

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 France, the Public Health Code (Code de la Santé Publique – CSP) is the main legal framework governing the import, wholesale distribution, retail sale, and export of therapeutic products, alongside directly applicable EU pharmaceutical and medical-device rules.

The main competent authorities are:

- The Ministry of Health (Ministère de la santé, des familles, de l'autonomie et des personnes handicapées), which defines public health policy and oversees the general regulatory framework.
- The French National Agency for the Safety of Medicines and Health Products (Agence Nationale de Sécurité du Médicament et des produits de santé – ANSM), which grants marketing authorisations for medicinal products, supervises clinical research, manufacturing, import, export, wholesale distribution and advertising and possibly issues health policy decisions to ensure the security of products and processes and safety of patients and healthcare professionals.
- The Directorate General of Customs and Indirect Taxes (Direction Générale des Douanes et Droits Indirects – DGDDI), which controls imports and exports at the borders.
- The Directorate General for Competition, Consumer Affairs and Fraud Control (Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes – DGCCRF), which is responsible for commercial compliance, protection of consumers and anti-fraud enforcement.
- The French High Authority for Health (Haute Autorité de santé – HAS), which is primarily involved in the assessment of medicinal products and medical devices for reimbursement purposes.
- The Regional Health Agencies (Agences Régionales de Santé – ARS), which monitor the implementation of health policies in French territorial regions and may authorise certain activities.

Therapeutic products in France are regulated at national level by the central State. Certain matters may then be implemented locally by the Regional Health Agencies.

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?

In France, therapeutic products are classified under the CSP and EU rules, which govern their marketing and distribution.

For medicinal products, French law mainly distinguishes between prescription-only, OTC, hospital-use, narcotic, and investigational products. Prescription-only products require a prescription and a Market Authorisation (MA); OTC products do not need a prescription. Hospital-use products are restricted to healthcare establishments, narcotics are subject to strict controls, and investigational products may be used only in authorised clinical trials. These products are subject to mandatory pharmacovigilance (PV) requirements.

Medical devices are classified into four risk classes ‘I, IIa, IIb and III’ under Regulation (EU) 2017/745 (MDR) (Arts L. 5211-1 et seq. of the CSP); or ‘A, B, C, D’ under Regulation (EU) 2017/746 (IVDR) (Arts L. 5221-1 et seq. of the CSP). CE marking is required, via self-certification or notified-body certification depending on the class of the product. In France, devices may also be prescription-only, non-prescription, or hospital-use-only.

Manufacturers must justify classification in their technical documentation. Medical devices are subject to mandatory materiovigilance (MV) requirements.

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 France, the marketing of drugs, including wholesale distribution, requires an ‘*exploitant*’ licence. Under Article R. 5124-2 of the CSP, the ‘*exploitant*’ is the entity responsible for medicinal product operations such as wholesale supply, advertising, information, pharmacovigilance, batch traceability, recalls and, where applicable, storage. This role may be performed by the MA holder itself or by a third party acting on its behalf or by both, according to a pre-agreed allocation of tasks.

Under French law, the wholesale distribution of drugs requires ANSM authorisation to open a pharmaceutical establishment. This notably requires the appointment of a responsible pharmacist. A new authorisation is needed in the event of a substantial change, while non-substantial changes must be declared.

Once authorised, the company must strictly comply with the 2014 Good Distribution Practice guidelines (Bonnes Pratiques de Distribution en Gros – BPDG). These BPDG guidelines impose various obligations relating to quality management, personnel, premises and equipment, documentation, and logistics.

All of these requirements are subject to regular inspections by the ANSM or by the Regional Health Agencies, which may suspend or withdraw the authorisation if applicable legal or regulatory obligations are breached. These inspections are strictly regulated.

EU law does not require a dedicated wholesale distribution licence for medical devices.

Wholesalers are generally treated as distributors (and sometimes importers) and must comply with the MDR or IVDR.

In addition, actor registration in the European Database on Medical Devices (EUDAMED) mainly concerns manufacturers, authorised representatives, and importers, not distributors as

such. In France, the wholesale distribution of medical devices is also subject to declaration to the ANSM.

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 France, retail distribution of therapeutic products is subject to a regime distinct from wholesale distribution, with specific authorisation or notification requirements and strict good-practice rules to ensure safety, traceability, and proper use. Under Article L.4211-1 CSP, retail sale and dispensation to the public, including online, of medicinal products and in vitro diagnostic medical devices fall within pharmacists' monopoly, except for pregnancy and ovulation tests.

