# 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?**

Switzerland regulates therapeutic products under the Federal Act on Medicinal Products and Medical Devices[1] (HMG), complemented by ordinances on establishment licensing, good practices, marketing authorisation[2] (AMBV), advertising and medical device-specific rules that are aligned with European Union Medical Device Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR) concepts.[3]

Swissmedic is the central federal authority for granting marketing authorisations, establishment licences for the manufacture, import, export and wholesale of medicinal products, quality oversight and market surveillance, while cantonal pharmacist services licence and supervise retail outlets and professional practice. The Federal Office of Public Health (*Bundesamt für Gesundheit or* BAG) is responsible for the supervision of controlled substances, pricing and reimbursement and radiation protection, and the Federal Office for Customs and Border Security (*Bundesamt für Zoll und Grenzsicherheit* or BAZG) enforces border controls.

The import, wholesale and export of medicinal products require a Swissmedic establishment licence and compliance with the AMBV,[4] with additional BAG permits issued for narcotics and precursors. Medical device importers/distributors must follow the Medical Devices Ordinance[5] (MepV) and the Ordinance on In Vitro Diagnostic Medical Devices[6] (IvDV). Wholesale distribution is governed by Swissmedic under the AMBV and vigilance rules for medicines, and by the MepV for devices. Veterinary medicines follow the same framework, with the Federal Food Safety and Veterinary Office (*Bundesamt für Verbraucherschutz und Lebensmittelsicherheit* or BLV) as the interface.

[1] SR 812.21 - Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) | Fedlex www.fedlex.admin.ch/eli/cc/2001/422/en last accessed on 15 May 2026.
[2] SR 812.212.1 - Ordinance of 14 November 2018 on Licensing in the Medicinal Products Sector (Medicinal Products Licensing Ordinance, MPLO) | Fedlex www.fedlex.admin.ch/eli/cc/2018/786/en last accessed on 15 May 2026.
[3] EUR-Lex - 02017R0745-20240709 - EN - EUR-Lex https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0745-20240709 last accessed on 15 May 2026.
[4] See n 2 above.
[5] SR 812.213 - Medical Devices Ordinance of 1 July 2020 (MedDO) | Fedlex www.fedlex.admin.ch/eli/cc/2020/552/en last accessed on 15 May 2026.
[6] SR 812.219 - Ordinance of 26 May 2022 on In Vitro Diagnostic Medical Devices (IvDO) | Fedlex www.fedlex.admin.ch/eli/cc/2022/291/en last accessed on 15 May 2026.

Retail supply is mainly under cantonal control for licensing and inspection (Article 30 para. 3 of the HMG), while Swissmedic defines product categorisation and supervises advertising (Article 58 of the HMG).

**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 the conclusion of a premarket review and approval process required by a competent authority?**

Switzerland classifies medicines by dispensing category and devices by risk, and these classifications determine who may supply, how and under what controls.

Medicines are classified as prescription only (Categories A and B) or over the counter (OTC) (Categories D and E) by Swissmedic at approval, based on the risk posed and use (Article 23 f. of the HMG; note that an intermediary Category C was abolished in a 2019 revision of the law).

Prescription medicines generally require dispensing by authorised professionals' and a prescription (Article 24 of the HMG). Category D needs professional counselling and Category E is freely sellable by all persons (Article 25 of the HMG). Distance selling for Categories A, B and D is limited to public pharmacies with a mail order authorisation (Article 27 of the HMG). Public advertising of prescription medicines is prohibited; all promotions must be accurate and not misleading (Article 31 f. of the HMG).

Medical devices are risk classified (Classes I, IIa, IIb, III). Higher classes trigger notified body involvement and tighter post-market controls. All devices must meet safety, performance and conformity assessment requirements, which includes unique device identification (UDI) and CH registration as needed (Article 47 of the HMG; Article 6, 15, 21 and 55 et seq. of the MepV), and be supplied as per the manufacturer's intended use. Some devices are for professional use only and come with facility and competency requirements. Public advertising for these types of devices is prohibited (Article 69 para. 3, 70 and Annex 6 of MepV). No Swissmedic licence is needed for the import, wholesale and export of medical devices. Cantons supervise retail sales, while Swissmedic oversees market surveillance (Article 58 of the HMG; Article 76 of the MepV).

