PhRMA
RESEARCH • PROGRESS • HOPE

670 Maine Avenue, SW • Suite 1000, Washington, DC 20024 • PHRMA.ORG

August 10, 2026

PUBLIC DOCUMENT
USTR-2026-0463

Ms. Jennifer Thornton
General Counsel
Office of the U.S. Trade Representative
600 17th Street, N.W.
Washington, DC 20508

Re: Initiation of Section 301 Investigation; Hearing; and Request for Public Comments: Germany's Persistent Underpayment for Innovative Pharmaceutical Products, 91 Fed. Reg. 38072 (June 24, 2026)

Dear Ms. Thornton:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates this opportunity to provide the following submission in response to the request for comments regarding an investigation initiated pursuant to section 302(b)(1)(A) of the Trade Act of 1974, as amended (the Trade Act), to determine whether Germany's persistent underpayment for innovative pharmaceutical products is actionable under section 301(b) of the Trade Act ("Request for Comments"). This timely investigation appropriately focuses on acts, policies and practices of the Government of Germany that unreasonably undervalue innovative medicines and burden or restrict U.S. commerce by suppressing investment in research and development (R&D) and shifting the costs of innovation onto the United States. PhRMA welcomes USTR's investigation of these policies and encourages the U.S. government to pursue a binding agreement with Germany that requires it to pay its fair share for innovative medicines.

This submission provides the following information in response to the request for comments:

- **Section I** provides information regarding the innovative biopharmaceutical sector's extensive U.S. economic footprint and the ways in which unreasonable pharmaceutical pricing and reimbursement policies abroad burden the U.S. economy and patients.

- **Section II** identifies specific acts, policies and practices in Germany that are "unreasonable or discriminatory and burden[] or restrict[] U.S. commerce," and thus actionable under section 301(b)(1) of the Trade Act. As detailed below, Germany operates a complex regime aimed at regulating the pricing and reimbursement of pharmaceuticals and, in so doing, controlling the costs of pharmaceuticals for the statutory social security system. This regime systemically denies fair market value and access to innovative medicines, including by rejecting clinical trial evidence to deny the benefits of new medicines, using older inferior medicines and generics as price benchmarks, imposing mandatory rebates on pharmaceuticals and imposing a price freeze since 2010 on publicly reimbursed medicines. As a result of these longstanding policies, Germany spends only 0.64 percent of its gross

domestic product (GDP) on innovative medicines, compared to 1.32 percent in the United States.[1] The Statutory Health Insurance Contribution Rate Stabilization Act enacted by the German Parliament on July 10, 2026, will exacerbate this imbalance by introducing additional mandatory rebates, stricter price regulations and other new cost-containment measures. Together, these policies disproportionately shift the costs of funding innovation onto the United States, deprive biopharmaceutical innovators in the United States of the expected return on investment from the development of innovative medicines and restrict market access and exports for the U.S. biopharmaceutical industry.

- **Section III** proposes that the United States should address these unfair policies by negotiating a bilateral agreement with Germany on pharmaceutical pricing that reduces the gap between what the United States and Germany spend on innovative medicines and commits Germany to implement specific policy reforms.

PhRMA appreciates USTR's attention to the rapidly deteriorating pricing environment in Germany and looks forward to working with the U.S. and German governments to ensure that a binding agreement is reached, consistent with section 301(c)(1)(D) of the Trade Act, to resolve the concerns raised in this submission. Given that Germany's recent legislative actions will significantly increase the burden on U.S. commerce described in this submission, PhRMA urges USTR to pursue negotiations with Germany on an expedited basis.

I. U.S. Trade Policy Should Ensure that High-Income Countries Pay Their Fair Share for Innovative Medicines

PhRMA and its members welcome efforts by the U.S. Government to eliminate foreign government acts, policies and practices that have "the effect of forcing American patients to pay for a disproportionate amount of global pharmaceutical research and development, including by suppressing the price of pharmaceutical products below fair market value in foreign countries."[2] Such acts, policies and practices artificially devalue innovative medicines and important therapeutic research developed in the United States, depress U.S. exports and enable foreign governments to enjoy the benefits of U.S. biopharmaceutical development without paying their fair share for the innovations and resulting health care advancements, causing significant harm to American workers and patients.

