

## TRADE AND DISTRIBUTION OF THERAPEUTIC PRODUCTS (PHARMACEUTICALS/BIOLOGICS AND MEDICAL DEVICES)

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### REGULATORY FRAMEWORK AND COMPETENT AUTHORITIES

**1. What are the principal statutes, regulations, and competent authorities that govern the import, wholesale distribution, retail sale, and export of therapeutic products (ie, for pharmaceuticals/biologics and medical devices, noting any separate or overlapping regimes)? In the case of a federal state, what is the division of powers between the federal government and the states?**

In Germany, medicinal products are primarily regulated under the Medicinal Products Act (AMG).<sup>1</sup> The AMG regulates the distribution, authorisation and manufacturing of medicinal products and sets out requirements regarding quality, efficacy and vigilance. An import of medicinal products from outside the EU/EEA generally requires an import authorisation under section 72, AMG.

This AMG is complemented by specific ordinances, such as the AMWHV and the AM-HandelsV.<sup>2</sup> The AMWHV implements the principles of EU Good Manufacturing Practice (GMP), whereas the AM-HandelsV incorporates the EU Good Distribution Practice (GDP) guidelines.

The Federal Institute for Drugs and Medical Devices (BfArM) is the central federal authority responsible for the marketing authorisation of most medicinal products, while the Paul-Ehrlich-Institut (PEI) is the competent federal authority for specific biologics, including vaccines and blood products. The competent authorities of the federal states (Länder) are responsible for the execution of the federal laws, including granting licences for manufacturing (s 13, AMG), import (s 72, AMG) and wholesale distribution (s 52a AMG), as well as licensing and supervising of public retail pharmacies under the Pharmacy Act (ApoG).<sup>3</sup>

Medical devices are primarily regulated by directly applicable EU law. These are the EU Regulation 2017/745 on medical devices (MDR), and the EU Regulation 2017/746 on in vitro diagnostic medical devices (IVDR).<sup>4</sup> In vitro diagnostics (IVDs) are subject to specific performance evaluation and conformity assessment procedures due to their unique risk profile,

<sup>1</sup> German Federal Ministry of Justice and Consumer Protection, 'Act on the Circulation of Medicinal Products', [www.gesetze-im-internet.de/amg\\_1976](http://www.gesetze-im-internet.de/amg_1976) accessed 18 May 2026.

<sup>2</sup> German Federal Ministry of Justice and Consumer Protection, 'Regulation on the application of Good Manufacturing Practice in the manufacture of medicinal products and active pharmaceutical ingredients and on the application of Good Professional Practice in the manufacture of products of human origin', [www.gesetze-im-internet.de/amwhv/](http://www.gesetze-im-internet.de/amwhv/); 'Ordinance on Wholesale Trade and Drug Brokerage', [www.gesetze-im-internet.de/amgrhdlbetrv/](http://www.gesetze-im-internet.de/amgrhdlbetrv/) accessed 18 May 2026.

<sup>3</sup> German Federal Ministry of Justice and Consumer Protection, 'Law on Pharmacy Affairs', [www.gesetze-im-internet.de/apog](http://www.gesetze-im-internet.de/apog) accessed 18 May 2026.

<sup>4</sup> EU Document 32017R0745, <https://eur-lex.europa.eu/eli/reg/2017/745/oj/eng>; Document 32017R0746 <https://eur-lex.europa.eu/eli/reg/2017/746/oj/eng> accessed 18 May 2026.

which focuses on the impact of diagnostic information rather than their direct physical interaction with the patient.

EU law is supplemented nationally by the Medical Devices Law Implementation Act (MPDG) which sets national procedures, vigilance and sanctions as well as the Medical Device Operator Ordinance (MPBetreibV).<sup>5</sup> The MDR/IVDR is administered through Notified Bodies.

BfArM is the competent federal authority for medical devices under the MPDG for market surveillance, special approvals and the management of the German Medical Devices Information and Database System (DMIDS) database interface.

The Central Office of the Federal States for Health Protection in Medicines and Medical Devices (ZLG) coordinates the supervision of the Notified Bodies. Direct market surveillance and on-site inspections of economic operators fall within the responsibility of the authorities of the federal states.