## LICENSING, AUTHORISATIONS AND DISTRIBUTION CHANNELS

**3. Which licences, authorisations, registrations or other official permissions are required for businesses to engage in the wholesale distribution of therapeutic products, and what key conditions (such as good distribution practices, facility standards, personnel-related requirements and insurance or financial guarantees) are attached to them?**

For medicines, a Swissmedic establishment licence is required for wholesale, and operations must comply with Good Distribution Practice (GDP) requirements. Key requirements include a quality control system, appropriate organisation and facilities, qualified personnel, a person responsible person GDP compliance and the traceability of all transactions and batches (Article 28 f. of the HMG; Article 11 et seq. of the AMBV). Where the marketing authorisation holder releases a finished product onto the Swiss market, an additional market release process by the responsible person applies that involves retained samples and pharmacovigilance arrangements (Article 12 f. of the AMBV).

For medical devices, no Swissmedic wholesale licence is required. Importers and distributors must instead comply with the economic operator regime, including verification of conformity and marking before placing the device on the market, identification on or in relation to the product, appropriate storage and transport, cooperation with the authorities, registration of the economic

operators involved and the product where required and recordkeeping for traceability purposes, with duties cross-referencing the EU MDR requirements (Article 47 et seq. of the HMG; Art. 6, 21, 53 et seq. and 64 of the MepV).

**4. Are there any 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 are attached to them?**

Retail supply is mainly regulated by the cantons. Community pharmacies and drugstores need a cantonal retail licence, must be led by a qualified pharmacist or authorised professional, must dispense Swissmedic-authorised medicines, offer counselling and adhere to pharmacovigilance obligations (Article 30 of the HMG). Internet/mail-order supply requires a specific cantonal mail-order licence and a documented quality system (Article 18 et seq. and 27 of the HMG; Article 55 of the VAM). Non-qualified retailers may only sell the least restricted OTC products (Category E), subject to specific restrictions regarding labelling, storage and the provision of advisory practices (Article 23 and 25 of the HMG; Article 44 para. 2 of the VAM).

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

In principle, offline rules also apply to online sales, with specific provisions for distance sales and online interfaces. Geo-targeted websites that address Switzerland must follow Swiss law. For medicines, only authorised Swiss retailers may supply medicines based on online orders (Article 27 of the HMG), following Swiss categorisation, counselling and advertising rules (Art. 23 et seq., 30 and 32 of the HMG).

For medical devices, any online offer to Swiss users triggers Swiss conformity, labelling and operator duties (Article 7 of the MepV).

Authorities can order, remove, block or restrict unlawful online supply and advertising (Article 66 of the HMG; Article 75b of the MepV).

**IMPORT**

**6. What requirements are set as part of 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)?**

Switzerland regulates therapeutic product imports through the HMG and customs law. Importing medicines requires a Swissmedic establishment licence, as well as compliance with the GDP requirements and is generally only allowed for authorised products (Article 9 and 18 et seq. of the HMG; Article 11 et seq. of the AMBV). The authorisation requirement also applies to entities engaged in brokering or those acting as agents in the wholesale trade of medicinal products (Article 18 para. 1 letter d of the HMG). Swissmedic may restrict shipments of certain blood and immunological products (Article 44 et seq. of the AMBV).

For medical devices, no Swissmedic import licence is generally needed, but importers must ensure conformity, correct labelling and fulfil economic operator duties, including registration when required (Article 45 et seq. of the HMG; Article 6, 21 et seq., 53 and 55 of the MepV).

Customs classification and tariff treatment follow Swiss customs law, with cooperation between Swissmedic and the customs authorities during clearance and enforcement (Article 66 para. 4 of the HMG; Article 65 of the AMBV). Border controls are risk based. Customs can hold consignments, and Swissmedic or the cantons may block, seize, order the return or prohibit the

import of non-compliant goods (Article 58 and 66 para. 4 of the HMG; Article 65 of the AMBV; Article 97 of the MepV).

**7. To what extent may consumers import therapeutic products for personal use (whether by taking the products across the border or receiving them by post), and what quantitative limits, prescription requirements, customs declarations, duties or other restrictions apply?**

Consumers may import small quantities of therapeutic products for personal use, subject to the relevant therapeutic products and customs regulations. For medicines, individuals can bring into the country non-authorised products in limited amounts without a licence, except for certain items like genetically modified organisms (GMOs) (Article 20 para. 2 of the HMG; Article 48 f. of the AMBV). Swissmedic can further restrict or ban imports for health reasons, including requiring permits for specific medicines (Article 20 para. 3 of the HMG; Article 44 et seq. of the AMBV). Professional small-quantity imports are separately regulated and are allowed if the medicine is intended for a specific patient or emergency use, is authorised in a country with comparable medicines control and if either no alternative equivalent medicine is authorised in Switzerland, the authorised alternative is unavailable on the Swiss market or switching to a Swiss-authorised and available alternative is not appropriate (Article 49 of the AMBV).

