

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

Authors: Olivier Van Obberghen and Pieter Wyckmans

Firm: Quinz

olivier.vanobberghen@quinz.be, pieter.wyckmans@quinz.be

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?

Medicinal products for human use are primarily governed by the Law of 25 March 1964 on medicinal products (the Medicines Act) and its implementing Royal Decree of 14 December 2006. These instruments regulate, inter alia, marketing authorisation, manufacturing, import, wholesale distribution and advertising. The national framework is supplemented by other implementing legislative acts, as well as directly applicable EU legislation and related documentation, such as the Good Distribution Practice (GDP) guidelines.

Medical devices (MDs) are governed by Regulation (EU) 2017/745 on medical devices (MDR), which is directly applicable in Belgium. National implementation and enforcement measures are set out in the Law of 22 December 2020 on medical devices. In vitro diagnostic medical devices (IVDs) fall under Regulation (EU) 2017/746 (IVDR), supplemented by the Law of 15 June 2022 on in vitro diagnostic medical devices.

The competent national authority for the authorisation, licensing, and supervision of medicinal products and medical devices is the Federal Agency for Medicines and Health Products (FAMHP). The FAMHP is responsible for granting marketing authorisations (under national, mutual recognition, and decentralised procedures), manufacturing and import authorisations, and wholesale distribution authorisations for medicinal products, as well as for market surveillance and enforcement in respect of medical devices. For certain categories of medicinal products, the marketing authorisation is granted at EU level through the centralised procedure administered by the European Medicines Agency (EMA).

Belgium is a federal state, and competences in the field of healthcare are divided between the federal authority, notably the FAMHP, and the federated entities. While the organisation and delivery of healthcare services are largely devolved, the regulation of therapeutic products (including their authorisation, import, wholesale distribution, retail sale, and export) constitutes a core federal competence.

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?

Marketing a medicinal product in Belgium always requires a marketing authorisation. In the application, the applicant must propose the product's classification. Medicinal products are

classified according to whether a prescription is required, and the final classification decision is taken by the Ministry of Social Affairs and Public Health. Over-the-counter medicines (OTCs) may be freely supplied by pharmacists, while prescription-only medicines (POMs) require a prescription from a qualified healthcare professional. Depending on their risk, use, and composition, POMs may fall into subcategories that impose additional limits on prescribing and supply. Certain POMs may therefore only be prescribed by specific medical specialists or dispensed exclusively through hospital pharmacies. POMs are generally prohibited from remote sale to patients and may not be promoted to the general public.

Medical devices are classified under the MDR based on risk and intended purpose. They are categorised into Class I, IIa–IIb, and III, with Class III representing the highest risk. IVDs follow a similar system under the IVDR, ranging from Class A (low risk) to Class D (high risk). Nonsterile Class I devices and nonsterile Class A IVDs do not require prior involvement of the FAMHP. For all other classes, prior notification to a notified body designated by the FAMHP is required in order to obtain CE-marking. In specific cases where no alternative therapeutic products are available, the Minister of Public Health may authorise marketing without CE-marking.

As of May 2026, registration of medical devices, IVDs, and related distribution and import activities in EUDAMED will become mandatory.

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?

Anyone wishing to perform wholesale activities with respect to medicinal products for human use must hold a wholesale authorisation (Art 12ter Medicines Act). Wholesale authorisations delivered in other EU Member States will automatically be recognised in Belgium and a manufacturing authorisation automatically includes a wholesale authorisation, but not vice versa (Art 12bis Medicines Act).

To obtain a wholesale authorisation, the applicant must meet the following requirements:

- have suitable and adequate business premises, facilities and equipment to ensure the proper storage and distribution of the medicines;
- have qualified personnel, in particular a qualified person designated as responsible; and
- undertake to comply with the obligations listed in Art 94 of the Royal Decree of 14 December 2006, of which, key obligations include –
 - ensuring that medicinal products are only obtained from persons who are themselves in possession of a wholesale authorisation;
 - verifying that the medicinal products received are not falsified;
 - maintaining a quality system setting out responsibilities, processes and risk management measures in relation to the conducted activities; and
 - complying with GDP guidelines to ensure that the products are stored, transported, and handled under appropriate conditions at all times.

It should be noted that Belgian law makes a distinction between wholesalers and wholesaler-distributors of medicinal products for human use. Wholesaler-distributors are wholesalers that

have certain public service obligations, most notably obligations concerning minimum stock (see response to Question 13).