**2. How are therapeutic products classified for regulatory purposes (eg, prescription-only, over-the-counter, hospital-use, risk classes for devices, etc.) and what legal consequences attach to each classification with respect to trade and distribution? In particular, is premarket review and approval required by a competent authority?**

Medicinal products are classified as prescription-only (Rx), pharmacy-only or over-the-counter (OTC) medicinal products. The classification is determined by respective ordinances on the basis of the AMG, in particular the Ordinance on Prescription Drugs (AMVV) and the Ordinance on Pharmacy-and Over-the-Counter Medicinal Products (AMVerkRV).

In Germany, prescription and most other medicinal products may only be dispensed by licensed pharmacies (s 43, AMG).

Narcotics (BtM) are subject to stricter controls under the National Narcotics Act (BtMG) and must be prescribed using specific forms pursuant to the Regulations on the Prescription of Narcotics (BtMVV).<sup>6</sup> Special regimes also apply to the registration of homeopathics (ss 38 and 39, AMG) and traditional herbal medicinal products (s 39a–d, AMG).

All medicinal products generally require a respective marketing authorisation, unless exemptions exist at EU or national level.

Medical devices are risk-classified (Classes I, IIa, IIb, and III) based on their risk potential pursuant to Annex VIII of Regulation (EU) 2017/745 (MDR). Class I (low risk) generally allows for self-certification by the manufacturer. Classes IIa (medium risk), IIb (high risk), and III (very high risk), however, require the mandatory involvement of a notified body for a conformity

<sup>5</sup> German Federal Ministry of Justice and Consumer Protection, 'Act on the Implementation of Union Law Provisions on Medical Devices', [www.gesetze-im-internet.de/mpdg](http://www.gesetze-im-internet.de/mpdg); 'Regulation on the operation and use of medical devices (Medical Devices Operator Regulation - MPBetreibV)' [www.gesetze-im-internet.de/mpbetreibv\\_2025/BJNR0260B0025.html](http://www.gesetze-im-internet.de/mpbetreibv_2025/BJNR0260B0025.html) accessed 18 May 2026.

<sup>6</sup> German Federal Ministry of Justice and Consumer Protection, 'Act on the Traffic in Narcotics', [www.gesetze-im-internet.de/btmg\\_1981](http://www.gesetze-im-internet.de/btmg_1981); 'Regulation on the Prescribing, Dispensing and Documentation of the Whereabouts of Narcotics (Narcotics Prescription Regulation – BtMVV)' [www.gesetze-im-internet.de/btmv\\_1998/BJNR008000998.html](http://www.gesetze-im-internet.de/btmv_1998/BJNR008000998.html) accessed 18 May 2026.

assessment (Art 52, MDR). In vitro diagnostic medical devices are categorised within classes A, B, C and D in accordance with Annex VIII of the IVDR. Class D represents the highest risk class.

Unlike medicinal products, medical devices do not undergo a state-run premarket approval process. Instead, they must carry a CE marking to demonstrate compliance with safety and performance standards before being placed on the market (Art 20, MDR).

## LICENSING, AUTHORISATIONS, AND DISTRIBUTION CHANNELS

### **3. Which licences, authorisations, registrations, or other official permissions are required for businesses to engage in wholesale distribution of therapeutic products, and what key conditions (such as Good Distribution Practice, facility standards, personnel, insurance, or financial guarantees) attach to them?**

Any wholesale activities related to medicinal products generally require a wholesale distribution licence under section 52a, AMG. The competent authorities of the federal state in which the place of the wholesale business is located grant the respective licence if the applicant specifies the premises, activities, and medicinal products involved, and provides evidence of suitable and sufficient facilities and equipment to ensure proper storage and distribution. Key conditions include the appointment of a responsible person with sufficient expert knowledge. Moreover, the business is legally required to comply with the rules governing proper wholesale operations, specifically the principles of Good Distribution Practice (GDP). The licence may be refused if the applicant or the responsible person lacks the necessary reliability (s 52a, para 3, AMG).

