
Comments by the German Chamber of Industry and Commerce (DIHK) on the Section 301 Investigation Relating to Germany's Persistent Underpayment for Innovative Pharmaceutical Products

The German Chamber of Industry and Commerce (DIHK) respectfully submits the following comments in response to the Office of the United States Trade Representative's (USTR) investigation under Section 301 of the Trade Act of 1974 concerning Germany's alleged persistent underpayment for innovative pharmaceutical products.

The DIHK and its members advocate for open markets, fair competition, and an innovation-friendly regulatory environment. It rejects the premise that Germany's pharmaceutical pricing and reimbursement framework constitutes an unreasonable or discriminatory practice that burdens or restricts U.S. commerce within the definitions of Section 301 of the Trade Act of 1974.

This investigation comes amid recent U.S. policy initiatives concerning "Most-Favored-Nation" prescription drug pricing, as well as broader concerns about how the costs of pharmaceutical innovation are distributed internationally. It appears to be based, in part, on the assumption that differences in pharmaceutical prices between countries necessarily imply an unfair distribution of the costs of global pharmaceutical innovation and that lower pharmaceutical prices in Germany may force U.S. patients and consumers to bear a disproportionate share of global research and development costs. The DIHK does not consider price differences alone sufficient to support such a conclusion.

Pharmaceutical innovation is generated within complex public and private ecosystems. It depends not only on medicine prices and reimbursement levels, but also on scientific excellence, public and private research investment, access to talent, clinical research infrastructure, regulatory predictability, intellectual property protection, production capabilities, and cooperation between companies, universities, healthcare providers, and publicly funded research institutions. Assessing a country's contribution to pharmaceutical innovation solely through the lens of pharmaceutical prices would therefore provide an incomplete and misleading picture.

Germany contributes to the global life sciences innovation ecosystem in multiple ways. In addition to private investment by pharmaceutical and life sciences companies, Germany maintains a broad publicly supported research landscape, including universities, university hospitals, publicly funded research institutions, and public research programs. These

institutions underpin pharmaceutical innovation by conducting the basic, translational, and applied biomedical research that provides the scientific foundation for the development of new medicines.

This does not mean that public research funding substitutes for private pharmaceutical research and development or for the costs of late-stage clinical development, regulatory approval, manufacturing scale-up, and market access. However, it does mean that pharmaceutical innovation cannot be attributed exclusively to the level of medicine prices in any one country. Contributions to innovation arise from the interaction of public research systems, private investment, healthcare systems, and international scientific and industrial cooperation. Germany's contribution therefore extends beyond pharmaceutical purchasing and reimbursement and includes investments in research capacity, scientific infrastructure, clinical research, and early patient access to innovative medicines.

Accordingly, differences between U.S. and German pharmaceutical prices primarily reflect structural differences between healthcare systems, financing arrangements, market-access rules, and approaches to healthcare expenditure management. They do not, by themselves, establish that Germany is unfairly shifting the costs of pharmaceutical innovation onto U.S. patients or consumers.

Price levels observed in one market are thus not necessarily directly comparable to those in another, as they may reflect different combinations of list prices, negotiated reimbursement arrangements, statutory discounts, health technology assessment (HTA) and benefit assessment procedures, insurance structures, and payment mechanisms. For this reason, observed price differentials alone provide only a limited basis for conclusions regarding the overall distribution of the costs of pharmaceutical innovation.

The German framework for pharmaceutical pricing and reimbursement applies to all pharmaceutical companies active in the German market, irrespective of nationality, ownership structure, or place of incorporation. It does not establish one set of rules for domestic companies and another for foreign or U.S. companies. German, European, U.S., and other international pharmaceutical manufacturers are subject to the same general statutory and procedural framework.

Pricing and reimbursement for innovative pharmaceutical products in Germany are governed by a framework that combines market entry at the manufacturer's price, early benefit assessment, reimbursement negotiations, and statutory pricing mechanisms. Mandatory price discounts, temporary price-freeze mechanisms, and other cost-related instruments likewise apply equally to all manufacturers, regardless of nationality. This framework is neither designed nor implemented to target U.S. companies, U.S. products, or U.S. commerce.

In this process, Germany should not be characterized as an outlier whose pharmaceutical system is defined by exceptionally low prices. Germany is one of Europe's major pharmaceutical markets and an important early-launch market for innovative medicines.

