OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket Nos. USTR-2026-0463 and USTR-2026-0464]

Initiation of Section 301 Investigation; Hearing; and Request for Public Comments: Germany's Persistent Underpayment for Innovative Pharmaceutical Products

AGENCY: Office of the United States Trade Representative (USTR).

ACTION: Notice of initiation of investigation and a hearing, and a request for comments.

SUMMARY: The United States Trade Representative (U.S. Trade Representative) has initiated an investigation pursuant to the Trade Act of 1974, as amended (Trade Act), with respect to Germany's persistent underpayment for innovative pharmaceutical products. The inter-agency Section 301 Committee is holding a public hearing and seeking public comments in connection with this investigation.

DATES:

June 18, 2026: The U.S. Trade Representative initiated the investigation.

June 25, 2026: USTR will open the docket for submission of written comments.

August 10, 2026, at 11:59 p.m. EDT: To be assured of consideration, submit written comments and requests to appear at the hearing, along with a summary of testimony, by this date.

September 22, 2026: The Section 301 Committee will convene a public hearing in the main hearing room of the U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, beginning at 10:00 a.m. If necessary, the hearing may continue on the next business day.

Seven calendar days after the last day of the public hearing: Due date for submission of post-hearing rebuttal comments.

ADDRESSES: Submit documents in response to this notice, including written comments, hearing appearance requests, summaries of testimony, and post-hearing rebuttal comments through the online USTR portal: https://comments.ustr.gov/s/.

FOR FURTHER INFORMATION CONTACT: For procedural questions concerning comments or participating in the public hearing, contact the USTR Section 301 support line at (202) 395-5725. Direct all other questions regarding this notice to Philip Butler, Chair of the Section 301 Committee, or Catherine Gibson, Deputy Assistant U.S. Trade Representative for Monitoring & Enforcement, at (202) 395-5725.

SUPPLEMENTARY INFORMATION:

I. Background

On May 12, 2025, the President issued Executive Order 14297, titled *Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients* (EO). *See* 90 FR 20749. Pursuant to the EO, on May 30, 2025, USTR issued a "Request for Comments Regarding Foreign Nations Freeloading on American-Financed Innovation," including on foreign country acts, policies, and practices that have the effect of forcing American patients to pay for a disproportionate amount of global pharmaceutical research and development (R&D), including by suppressing the price of pharmaceutical products below fair market value in foreign countries. *See* 90 FR 23105 (May 30, 2025 notice). USTR solicited comments in the May 30, 2025 notice to augment information on unfair pharmaceutical pricing practices obtained in response to previous requests for comments by USTR, including USTR's February 25, 2025 "Request for Comments to Assist in Reviewing and Identifying Unfair Trade Practices and Initiating All Necessary Actions to Investigate Harm From Non-Reciprocal Trade Arrangements." *See* 90 FR 10677 (February 25, 2025 notice).

Evidence indicates that Germany implements unfair pricing policies and practices with regard to innovative pharmaceutical products. Evidence further suggests that

reduced revenue associated with these acts, policies, and practices contributes to, among other things, reduced investment for R&D that supports the development of innovative pharmaceuticals. As a result, the United States pays a disproportionate share of global R&D costs for innovative pharmaceuticals. U.S. consumers pay approximately 3.9 times as much as the prices consumers in Germany pay for brand-name drugs. Lower prices in Germany resulting from unreasonable pricing policies and practices reduce pharmaceutical companies' incentives to innovate and, in turn, diminish their investment in R&D. In contrast, higher U.S. prices support and fund global R&D costs for innovative pharmaceutical manufacturers and, thereby, unfairly shift Germany's fair share of costs for pharmaceutical innovation onto U.S. patients and consumers.

This investigation will focus initially on the following means and tools that Germany uses to implement its unfair pricing policies and practices:

Germany conditions the confidentiality of manufacturers' pharmaceutical pricing on certain criteria, including acceptance of a 9 percent price discount and payment of additional administrative costs.

In 2026, Germany's Ministry of Health introduced draft legislation designed to reduce pharmaceutical spending. This legislation would impose an additional mandatory rebate for patented medicines starting in 2027. The current proposal envisions a fixed rate at 3.5 percent for the first half of 2027 and would thereafter change into a variable rate based on the difference between actual and target expenditures of the health insurance funds for all medicines, divided by sales of innovative medicines. According to one estimate, this dynamic rebate will reach 20 percent by 2030.

II. Initiation of Section 301 Investigation

Section 302(b)(1)(A) of the Trade Act authorizes the U.S. Trade Representative to initiate an investigation to determine whether an act, policy, or practice of a foreign country is actionable under Section 301 of the Trade Act. Actionable conduct under

Section 301 includes acts, policies, and practices of a foreign country that are unreasonable or discriminatory and burden or restrict U.S. commerce. An act, policy, or practice is unreasonable if, while not necessarily in violation of, or inconsistent with, the international legal rights of the United States, it is otherwise unfair and inequitable.