For a pharmacy to dispense medicinal products, whether in person or online, it must be lawfully established and licensed as a 'community pharmacy' (*pharmacie d'officine*), and the pharmacist must hold the right to operate in accordance with Article L. 5125-1 and Article L. 5125-18 of the CSP. In the case of online sales, the website must also be linked to an existing physical pharmacy, and the creation of the website is subject to prior declaration with the competent Regional Health Agency (ARS), as well as notification to the territorially competent delegation of the National Council of the Order of Pharmacists (Ordre national des Pharmaciens – ONP) (Art L. 5125-36 of the CSP). From 30 April 2026, online sale of medicines by pharmacies will no longer require prior ARS authorisation, but only a prior declaration covering both the e-commerce activity and the website. The declaration must include the information set out in the Order of 27 February 2026. If the ARS does not object within 21 days, the pharmacy may start operating and must inform the competent Order of Pharmacists within seven days.

Retail sales, in-store or online, are subject to good dispensing practices and pharmacists' ethical rules. Dispensing must remain under the effective control of a pharmacist registered with the Order, and breaches may be criminally sanctioned. Other good practices also apply to the preparation, import, export, wholesale distribution, and brokering of medicinal products.

Retail supply of medical devices follows similar principles, but pharmacists' monopoly does not extend to non-IVD devices. Pharmacists are generally treated as distributors under the MDR/IVDR, and French law may impose specific retail restrictions for certain devices.

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

The sale of medicinal products to consumers over the internet is governed by Chapter V bis of the CSP, which provides in particular that:

- a. only pharmacists may create and operate an online medicinal-product sales website;
- b. the website must be linked to a physical community pharmacy (*officine*);
- c. only non-prescription medicines may be sold online;
- d. the pharmacist remains fully responsible for the activity and must comply with applicable ethical and dispensing rules;
- e. the activity and website are subject to prior declaration with the competent ARS, after which the pharmacy may start operating if no incompleteness notice is issued within the applicable period and within seven days, with the competent regional Order of Pharmacists.

The National Council of the Order of Pharmacists maintains an up-to-date list of authorised websites and makes it available to the public on its website.

Under French law, the online retail sale of in vitro diagnostic medical devices by pharmacists is subject to the same rules as above, as these products fall within pharmacists' monopoly. In practice, similar requirements will often apply to other medical devices sold by pharmacists. These national rules are, without prejudice to the general MDR and IVDR requirements, applicable to the distribution, import, and online sale of medical devices.

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 is strictly regulated by French law, in particular Articles R. 5121-108 et seq. of the CSP.

Importing medicinal products for human use into France requires the importer to be an authorised pharmaceutical establishment.

Imports are subject to prior ANSM authorisation. The application, filed via Impexweb, must state the product's nature, quantity, origin, and destination, including for EEA-origin products. Exceptions apply to products already authorised in France and presented in accordance with their MA, certain early-access or compassionate-use products, and products for authorised biomedical research. No authorisation is required for mere transit. For finished products, an import authorisation is generally required for each import, although it may cover multiple operations for one product over up to one year, and a fixed total quantity. Each shipment also requires a customs declaration, including reference to the ANSM authorisation.

Authorities may carry out border controls through customs, in coordination with the ANSM. For medical devices, there is no standalone import licence, but importers must comply with the MDR/IVDR requirements applicable to EU importers. As a prerequisite to placing devices on the market, the relevant economic operator registrations are handled through EUDAMED for actors such as importers under Articles 30 and 31 MDR (or Arts 27, 28 and 30 IVDR).

Under French law, the ANSM can take national market-surveillance measures affecting imports (including decisions to suspend or withdraw import and marketing), which operates as a practical 'control lever' beyond customs formalities.

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?

Under French law, individuals may import medicinal products for personal use only in limited quantities and for prescribed treatment duration (or if prescription is absent, for three months only). Personal carriage does not require prior ANSM authorisation. Otherwise, prior authorisation is generally required, unless for instance the product is authorised in the EEA or in its country of origin and accompanied by a valid prescription. The ANSM may, in any event, ban the import on public-health grounds. Regarding medical devices, if a device is shipped from a non-EU country, it should be brought in via an EU importer meeting the importer obligations in Article 13 MDR or IVDR (verification, traceability, labelling), otherwise customs and market surveillance may treat it as a non-compliant placement on the EU market.

In France, customs guidance stress that when importing or exporting medical devices, it must be checked whether the device is subject to ANSM ‘police sanitaire’ restriction decisions, which can result in bans or suspensions that effectively block importation even for end users.

As a rule, French customs distinguish between personal use and commercial import based on the nature and quantity of the products. If the quantities appear commercial, the import will be treated as a professional (economic operator) import subject to the usual MDR/IVDR placing-on-the-market rules.

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 not sell medicinal products directly to French consumers online or by mail order. Such sales are reserved to pharmacists and may be made online only through a website linked to a physical French community pharmacy which has filed the required declaration with the ARS in accordance with the regime started on 30 April 2026. The same applies to in vitro diagnostic medical devices, except pregnancy and ovulation tests.

