

SWP Comment

NO. 45 OCTOBER 2026

Drug Pricing in Germany in the Crosshairs of the United States

Protection through EU Instruments and International Partnerships

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On 18 June 2026, the United States Trade Representative (USTR) launched an investigation under Section 301 of the Trade Act of 1974 into Germany's pharmaceutical policy. The investigation could ultimately lead to tariffs being imposed on German exports to the United States. This is the first time the US government has used these legal powers to challenge drug pricing abroad. Although the regulation of pharmaceutical costs falls within national competence, defensive measures against US tariffs fall within the exclusive competence of the European Union (EU), which could consider invoking its Anti-Coercion Instrument. The German government should work with its EU partners to respond to this attempt to interfere with Germany's public policies on drug pricing. Further partnerships, including with non-EU countries, could help address the transnational issue of drug pricing.

The investigation under Section 301 of the Trade Act of 1974 — initiated by the USTR to establish whether Germany engages in “unfair [pharmaceutical] pricing policies and practices” — is an integral part of the second Trump administration's agenda to reduce drug prices in the United States. This agenda was laid out in an Executive Order of 12 May 2025, in which high drug prices in the United States were attributed to, among other things, lower drug prices overseas. At the core of the Executive Order is the assumption that drug pricing should follow what the Trump administration calls Most-Favoured-Nation (MFN) pricing — a form of international reference pricing. Under this approach, pharmaceutical manu-

facturers would grant purchasers in the United States the lowest price they offer to other countries. Under this logic, a price reduction will lead to a lower total volume of investment in research and development (R&D) by pharmaceutical companies, usually calculated as a percentage of their revenue. There is, however, a lack of transparency internationally regarding what share of the prices of individual drugs is attributable to their R&D costs.

The US government's argument for MFN pricing rests on the assumption that multinational pharmaceutical companies base their R&D expenditure on the average price negotiated across all countries. This assumption is simplistic: If Germany spends less on



new medicines, then the United States has to spend more so that pharmaceutical companies will invest in R&D. But the factors behind higher US drug prices are more complex, as the following analysis explains.

Challenges in comparing drug prices across countries

A major obstacle to cross-country comparisons of drug prices is the wide variation in the regulatory procedures for determining how much will be paid for patent-protected and brand-name medicines and what proportion of those payments will come from public and private sources. In Germany, there is strictly speaking no binding drug price requirement. Instead, a manufacturer introducing a drug to the market initially sets a launch price. Then, negotiations are conducted to determine the reimbursement amount paid to manufacturers by statutory and private health insurers (*Krankenkassen*).

The determination of reimbursement amounts for new drugs in Germany takes into account both scientific and market-based considerations. Once a medicine has been authorised by either the European Medicines Agency or the Paul Ehrlich Institute, the manufacturer must submit a dossier containing the required information about the medicine to the Federal Joint Committee – the main decision-making body in Germany’s self-governing healthcare system. The Federal Joint Committee then applies various criteria to assess the additional benefit the new medicine offers patients over the existing standard treatment for the corresponding disease or condition. This assessment is conducted without any interference from the government or private actors.

On the basis of the assessment by the Federal Joint Committee, the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) – representing Germany’s statutory health insurance funds – and the manufacturer have six months to negotiate the reimbursement price.

This procedure for determining pharmaceutical expenditure in Germany is based on self-governance within Germany’s federal healthcare system and, as such, is not comparable to other systems with different decision-making structures. As discussed below, drug pricing and expenditure in other countries, such as the United States and the United Kingdom, have different features that must be taken into account in international agreements on pharmaceutical policy.

US external economic policy on the offensive in the pharmaceutical sector

In its announcement of the Section 301 investigation, the USTR cites preliminary evidence that German drug price regulation is unfair, including the then draft legislation of the Statutory Health Insurance Contribution Rate Stabilization Act (*GKV-Beitragssatzstabilisierungsgesetz*). This law was adopted in July 2026 and provides, among other things, for a reduction in public expenditure on medicines, primarily through an increase in the mandatory manufacturer rebate of the total sale of a medicine to statutory health insurance funds (*gesetzliche Krankenkassen*) from 7 per cent to 15.5 per cent. However, the USTR’s announcement also refers to Germany’s “persistent underpayment for innovative pharmaceuticals”, which suggests that the scope of the investigation may extend beyond the recently adopted legislation.