---

[1] PhRMA, "High-Income Countries Under-Spend on Innovative Medicines," August 2026, available at https://phrma.org/resources/spending-on-all-innovative-medicines-by-high-income-countries. Innovative medicines refers to medicines during the periods of protection afforded by patents or other regulatory protections such as data protection. Previous analysis by EY showed that Germany spends only 0.36 percent of its GDP on new innovative medicines launched globally during the past ten years, compared to 0.78 percent in the United States. The relative spending imbalance for biopharmaceutical innovation between Germany and the United States is similar when comparing spending on the larger group of all innovative medicines instead of only the subset of innovative medicines that are newer and launched globally during the past ten years. For both sets of innovative medicines, Germany contributes less than half as much as the United States as a share of GDP.

[2] Trump, Donald J. *Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients*. *Federal Register*, vol. 90, no. 95, May 15, 2025, pp. 20749–20751. Executive Order 14297 at Sec. 3, available at https://www.federalregister.gov/documents/2025/05/15/2025-08876/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients.

The United States leads the world in the R&D of new medicines, accounting for 55 percent of global biopharmaceutical R&D investment.[3] The U.S. innovative biopharmaceutical industry supports over 4.9 million U.S. jobs and contributes more than $1.65 trillion in annual economic output, while also developing cutting-edge treatments and cures that save and improve the lives of patients in the United States.[4] The innovative biopharmaceutical industry is also a leader in U.S. manufacturing, producing $333 billion in gross output in 2024.[5] In 2025, the U.S. pharmaceutical industry exported more than $119 billion of biopharmaceutical goods.[6]

The R&D necessary to bring these new medicines to market involves substantial upfront costs and because only a small percentage of potential new medicines ever make it to market, these investments entail significant financial risk. Consequently, innovation in the biopharmaceutical sector depends on the ability of innovators to obtain an appropriate return on their investment through use and commercialization of their intellectual property and any resulting new treatments. However, foreign governments in high-income countries impose price controls on innovative medicines that depress global prices and decrease returns on investment in R&D, thereby undermining the commercial incentives to invest in these life-saving technologies. As the world leader in the development of innovative medicines, these foreign price controls particularly impact companies conducting R&D in the United States and result in U.S. patients and taxpayers bearing a disproportionate share of the costs associated with developing new treatments and cures.

The U.S. Government has long recognized the risks of foreign price controls to the U.S. economy and consumers, as well as the risk such measures pose to the innovation needed to bring new medicines to market. In a 2004 study, the Department of Commerce concluded that foreign measures that set prices for new pharmaceuticals by "government fiat rather than competition" effectively "reduce company compensation to levels closer to direct production costs," and leave less revenue for the R&D "that would provide substantial health benefits to all."[7] The study concluded that foreign drug pricing regimes result in a delay in the "the launch of drugs in different markets, thereby adversely affecting patients' access to new medicines," while also "reduc[ing] social welfare by depressing the number of new drugs."[8]

More recently, a 2018 report by the Council of Economic Advisors (CEA) within the Executive Office of the President concluded that the setting of foreign drug prices at levels below those that

---

[3] Amitabh Chandra et al., "Comprehensive Measurement of Biopharmaceutical R&D Investment," *Nature Reviews Drug Discovery* 23 (2024): 652–653, available at https://www.nature.com/articles/d41573-024-00131-2.

[4] TEConomy Partners, LLC, *The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates* (May 2024), available at https://cdn.aglty.io/phrma/policy-issues/research-ecosystem/economy/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf.

[5] U.S. Department of Commerce Bureau of Economic Analysis, Gross Output by Industry, 2024 (accessed July 27, 2026).

[6] U.S. Bureau of Economic Analysis, International Accounts Products for Detailed Goods Trade Data, 2025, available at https://www.bea.gov/international/detailed-trade-data (accessed July 27, 2026).

[7] U.S. Department of Commerce, International Trade Association, Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development and Innovation (Dec. 2004), p. vii, available at https://web.archive.org/web/20190414170009/https://2016.trade.gov/td/health/DrugPricingStudy.pdf.

[8] *Id.* at pp. x, 3, 31.

prevail in the United States "erode[s] the returns to innovation manufacturers might otherwise see from selling in their Markets" and led to American patients and taxpayers financing global medical innovation.[9] In a 2020 report, the CEA similarly found that foreign drug pricing regimes disproportionately burden the United States, as well as U.S. patients and taxpayers, and that the incidence of foreign "free-riding" on U.S. investments and innovation in drug development has only increased over time.[10] A 2026 study by the Department of Health and Human Services, Assistant Secretary for Planning and Evaluation found that "the global financing of pharmaceutical innovation remains highly concentrated in the United States" and observed that "[a] system in which one country finances most pull-side incentives while many peer countries contribute substantially less than their population or GDP weight is unlikely to be stable indefinitely."[11]