For medical devices, there is no specific consumer import regulation, but the authorities may restrict or prohibit imports of certain device groups to protect health (Article 50 of the HMG).

Customs declarations, tariff classifications and the application of duties/value-added tax (VAT) follow ordinary customs law.

**8. Are foreign suppliers allowed to 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?**

Foreign suppliers cannot ship medicines directly to Swiss consumers unless using a Swiss-licensed pharmacy with a cantonal mail-order authorisation. Mail-order pharmacies must verify their identity, provide counselling, ensure safe delivery of the product and be listed by the canton (Article 27 of the HMG; Article 55 f. of the VAM). Medicines for the Swiss market must be authorised and handled by Swiss licensees, with a Swiss domicile or branch (Article 9 f. and 18 et seq. of the HMG; Article 11 et seq. of the AMBV).

Foreign sellers of medical devices may only target Swiss users if they comply with Swiss regulations. Any online offer to Swiss users qualifies as placing the product on the Swiss market (Article 7 of the MepV). Non-Swiss manufacturers must appoint a Swiss authorised representative (CH-REP), and importers established in Switzerland must carry out conformity and labelling checks before the device is placed on the market (Article 51 and 53 of the MepV). Economic operators must register for a Swiss registration number (CHRN; Article 55 of the MepV). Device labelling and instructions must follow Swiss language and content rules, with limited exceptions (Article 16 of the MepV). Advertising directly to consumers is forbidden for devices meant only for professional use (Article 69 para. 3 of the MepV).

**9. How is the 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 the product's original quality, safety and traceability?**

Parallel trade of therapeutic products is permitted in Switzerland but strictly regulated to ensure patient safety and traceability. For human medicines, Swissmedic allows simplified authorisation

for parallel imports if the product is identical to one that is already authorised (Article 14 para. 2–3 of the HMG). The labels, packaging and patient/professional information must match the Swiss reference, with Swiss-compliant secondary packaging and clear identification of both the original authorisation holder and the Swiss importer (Article 26 et seq. of the VAM). Safety-relevant differences (eg, dosage form, strength, excipients) are prohibited. Importers require Swissmedic licences and must comply with the Good Manufacturing Practice (GMP)/GDP requirements, maintain full distribution records and report any quality defects (Article 18 et seq. of the HMG; Annex 4 of the AMBV; Article 61 et seq. of the VAM). If the reference authorisation changes, Swissmedic may adjust the parallel import accordingly.

Medical devices may also be traded in parallel. Importers and distributors must verify conformity, ensure Swiss labelling and instructions are provided, appoint a Swiss authorised representative if needed, register where applicable and ensure UDI-based traceability. Post-market surveillance and recall duties apply regardless of the product origin (Article 45 and 47 et seq. of the HMG; Article 16, 53 et seq., 56 et seq. and 64 of the MepV).

**EXPORT**

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

For medicines, exporting and trade abroad (ie, the trade of medicines outside of Switzerland but by a Swiss domiciled entity) require a Swissmedic establishment licence, and exports must meet the relevant due diligence duties (Article 18 f. of the HMG; Article 11 et seq. and 21 f. of the AMBV). Exports may be prohibited or restricted, including per-shipment controls, for products banned in the destination country, suspected of unlawful use or for other health protection-related reasons. Swissmedic can list export-restricted or export-banned products and grant case-by-case exemptions (Article 21 of the HMG).

During supply shortages or emergencies, Swissmedic may authorise temporary measures on supply and enforce distribution controls and allow the temporary import of equivalent medicines from countries with similar regulatory standards until normal supply resumes (Article 9b and 58 of the HMG). The Federal Council may also, in order to protect public health, facilitate the import of essential medicinal products for combatting communicable diseases or restrict or prohibit the export of medicinal products (Article 44 para. 2 letter c of the Epidemics Act (EpG)). For medical devices, the Federal Council may impose import and export restrictions to protect health, including during public health emergencies (Article 50 of the HMG).

**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?**

A medicinal product that holds an export licence from Swissmedic may not be distributed in Switzerland. Export licences do not contain any approved product information text (eg, packaging texts or patient information) apart from the basic medicinal product information, and Swissmedic does not approve pack sizes for export licences.

For medical devices, there is no export-only authorisation. Devices made in Switzerland for export need not meet Swiss conformity or labelling rules unless placed on the Swiss market, although the Federal Council can impose health-based restrictions (Article 50 of the HMG; Article 16 of the MepV).