Pursuant to Art 12quinquies of the Medicines Act, wholesalers of medicinal products are, as far as their responsibilities allow, required to ensure the continuous supply of medicinal products in sufficient quantity to meet patient needs.

Distributors of MDs and IVDs are obliged to register with the FAMHP through a designated web portal (available at: <https://www.vas.ehealth.fgov.be/portal/nl>). Distributors must provide, among other things, the type and classification of the distributed products and the names of the manufacturers. The registered data must be confirmed annually, and any change in the registered data, except for a change as to the names of the manufacturers, must be notified to the FAMHP within 15 days.

Distributors of MDs and IVDs must further have a point of contact for materiovigilance and notify to the FAMHP the identity and contact details of the person responsible for the point of contact, as well as any change in such details. The point of contact is responsible, among other things, for communicating incidents to the manufacturer and the FAMHP without delay.

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?

Only pharmacists are permitted to supply medicinal products directly to consumers (Art 1, 17° and 24° Medicines Act). To exercise the profession of pharmacist, an individual must possess a degree in pharmacy (Art 6 s 1 and art. 5/1 Law of 10 May 2015). The opening of a public pharmacy requires authorisation by the Minister of Public Health. It is not currently possible to open any new establishments (Art 44 Royal Decree of 16 January 2022). Existing pharmacies can be relocated or fused, both actions require authorisation from either the establishment official or the Minister of Public Health.

The quality of wholesaler(-distributor) is incompatible with the quality of pharmacist (Art 12ter, s1, para 10 Medicines Act).

A retailer supplying MDs or IVDs directly to consumers (ie, natural persons who acquire or use MDs or IVDs exclusively for non-professional purposes) is also considered a distributor and, hence, the same requirements as stated in the response to Question 3 (above) apply.

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

In principle, medicinal products must be physically and personally delivered to the patient in a brick-and-mortar pharmacy (Art 3 s 4 Medicines Act, Art 21 s1 Royal Decree of 21 January 2009). An exception to this rule applies to the online sale of OTC medicinal products through the official website of a licensed public pharmacy (Art 29 Royal Decree of 21 January 2009 and Circular no. 536). Such online sales of OTC medicinal products must comply with several requirements, including those relating to quality, patient rights and good officinal practices. Belgian authorities treat the pharmacy's online shop as an extension of the physical pharmacy, meaning that the sale and supply of medicinal products always remain under the responsibility of the pharmacist operating the physical pharmacy. This gives rise to several compliance requirements which sales conducted directly through social media or marketplace platforms typically cannot meet and are therefore not permitted.

The online sale of prescription-only medicinal products (POMs) is forbidden. POMs must be delivered to the patient or such patient's authorised representative in person in a brick-and-mortar pharmacy. Note that Belgian law does allow the reservation of POMs online, as long as the medicine is paid for and picked up by the patient at the physical pharmacy. Only in exceptional circumstances (eg, where the patient is unable to travel to the pharmacy) may the pharmacist deliver the POM in person or, subject to certain conditions, via a courier service to the patient's residence or domicile.

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, a medicinal product may only be imported for commercial supply if the medicinal products have a Belgian national marketing authorisation, a centralised EU marketing authorisation, a parallel import authorisation (PIA) (EEA parallel trade), or a specific exceptional authorisation. Examples of such exceptional pathways are named patient use or shortage-based exemption. Investigational medicinal products follow a separate import pathway.

Imports from outside the EEA typically require a Belgian manufacturing/import authorisation (MIA), full GMP compliance and Qualified Person (QP) batch certification prior to release. Intra-EEA imports generally require only a wholesale distribution authorisation (WDA) and GDP compliance, unless the importer performs manufacturing operations such as repackaging, in which case a MIA is also triggered.

Belgian Customs may verify the existence of the relevant authorisations, detain suspicious shipments and enforce falsified-medicines controls at the border. In practice, Belgium is regarded as a high-enforcement jurisdiction where non-compliant imports can lead to seizure of goods, and administrative or criminal sanctions.

Belgium applies certain product-specific import regimes for medicinal products, such as enhanced controls for narcotic and psychotropic medicines, which include shipment-specific authorisation.

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?

Natural persons moving around within the EEA have the right to carry a reasonable quantity of medicinal products lawfully obtained for their personal use and consistent with their treatment. The products should remain in their original packaging and, if applicable, be supported by a valid prescription. For narcotic or psychotropic medicines, travellers within the Schengen Area are typically required to carry a Schengen certificate issued by the competent authority, in addition to the prescription.