Given these adverse effects, the United States appropriately has used recent reports, including the 2026 National Trade Estimate Report and the 2026 Special 301 Report, to highlight its concerns with foreign government price controls on new medicines[12] and has discouraged governments from adopting these and other unfair drug pricing measures. Additionally, the United States repeatedly has called on foreign countries to contribute their fair share to R&D costs of new treatments and cures.[13] On May 12, 2025, the President issued Executive Order 14297, which, *inter alia*, instructed the Secretary of Commerce and the Trade Representative to:

> take all necessary and appropriate action to ensure foreign countries are not engaged in any act, policy, or practice that may be unreasonable or discriminatory or that may impair United States national security and that has the effect of forcing American patients to pay for a disproportionate amount of global pharmaceutical research and development, including by suppressing the price of pharmaceutical products below fair market value in foreign countries.[14]

Further to the President's instruction, the Administration engaged in constructive negotiations with the United Kingdom (UK) to address the UK's persistent underpayment for innovative

---

[9] Council of Economic Advisors, Reforming Biopharmaceutical Pricing at Home and Abroad (Feb. 2018), available at https://trumpwhitehouse.archives.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf.

[10] Council of Economic Advisors, Funding Global Benefits to Biopharmaceutical Innovation (Feb. 2020), available at https://trumpwhitehouse.archives.gov/wp-content/uploads/2020/02/Funding-the-Global-Benefits-to-Biopharmaceutical-Innovation.pdf.

[11] Murphy, S. *Measuring the pull-side innovation burden for pharmaceutical drugs by OECD country*. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. June 23, 2026, available at https://aspe.hhs.gov/reports/innovation-burden-pharmaceutical-drugs.

[12] USTR, 2026 National Trade Estimate Report (Mar. 31, 2026), available at https://ustr.gov/sites/default/files/files/Press/Releases/2026/National%20Trade%20Estimate%20Report%202026.pdf ; USTR, 2026 Special 301 Report (Apr. 30, 2026), pp. 24-28, available at https://ustr.gov/sites/default/files/files/Press/Releases/2026/2026%20Special%20301%20Report.pdf.

[13] *Id.* at p. 29; *see also* USTR, 2018 Special 301 Report (Apr. 2018), p. 6, available at https://ustr.gov/sites/default/files/files/Press/Reports/2018%20Special%20301.pdf.

[14] Executive Order 14297, Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients, 90 Fed. Reg. 20,749 (May 15, 2025).

medicines. On April 2, 2026, the two governments finalized the U.S.-UK Arrangement on Pharmaceutical Pricing, which establishes important first steps by the UK to pay its fair share for innovative medicines.[15] Nonetheless, Germany and several other high-income countries, including Australia, Canada, Denmark, France, Italy, Japan, Korea, Spain and Switzerland, have maintained and in some cases taken actions to worsen their drug pricing regimes that disadvantage the United States and U.S. innovators. PhRMA supports the U.S. Government's efforts to secure additional bilateral agreements that eliminate unreasonable pricing and reimbursement policies in these markets.

II. Germany's Pharmaceutical Pricing and Reimbursement Policies are Unreasonable and Burden or Restrict U.S. Commerce

A. Overview of Germany's Pharmaceutical Pricing and Reimbursement Policies

Germany is one of the world's most developed economies, but its policies systematically undervalue and restrict access to U.S. innovative medicines. Germany's Pharmaceutical Market Restructuring Act (*Arzneimittelmarktneuordnungsgesetz*, or *AMNOG*) of 2011 restructured its pricing and reimbursement process away from market-based pricing toward a government-managed and payer-led system of clinical evaluation and price setting. Germany now operates a centralized price-setting and reimbursement regime aimed at controlling the cost of pharmaceuticals for the statutory social security system by undervaluing innovative medicines and restricting their use by patients. As a result of longstanding acts, policies and practices, Germany spends only 0.64 percent of its GDP on innovative medicines, compared to 1.32 percent in the United States.[16] The Statutory Health Insurance Contribution Rate Stabilization Act (*GKV-Beitragssatzstabilisierungsgesetz,* or *GKV-BStabG)* enacted by the German Parliament on July 10, 2026, will exacerbate this imbalance and further reduce pharmaceutical spending by increasing mandatory rebates on innovative medicines, extending and expanding a more than 15-year price freeze and requiring more stringent price-volume rebate agreements in statute. In addition, the new law allows statutory health insurance providers to restrict further physicians' ability to prescribe innovative medicines while extracting additional rebates from innovative biopharmaceutical manufacturers.[17] Germany enacted this legislation despite the U.S. Government's clearly stated position that U.S. trading partners must pay their fair share for biopharmaceutical innovation.