A foreign supplier therefore cannot rely on this regime to sell such products directly to consumers. It may, however, sell certain non-IVD medical devices, as well as pregnancy or ovulation tests, subject to compliance with the MDR/IVDR.

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 of medicinal products is permitted in France, subject to the prior granting of a parallel import authorisation (*Autorisation d’Importation Parallèle – AIP*) by the ANSM.

Governed by Articles R. 5121-115 to R. 5121-132 of the CSP, parallel import applies to medicinal products with an EU marketing authorisation that are identical in composition, pharmaceutical form and therapeutic effect to the product marketed in France, subject only to limited differences without therapeutic impact or public health risk. Such differences may only relate to shelf life and storage conditions (when more stringent than those for the product marketed in France), appearance (through size, shape, colour, engraving, printing or other marking), excipients composition, or leaflet last revision date. Batches must have been released, and the importer must be duly authorised in the EU/EEA. Parallel import authorisation is granted for five years, specifies the relevant differences, and is published by the ANSM.

The French Intellectual Property Code also applies to parallel imports, notably regarding patents and SPCs. Such imports must not infringe rights held in France, except where exhaustion of rights applies and no legitimate grounds justify objection (Art L. 613-6 of the Intellectual Property Code).

Re-labelling or re-packaging must be carried out in an authorised establishment, comply with ANSM rules, preserve the product’s quality and safety, with no alteration of its original condition. Labelling must match the French reference product, and the leaflet must be in French.

Regarding medical devices, if the parallel importer relabels, repackages, or translates information, Article 16 of the MDR or IVDR applies and can trigger manufacturer-type obligations; in particular, the operator must notify the manufacturer and the competent authority at least 28 days in advance (Art 16(4) MDR).

Regarding IP, within the EEA, resale is usually allowed once the trademark owner first sells the product. However, the brand can block parallel imports if the importer changes the packaging or labelling unless such changes are strictly necessary and do not harm the product or the trademark.

In France, the ANSM is the competent authority for medical-device market surveillance, so it is the authority typically concerned by MDR or IVDR notifications and oversight tied to those relabelling and repackaging activities.

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?

In principle, exports of therapeutic products from France are not subject to general quotas. However, they may be restricted for public health reasons, particularly to prevent or manage shortages. The CSP requires MA holders to ensure continuous supply of the French market, allowing the ANSM to limit exports where patient needs in France could be affected, especially for MITMs. A public list of such products is made available by the ANSM, while the latter maintains a public register of MITM that are currently experiencing supply difficulties and for which there are no or insufficient therapeutic alternatives available on the French market.

In addition, for public health reasons, the ANSM may ban the export of medicinal products that do not benefit from a marketing authorisation (or whose authorisation has been suspended or withdrawn), or which are likely to expose patients to risks that are disproportionate to the expected benefits (Art L. 5124-11 of the CSP).

For medical devices, the MDR does not generally impose EU-wide export permits or quotas, but focuses on EU market access and post-market surveillance. In emergencies, EU law provides shortage-monitoring mechanisms for critical devices. In France, the ANSM may also restrict or suspend exports through public-health policing measures, enforceable through inspections and sanctions under the CSP.

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?

French law allows the manufacture and export of medicinal products not authorised in France, provided they are intended exclusively for non-EU markets.

This regime, deriving from EU law, is based on Articles L. 5124-11 and R. 5121-135 of the CSP, which require that the export of medicinal products to non-EU countries not holding a marketing authorisation in France are subject to a declaration to (in fact an authorisation from) the ANSM.

In France, manufacture must be carried out by an authorised pharmaceutical establishment and declared to the ANSM, with key information on the product and the reasons why it has no French MA. The ANSM may ban export on public-health grounds. By contrast, the MDR/IVDR do not provide any specific EU ‘export-only’ authorisation for medical devices not approved for EU marketing.

If a device is CE-marked and can be marketed in the EU, a Member State may issue a Certificate of Free Sale for export purposes under Article 60 MDR or Article 55 IVDR, among other items, the certificate shall confirm that the device bearing CE marking may be marketed in 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?

Under French law, imported therapeutic products must comply with strict labelling, information, and traceability requirements, and the same broadly applies to exported products. For medicinal products, outer packaging must be in French and include key information such as the product name, dosage, active substances, pharmaceutical form, warnings, batch number, expiry date, and the MA holder's name and address. Specific provisions also apply to the package leaflet (Arts R. 5121-147 to R. 5121-149 CSP) and the summary of product characteristics (Order of 6 May 2008). Mentions may vary depending, among other criteria, on the nature of the MA (centralised or national), on whether or not the product is under compulsory medical prescription and on the existence (or not) of a primary packaging and its size.