Importing medicines by mail is tightly restricted in Belgium. The distance selling or supply of prescription-only medicines (POMs) to the public is in banned principle, and accordingly consumers may generally not lawfully obtain POMs by mail outside narrowly defined exceptional pathways (see response to Question 5). OTC medicines may in principle be received by mail, but only where the product is dispensed by a duly authorised (online) pharmacy in compliance with the applicable EU and Belgian distance-selling rules.

In practice, parcels from non-compliant or non-EEA sellers are frequently intercepted by the authorities.

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?

Foreign suppliers may ship therapeutic products directly to consumers via e-commerce or only mail order in limited circumstances.

First, the supply of POMs directly to consumers via e-commerce or mail order is banned in principle (see responses to questions 5 and 7, above).

For OTC medicines, cross-border distance sales to Belgian consumers are only permitted where the seller is a duly authorised pharmacy in its home EEA Member State and fully complies with both the general legal framework governing distance sales of goods and services and the specific rules applicable to the remote sale of medicinal products. Compliance with the latter, including applicable information and language requirements, is likely to be subject to closer scrutiny where the Belgian market is actively targeted.

Foreign suppliers established outside the EEA generally cannot lawfully ship medicines directly to Belgian consumers.

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 import is defined as the placing on the Belgian market of a medicinal product authorised in another EU Member State, for which a reference medicinal product is authorised in Belgium, and which is imported independently of the marketing-authorisation holder of that reference product. It is subject to a parallel import authorisation (PIA) granted by the FAMHP. A PIA applicant must demonstrate that the imported product is identical or sufficiently equivalent to the reference medicinal product authorised in Belgium (Art 6 of the Royal Decree of 10 November 2025 on parallel distribution and parallel importation of medicinal products for human use). To substantiate this equivalence, the applicant must submit a mandatory comparison form, together with the PIA dossier.

Parallel-imported medicinal products must comply with national labelling, language and transparency requirements, which in practice frequently necessitate re-labelling (over-stickering) and sometimes full repackaging. Belgian law does not automatically require repackaging: parallel importers must in principle use the least intrusive measure capable of ensuring lawful marketing. Any relabelling or repackaging that affects the presentation of the trademarked product must satisfy the cumulative conditions developed by the Court of Justice in the *Bristol-Myers Squibb (BMS)* case (CJEU, 11 July 1996, C-427/93, C-429/93 and C-436/93), including that the repackaging is objectively necessary, does not affect the condition of the product, clearly identifies the re-packer, and does not damage the reputation of the trademark or its proprietor, and that the trademark proprietor receives prior notice together with a specimen. Belgian authorities and courts apply a strict proportionality assessment and closely scrutinise claims that full repackaging is necessary. As recent Belgian case law confirms, especially in generic-to-originator scenarios, interventions going beyond what is strictly required for regulatory compliance are likely to be prohibited.

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?
<p>Generally, there are no permanent quantitative export quotas. However, exports may be restricted on a conditional, case-by-case basis under the Royal Decree of 19 January 2023 implementing Article 12septies of the Law of 25 March 1964 on medicinal products. This regime operates in conjunction with Article 6, section 1 of the same law, which requires marketing authorisation holders to notify the FAMHP of actual or foreseeable unavailability of a medicine. Where such unavailability has been notified or established, is probable or certain for at least one month, the medicine is urgently necessary to prevent serious deterioration of health or death, and no therapeutically equivalent alternatives are available, the Minister of Health or a delegated authority may subject the export of medicines intended for the Belgian market to prior authorisation. Wholesalers must then submit an application to the FAMHP identifying the product, including its name, marketing authorisation number, and the quantity proposed for export. The FAMHP must decide within five working days whether to authorise the export, impose quantitative limits, or ban export. In the absence of a decision within that period, the export is deemed authorised. Any restriction must be proportionate, limited to the expected duration of unavailability, and is automatically lifted once supply is restored.</p>
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?
<p>Belgian law provides a mechanism for exporting medicinal products that do not hold a Belgian or EU marketing authorisation, so long as a specific export declaration is obtained from the FAMHP. Article 120 of the Royal Decree of 14 December 2006 specifically provides that a medicine for which no marketing authorisation has been granted in Belgium or in another EU Member State may be exported, provided that a specific export declaration is obtained from the FAMHP. The exporter must submit a declaration for export to the FAMHP that complies with the formal requirements of said Article 120. This authorisation is frequently described in regulatory practice as an ‘export only’ declaration or authorisation. However, this is not a separate regime with reduced standards.</p> <p>Manufacturers must hold a standard manufacturing authorisation and comply with all Good Manufacturing Practice (GMP) standards, even for medicines intended solely for export. They must establish and maintain an effective pharmaceutical quality system, employ sufficient qualified personnel, and maintain comprehensive documentation systems guaranteeing data quality and integrity. While there are no specific Belgian labelling rules tied exclusively to export-only status, the general labelling rules remain relevant for quality and identification purposes if the product is packaged for export and export documentation should make clear that the product is not authorised for sale in Belgium. In addition, general pharmaceutical regulatory practice in respect of record retention, inspection and audits, equally apply.</p>
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?

