act early, build credible plans, and align with U.S. priorities will be best positioned to minimize the financial impact of these changing policies, secure regulatory alignment, and gain a long-term competitive advantage.

Get in touch today to learn how Bora Pharmaceuticals can support your program.