Parallel-imported medicines or medicines aimed at being exported, must be packaged in a certain way to comply with French legal requirements. This packaging involves applying labels or placing the product in new packaging, which must be carried out by an authorised pharmaceutical facility.

In addition, Directive 2011/62/EU and Delegated Regulation (EU) 2016/161 require medicinal product packaging to bear a unique identifier and an anti-tampering device. In France, this system is implemented through CIP, the national medicines verification organisation.

For medical devices, the rules are primarily set out in Regulations (EU) 2017/745 and 2017/746, which apply directly into French law (compared to, in particular s 23, Ch III, Annex 1 of the MDR and s 20, Ch III, Annex 1 of the IVDR). These regulations require a system of unique device identification (UDI), enhanced traceability, and labelling and instructions for use in the official language of the EU Member State where the device is made available. These requirements are incorporated into Articles L. 5211-1 et seq. and Articles L.5221-1 et seq. of the CSP.

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?

There are several economic and administrative regulatory frameworks which influence the distribution channels and availability of therapeutic products under French law.

Prices of reimbursable medicines are set by agreement between the Economic Committee for Health Products (*Comité Economique des Produits de Santé* – CEPS) and pharmaceutical companies (Art L. 162-16-4 of the Social Security Code), based on the prior opinion of the HAS (High Authority for Health) on the eligibility of the product to, and if eligible its level of, reimbursement. Reimbursement by health insurance is conditional on the drug's inclusion on the list(s) provided for in Articles L. 162-17 or L. 162-22-7 of the CSP. Similar rules apply to reimbursable medical devices.

For medicinal products, the CSP imposes continuity-of-supply and stockholding obligations on key supply-chain actors, especially MA holders, operators, and wholesale distributors, to help prevent shortages, particularly for MTIM. For medical devices, on the other hand, the MDR does not harmonise prices, reimbursement, or procurement (which fall within French national jurisdiction), although supply-chain actors remain subject to MDR distribution obligations.

In France, reimbursement materially shapes market access because individual-use medical devices are only reimbursed only if they are listed on the LPPR/LPP under Article L.165-1 of the *Code de la sécurité sociale*.

Public hospitals and other public purchasers generally procure devices through public procurement procedures governed by the French Code of Public Procurement, in particular the principles of equal treatment and transparency, efficiency and continuity of supply.

France also has a specific shortage regime for medical devices under Article L. 5215-1 CSP, which may affect availability and distribution in practice. Public procurement of therapeutic products is also governed by the French Public Procurement Code, including competitive tendering requirements.

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?

Under the CSP, the ANSM may inspect sites, access professional premises, request documents, take samples, and investigate manufacturers, operators, importers, distributors, and wholesalers, notably in cases of shortages, non-compliance, traceability failures, or unlawful distribution. When violations are identified, a range of sanctions and corrective measures may apply, as outlined below.

Administrative

The ANSM may issue formal notices, suspend or withdraw authorisations, order recalls or withdrawals of batches or products, temporarily ban certain activities, or impose financial penalties proportionate to the severity of the breach, with daily penalties for non-compliance (Arts L. 5311-1 et seq. of the CSP).

Criminal

Offences such as the marketing or distribution of non-compliant, falsified, or unauthorised therapeutic products are punishable under Articles L. 5421-1 et seq. and L5461-1 et seq. of the CSP, which provide for fines and imprisonment.

Civil

Operators may incur civil liability under general law or specific liability regimes for defective products, in particular Articles 1245 et seq. of the French Civil Code.

15. Are there recent 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?

At the French national level, the 2025 Social Security Financing Act (LFSS 2025) strengthened the legal framework against shortages by expanding the obligations to report supply tensions. It increases financial penalties for non-compliance with safety stock requirements and specifies new public health enforcement measures applicable to marketing authorisation holders, as detailed in Decree No. 2025-760 of 4 August 2025 on the prevention of medicine shortages and the anticipation of supply disruptions.

More broadly, reimbursement of therapeutic products is trending downward. At EU level, the ‘pharma package’ reform agreed in December 2025 aims to strengthen supply security, reduce shortages, and improve competitiveness. In parallel, recent reforms are already affecting medical-

device distribution, notably Regulation (EU) 2023/607, which extended MDR transition periods and removed the sell-off deadline. EUDAMED is also moving from ‘voluntary’ to ‘mandatory’: following the Commission notice, the first four modules (Actor registration; UDI/device registration; Notified Bodies & Certificates; Market Surveillance) will become mandatory on 28 May 2026. This will materially change compliance workflows for stakeholders, and improve transparency, traceability, cross-border cooperation as well as market surveillance.

France has also strengthened shortage controls for devices: the CSP now contains a dedicated shortage regime for devices (in particular Article L.5215-1 of the CSP, modified in April 2025).