As a baseline, for placing medicines on the Belgian market, the outer/primary packaging text and the patient information leaflet (PIL) must be available in the three national languages (Dutch, French, German). Certain key particulars should appear in Braille as well. For exportation, the destination country's labelling language regime will typically determine which language is to be specified. The labelling and Instructions for Use (IFU) of medical devices must generally be provided in Dutch, French, and German for devices sold to the public, with English permitted in certain contexts (notably professional use and some patient-choice scenarios). EU MDR/IVDR traceability/UDI and Belgian operator-registration obligations may apply depending on the economic-operator role and activities performed in Belgium. For most prescription medicines (and certain OTC categories), the outer packaging must carry a unique identifier, and an anti-tampering device, with upload/verification via the EU repositories system. For export outside the European Union, wholesalers must decommission the unique identifier before exporting. The features imposed by the EU Falsified Medicines Directive (2D Data Matrix Code, Anti-Tampering Device) must be included. Manufacturers must onboard with the Belgian Medicines Verification Organisation for end-to-end verification. A specific digit Belgian identifier essential for reimbursement (CNK) is often printed on packs or embedded in barcodes. Medical devices must bear a Unique Device Identifier (UDI) in both human-readable and machine-readable formats; implantable devices also trigger patient-facing traceability tools (eg, implant card concepts under MDR). For standard medicines, wholesalers and pharmacists must maintain batch-level traceability. 'Vein-to-vein' traceability is required for biologicals and Human Body Material (HBM), linking the donor to the recipient while maintaining data privacy (GDPR). Belgium requires distributors of medical devices to register on the FAMHP portal.

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?

All medicinal products, whether reimbursed or not, are subject to price control in the sense that there is a maximum price (both ex-factory and public). A maximum ex-factory price is determined by the Minister of Social Affairs and Public Health (the Minister) on the basis of a pricing dossier submitted by the company, and following an application and negotiation process with the company. A pharmaceutical company can only effectively market a medicinal product if an official price has been determined. A specific procedure applies for price increases, which is similar to the procedure for obtaining the initial price.

To calculate the maximum price that can be charged to patients, a distinction is made between the public price of medicinal products sold in a retail pharmacy and those sold through a hospital pharmacy. The public price is calculated using pre-defined profit margins for wholesalers and/or pharmacists. These profit margins are maximum margins, meaning that wholesalers and pharmacists may not apply higher profit margins when selling the medicinal product to the pharmacist or patient respectively.

The Belgian compulsory health insurance only reimburses medicinal products that are included on the list of reimbursable pharmaceutical specialties. To obtain reimbursement of a medicinal product, pharmaceutical companies must submit a reimbursement application with the NIHDI

simultaneously with the pricing application. The final reimbursement decision is taken by the Minister on the advice of the NIHDI.

The Belgian legal system includes several mandatory price reduction mechanisms that force pharmaceutical companies to reduce prices below the initially approved maximum. One such mechanism is the so-called ‘patent cliff’ or ‘bio-cliff’, which provides for a reduction in the reimbursement basis and price of the medicinal product upon market entry of a generic or, respectively, a biosimilar product.

All medicinal products purchased by hospitals in Belgium are subject to public procurement legislation. The total duration, including any potential renewals, of such public procurement contracts may not exceed four years. Unless otherwise provided in the public procurement contract, a pharmaceutical company may not withdraw from its tender obligations (without paying a termination indemnity), except in exceptional cases. Hospitals are, however, exempt from following a tender procedure, and are therefore free to conclude a direct contract with the market player of their preference, if the total aggregate value of their orders over a 12-month period remains below €30,000.

