

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?
<p>The key Bulgarian acts regulating therapeutic products are the Law on Medicinal Products in Human Medicine (LMPHM) and the Law on Medical Devices (LMD), as well as a number of ordinances for their implementation.</p> <p>The Bulgarian Drug Agency (BDA) is the competent regulatory authority for both medicinal products and medical devices. The BDA is responsible for granting all types of authorisations for medicinal products (for marketing, import, export, wholesale, retail, parallel import, and advertising), as well as for registration of persons placing medical devices on the market, for wholesale and for conformity assessment of medical devices. The BDA also has oversight and control powers regarding the quality, efficacy and safety of medicinal products and medical devices placed on the market. It organises and maintains a pharmacovigilance system and a system for recording and analysing reports of incidents involving medical devices. The BDA is also the competent body for transfusion oversight.</p> <p>The Minister of Healthcare is entitled to order the authorisation of medicinal products in specific cases (Arts 10 and 11 LMPHM).</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>Medicinal products are classified depending on the method of dispensing as: prescription-only or over-the-counter (OTC) (Art 171 LMPHM). The person applying for marketing authorisation shall indicate the method of dispensing in the application, however, the BDA determines the dispensing status of a medicinal product.</p> <p>Prescription-only products are further classified into three subcategories: (1) medicinal products subject to restricted medical prescription, intended for use only in certain specialised fields; (2) medicinal products subject to special medical prescription; and (3) medicinal products for multiple or single dispensing under the same medical prescription (Art 172 LMPHM).</p> <p>Different legal consequences are attached to each category. OTC drugs can be sold in pharmacies and in drugstores (Art 238 LMPHM); advertising to the public is only permitted for OTC drugs (Art 247 LMPHM); and advertising over the internet of prescription-only drugs is explicitly</p>

forbidden, except for vaccination campaigns conducted pursuant and approved by the competent authorities (Art 248a LMPHM).

The classifications of medicinal products also have different implications for the purposes of determining their prices by the National Council on Pricing and Reimbursement of Medicinal Products (NCPMP). The ceiling prices of prescription-only drugs are determined by the NCPMP in accordance with the lowest reference prices in the designated Member States (Art 261a(1)(2)), whereas the NCPMP registers the maximum prices for OTC drugs (Art 261a(3)).

Medical devices are classified depending on their intended use, as determined by their manufacturer. The classifications are as follows: (1) in vitro diagnostic medical devices (IVDs); (2) active implantable medical devices and (3) medical devices other than those referred to in items (1) and (2). The IVDs are risk classified into List A and B, self-testing devices and other groups: where List A includes higher risk devices, eg, for blood type testing, HIV and hepatitis screening; and List B includes devices with lower risk. The lists determine the type of conformity assessment procedures to be applied by the manufacturer. The other devices under item (3) above are risk classified into Classes I, IIa, IIb and III (with higher groups corresponding to a higher level of risk). The classes again are relevant for the type of conformity assessment procedures to be applied by the manufacturer and instructions for use are not required for the medical devices Classes I and IIa which, in the manufacturer's assessment, can be used safely without them.

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?

Medicinal products can be placed on the market after receiving marketing authorisation (MA) or certificate of registration (CR) by the BDA pursuant to a national procedure or a decentralised procedure/mutual recognition procedure, where the latter procedure applies if the person applying for MA/CR before the BDA has already received such by the competent authority in another EU Member State, or by the European Drug Agency pursuant to a centralised procedure (Art 23(1) and (3) LMPHM). Only medicinal products with a MA/CR holder established in a Member State may be placed on the market in Bulgaria (Art 23(4) LMPHM). Certificates for registration are only issued for homeopathic and traditional herbal medicinal products and can be subject to a simplified procedure if certain conditions are met (Art 35 – 41 LMPHM).

Wholesale distribution authorisation (WDA) issued by a competent authority of an EU Member State is required (Art 195(1) LMPHM), and where the WDA holder has warehouse facilities in Bulgaria a separate BDA authorisation is required (Art 195(2) LMPHM). A WDA holder may not be the holder of a retail trade authorisation for the sale of medicinal products in a pharmacy, issued under the LMPHM (Art 195a LMPHM). A manufacturer of medicinal products may only carry out the wholesale distribution of medicinal products for which it holds a manufacturing authorisation; and an importer of medicinal products – only for the medicinal products for which it holds an import authorisation (Art 196 LMPHM). An additional licence for medicinal purposes issued by the Minister of Healthcare or a designated deputy is required for medicinal products containing narcotic substances (Art 32 of the Law on Control of Narcotic Substances and Precursors).

The WDA holder shall have suitable premises, equipment and facilities, appropriate means of transport, ensuring the proper storage, distribution and transportation of medicinal products in accordance with the requirements of the Good Distribution Practice, as well as qualified

personnel and a responsible pharmacist with at least two years' professional experience (Art 197 LMPHM). Further, the WDA holder shall have a system for blocking and recalling medicinal products which are not compliant with the requirements for quality, safety and efficacy, and is required to block and recall them (Art 207 LMPHM).

A WDA issued by the BDA or the competent authority of another EU/EEA country is required for medical devices (Art 77(1) LMD). WDA is not required for the manufacturers established on the territory of the Republic of Bulgaria (Art 77(2) LMD). Manufacturers of certain medical devices are required to register with the BDA.