The launch of a Section 301 investigation into drug pricing practices in Germany and the threat of tariffs if “unfair trade practices” are found exemplify the use of external economic policy tools by the Trump administration to achieve domestic policy goals. This investigation is part of broader efforts by the Trump administration to use trade policy to reduce drug prices for US consumers and create incentives for investment in the United States.

The Section 301 investigation into Germany’s pricing practices is one of several

interconnected trade measures recently adopted by the US government. In a presidential proclamation of April 2026, the president imposed tariffs on imports of certain patented pharmaceuticals and associated ingredients. The legal basis for this presidential proclamation — unlike that for the Section 301 investigation — is Section 232 of the Trade Expansion Act of 1962, which authorises the president to “adjust imports” if, following a Commerce Department investigation, he agrees that they threaten to impair US national security. The presidential proclamation aims in particular to reduce US dependence on imported pharmaceutical products and sets a default tariff rate of 100 per cent on imports, but a reduced rate of 15 per cent for such pharmaceutical products originating in the EU and certain other countries. This is the first time the United States has raised tariffs from the standard zero-baseline, which had prevailed since the WTO Agreement on Trade in Pharmaceutical Products of 1994. Nevertheless, a zero rate applies to qualifying companies that have agreements with the US government concerning both MFN pricing and the onshoring of production.

Besides being unprecedented in the field of drug pricing, the USTR’s Section 301 investigation should lead to political discussions among EU countries and with third countries on developing a common approach to fair pricing practices in the pharmaceutical sector. Although Germany is the first country targeted by a Section 301 investigation over drug pricing, the multinational nature of the pharmaceutical sector means that other countries could also be targeted in the future over their pricing policies.

The MFN principle and drug pricing policy

The MFN principle, a founding principle of the multilateral trading system, has traditionally applied to relationships between states. The best-known formulation of MFN

is found in the law of the World Trade Organization (WTO). In short, the MFN principle requires WTO members to grant the best market access conditions provided to one member automatically to all other members. This allows all members to benefit, without further negotiation, from concessions that may have been agreed between trading partners. Such benefits may extend to goods, services and intellectual property rights. There is, to date, no WTO dispute concerning MFN in the field of drug pricing.

In the pharmaceutical sector, the term MFN is being used by the US government to refer to pricing arrangements between governments and pharmaceutical companies rather than obligations between states. Consequently, states are not required to adopt the outcomes of other states’ negotiations with pharmaceutical companies. Decisions about drug prices and the resulting public expenditure instead remain within the exclusive competence of the state concerned.

The Trump administration’s MFN policy is essentially a form of international or external reference pricing, whereby drug prices are linked to prices paid for the same medicines in other countries. This practice is widely used in other high-income countries, including — to a certain extent — in Germany, but has historically played little role in the United States. Where the US MFN policy differs from usual practice, however, is in pegging prices to the lowest price set by a group of reference countries — along with efforts to increase prices in those countries.

In the Executive Order of 12 May 2025, President Donald Trump claims that lower drug prices in other countries contribute to high prices in the United States. According to a study from the RAND Corporation, US prescription drug prices are several times higher than in other high-income economies. Per capita spending on retail pharmaceuticals in the United States is also more than double the OECD average. Two major contributing factors are that both cost-effectiveness evaluations and centralised negotiations with drug companies over

prices are much less common in the United States.

In its drug pricing policy, the Trump administration has interpreted and applied the MFN principle in a way that differs from its framing in WTO law. There are two key problems. First, it is unclear which foreign drug prices are being used to determine baseline MFN prices for patent-protected brand-name medicines and how the resulting MFN prices will be enforced in practice. Furthermore, there remains an open question on whether each country would have a say on how it “binds” a specific commitment on drug pricing, as it does at the WTO. Clearly, neither the United States nor transnational pharmaceutical companies should unilaterally determine what constitutes a “fair” MFN baseline price.