1. Coverage Under Public Health System

Under the statutory health care system, medicines are paid for mainly by statutory health insurance providers (*Krankenkassen*, or "sickness funds") with a modest co-payment by patients. The statutory health care system covers 90 percent of the German population. For most

[15] USTR, "Successful Conclusion of the United States–United Kingdom Arrangement on Pharmaceutical Pricing," April 2, 2026, available at https://ustr.gov/about/policy-offices/press-office/press-releases/2026/april/successful-conclusion-united-states-united-kingdom-arrangement-pharmaceutical-pricing.

[16] PhRMA, "High-Income Countries Under-Spend on Innovative Medicines," August 2026, available at https://phrma.org/resources/spending-on-all-innovative-medicines-by-high-income-countries.

[17] *GKV-BStabG*, available at https://www.bundesgesundheitsministerium.de/service/gesetze-und-verordnungen/detail/gkv-beitragssatzstabilisierungsgesetz.

medicines, coverage under the system determines market access, as there is only a limited role for private health insurance in Germany.

The rules for drug coverage are set forth under the Social Code, book 5 (*Sozialgesetzbuch Fünftes Buch*, or *SGB V*). The Joint Federal Committee (*Gemeinsamer Bundesausschuss*, or *G-BA*), makes key decisions as to whether a new medicine provides additional benefit over existing treatments and can rely on a scientific advisory body, the Institute for Quality and Efficiency in Healthcare (*Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen* or *IQWiG*), to do so. After a *G-BA* decision, the federal association of sickness funds (*GKV-Spitzenverband*) plays the key role in price-setting discussions with biopharmaceutical companies.

While innovative medicines are available faster in Germany compared to other European countries, Germany's assessment and rebate policies set prices systematically below the market value of innovation while also steering physicians and patients toward the use of older, inferior medicines. Physicians in Germany face the threat of financial penalties if they prescribe medicines not deemed "economical" by the *G-BA*.[18] In addition, the *G-BA* can exclude or restrict the coverage of certain medicines by the statutory social security system based on medical and economic grounds.[19] These decisions are contained in guidelines (*Richtlinien*) to be followed by physicians. Germany's public health insurance provides reimbursement coverage for just 58 percent of new innovative medicines launched globally during the past ten years, while the Medicare program in the United States reimburses 88 percent. Worse access in Germany results from a 14-month average delay from when a medicine is first launched globally, typically in the United States, to when it is reimbursed by public health insurance in Germany,[20] and because 10 to 15 percent of new innovative medicines exit the German market after launching due to the outcome of Germany's benefit assessment, pricing and rebate policies.

2. Prices

The German Medicines Act (*Arzneimittelgesetz,* or *AMG*) and the Federal Government's Ordinance on Drug Prices (*Arzneimittelpreisverordnung,* or *AMPreisV*) regulate the pricing of pharmaceuticals. Section 78(3a) of the *AMG* creates a link between the regulatory pharmaceutical pricing rules and the reimbursement and coverage laws. Specifically, the rules require biopharmaceutical companies to ensure a uniform pharmacy dispense price for prescription pharmaceuticals (and certain over-the-counter pharmaceuticals) throughout the country. In so doing, biopharmaceutical companies cannot charge a higher price to different payor groups. The *AMPreisV* also regulates the minimum and maximum margins that pharmacies and wholesalers may charge for a pharmaceutical product.

---

[18] Life Sciences Access Hub, "German doctors demand exemption from liability for the prices of innovative medicines," (Oct. 6, 2025), available at https://www.lisah.org/resource/german-doctors-demand-exemption-from-liability-for-the-prices-of-innovative-medicines.html.

[19] Sec. 92(1) SGB V, available at https://www.gesetze-im-internet.de/sgb_5/__92.html (German).

[20] PhRMA, "Access to New Medicines in the United States vs. Other High-Income Countries," May 2026. Note: New innovative medicines refer to new active substances first launched in any country between January 1, 2016, and December 31, 2025, and approved by the FDA, EMA and/or PMDA.