No specific licence requirement exists for the wholesale of medical devices. Importers and distributors of medical devices must, however, comply with the economic operator regime, including verification of conformity and CE-marking, appropriate storage and transport, and recordkeeping in accordance with the MDR (Arts 13-14, MDR).

### **4. Are there distinct licensing or notification requirements for businesses that provide therapeutic products directly to consumers (including community pharmacies, internet pharmacies, or other retailers), and what key conditions attach to them?**

In Germany, most medicinal products may only be to costumers dispensed by licensed pharmacies. The licence requirements are set out the Pharmacy Act (ApoG). Under ApoG, a licence for pharmacies located in Germany is granted to pharmacists as natural persons only; third-party ownership is not allowed. The Ordinance on the Operation of Pharmacies (ApoBetrO) sets out detailed requirements as to the pharmacy premises and the operation of the respective pharmacy.<sup>7</sup>

In Germany, if a pharmacy conducts mail-order trading of medicinal products, a specific mail-order trading licence is required in addition to the general pharmacy licence (s 11a, ApoG). The mail-order trading of medicinal products is generally allowed both for prescription and non-prescription medicinal products (s 43, AMG). Germany is one of the few EU countries, in which mail-order trading of prescription medicinal products is permitted.

<sup>7</sup> German Federal Ministry of Justice and Consumer Protection, 'Ordinance on the Operation of Pharmacies (Pharmacy Operating Regulations – ApBetrO)', [www.gesetze-im-internet.de/apobetro\\_1987/BJNR005470987.html](http://www.gesetze-im-internet.de/apobetro_1987/BJNR005470987.html); accessed 18 May 2026.

Pharmacies located in other EU countries may dispense medicinal products to customers located in Germany by way of mail-order trading under section 73, paragraph 1a, AMG, provided that: (1) the respective EU pharmacy is licensed to mail-order trading under its national law; and (2) the respective provisions under the applicable national law comply with German standards on mail-order trading. In 2011, the Federal Ministry of Health (BMG) issued a list of EU countries from which EU pharmacies are eligible to dispense medicinal products to customers in Germany, under certain conditions (Länderliste). The list includes the Czech Republic, Iceland, the Netherlands, Sweden, and the UK (the latter shows that the list is now outdated).

For medical devices, no pharmacy privilege exists. The dispense of medical devices to customers is not explicitly reserved by law to specific providers. However, given the regulatory requirements under the MDR, medical devices that are not specifically determined for lay use are generally dispensed by pharmacies, medical supply stores and physicians as part of the respective treatment.

#### **5. What rules govern the sale of therapeutic products to consumers over the internet (including social-media and marketplace platforms)?**

In addition to the requirements for mail-order pharmacies in section 11a, ApoG, specific conditions for internet sales are set out in section 67, paragraph 8 AMG. Any party intending to offer medicinal products for retail sale via the internet must notify the competent authority before commencing such activities, providing: the name or company, the delivery address, and the identification details of all used internet portals. The internet portal must display the contact details of the competent authority, the common EU mail-order logo, and a functional link to the portal of the Federal Institute for Drugs and Medical Devices (BfArM) to ensure authenticity.

For medical devices, any online offer to EU users triggers EU conformity, labelling, and operator duties (Art 6, 7 MDR). Pursuant to Article 6, paragraph 3 MDR, any natural or legal entity offering medical devices through distance sales must provide a copy of the EU declaration of conformity for the product in question at the request of a competent authority.

### **IMPORT**

#### **6. What is the import-control framework for therapeutic products (eg, import licences, product registration or listing prerequisites, customs classification, tariff rates, national or regional exemptions, and routine or risk-based border inspections)?**

The import of medicinal products from outside the EU generally requires an import licence (s 72 AMG) and a certificate confirming compliance with GMP standards (Good Manufacturing Practice; s 72a AMG). Generally, medicinal products may only be imported if they are authorised or registered in Germany (s 73 AMG). The Federal Ministry of Finance and the designated customs offices are responsible for monitoring the movement of medicinal products (s 74, para 1 AMG).

The import of medical devices is regulated under EU law. For medical devices, no specific import licence is required under the MDR (Medical Device Regulation (EU) 2017/745), but importers must ensure product conformity, correct labelling, and that they fulfil registration and economic operator duties (Art 13 MDR).