Second, transnational pharmaceutical companies do not dedicate a fixed percentage of their annual revenue to R&D. Yet an MFN principle in this field could only be conceivable if a percentage of the price is directly earmarked for R&D. If a country were to adopt legislation to enforce this, however, it could face legal challenges in domestic courts. Moreover, a legal requirement to earmark revenue for R&D would likely distort investment decisions by private companies across countries because such decisions would no longer be made using a market rationale.

The United States currently enforces MFN pricing domestically as a manufacturer-specific rebate on external tariffs rather than legislation. Thus, manufacturers that sign MFN pricing agreements with the US government secure exemptions from Section 232 duties. According to publicly available information, 26 pharmaceutical companies had joined this pricing scheme, including German ones such as Boehringer Ingelheim and Merck. These MFN pricing agreements, however, do not represent a structural change in pricing practices, as they are manufacturer- and even product-specific. Thus, the Trump administration is currently planning for a so-called Great Healthcare Plan, which would address drug pricing issues more broadly through legislation.

Section 301 of the Trade Act: A tool of offensive external economic policy

Section 301 of the Trade Act of 1974 grants the president of the United States several legal powers that were formerly reserved for Congress. In broad terms, Section 301 allows the United States to adopt unilateral trade measures against third countries engaging in “unfair trade practices”. Before adopting trade measures such as tariffs, import restrictions and suspension of trade concessions against third countries, the USTR must identify and initiate investigations of practices in those countries. The trade measures subsequently imposed under Section 301 are meant to pressure third countries to change their policies, including by withdrawing administrative measures or even amending their national legislation.

Past investigations and trade measures adopted under Section 301 have been used to remove barriers to market access for US goods and services, as well as to strengthen the protection of intellectual property rights. This legal tool has been used to achieve several objectives of US trade policy, including compelling other countries to open markets to US products. Recently, the USTR categorised products from the EU as belonging to economies that do not properly enforce provisions against “forced labour” and, therefore, decided to impose a broad 10 per cent tariff under Section 301. However, where separate tariff rates already apply to the goods concerned, the combined total percentage of additional tariffs must not exceed 10 per cent. Product-specific exceptions apply, including for numerous pharmaceutical products.

The USTR has previously criticised drug pricing policies in other countries. Through its annual Special 301 Reports, the USTR reviews the economic policies of foreign governments that might require further attention due to their possible engagement in “unfair trade practices”, without necessarily triggering a Section 301 investigation. Germany’s mandatory manufacturer rebate

system — through which pharmaceutical manufacturers must grant a rebate on the price of medicines reimbursed by the statutory health insurance funds — was directly criticised in the 2005 Special 301 Report. The 2026 Special 301 Report raises concerns about the drug pricing policies of Australia, Canada, Japan and South Korea. Therefore, while the Section 301 investigation into Germany's drug pricing policies is the first of its kind, those countries are arguably at risk of facing investigations.

The US-UK bilateral agreement on drug pricing

In April 2026, in order to avoid tariffs on its medicine exports to the United States, the United Kingdom reached an agreement in principle with the United States under which the National Health Service (NHS) spends more on prescription drugs. By 2036, the share of UK gross domestic product spent on new medicines is to double, and prices for new medicines are to rise by 25 per cent. Measures to achieve this include raising the cost-effectiveness threshold used by the National Institute for Health and Care Excellence (NICE) — resulting in the NHS subsidising more medicines that are marginally cost-effective in comparison to subsidised drugs. To allow the cost-effectiveness threshold to be changed, UK ministers were for the first time given powers over NICE's drug decision-making processes, which the agency had previously handled independently. This stands in contrast to Germany, where NICE's German counterpart — the Federal Joint Committee — maintains its autonomy as a decision-making body of Germany's self-governing healthcare system.

