

TRADE AND DISTRIBUTION OF THERAPEUTIC PRODUCTS (PHARMACEUTICALS/BIOLOGICS AND MEDICAL DEVICES)
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REGULATORY FRAMEWORK AND COMPETENT AUTHORITIES
<p>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?</p>
<p>In Austria therapeutic products are regulated under the Austrian Medicinal Products Act (<i>Arzneimittelgesetz – AMG</i>) and the Austrian Medicinal Products Import Act (<i>Arzneiwareneinfuhrgesetz – AWEG</i>). These are supplemented by ordinances on good manufacturing and distribution practice (eg, the <i>Arzneimittelbetriebsordnung – AMBO</i>), pharmacovigilance, advertising and pharmacy operations. Medical devices and in vitro diagnostics are governed primarily by the EU Medical Devices Regulation (MDR) and IVD Regulation (IVDR), supplemented at the national level by the Austrian Medical Devices Act 2021 (<i>Medizinproduktegesetz – MPG</i>) and national implementing ordinances, together with the Austrian Trade Act (<i>Gewerbeordnung 1994 – GewO</i>).</p> <p>Austria has a federal government and nine state governments, but regulation of therapeutic products is almost entirely federal. Licensing, import/export control and market surveillance are exercised by the Federal Office for Safety in Health Care (<i>Bundesamt für Sicherheit im Gesundheitswesen – BASG</i>) and the Federal Ministries. Austrian state governments have only limited roles, mainly in supervision of pharmacies and local inspections and do not operate independent regulatory regimes.</p> <p>Import, wholesale and export of medicinal products require an authorisation from BASG under the AMG and AWEG, with additional permits required for narcotics and psychotropic substances. Imports from third countries are subject to specific authorisation under the AWEG and batch-release requirements, while intra-EEA movements follow EU law. Wholesale distribution is governed by AMG and AMBO according to which retail supply of most medicines is restricted to public and hospital pharmacies licensed under Austrian pharmacy law.</p> <p>For medical devices and IVDs, importers and distributors must comply with MDR/IVDR obligations (economic operator registration, traceability, vigilance) and national registration duties under the MPG. Export to third countries may require BASG certificates of free sale.</p>
<p>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?</p>
<p>In Austria, medicinal products for human use are classified under the AMG into prescription-only, pharmacy-only (non-prescription) and general-sale OTC products. In addition, certain</p>

medicines are restricted to hospital use or specialist administration (eg, many biologics, injectables and oncology products).

Classification is determined as part of the marketing authorisation procedure or by regulatory designation by BASG. The prescription status directly determines the distribution channel: prescription-only medicines may only be dispensed by pharmacies against a prescription of a physician, while pharmacy-only OTC medicines may be sold without prescription but still only through licensed pharmacies. Products classified for hospital use may be supplied only to healthcare institutions and not to the retail pharmacy market.

With limited exceptions BASG or European Medicines Agency (EMA) authorisation is mandatory before a medicinal product may be placed on the Austrian market. Centrally authorised EU products are valid in Austria without national re-approval, while only nationally authorised products require BASG approval under the AMG. This authorisation also defines the approved indications, prescription status, pack sizes and distribution restrictions.

Medical devices and in vitro diagnostic devices are classified according to MDR and IVDR risk classes, based on the intended purpose and potential risk to patients and users. The higher the risk class, the more stringent the conformity assessment, involving a notified body for all but the lowest-risk devices. Unlike medicines, medical devices are not subject to a central pre-market marketing authorisation by BASG; instead, they must undergo conformity assessment and bear a CE mark before being placed on the Austrian/EU market.

Risk classification directly affects who may import, distribute and use a medical device. Higher-risk devices are subject to stricter traceability, post-market surveillance and vigilance and, in practice, are often restricted to professional or hospital supply channels.

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?

In Austria, wholesale distribution of medicinal products requires a wholesale distribution authorisation (*Großhandelsbewilligung*) issued by BASG. The authorisation is required for any entity that procures, stores, supplies or brokers medicines, including virtual wholesalers and logistics providers acting on behalf of marketing authorisation holders. Applicants must demonstrate compliance with EU Good Distribution Practice (GDP) and AMBO, including qualified responsible persons, validated quality systems, temperature-controlled and secure premises, traceability procedures, recall capabilities and protection against falsified medicines. Appropriate insurance coverage and financial reliability must also be demonstrated.