On June 18, 2026, the U.S. Trade Representative initiated a Section 301 investigation with respect to Germany's persistent underpayment for innovative pharmaceutical products. This investigation will focus initially on the extent to which Germany engages in acts, policies, and practices that have the effect of suppressing the prices of pharmaceuticals in its market below fair market value, thereby forcing American patients to underwrite a disproportionate amount of global pharmaceutical R&D, as described in Section I above, and similar acts, policies, and practices.

Pursuant to Section 302(b)(1)(B) of the Trade Act, USTR has consulted with appropriate advisory committees and the inter-agency Section 301 Committee. Pursuant to Section 303(a) of the Trade Act, USTR is requesting consultations with the Government of Germany.

Pursuant to Section 304 of the Trade Act, on the basis of this investigation, the U.S. Trade Representative must determine whether an act, policy, or practice of Germany is actionable under Section 301. If that determination is affirmative, the U.S. Trade Representative must determine whether action is appropriate, and if so, what action to take.

III. Request for Public Comments

You may submit written comments on any issue covered by the investigation. In particular, USTR invites comments regarding:

- The acts, policies, and practices described in Section I above.
- Information on other acts, policies, and practices of Germany related to persistent underpayment for innovative pharmaceutical products.

- Whether the acts, policies, and practices of Germany are unreasonable or discriminatory.
- Whether the acts, policies, and practices of Germany burden or restrict U.S. commerce, and if so, the nature and level of burden or restriction on U.S. commerce.
- Whether the acts, policies, and practices of Germany are actionable under section 301(b) of the Trade Act, and what action, if any, should be taken, including tariff and non-tariff actions.
- The extent to which Germany's unreasonable acts, policies, and practices relating to pricing for innovative pharmaceutical products, including through the means and tools described in Section I, result in the United States paying a disproportionate share of global R&D costs for innovative pharmaceuticals.

To be assured of consideration, USTR must receive written comments by 11:59 p.m. EDT on August 10, 2026. Additional instructions on how to submit written comments are provided below in Part V.

IV. Hearing Participation

The Section 301 Committee will convene a public hearing on September 22, 2026, and if needed, the hearing will continue on September 23, 2026. To testify at the hearing, you must submit a request to appear using the electronic portal at https://comments.ustr.gov/s/, following the instructions in Part V below. Requests to appear must include a summary of testimony, and may be accompanied by a prehearing submission. Remarks at the hearing are limited to five minutes to allow for possible questions from the Section 301 Committee. All submissions must be in English. To be assured of consideration, USTR must receive your request to appear and summary of the testimony by August 10, 2026.

Post-hearing rebuttal comments, which should be limited to rebutting or supplementing testimony presented at the hearing, may be submitted within seven

calendar days after the last day of the public hearing. Rebuttal comments must be submitted using the electronic portal at https://comments.ustr.gov/s/, following the instructions in Part V below.

V. Submissions Instructions

Interested persons must submit written comments, requests to appear at the hearing, summaries of testimony, and post-hearing rebuttal comments using the appropriate docket on the portal at https://comments.ustr.gov/s/. To make a submission, use the docket on the portal entitled 'Request for Comments on the Section 301 Investigation Regarding Germany's Persistent Underpayment for Innovative Pharmaceutical Products,' docket number USTR-2026-0463. Interested persons wishing to provide testimony at the hearing must submit a notification of intent and summary of testimony using the docket entitled 'Request to Appear at the Hearing on the Section 301 Investigation Regarding Germany's Persistent Underpayment for Innovative Pharmaceutical Products,' docket number USTR-2026-0464.

You do not need to establish an account to submit comments or a notification of intent to testify. The first screen allows you to enter identification and contact information. Third-party organizations such as law firms, trade associations, or customs brokers should identify the full legal name of the organization they represent and identify the primary point of contact for the submission. Information fields are optional. However, USTR may not consider your comment or request if insufficient information is provided. Fields with a gray Business Confidential Information (BCI) notation are for BCI information that will not be made publicly available. Fields with a green (Public) notation will be viewable by the public. After entering the identification and contact information, you can complete the remainder of the comment, or any portion of it, by clicking 'Next.' You may upload documents at the end of the form and indicate whether USTR should treat the documents as business confidential or public information. Any page containing

BCI must be clearly marked 'BUSINESS CONFIDENTIAL' on the top of that page and the submission should clearly indicate, via brackets, highlighting, or other means, the specific information that is BCI. If you request business confidential treatment, you must certify in writing that the information would not customarily be released to the public. Parties uploading attachments containing BCI also must submit a public version of their comments. If these procedures are not sufficient to protect BCI or otherwise protect business interests, please contact the USTR Section 301 support line at (202) 395-5725 to discuss whether alternative arrangements are possible. USTR will post attachments uploaded to the docket for public inspection, except for properly designated BCI. You can view submissions on USTR's electronic portal at https://comments.ustr.gov/s/.

Jennifer Thornton,

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Office of the United States Trade Representative.

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