In determining the price of an innovative medicine, the *G-BA* assesses whether the medicine provides an additional clinical benefit over existing treatments. However, the *G-BA* imposes strict requirements on the evidence it will consider when assessing additional clinical benefit and it often selects inappropriate, outdated comparator therapies for the assessments. As a result, the *G-BA* regularly rejects clinical evidence, often simply because clinical trials did not include *G-BA* selected comparators. The *G-BA* asserts that 55 percent of new innovative medicines provide no additional benefit over comparator treatments even though many of these same medicines have been widely recognized as important, breakthrough therapies in the United States and other countries.[21] Initially, Germany's pricing and reimbursement policies acknowledged the greater challenges of gathering evidence for rare disease treatments. When AMNOG was implemented in 2011, an innovative orphan drug with annual sales below €50 million was exempted from the regular assessment procedure and thereby not subject to *G-BA* assertions that there was no evidence of additional benefit. However, rare disease treatments have become increasingly subject to the *G-BA* asserting no evidence of additional clinical benefit because the orphan drug sales threshold was never updated for inflation over the next eleven years, and then it was lowered from €50 million to only €30 million in 2022.[22]

Finding no evidence of additional benefit is one way that the *G-BA* subjects a new medicine's valuation to unreasonable prices because, without an additional benefit determination, older inferior medicines and generics can more directly set price benchmarks for innovative medicines. An analysis of *G-BA* decisions indicates that generics were selected as a comparator therapy in 74 percent of *AMNOG* assessments for innovative medicines.[23] For some medicines deemed by the *G-BA* to provide no additional benefit, reimbursement by statutory health insurance providers is limited to a reference price (*Festbetrag*) for a group of comparable products.[24] The groups are established by the *G-BA* and can cover three types of clusters: (1) pharmaceuticals with the same active substance; (2) pharmaceuticals with different but pharmacologically and therapeutically comparable active substances; and (3) pharmaceuticals with therapeutically comparable action and in particular combination products. Groups (2) and (3) can include innovative products (which are then grouped together with generic products) unless the manufacturer can demonstrate a new mechanism of action or a therapeutic improvement. Under this system, the reference price cannot exceed the highest price in the lowest one third of the group.

Reference group pricing steers physicians and patients toward older, inferior medicines and pressures innovative manufacturers to accept prices that do not reflect the therapeutic value of their medicine. If a manufacturer charges a higher price, the patient must pay the difference and the prescribing physician is obligated to officially inform the patient thereof.

---

[21] AMNOG-Monitor, Early Benefit Assessment: Detailed Analysis of All G-BA Resolutions (June 2025), available at https://www.amnog-monitor.com. This analysis excludes orphan drugs with sales below a threshold that makes them ineligible to receive a rating of offering no added benefit.

[22] The sales threshold for orphan indications was reduced from €50 million to €30 million for each indication by the Statutory Health Insurance (SHI) Financial Stabilization Act of 2022.

[23] AMNOG-Monitor, Early Benefit Assessment: Detailed Analysis of All G-BA Resolutions (June 2025), available at https://www.amnog-monitor.com. Note: The *G-BA* defines at least one generic comparator in 74 percent of subpopulation assessments. Analysis excludes assessments with non-drug comparators (e.g., surgery).

[24] The reference pricing system is contained in section 35 SGB V, available at https://www.gesetze-im-internet.de/sgb_5/__35.html (German).

The newly adopted *GKV-BStabG* allows statutory health insurance providers to employ tender-style rebate contracts to direct physicians and patients further away from innovative medicines, even if the innovative medicine provides an additional clinical benefit officially acknowledged by the *G-BA*. Under this new policy, statutory health insurance providers can contract exclusively with the lowest-cost innovative medicine and thereby restrict physicians and patients from other innovative medicines in the therapy group. This policy will set a problematic precedent if tender-style rebate contracts, normally used for off-patent medicines with generic or biosimilar competitors, are expanded beyond the initial pilot program described in the new law and if only price, rather than therapeutic value, shape patient access and valuations for an expanding number of innovative medicines.

3. Price Freezes

Since August 2010, Germany has operated a price freeze for pharmaceuticals reimbursed by the statutory health care system. The price freeze was implemented originally for a limited period but has been extended several times. The newly adopted *GKV-BStabG* extended the price freeze through 2030 and expanded it to include innovative vaccines. A key negative impact of the price freeze is that it also indirectly lowers prices for innovative medicines by freezing the prices of comparator therapies used as price benchmarks.

The freeze is *de facto* implemented through a mandatory rebate to the sickness funds that is equal to any price increases implemented by the biopharmaceutical manufacturer.[25] The price freeze does not apply to pharmaceuticals that are covered by the reference price system (described above). Starting in 2018, manufacturers can request an adjustment to their list price to account for inflation that occurred during the year. However, the net price set by the government through the benefit assessment process does not change and additional rebates still apply, thereby negating the revenue benefit.