Companies importing medicines from third countries must also hold an AWEI import authorisation, and for certain products (eg narcotics, psychotropics, blood products) additional authorisations are required. Export of medicinal products to non-EEA countries is subject to BASG certification, such as Certificates of Pharmaceutical Product or export attestations.

In addition to pharmaceutical authorisations, wholesale and commercial distribution of therapeutic products in Austria requires a trade licence under the GewO.

No wholesale licence comparable to the AMG regime exists for medical devices and in vitro diagnostics. Instead, wholesalers qualify as distributors or importers under the EU framework and must comply with their statutory obligations, including registration in the MPG, verification of

CE marking and declarations of conformity, traceability and Unique Device Identification (UDI) record-keeping, complaint handling and vigilance reporting. Commercial distribution activities may also require a trade licence under the GewO. Storage and transport conditions must preserve device conformity and safety, and written quality procedures must be in place.

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?

The retail supply of medicinal products is governed by the AMG together with the Austrian Pharmacies Act (*Apothekengesetz – ApoG*) and related ordinances. Prescription-only and most non-prescription medicines may only be dispensed by licensed public pharmacies or hospital pharmacies. Pharmacies require a concession issued by the competent provincial authority, subject to requirements on qualified pharmacists, premises, storage conditions, quality systems, opening hours and professional supervision. Pharmacies are also subject to regular inspections by the authorities and by the regional chambers of pharmacists.

Mail-order and internet pharmacies are only permitted under tightly controlled conditions. Only EU-licensed pharmacies may sell medicines online and only non-prescription medicines may be supplied by distance selling – online sales or by mail order. The pharmacy must notify and register its online activity with BASG. Cross-border internet sales of medicines to Austrian consumers are therefore generally restricted and subject to EU and national controls.

A small category of general-sale OTC medicines may be sold outside pharmacies (eg, in drugstores), but only if they are specifically classified for this channel and subject to retail trade licensing and supervision.

For medical devices and in vitro diagnostics, retail sale to consumers is not limited to pharmacies. Devices may be supplied by pharmacies, medical supply stores, opticians, hearing aid providers and other licensed retailers, depending on the type of product. Retailers qualify as distributors under the MDR/IVDR and must comply with registration, traceability, complaint handling and vigilance obligations. A trade licence under the GewO is generally required.

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

For medicinal products, internet and mail-order sales are highly restricted. Only EU-licensed pharmacies may offer medicines for sale online. Prescription-only medicines may not be supplied by distance selling and must be dispensed in person at a pharmacy against a valid prescription. Non-prescription (pharmacy-only) medicines may be sold online, but only by an authorised EU pharmacy that has notified BASG of its internet activity and is entered in the national and EU register of legal online pharmacies.

The pharmacy must display the EU common logo, provide full contact details, ensure pharmaceutical counselling and comply with GDP-equivalent storage, transport and pharmacovigilance obligations.

Cross-border online sales to Austrian consumers are only permitted from EU-registered internet pharmacies which comply with their home-state law and EU distance-selling rules; sales from third-country websites are prohibited. Advertising and promotion of prescription medicines to the public, including via the internet and social media, is prohibited and all online advertising of non-prescription medicines is subject to the AMG's advertising rules.

For medical devices and in vitro diagnostics, online sales via web shops, social-media channels or online marketplaces are permitted in principle, but the seller qualifies as a distributor or importer under MDR/IVDR and must be registered with BASG, verify CE marking and conformity, ensure traceability and complaint handling and meet vigilance reporting obligations. Online marketplaces which facilitate device sales may also bear regulatory responsibility if they present themselves as sellers or control key aspects of the supply chain.

Digital marketing and online sales are further subject to EU consumer law, Austrian e-commerce law and product-safety and advertising rules, including obligations on clear product information, transparency and withdrawal rights.

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)?

In general, medicinal products must be authorised for the Austrian or EU market before they may be imported for commercial use. Limited exemptions exist for named-patient supply, clinical trials and compassionate use, but these are subject to prior regulatory approval. Customs classification and tariff treatment follow the EU Combined Nomenclature; most medicines benefit from zero or reduced customs duty within the EU, but VAT and import formalities still apply.

Centrally authorised EU products may circulate freely within the EEA, whereas third-country imports are subject to regulatory controls, testing and certification. Therefore, the import of medicinal products from third countries requires an AWEG import authorisation held by the importer, which must be an EU/EEA-established entity, such as a licensed wholesaler, pharmacy or manufacturer. Furthermore, third-country medicinal products must comply with EU GMP regulations and must be certified by a qualified person before they can be released for the EU market. For certain categories, for example, vaccines, blood products, plasma-derived products and some biologicals, additional official batch release or prior notification to BASG is required. Narcotics, psychotropic substances and precursors require additional authorisations by the Minister of Health in accordance with the Regulation (EU) No 111/2005.