Finally, certain stock/supply obligations apply. The marketing authorisation holder and wholesaler of a medicinal product have an obligation effectively to ensure that their medicinal product is available to hospital or retail pharmacies continuously in sufficient quantity to meet the needs of patients (Art 12quinquies of the Law of Medicinal Products). Wholesaler-distributors, most notably, have the obligation to: (1) maintain a permanent safety stock of medicinal products that enables them to meet the usual needs of their region on a daily basis, which must correspond to two-thirds of the number of medicinal products then marketed in Belgium, and the average value of the monthly turnover during the previous year per medicinal product; and (2) deliver a medicinal product within 24 hours in case of urgent deliveries (Art 227 of the Royal Decree on Medicinal Products).

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?

Non-compliance with trade and distribution rules for therapeutic products is primarily enforced through FAMHP/AFMPS inspections and market surveillance, with escalation where needed to administrative measures and, for serious cases, criminal prosecution. Civil remedies may also be pursued by affected parties. Outlined below is a high-level overview of the main remedies typically available in practice, without attempting to be exhaustive or to cite the specific legislative bases.

Investigative powers

- On-site inspections/audits of relevant operators (eg, manufacturers, MAHs, wholesalers, pharmacies).
- Requests for information and access to records (eg, quality/GDP documentation, traceability, temperature controls, complaints/returns).
- Sampling, verification activities, and follow-up investigations (including vigilance and incident reports).

Sanctions and remedial measures

- Cautionary notice (statement of compliance without sanctions).
- Corrective action requirements (CAPAs) with defined timelines and follow-up inspections.
- Restrictions on activities and, where applicable, suspension/withdrawal of permits/authorisations.
- Market measures such as quarantines, withdrawals/recalls, and other corrective safety actions.
- Administrative financial measures may be available depending on the regime and the nature of the breach.
- Criminal sanctions (notably fines, and in severe cases imprisonment for individuals), typically for intentional, serious, or repeated infringements.

Use in practice

Enforcement is typically risk-based and progressive: remediation and compliance restoration first, with stronger measures where patient safety, product integrity, or supply-chain security is affected, or where non-compliance is repeated or deliberate.

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 following is a non-exhaustive list of noteworthy new legislative changes in this area:

- From 10 January 2025, manufacturers must notify any interruption or discontinuation in the supply of medical devices (MDs) and in vitro diagnostic devices (IVDs) when it can reasonably be expected that such a disruption could endanger patient health or public health in one or more EU Member States. Manufacturers bear the legal responsibility for submitting these notifications to their designated competent authority. Manufacturers established in Belgium must send the designated form to the Federal Agency for Medicines and Health Products (FAMHP) via shortage.meddev@fagg.be. The obligation does not apply for custom-made devices.
- To address persistent and severe medicine shortages across EU Member States, the European Commission has proposed the Critical Medicines Act (CMA), a new Regulation aimed at strengthening the availability and security of supply of essential medicines in the Union. The CMA introduces an industrial policy toolbox designed to boost EU manufacturing capacity and diversify supply chains. The CMA is intended to complement the broader revision of the EU's pharmaceutical legislation and forms part of a more comprehensive strategy to reinforce the EU's resilience against future shortages.
- The European Commission has introduced two initiatives under its broader Preparedness Union Strategy to reinforce the EU's ability to safeguard access to essential goods and lifesaving medical tools. The first initiative, the EU Stockpiling Strategy, is designed to secure reliable supplies of critical products, such as medicines, by fostering a coordinated approach among Member States. The Medical Countermeasures Strategy, in turn, focuses on strengthening the EU's capacity to develop, manufacture, and rapidly deploy key medical tools needed in health emergencies. This includes vaccines, treatments, diagnostics, and protective equipment.

- On 11 December 2025, a new Royal Decree on the parallel import and parallel distribution of human medicinal products entered into force, introducing several key updates to the existing legal framework.
- With the adoption of the proposed law on the resilience of critical entities in December 2025, the Belgian Parliament is finalising the national implementation of the Critical Entities Resilience Directive (CER). The CER requires Member States to ensure that essential services underpinning vital societal functions or economic activities remain uninterrupted. Manufacturers and distributors of medicinal products, manufacturers of medical devices as well as entities engaged in pharmaceutical research and development, are in scope of the CER and can be designated as critical entities.