4. Compulsory Manufacturer Rebates

Germany also imposes a mandatory rebate to be granted by biopharmaceutical manufacturers (*via* the dispensing pharmacies) to the sickness funds. The *GKV-BStabG* added a nine percent mandatory rebate for innovative vaccines that is applied on top of existing rebates of seven percent or a rebate amount based on referenced European country prices. The new law also increased the mandatory rebate on all other innovative medicines from seven percent to 15.5 percent.[26] These rebates are designed like retroactive markdowns, which means that the biopharmaceutical manufacturer must refund this amount at the end of the respective billing cycle to the sickness funds through the pharmacies. Innovative medicines can be exempt from the new law's additional mandatory rebates if at least five percent of clinical trial participants for that medicine were enrolled in a clinical trial in Germany.

---

[25] Sec. 130a-(3a) SGB V, available at https://www.gesetze-im-internet.de/sgb_5/__130a.html (German).

[26] *GKV-BStabG*, available at https://www.bundesgesundheitsministerium.de/service/gesetze-und-verordnungen/detail/gkv-beitragssatzstabilisierungsgesetz.

The *GKV-BStabG* introduces other additional rebates on biopharmaceutical manufacturers by establishing a statutory formula for price-volume "agreements," which is egregious because it deliberately targets successful treatments that generate greater patient demand. The formula calculates the rebate percent reduction, starting in a product's fourth year, as equal to 1.5 percent per €100 million of sales plus 1.7 percent applied to the growth in sales post launch year. The Government of Germany understated the likely impact of this policy on biopharmaceutical manufacturers because the policy will be only partially phased in by 2030. For many innovative medicines, the change in price-volume rebates will grow to exceed the increased mandatory rebates under the new law. The overall impact of the policy could grow more quickly depending on the extent to which the government uses its new authority under the *GKV-BStabG* to unilaterally "renegotiate" prior pricing decisions to implement the statutory rebate formula.

The new law also creates another layer of rebates by empowering statutory health insurers to use tender-style rebate agreements to set prices for innovative medicines. As described above, insurers can award exclusive contracts to the lowest-cost innovative medicine in a group even if medicines in that group have additional clinical benefits acknowledged by the *G-BA*, thereby potentially erasing the value of those therapeutic benefits with larger rebates. The impact of this policy on biopharmaceutical manufacturer revenues could also exceed that of the increased mandatory rebates if the pilot program is brought to scale.

The price reductions caused by these compulsory rebates are layered on top of one another, compounding the harm that these policies inflict on the U.S. innovative biopharmaceutical industry.

B. Germany's Acts, Policies and Practices Are Unreasonable

Section 301 states that acts, policies or practices of a foreign country are actionable if they are unreasonable or discriminatory and burden or restrict U.S. commerce.[27] "[U]nreasonable" refers to an act, policy or practice that "while not necessarily in violation of, or inconsistent with, the international legal rights of the United States is otherwise unfair and inequitable."[28] The statute further provides that acts, policies and practices should be considered unreasonable if they deny "fair and equitable … market opportunities"[29] or "nondiscriminatory market access opportunities for United States persons that rely upon intellectual property protection."[30] In addition, in determining if a foreign country's practices are unreasonable, whether U.S. companies are being denied reciprocal opportunities to those provided in the United States for foreign nationals and firms "shall be taken into account to the extent appropriate."[31] For the following reasons, Germany's acts, policies and practices are unreasonable:

[27] 19 U.S.C. § 2411(a)–(b).

[28] *Id*. § 2411(d)(3)(A).

[29] *Id*. § 2411(d)(3)(B)(i)(IV).

[30] *Id*. § 2411(d)(3)(B)(i)(III).

[31] *Id*. §2411(d)(3)(D).

1. Germany's Acts, Policies and Practices Systematically Undervalue U.S.-Developed Innovative Medicines

By setting drug prices using older and inferior medicines and generics as price benchmarks, not recognizing additional clinical benefit in price determinations for innovative medicines, imposing additional mandatory rebates to achieve lower drug prices and extending and expanding a price freeze since 2010, Germany's acts, policies and practices unreasonably undervalue the benefits provided by innovative medicines developed and produced in the United States. These policies unfairly deprive the U.S. innovative biopharmaceutical industry of the expected return on investment for the development of innovative medicines and contribute to an unfair and inequitable distribution of the global cost of biopharmaceutical development, whereby Germany enjoys the benefits of U.S. biopharmaceutical innovations without proportionately paying for these innovations. The longstanding acts, policies and practices described above result in Germany spending less than half as much on innovative medicines as a share of GDP as the United States, and Germany will spend an even lower share once the *GKV-BStabG* is implemented. Further, these policies result in nonreciprocal opportunities for U.S. companies operating in Germany relative to German companies operating in the United States, as the latter are able to benefit from U.S. policies that more appropriately reflect the market value of innovative medicines.