<p><b>7. To what extent may consumers import therapeutic products for personal use (whether by taking the products across the border or receiving them by mail), and what quantitative limits, prescription requirements, customs declarations, duties, or other restrictions apply?</b></p>
<p>For medicinal products, the requirement for an import licence under section 73 AMG only applies to commercial importers and not to individuals. Therefore, consumers do not require a specific import licence. Furthermore, according to section 73, paragraph 1, sentence 1, no. 6 and 7 AMG, the general transfer ban does not apply to medicinal products brought into the country in a quantity corresponding to usual personal need. The customs administration defines ‘usual personal need’ as a quantity required for up to three months, considering the recommended dosage of the respective drug.</p> <p>For medical devices, there are no specific consumer import regulations. The obligations for importers under Article 13 MDR do not apply to consumers, as Article 2, no. 33 MDR defines an ‘importer’ as any natural or legal person established within the EU that places a device from a third country on the EU market. Consequently, these duties do not apply to individuals who import medical devices solely for their own personal use.</p>
<p><b>8. May foreign suppliers ship therapeutic products directly to consumers via e-commerce or mail order, and what local presence, platform registration, verification, or labelling obligations – if any – must they satisfy?</b></p>
<p>Medicinal products may only be shipped directly to consumers in Germany by EU/EEA pharmacies from countries that fulfil the requirements of the ‘country list’, see response to Question 4, above.</p> <p>No specific regulations regarding direct shipping to consumers exist for medical devices. Therefore, direct shipment is generally permitted, provided the products themselves comply with the requirements of Regulation (EU) 2017/745 (MDR).</p>
<p><b>9. How is parallel importation (ie, of products licensed and sold in other jurisdictions) of therapeutic products by businesses regulated, particularly with respect to intellectual property rights, product re-labelling or re-packaging, and requirements to maintain original quality, safety, and traceability?</b></p>
<p>Parallel importation of therapeutic products is permitted in Germany but strictly regulated to ensure patient safety. For medicinal products, according to section 21 in conjunction with section 73 AMG, products must be authorised in Germany to be marketable. Parallel imported medicines undergo a ‘simplified authorisation procedure’ provided they are regularly authorised in their EU/EEA country of origin and are essentially identical to a reference product already authorised in Germany.</p> <p>In addition, parallel importers must meet the following requirements: they may only store medicinal products, label them in German; and, where necessary, repackage them in new outer packaging if they hold a manufacturing authorisation (s 13 AMG). Furthermore, they must</p>

appoint a pharmaceutical programme coordinator (s 63a AMG) and an information officer (s 74a AMG), who monitor drug risks and ensure that labels and package leaflets comply with the authorisation.

Medical devices may also be traded in parallel, provided that they have already been placed on the market in another EU/EEA country. The products must comply with safety standards and bear a CE mark. Repackaging and relabelling for the German market is generally permitted without constituting a trademark infringement, provided that the original quality is maintained.

## EXPORT

### **10. Are there quantitative quotas, permits, or other measures that restrict or condition the export of therapeutic products (eg, to mitigate shortages or address public health emergencies), and how are such measures administered and enforced?**

The export of medicinal products from Germany outside the EU/EEA is generally permitted provided the products comply with the provisions of the AMG and do not constitute prohibited products such as counterfeit or unsafe products. A Certificate of Pharmaceutical Product (CPP) is often required to certify that the product is eligible for marketing in Germany.

No routine export quotas exist. However, the competent federal authority is entitled to prevent or mitigate supply shortages of medicinal products under section 52b AMG to take ‘appropriate measures’, including potential export bans. The process is managed by BfArM which relies on a specialised Advisory Board of stakeholders to monitor the market continuously. BfArM publishes lists of supply-critical substances and reported shortages on its website (s 52b, para 3c AMG).