There is no product-specific import licence for medical devices and in vitro diagnostics. Instead, the EU-based importer must be registered under MDR/IVDR and with BASG and must ensure that the device bears a valid CE mark, is correctly labelled and is accompanied by a declaration of conformity and UDI information. Devices may only be imported after they have been lawfully placed on the EU market.

Border controls are risk-based. Customs may detain shipments of medicines or devices and refer them to BASG for regulatory verification, including checks on authorisation status, CE marking, falsified-medicine safeguards and documentation. BASG may order laboratory testing, quarantine, rejection or destruction of non-compliant or unsafe products.

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?

For medicinal products, private individuals may not generally import medicines by post or courier from abroad. Mail-order imports from non-EU/EEA countries are banned, and even

imports from other EU Member States are only allowed in narrow circumstances. A limited exception applies where a medicine is lawfully marketed in another EU/EEA country, is for an individual's personal therapeutic use, and is supplied by a legally authorised pharmacy in that country.

When travelling, individuals may bring medicines with them for personal use, provided they are in reasonable quantities corresponding to the duration of treatment. For prescription medicines, travellers should carry a valid prescription or doctor's certificate. Narcotic drugs and psychotropic substances are subject to much stricter rules: only limited quantities for personal medical use may be carried, typically supported by a Schengen medical certificate and import by post is not permitted.

All medicinal products entering Austria from outside the EU must be declared to customs. Even where import is permitted, VAT and import formalities may apply and customs may seize medicines that lack proper authorisation, labelling or documentation.

Personal imports of medical devices are treated more leniently. Consumers may generally bring or receive CE-marked devices for personal use, including by mail order, provided the device is not subject to professional-use restrictions and does not pose a safety risk. However, custom-made, prescription-based or higher-risk devices (eg, certain implants or IVDs) may be subject to additional controls and professional supply requirements.

In all cases, BASG and customs authorities may detain, test or destroy therapeutic products imported by consumers if they are unauthorised, falsified, unsafe or incorrectly labelled, regardless of whether duties have been paid.

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?

Direct-to-consumer supply of medicinal products is highly restricted. Prescription-only medicines may not be supplied by distance selling to Austrian consumers under any circumstances. Non-prescription medicines may be supplied by mail order only by EU-licensed pharmacies that are legally authorised in their home Member State and registered in the EU common logo system. Austrian pharmacies engaged in distance selling must additionally notify BASG and be listed in the Austrian register. Third-country suppliers (outside the EU/EEA) are entirely excluded from supplying medicines to Austrian consumers by post or courier.

Any pharmacy lawfully engaged in distance selling into Austria must comply with EU and Austrian pharmacy law, AMG advertising restrictions, pharmacovigilance duties and GDP-equivalent storage and transport requirements and must provide pharmaceutical advice and full business identification on its website.

For medical devices and in vitro diagnostics, foreign suppliers may in principle sell directly to Austrian consumers via web shops, marketplaces or social-media platforms, provided the devices are lawfully placed on the EU market. A non-EU manufacturer must appoint an authorised representative within the EU and an EU-established importer must assume regulatory responsibility under the MDR/IVDR. The importer and distributor must be registered with BASG, verify CE marking and conformity, ensure UDI traceability, handle complaints and vigilance reporting and ensure compliant labelling and instructions in German where required.

Online marketplaces and platforms may incur regulatory obligations where they control key aspects of the sale, such as product presentation, fulfilment or payment processing and BASG may order takedowns or sales bans for non-compliant offers.

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?

Parallel imports are permitted for medicinal products, where a medicine has been lawfully placed on the market in another EU or EEA Member State by or with the consent of the rights holder, under the EU/EEA principle of regional exhaustion of intellectual-property rights. The parallel importer must obtain a BASG parallel-import authorisation (or simplified notification) demonstrating that the imported product is essentially similar to a reference product authorised in Austria. The importer must be established in the EU/EEA and hold a valid wholesale distribution authorisation under the AMG.