## LABELLING, TRACEBILITY 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 must be in at least two official languages (Article 26 para. 1 of the VAM), while professional and patient information must be in all three of Switzerland's official languages, ie, German, French and Italian (Article 26 para. 2 of the VAM). Required elements include the product name, batch number, expiry date, composition, dosage, storage instructions and warnings. Traceability is ensured via batch numbers, expiry dates and Global Trade Item Number (GTIN)/DataMatrix codes. The design must ensure that all of the mandatory information, as stipulated in Article 12 of the AMZV in conjunction with Annex 1, 1a or 1b of the AMZV, is clearly visible. Logos and pictograms are allowed under strict rules.

Medical devices must carry a conformity mark (Swiss or EU MDR) and, if applicable, the notified body's number (Article 13 f. of the MepV). Devices are classified by risk and according to their intended use (Article 15 of the MepV), and product information must be in all three official languages, unless they are solely for professional use (Article 16 of the MepV).

Each device must have a UDI and must be registered in the Swiss database (swissdamed[7]) or EUDAMED[8] (Article 17 of the MepV; Article 47 of the HMG). Manufacturers must ensure compliance with the applicable rules, affix the conformity mark and conduct clinical evaluations (Article 46 of the MepV). Importers and distributors must verify conformity, correct labelling and UDI inclusion before market entry (Article 53 f. of the MepV).

## PRICING, REIMBURSEMENT AND MARKET ACCESS

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

Therapeutic products must be included on a positive list, such as the List of Pharmaceutical Specialities (SL), or the List of Medical Devices (MiGeL), in order to be reimbursed by mandatory health insurance (OKP; Article 52 of the Health Insurance Act (KVG)). The SL includes ready-to-use medicines, including biologics, generics and biosimilars. Maximum prices are determined based on the effectiveness, appropriateness and economic efficiency of the medicinal product (Article 32 of the KVG). Similarly, the MiGeL defines the maximum prices of medical devices reimbursed by OKP.

If a medicine is authorised but not marketed within three years, or is withdrawn from the market for three consecutive years after launch, the authorisation may be revoked (Article 16a para. 1 of the HMG).

The Ordinance on Compulsory Stockpiling of Medicinal Products requires companies marketing certain essential medicines, such as antibiotics and chronic disease treatments, to maintain reserves covering about three months of normal use.

## ENFORCEMENT, COMPLIANCE AND RECENT DEVELOPMENTS

[7] swissdamed https://swissdamed.ch/ last accessed on 15 May 2026.
[8] EUDAMED https://ec.europa.eu/tools/eudamed/#/screen/home last accessed on 15 May 2026.

**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?**

Swissmedic is generally responsible for market surveillance (Article 59 of the HMG), while cantonal authorities supervise retail outlets (Article 30 of the HMG).

When non-compliance is found, Swissmedic may impose administrative measures (Article 66 para. 1 of the HMG), such as product seizures, facility closures or the suspension/revocation of authorisations (Article 60 of the HMG; Article 42 of the AMBV). It can also inform the public about any such measures and issue health warnings (Article 67 of the HMG).

Criminal sanctions may apply under Article 86 and 87 of the HMG, which cover offenses such as unauthorised manufacturing or distribution of therapeutic products. In cases of corporate misconduct, Article 102 of the Swiss Criminal Code allows for corporate criminal liability if a company fails to take adequate organisational measures to prevent violations. Fines under this provision can reach up to CHF 5m.

**15. Is there any 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 swissdamed actors module (the mandatory Swiss registration system for economic operators, including manufacturers, authorised representatives and importers, placing medical devices on the Swiss market) has been mandatory for medical devices since 6 August 2024. Voluntary UDI/device registration started in August 2025, with full registration required by 1 July 2026 and a transition period available until 31 December 2026. IvDV amendments of 1 January 2025 align Swiss timelines with the EU IVDR and maintain flexible CH-REP and importer labelling obligations to support supply.

Enforcement at the border stayed active, with 5,668 illegal medicinal product consignments handled in 2024 and a rising share in psychotropics, underlining the continued scrutiny of small-parcel cross-border flows.

In 2025, the Swiss Federal Council proposed revising the HMG to introduce an EU-aligned advanced therapy medicinal products (ATMP) regime, improved post-market traceability and Swissmedic oversight, mandatory e-prescriptions and electronic medication plans, harmonisation with EU veterinary law and specific import/export rules for international organisations.