There are no specific German laws regarding export restrictions regarding devices. However, during public health emergencies, the federal government may impose temporary export restrictions or quotas for critical equipment under the general rules of the Foreign Trade Act (AWG).<sup>8</sup>

### **11. Is there any form of ‘export-only’ or ‘dual-labelling’ authorisation that permits the manufacture and export of therapeutic products not approved for domestic marketing, and if so, what standards, labelling, or record-keeping obligations apply?**

There are no specific ‘export-only’ or ‘dual-labelling’ authorisations for medicinal products or medical devices in Germany.

The manufacture of medicinal products not approved for domestic marketing requires a respective manufacturing authorisation pursuant to section 13 AMG.

According to section 73a, paragraph 1 AMG, medicinal products which would otherwise be prohibited in Germany under section 5 (questionable products) or section 8, paragraphs 1 and 2 AMG (eg, quality defects or misleading labelling) may be exported if the competent authority of the destination country has authorised the import. This authorisation must confirm that the

<sup>8</sup> German Federal Ministry of Justice and Consumer Protection, ‘Foreign Trade Act’, [www.gesetze-im-internet.de/awg\\_2013](http://www.gesetze-im-internet.de/awg_2013); accessed 18 May 2026.

foreign authority is aware of the specific reasons preventing the product from being placed on the German market.

There is no separate export-only regulation for medical devices. Products manufactured solely for export to non-EU/EEA countries do not require CE marking or German labelling, provided they are not placed on the EU market. Manufacturers may obtain Certificates of Free Sale to facilitate export, and they remain subject to general quality management and record-keeping obligations to ensure quality and traceability.

## **LABELLING, TRACEABILITY, AND PRODUCT INFORMATION**

### **12. What local language labelling, patient information, unique device identification, serialisation, anti-counterfeiting, or traceability requirements must be met before imported therapeutic products may circulate domestically or before therapeutic products may be exported?**

Packaging of finished medicinal products must bear detailed information in German and in clearly legible writing (s 10 AMG). Furthermore, products must include a German-language patient information leaflet covering identification, usage, risks, and composition (s 11, para 1 AMG). To ensure authenticity and traceability, packaging must also contain specific safety features, such as a 2D Data Matrix code and an anti-tampering device, in accordance with EU law (s 10, para 1c AMG).

Medical devices must be provided with user information, including labelling and instructions for use, in German (s 8, para 1 MPDG) and must bear the CE marking to demonstrate compliance with safety and performance standards. To ensure traceability, each device must carry a Unique Device Identification (UDI) pursuant to Article 27 MDR, consisting of a device identifier (UDI-DI) specific to the manufacturer and the product, and a production identifier (UDI-PI) identifying the production unit and relevant manufacturing data.

## **PRICING, REIMBURSEMENT, AND MARKET ACCESS**

### **13. Are there any price-control, reimbursement, public procurement, or stock/supply-obligation regimes that (while not trade measures per se) materially influence the distribution channels or availability of therapeutic products?**

Uniform pharmacy retail prices exist for prescription medicinal products dispensed by German pharmacies. Section 78 AMG and Regulation on the Pricing of Medicinal Products (AMPreisV) provide that the manufacture may freely determine the manufacturer's sales price to which fixed wholesale and pharmacy margins are added in order to ensure a uniform retail price. In 2016, the European Court of Justice (ECJ) held that the former provision in section 78, paragraph 1, sentence 4 AMG under which EU pharmacies were also bound to the fixed pricing regime when dispensing prescription medicines to German customers by way of mail-order trading violated the free movement of goods (Art 34 Treaty on the Functioning of the European Union (TFEU), case C-148/15). As a reaction to this ruling, the German legislator lifted the former provision and introduced a new provision in section 129, paragraph 3 Fifth Book of the Social Code (SGB V), under which EU pharmacies are bound to the fixed pricing regime only when dispensing prescription drugs to statutory health insurance patients. The new legislation is currently being challenged before the courts.

No uniform sales prices exist for non-prescription medicinal products, and price competition is permitted.

In addition, various measures of reimbursement regulation – such as price caps (Festbeträge) for specific clusters of products; statutory discount obligations (Herstellerabschläge); and rebate contracts (Rabattverträge) – exist for medicinal products that are dispensed to statutory health insurance patients, who account for more than 90 per cent of the German population.