Re-labelling or re-packaging is permitted only to the extent necessary to market the product in Austria (eg, to add German-language labelling or patient information leaflets or to adjust pack size). The parallel importer must notify the trademark owner in advance, preserve the original condition and quality of the product and clearly identify itself as the repackaging entity. All safety features required under the Falsified Medicines Directive (unique identifier and anti-tampering device) must be correctly verified or re-applied.

Parallel-imported medicines remain subject to pharmacovigilance, batch traceability, recall and GDP obligations and BASG may inspect, suspend or revoke authorisations where compliance or product equivalence is not ensured.

For medical devices and in vitro diagnostics, parallel trade is similarly permitted within the EU/EEA once a product has been lawfully CE-marked and placed on the market. Intellectual property rights are exhausted at the EU/EEA level, but any re-labelling or re-packaging must not affect the device's conformity with the MDR/IVDR. The parallel importer qualifies as a distributor or importer with full responsibility for traceability, complaint handling, vigilance and UDI records and must be registered with BASG. Where the importer modifies packaging, labelling or instructions for use, it may also assume manufacturer-like obligations under MDR/IVDR.

In both sectors, maintaining product integrity, safety and traceability throughout the supply chain is a regulatory prerequisite and non-compliant parallel imports may be blocked, recalled or destroyed by BASG and customs authorities.

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?

Austria operates a system of shortage monitoring and supply-security obligations for medicinal products. Marketing authorisation holders and wholesalers must notify BASG in advance of anticipated supply interruptions or permanent discontinuations. Where there is a risk of shortage of a medicinal product of public-health importance, Austria, acting through BASG and in coordination with the European Commission, may impose temporary and proportionate export-restrictive measures, such as quantity limits, prior-authorisation requirements or, in exceptional cases, export bans for affected products, in order to protect public health and security of supply.

In addition, wholesalers are subject under EU GDP rules and Austrian law to an obligation to ensure adequate and continuous supply of the Austrian market. If a wholesaler's export activities

jeopardise domestic availability, BASG may order corrective measures, including restrictions on exports, stock-holding obligations or administrative penalties.

Exports of controlled substances (ie, narcotics, psychotropics and precursors) always require individual export permits from the Minister of Health and are subject to international control provisions, (eg, Regulation (EU) No. 111/2005). Biologicals, blood products and vaccines may also be subject to additional certification or batch documentation for export, particularly to third countries.

No general export licensing regime applies for medical devices and in vitro diagnostics, but during public-health emergencies the EU or Austria may introduce temporary export controls on critical products (such as personal protective equipment, test kits or ventilators) through EU regulations or national emergency measures, enforced by customs authorities in cooperation with BASG.

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?

For medicinal products, the AMG allows manufacturers to produce medicines exclusively for export to countries outside the EU, even if the product is not authorised for use in Austria or the EU, provided that the manufacturer holds a BASG manufacturing authorisation and complies with EU Good Manufacturing Practice (GMP). The product must meet the regulatory requirements of the destination country and BASG may require proof that it is lawfully marketable there. Such products may not be placed on the Austrian or EU market.

Export-only medicines must be clearly labelled ‘for export only’ (or equivalent) and packaging and patient information must follow the law and language requirements of the importing country rather than Austrian rules. However, full EU GMP documentation, batch records and traceability must still be maintained. BASG may issue GMP certificates or Certificates of Pharmaceutical Product to support foreign registrations.

A comparable export-only regime applies for medical devices and in vitro diagnostics. Devices which do not comply with MDR/IVDR may be manufactured in Austria solely for export to third countries, provided they are not CE-marked and are clearly designated ‘for export only’. Separate production and stock controls must prevent diversion into the EU.

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?

For medicinal products, all packs placed on the Austrian market must bear labelling and a package leaflet in German, unless a narrow hospital-use or named-patient exemption applies. The content must correspond exactly to the marketing authorisation approved by BASG or the EMA. Under the EU Falsified Medicines Directive, most prescription medicines and certain non-prescription medicines must carry a unique identifier (2D barcode) and an anti-tampering device, which must be uploaded to and verified against the Austrian medicines verification system at the point of dispensing. Wholesalers and parallel importers must ensure batch traceability, recall capability and safety-feature verification and must report any suspected falsified medicines to BASG.

For imports from third countries, compliance with GMP, batch certification and safety-feature requirements must be verified before release to the Austrian market. For exports, BASG may issue Certificates for a Pharmaceutical Product or GMP certificates.

For medical devices and in vitro diagnostics, products placed on the Austrian market must bear a CE mark and be accompanied by instructions for use and safety information in German, unless restricted to professional or hospital use. Devices must carry UDI and economic operators must ensure traceability, registration and vigilance reporting via Austrian and EU databases.