2. Germany's Acts, Policies and Practices Restrict Market Access for U.S.-Developed Innovative Medicines

Germany's acts, policies and practices unreasonably restrict market access for U.S. biopharmaceutical products and result in nonreciprocal market access opportunities for U.S. companies operating in Germany relative to German companies operating in the United States. Whereas innovative biopharmaceutical manufacturers are able to launch and receive public reimbursement for 88 percent of innovative medicines in the United States, only 58 percent of innovative medicines are publicly reimbursed in Germany.[32] In addition, Germany's policies fail to provide "nondiscriminatory market access opportunities for United States persons that rely upon intellectual property protection," and are therefore unreasonable within the meaning of section 301(d)(B)(III). As noted above, Germany provides more favorable pricing terms to biopharmaceutical manufacturers if at least five percent of clinical trial participants for a medicine were enrolled in clinical trials in Germany. In doing so, Germany unfairly discriminates against biopharmaceutical innovators who locate these important clinical research activities in the United States.

C. Germany's Acts, Policies and Practices Burden or Restrict U.S. Commerce

The acts, policies and practices described above are trade barriers that allow Germany to enjoy the benefits of U.S. biopharmaceutical development without proportionately paying for these innovations. In doing so, they harm: (1) American patients and taxpayers, who bear a disproportionate share of the cost of researching and developing innovative medicines; (2)

[32] PhRMA, Access to New Medicines in the United States vs. Other High-Income Countries, May 13, 2026, available at https://phrma.org/resources/access-to-new-medicines-in-the-united-states-vs-other-high-income-countries.

biopharmaceutical companies operating in the United States, who are not fairly compensated for their innovation, thereby distorting markets and compromising these companies' global competitiveness; and (3) the U.S. economy, in that they reduce the amount that innovators could further invest in the United States and suppress U.S. employment opportunities and exports.

The extent to which Germany's existing acts, policies and practices burden or restrict U.S. commerce is demonstrated by the fact that Germany spends a much smaller share of GDP on innovative medicines than the United States. Germany spends less than half as much on innovative medicines as a share of its GDP as the United States.[33] In 2023, Germany spent only 0.64 percent (€26 billion) of its GDP on innovative medicines, compared to 1.32 percent in the United States. Germany's underspend of 0.68 percent (€28 billion) of its GDP in 2023 resulted in American patients and taxpayers disproportionately paying an additional 0.15 percent ($39 billion) of their GDP in 2023 for biopharmaceutical innovation. The *GKV-BStabG* significantly increases this burden on the United States by further reducing spending on all innovative medicines in Germany's statutory health insurance system over the next several years by approximately 15 percent, resulting in American patients and taxpayers disproportionately paying, in total, an additional 0.17 percent ($45 billion) of GDP for biopharmaceutical innovation.[34] In addition, because Germany is frequently used as a reference country in foreign pricing systems, Germany's suppression of prices may also suppress prices elsewhere, further reducing returns on biopharmaceutical innovation and magnifying the burden on U.S. commerce.

III. USTR Should Ensure that Germany Pays its Fair Share for Innovative Medicines Through a U.S.-Germany Agreement on Pharmaceutical Pricing

PhRMA supports USTR's efforts to negotiate a bilateral agreement with Germany that addresses Germany's persistent underpayment for innovative medicines. This agreement should eliminate the burden on U.S. commerce described in this submission by reducing the gap between what the United States and Germany spend on new medicines. Consistent with the U.S.-UK Arrangement on Pharmaceutical Pricing, the agreement should require Germany to achieve a minimum level of spending on innovative medicines based on its relative ability to pay. Specifically, the agreement should require Germany to spend the same share of its GDP on innovative medicines as the United States. To achieve this, the United States should require Germany to adopt binding and enforceable trade commitments, as follows:

A. Increase Share of GDP Spent on Innovative Medicines

Germany should commit to spend at least the same share of GDP on innovative medicines as the United States. Currently, Germany spends less than half as much on innovative medicines as a share of GDP compared to the United States due to its longstanding policies that undervalue innovative medicines and restrict their use by patients. The newly adopted policies in the *GKV-*

[33] PhRMA, "High-Income Countries Under-Spend on Innovative Medicines," August 2026, available at https://phrma.org/resources/spending-on-all-innovative-medicines-by-high-income-countries.