The Federal Joint Committee (G-BA) conducts an early benefit assessment on market entry for newly authorised medicinal products with new active substances. This is to determine the ‘added benefit’ over a standard comparative therapy (s 35a SGB V). The result of the early benefit assessments serves as the basis for reimbursement price negotiations between the pharmaceutical company and the statutory health insurance companies. If no agreement is reached, the reimbursement price is determined by an arbitrary body. This price regulation scheme for new drugs is referred to as ‘AMNOG framework’, named after the respective AMNOG law which entered into force in 2011.

Medical devices and aids must be included in the Medical Aids Directory (Hilfsmittelverzeichnis) to be eligible for reimbursement in the statutory health insurance. The National Association of Health Insurance Funds (GKV-Spitzenverband) administers the respective list, which defines specific quality, safety, and functional requirements for each product group (s 139, para 2 SGB V).

## **ENFORCEMENT, COMPLIANCE, AND RECENT DEVELOPMENTS**

### **14. What investigative powers, sanctions, and remedial measures (administrative, civil, or criminal) are available to regulators when they detect non-compliance with trade and distribution rules for therapeutic products, and how are these powers used in practice?**

Market surveillance in Germany is divided between federal and regional authorities. The federal authorities (BfArM and PEI) are responsible for scientific risk assessment (s 82 MPDG) and marketing authorisations (s 77 AMG); while the regional authorities of the federal states (Landesbehörden) conduct operational supervision and on-site inspections for medicinal products (s 64 AMG) and medical devices (s 77 MPDG).

The competent federal authorities may impose various administrative and remedial measures based on the general clause of section 69 AMG when non-compliance with medicinal products is identified. These include banning products from being placed on the market or ordering mandatory recalls. To avert urgent dangers to public safety, the authorities are also empowered to issue provisional orders, including the immediate closure of facilities or institutions (see s 64, para 4, no. 4 AMG). Furthermore, regulators have extensive investigative powers, enabling them to inspect business premises, take samples and examine all commercial documentation (s 64 AMG). Entities subject to regulation are legally required to tolerate these measures and provide the necessary information (s 66 AMG). Criminal sanctions and administrative fines are determined in section 95 *et seq* AMG.

In the field of medical devices, competent authorities may impose various administrative and remedial measures under section 78 MPDG to eliminate non-compliance and prevent future

violations. These include banning or restricting the placing on the market, the commissioning, or the actual use of a product. Authorities are specifically empowered to order product withdrawals, recalls, or seizures and can ban or restrict clinical trials. To avert imminent danger to public health, safety, or order, they may also issue provisional orders, such as the immediate closure of a facility. Furthermore, under section 82, para 1 MPDG, preventive health protection measures may be taken to prohibit or restrict the availability of products even in cases of potential or suspected risks. Criminal sanctions and administrative fines for non-compliance are determined in section 92 *et seq* MPDG.

**15. Is there recent case law, legislative or policy developments, noteworthy enforcement trends, or anticipated reforms that may significantly alter the regulation of trade, distribution, or cross-border movement of therapeutic products in the future?**

The current coalition government has initiated the ‘Pharmaceutical Dialogue’, a strategic initiative aimed at strengthening the industrial healthcare and life sciences sector in Germany. Its aims are to consolidate the pharmaceutical industry and medical technology as a key economic sector and make Germany a more attractive location for research and production. Six working groups are addressing issues of supply, innovation, digitalisation and reimbursement. The findings are to be incorporated into a national pharmaceutical and medical technology strategy for 2026.

In 2025, the Federal Constitutional Court (BVerfG) dismissed two constitutional complaints of several pharmaceutical companies against new price regulation measures that had been introduced in 2022 by the Statutory Health Insurance Financial Stabilisation Act (GKV-FinStG). The BVerfG considered these measures, including increased manufacturer discounts and a price moratorium, constitutional and adequate in order to safeguard the financial stability of the statutory health insurance system. The ruling confirms a very wide discretion of the legislator with respect to price regulation measures. The pharmaceutical industry fears that this decision will weaken Germany’s position as a pharmaceutical hub, which would be contrary to the aims of the Pharmaceutical Dialogue.