While the effects of recent legislative changes on future pricing and reimbursement levels have yet to be fully assessed, they do not alter the relevant legal standard. The question remains whether Germany maintains unreasonable or discriminatory practices that burden or restrict U.S. commerce. Based on the considerations set out above, the DIHK does not believe that this standard is met.

Whether individual domestic policy instruments are the most effective or appropriate means of addressing healthcare expenditure is a matter of domestic policy debate. Germany's healthcare expenditure is largely financed through wage-based social insurance contributions. As a result, debates concerning pharmaceutical expenditure take place in the broader context of efforts to limit increases in non-wage labor costs, preserve economic competitiveness, and maintain Germany as an attractive location for pharmaceutical research, development, production, and market access. The DIHK therefore has a strong interest in ensuring predictable and innovation-friendly framework conditions that support continued investment and innovation. At the same time, the DIHK has a strong interest in maintaining competitive labor costs for companies operating in Germany. These are important questions of domestic economic, industrial, and health policy. They do not, however, support the conclusion that Germany's pharmaceutical pricing and reimbursement framework is directed at foreign companies or U.S. commerce, nor should they be conflated with the separate question of whether Germany maintains unreasonable or discriminatory trade practices within the meaning of Section 301.

Germany is one of the largest foreign direct investors in the United States, with \$677 billion held through U.S. subsidiaries. To date 6200 German companies create close to 1 million jobs in the United States. In particular, the transatlantic economic relationship in the pharmaceutical and life sciences sectors is deeply integrated. German companies invest substantially in the United States, including in research and development, production, and high-value employment. Conversely, U.S. companies are active and successful participants in the German and European markets. Both economies benefit from open markets, reliable rules, strong intellectual property protection, scientific cooperation, resilient supply chains, and mutual investment.

Trade-restrictive measures in response to Germany's generally applicable healthcare framework would risk undermining this relationship. Additional duties or other trade measures would not address the structural differences between the U.S. and German healthcare systems that underlie pharmaceutical pricing and reimbursement decisions. Nor would such measures address the broader factors that drive pharmaceutical innovation, including public and private research investment, scientific infrastructure, clinical research capacity, and market-access conditions. Instead, they could increase costs for companies and consumers across a wide range of industries, disrupt transatlantic supply chains, and weaken investment and innovation on both sides of the Atlantic.

In conclusion, Germany does not maintain unreasonable or discriminatory acts, policies, or practices that burden or restrict U.S. commerce within the meaning of Section 301. The fact that pharmaceutical prices and reimbursement levels differ between healthcare systems does not, by itself, demonstrate unfair cost-shifting of global pharmaceutical research and development. Pharmaceutical innovation is supported by complex public and private ecosystems, to which Germany contributes through market access, industrial activity, public research infrastructure, and transatlantic investment.

The DIHK encourages continued dialogue between the United States, Germany, industry stakeholders, and healthcare policymakers. Given the complexity of pharmaceutical innovation, healthcare financing, and global supply chains, cooperative approaches are more likely to strengthen innovation and patient access than trade-related measures.

Accordingly:

- No action should be taken against Germany under this investigation; and
- No additional duties or import restrictions should be imposed on goods of German origin.

The DIHK encourages continued cooperation to strengthen transatlantic supply chains and mutually beneficial investment, particularly through the mutual reduction of trade barriers, including tariffs.

Who we are:

The 79 Chambers of Commerce and Industry (IHKs) are incorporated under the umbrella of the German Chamber of Commerce and Industry (DIHK). Our joint aim: to obtain the best conditions for successful business.

The DIHK represents the interests of the entire commercial economy in dealings with decision makers, administrations and the public at federal and European level. Several million companies representing trade, industry and services are legal members of an IHK, ranging from kiosk owners to DAX companies. DIHK and IHKs therefore provide a platform for a whole range of corporate concerns. We group them together in an organised procedure on a statutory basis to formulate the general interest of the commercial economy and thus contribute to the formation of opinions in economic policy.

Our statements are based on economic policy positions and position papers adopted by the DIHK taking into account the comments received by the DIHK from IHKs and their member companies prior to the submission of the statement.

The DIHK also coordinates the network of 150 German Chambers of Commerce Abroad, delegations and representative offices of the German economy in 93 countries, including five offices in the United States.