Parallel importers and distributors must ensure that any re-labelling or repackaging preserves regulatory conformity, safety features and traceability.

For export-only products, destination-country labelling may be used, but they must be clearly marked 'not for EU sale' and remain fully traceable in manufacturer records.

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?

In Austria, pricing and reimbursement regimes operate independently of trade regulation but are decisive for market access and distribution in practice.

For medicinal products supplied through the public health system, inclusion into the Reimbursement Code (*Erstattungskodex*) administered by the Austrian Umbrella Organisation of the Social Security Carriers (*Dachverband*) is essential for market access. Only medicines listed in the *Erstattungskodex* are routinely reimbursed by statutory health insurance and therefore widely prescribed and dispensed through pharmacies. Reimbursed medicines are subject to statutory price regulation, including international price comparison, price caps and mandatory discounts, which directly affect distribution margins and commercial viability. Manufacturers must accept these conditions to obtain reimbursement.

Austria also applies reference pricing and generic substitution rules, which steer demand towards lower-priced products and influence purchasing and stocking decisions by pharmacies and wholesalers. Many hospital medicines are supplied through public procurement procedures, including tenders and framework agreements, which determine which products are purchased and in what quantities.

In parallel, marketing authorisation holders and wholesalers are subject to supply-security obligations under the AMG. They must ensure adequate and continuous supply of medicines placed on the Austrian market and notify BASG of any actual or anticipated shortages. Where supply risks arise, BASG may order stockholding, allocation measures or export restrictions.

For medical devices and in vitro diagnostics, reimbursement by social insurance is governed by benefit catalogues, tariff systems and procurement contracts, particularly in hospitals. These mechanisms strongly influence which products are purchased and through which distribution channels.

Although these regimes do not formally regulate trade, they significantly shape pricing, channel structure and product availability in the Austrian therapeutic products market.

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?

In Austria, BASG enforces trade and distribution rules for therapeutic products under the AMG, AWEg and MPG, together with customs and criminal prosecutors.

Investigative powers include on-site inspections, document and system audits, sampling and laboratory testing, access to GDP and traceability records and detention or release of shipments by customs.

Where violations are found, BASG may impose the following administrative measures and sanctions:

- orders to remedy deficiencies and implement corrective and preventive actions;
- bans or restrictions on placing products on the market;
- product recalls, quarantines or destruction of non-compliant goods;
- suspension or revocation of wholesale, import or manufacturing licences.

Administrative fines

Under the AMG and MPG fines for regulatory breaches can reach up to approximately €25,000 per offence and significantly more for repeated or serious violations.

Under the AWEg fines for regulatory breaches can reach up to approximately €3,600 per offence and significantly more for repeated or serious violations.

In addition, for regulatory breaches pursuant to the GewO the trade authority might impose fines up to €3,600.

Criminal sanctions

If conduct involves intentional endangerment of public health, fraud or falsification of medicines or devices, it may constitute a criminal offence under the Austrian Criminal Code or sector-specific laws, punishable by criminal fines, and imprisonment, typically one-to-three years, and in aggravated cases (eg, large-scale or dangerous falsification) up to five years or more.

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?

Austria has in recent years introduced and is continuing to develop, measures that significantly affect the trade, distribution and cross-border movement of therapeutic products, with a strong focus on security of supply, traceability and enforcement.

A major development in the pharmaceutical sector is the introduction of supply-security and shortage-prevention rules for medicines of public-health importance. Marketing authorisation holders and, in certain cases, wholesalers are subject to notification, monitoring and stock-availability obligations and BASG may require minimum stock levels or allocation measures where shortages are threatened. These measures are designed to mitigate medicine shortages and may lead to export restrictions, stock-holding requirements and administrative sanctions if domestic supply is endangered. Several aspects of this regime have been challenged before the courts, but the overall policy direction towards tighter supply-chain control is established.

Austria is also preparing to implement the upcoming EU pharmaceutical legislation, which is expected to modernise marketing authorisation, supply-resilience obligations, data protection and

incentives for innovation. Once adopted at EU level, these reforms will require changes to national distribution, parallel-trade and exclusivity regimes.

In the medical-device sector, Austria has strengthened its national registration, vigilance and reporting framework to align with the MDR/IVDR, including expanded economic-operator and device registration. The gradual roll-out of EUDAMED will further increase EU-wide traceability and transparency for devices, importers and distributors.