In several public statements, the USTR and pharmaceutical companies have highlighted the benefits of the bilateral agreement between the United States and the United Kingdom. This agreement, however, has been criticised in light of independent impact assessments. Researchers from the United Kingdom and New Zealand have estimated that the change to the cost-effec-

tiveness threshold could cost £2.6 billion by the end of 2028 and more than £44 billion over the next decade. If these funds are drawn from existing funding for health, the resulting cuts to other NHS services could result in 229,000 excess deaths by 2036.

The legality of the UK-US bilateral agreement has also been challenged. Despite its implications for the healthcare system, this agreement was concluded as a non-binding Memorandum of Understanding and was therefore not subject to scrutiny by the UK Parliament. Moreover, in June 2026, a lawsuit was filed against the UK government by a campaign group seeking the revocation of the legislation that provides ministers with control over NICE's cost-effectiveness threshold. Consequently, although both the US government and the pharmaceutical industry have lauded the US-UK agreement on drug pricing, this model is not transferrable to Germany, nor should it be considered, especially given the country's substantial cuts to healthcare funding currently under way.

Drug pricing and expenditure in other countries under scrutiny

Following the conclusion of the deal between the United States and the United Kingdom on drug pricing, pharmaceutical lobbyists have called for other countries to strike similar deals. In July 2026, the USTR was reported as indicating that the United States was in discussions about drug pricing with France and other countries.

In the context of the US MFN pricing policy, some transnational pharmaceutical companies have objected to the prices offered for their drugs in countries used as comparators. For example, Eli Lilly was involved in a dispute over the proposed price and conditions for subsidising Mounjaro for type 2 diabetes in Australia. The dispute ultimately resulted in the company's withdrawal from negotiations to list Mounjaro on the Pharmaceutical Benefits Scheme (PBS) — the programme through which the government provides subsidised access to medicines in the community — in April

2026. Similarly, the manufacturers of the multiple sclerosis drugs Ocrevus and Kesimpta recently objected to planned price cuts, threatening to withdraw their products from the PBS. Following an outcry from patient groups, the Australian government agreed to maintain the existing prices of the drugs until the end of 2026, pending the results of a rapid review.

The MFN pricing policy appears designed to encourage drug companies to pressure non-US countries to raise prices, including by threatening to withdraw drugs from those markets. Through a lawsuit, the US consumer advocacy organisation Public Citizen obtained heavily redacted copies of MFN pricing agreements with Pfizer and Eli Lilly. According to Public Citizen, Eli Lilly's MFN pricing agreement enables the company to stop supplying the drug from the market in a reference country used in the price calculations and thereby have that country's price excluded from the calculation of the US MFN price. The withdrawal of Amgen's cholesterol-lowering drug Repatha from Denmark in February 2026 was reportedly linked to MFN pricing pressures, and Astellas Pharma secured a higher reimbursement price for its eye drug Izervay in Japan than would have been expected after arguing about MFN pricing in a submission to Japanese officials.

The EU's Anti-Coercion Instrument: A tool of defensive economic policy

As stated in its preamble, the EU's Anti-Coercion Instrument, established by Regulation (EU) 2023/2675, was adopted in 2023 to protect the EU and its member states from economic coercion by third countries to "interfere in [their] legitimate sovereign choices". "Economic coercion", in turn, is understood to occur either when the government of a third country applies a measure, such as tariffs, or, notably, "threatens" to impose it. Thus, the Anti-Coercion Instrument has a wide scope of application that takes into account attempts to use offensive

foreign economic policies even before they are applied. If the EU determines that a third country has applied or threatened to use these tools to interfere with sovereign decision-making anywhere within the EU, the Anti-Coercion Instrument allows the adoption of countermeasures as a defence against such interference.

In response to coercion by third countries, Regulation (EU) 2023/2675 allows the EU to adopt measures restricting trade and investment involving the third country exercising coercion. Examples of these measures include: import and export restrictions; limiting participation by the third country's government or private actors from public procurement through calls for tenders in the EU; restrictions on foreign direct investment from the third country; and restrictions on trade in services. Nevertheless, the EU's Anti-Coercion Instrument is intended to deter coercion, not merely respond to it. Before any of the response measures may be adopted under this instrument, the EU must "enter consultations" with third countries to attempt a diplomatic solution or potentially a third-party adjudication of the disagreement.