[34] Approximately nine of the 12 percent reduction in spending under the *GKV-BStabG* results from increasing the mandatory rebate to 15.5 percent, from the previous rate of seven percent. The remaining estimated impact results from changes in price-volume rebates, additional mandatory rebates on innovative vaccines and tender-style rebate contracts.

BStabG will further lower spending in Germany, increasing its spending and patient access gap with the United States.

B. Specific Policy Reforms

To ensure that Germany adopts and maintains the policy reforms necessary to increase spending on innovative medicines, Germany should commit to address or eliminate the unreasonable acts, policies and practices described above that contribute to price suppression and failure to adequately reflect the value of innovation. Germany should:

1. Increase the Net Price Paid for Prospective New Medicines and Ensure Access

Germany should increase the net price paid for prospective new medicines not yet launched in Germany, while ensuring rapid and equitable access to these new medicines by patients in Germany. Higher net prices will result from reforming the methods used to assess a new medicine's additional benefit, including the recognition of a broader range of clinical evidence and a science-based approach to selecting comparators. Rapid and equitable patient access will result from customizing benefit assessment methods for rare disease treatments and not allowing inappropriate benefit assessment scores to dissuade physicians from prescribing innovative treatments. To ensure these *AMNOG* reforms are implemented, the Government of Germany should:

- Amend the Social Code, Book 5 (*SGB V*) to incorporate a U.S. price benchmark (based on the U.S. Medicare net price adjusted for purchasing power parity) into the *AMNOG* price-setting process such that Germany does not pay a net price lower than the U.S. price benchmark.

- Amend *SGB V* so that (1) generic medicines cannot be used as an "appropriate comparative therapy" (*zweckmäßige Vergleichstherapie*, or *zVT*) for the purpose of setting prices for innovative medicines; and (2) the prices of innovative medicines used as the "appropriate comparative therapy" are adjusted to account for medical cost inflation that occurred during the price freeze.

- Allow net prices for innovative medicines to increase for inflation.

- Return the sales threshold for orphan indications to €50 million for each indication (the threshold prior to the reduction to €30 million made by the SHI Financial Stabilization Act of 2022) and adjust that figure annually for inflation.

- Remove the threat of financial penalties for physicians if they prescribe prospective new medicines.

2. Ensure that Increased Net Prices Are Not Offset or Materially Eroded

Because many different cost-containment polices in Germany's pricing and reimbursement system can affect net prices and patient access to innovative medicines, the Government of

Germany should ensure that the impact of the reforms described above are not offset or materially eroded by the imposition of statutory rebates, statutory price-volume agreements, tender-style rebate agreements or other cost-containment measures that lower net prices or restrict access or utilization. Further abolishing these cost-containment measures for all innovative medicines – not only prospective new medicines – is needed to ensure that Germany increases spending on innovative medicines as a share of GDP. In particular, the Government of Germany should abolish the statutory:

- nine percent and previously existing rebates for innovative vaccines and the 15.5 percent rebate for all other innovative medicines;
- price-volume agreements for innovative medicines; and
- tender-style rebate contracts for innovative medicines.

C. Compliance Mechanism

To reduce the burden on U.S. commerce, it is essential to ensure that the above reforms are fully implemented and sustained over time. The agreement therefore should establish milestones and a mechanism for bilateral consultation between the governments to ensure implementation and sustained compliance with these obligations.

* * *

PhRMA appreciates the U.S. government's investigation of Germany's persistent underpayment for innovative pharmaceutical products. As demonstrated above, Germany's pharmaceutical pricing policies unreasonably undervalue innovative medicines and burden U.S. commerce by suppressing U.S. investment and exports and forcing the United States to finance a disproportionate share of global biopharmaceutical innovation. Instead of reforming these longstanding and harmful policies, Germany has taken steps to further reduce its contributions to global innovation and increase the burden on U.S. patients and innovators. PhRMA supports urgent U.S. Government engagement to address the rapidly deteriorating pricing environment in Germany and secure policy reforms that appropriately value innovative medicines. We look forward to working with the U.S. and German governments to ensure a binding agreement is reached, consistent with section 301(c)(1)(D) of the Trade Act, to resolve the concerns raised in this submission.

Sincerely,

Kevin Haninger
Senior Vice President, International