So far, the EU Anti-Coercion Instrument has not yet been activated. Therefore, several criteria for its application remain open to interpretation. It is unclear whether the launch of a Section 301 investigation by the USTR, which does not always lead to actionable findings, constitutes a "threat" as understood in Regulation (EU) 2023/2675. Alternatively, it may be that the Section 301 investigation by the USTR, coupled with statements by President Trump and other US officials, offers sufficient grounds to view these actions as interference in Germany's sovereign decisions on pharmaceutical expenditure. Taken together, there are convincing arguments to frame all of these elements as "economic coercion", given the broad definition of this term in the EU's Anti-Coercion Instrument.

Options for Germany, the EU and beyond

Recent reports of talks between German and US officials to explore a bilateral agreement on drug pricing raise multiple questions about the available options. Bilateral agreements in this field carry significant drawbacks. First, they are an inefficient way to address the broader challenge of rising drug prices. The proliferation of bilateral agreements could lead to increasing fragmentation in approaches to “fair drug pricing” within the EU and beyond. Second, the application of an MFN principle as a basis for negotiating bilateral agreements is questionable because it does not readily align with the practices of private transnational companies. Third, the MFN principle does not determine whether prices rise or fall and could therefore be used to raise drug prices both in Germany and, as a result, in the United States if higher prices in one or more comparator countries are used for reference pricing.

Should it consider the bilateral option, Germany should reject any agreement modelled on the one between the United States and the United Kingdom. This is because of both the legal implications for institutions within Germany’s self-governing healthcare system and the detrimental effects of the higher drug prices sought by the United States. Furthermore, such an agreement risks directing public funds towards drugs that are minimally more effective than those already reimbursed – undermining the scientific and economic basis for reimbursement decisions and potentially leaving less funding for other parts of the healthcare system.

Whether or not Germany signs a bilateral agreement with the United States, it should ask the European Commission to examine whether the actions of the United

States constitute “economic coercion” for the purposes of the EU’s Anti-Coercion Instrument. The Commission could be consulted even while the Section 301 investigation by the USTR is ongoing. In addition to the consideration of potential response measures, this could help clarify the applicability of the instrument and pave the way for discussions with other member states on available strategies to defend national decision-making in the field of drug pricing. Furthermore, it could help develop a common strategy to prevent fragmentation and distortions within the EU arising from bilateral agreements with the United States or other third countries. To clarify whether the Anti-Coercion Instrument is applicable in this particular case, it would be useful to examine proposals for its use in other economic sectors. Experts at the think tank Bruegel have pointed out, for instance, that the instrument could be used to respond to US pressure to change EU regulations in the digital sector.

Lastly, Germany should coordinate with other countries that could be targeted under the MFN pricing policy and consider raising this issue at the WHO Fair Pricing Forum. The forum allows countries to exchange experiences on recent developments in drug pricing and expenditure and brings together stakeholders from government, civil society, academia and industry. The Fair Pricing Forum is an appropriate setting for comparing internationally agreed approaches to drug pricing that could provide better alternatives to MFN. At the same time, governments participating in the forum could jointly develop new strategies for dealing with external interference in national drug pricing policy. As signalled by the 2026 Special 301 Report, there is a risk that the USTR could target drug pricing practices in other countries besides Germany.



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ISSN (Print) 1861-1761
ISSN (Online) 2747-5107
DOI: 10.18449/2026C45

(English version of
SWP-Aktuell 51/2026)

Pedro A. Villarreal is a Senior Associate in the SWP Global Issues Research Division and Principal Investigator of the project “The legal determinants of (in)equity during public health emergencies (PANDEQUITY)”, which is funded by the German Research Foundation (DFG), project number 576151394. Luciano Bottini Filho is a Senior Lecturer at the Institute of Law and Social Sciences at Sheffield Hallam University, United Kingdom. Deborah Gleeson is a Professor of Public Health at the School of Psychology and Public Health at La Trobe University in Melbourne, Australia. Olugbenga Olatunji is a Senior Lecturer at the University of Sydney Law School, Australia.