Key conditions for wholesale distributors include: trading only medical devices which have not expired and have 'CE' marking affixed (for other requirements on the product information see the response to Question 12, below); maintaining their storage premises for medical devices, if any, in accordance with the storage requirements for the relevant type of device as determined by the manufacturer; maintaining a documented system for monitoring of the safety of medical devices placed on the market and for the blocking and recalling of medical devices which do not to comply with the safety requirements; storing the batch certificates of such devices for a five-year period; storing expired and blocked/recalled medical devices in a designated area with permanent warning signage until they are returned to the manufacturer or destroyed (Art 82 LMD).

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 sale of medicinal products can only be carried out in pharmacies and drugstores (Art 218 LMPHM). A retail trade authorisation (RTA) is required for the retail sale of therapeutic products in pharmacies. The RTA holder must complete an employment contract or a contract for the management of a pharmacy with a qualified pharmacist, who will manage the pharmacy on the site (Art 222 LMPHM). The LMPHM envisages a restriction that one RTA holder may open four pharmacies on the territory of Bulgaria at the maximum (Art 222 LMPHM) and that it cannot hold a WDA (Art 222a LMPHM).

Drugstores can be opened after registration with the relevant Regional Health Inspectorate (Art 239 LMPHM). Only OTC drugs and medicinal devices can be sold in drugstores, and the drugstore must be managed by an on-site healthcare professional (Art 238 LMPHM).

Some medicinal products, listed in an Ordinance by the Minister of Healthcare, may be sold through vending machines, which can only be owned by the RTA holder or the person holding a drugstore registration certificate (Art 234 LMPHM).

The LMD does not explicitly regulate retail sales of medical devices. The LMD only provides for fines (BGN10,000, approx. €5,100) for persons who carry out the retail sale of medical devices without the 'CE' marking affixed or which have expired and for persons who carry out the retail sale of medical devices outside the permitted establishments. The permitted establishments are opticians, pharmacies, veterinary pharmacies, drugstores, persons providing aids, adaptations, facilities and medical devices to persons with disabilities under the Law on Persons with Disabilities, and persons owning commercial sites where medical devices designated by order of the Minister of Health (or an authorised deputy minister) are offered.

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

The online sale of prescription-only medicines is prohibited (Art 234(4) LMPHM). OTC drugs may only be sold online by a pharmacy or drugstore which has received the BDA's website

approval and subsequently registered in the relevant register maintained by the BDA (Art 42-43 Ordinance No. 28 on the Structure, Procedures and Organisation of Pharmacies, ‘Ordinance No. 28’). When applying for the BDA’s approval, the pharmacy/drugstore must provide a declaration that it owns or has at its disposal means of transport ensuring the proper storage of medicinal products during transportation (Art 42(2) Ordinance No. 28).

The pharmacy/drugstore is required to have its own website, where it shall publish a common logo recognisable throughout the EU (Art 234(7) LMPHM), and provide certain information, for example, information about the economic operator (name, address, pharmacy/drugstore locations, RTA/registration certificate number), information about the products, transport costs, etc. (Art 41 Ordinance No. 28). Further, the pharmacy/drugstore must ensure proper packaging, consignment and delivery of the medicinal products; delivery of the medicinal products within 24 hours of receipt of the request; the maintenance of a documented system for tracking consignments (Art 44 Ordinance No. 28).

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)?

Importation into the territory of Bulgaria from a third country of all types of medicinal products, including medicinal products intended for clinical trials, may only be carried out by persons registered as merchants under the legislation of an EU Member State, who have obtained an import authorisation by the BDA (Art 161(1) LMPHM). To obtain an import authorisation, the person must have at least one qualified professional (holder of a master degree in medicine, pharmacy, chemistry, biotechnology or biology with at least two years’ experience) and a quality control laboratory and storage premises, equipped with the necessary technical facilities (Art 161(2) LMPHM). On receipt of the import authorisation application, the BDA carries out an on-site inspection of the control laboratory and the storage premises to establish their compliance with the requirements of Good Manufacturing Practice and Good Distribution Practice (Art 162 LMPHM).

The qualified professional shall issue a batch release certificate for each batch, certifying that the imported batch of a medicinal product from a third country has undergone a full qualitative and quantitative analysis and complies with local requirements for granting of a MA (Art 163(1) LMPHM). Where a batch release certificate has been issued by a qualified professional from another EU Member State or the EU has an agreement on the mutual recognition of the Good Manufacturing Practice certificates with said third country, no control testing is required (Art 163(2) and (3) LMPHM).

The qualified professional is required to keep records for each imported batch for a period of at least five years (Art 163(7) LMPHM). The import authorisation holder must maintain a system for the blocking and recalling of medicinal products which do not to comply with the quality requirements (Art 163(8) LMPHM).

Prevention of import of falsified medicinal products is carried out through cooperation between the BDA and the customs authorities, and they may conduct joint inspections (Art 17(7) and (8) LMPHM).

The LMD does not provide for a special import authorisation for medical devices, where their import shall comply with the general requirements.

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?

OTC drugs can be imported by Bulgarian citizens and foreigners with residence permits in the necessary quantity for their stay, up to a ceiling of three months, or a larger quantity if their stay is longer than three months and they hold a prescription.

Prescription-only drugs can only be imported by the patients they were prescribed to or by their authorised representative. They must certify their right to carry or transport the medicinal product with a pharmacist-certified copy of a filled prescription from the relevant pharmacy, prescribed for the specific treatment, and they can only carry such quantities that have been provided in the prescription.

All medicinal products imported by consumers must be in their original packaging.

Medicinal products which are not distributed on the Bulgarian market (but are authorised for use in an EU Member State and under the LMPHM) may also be imported for specific patients when no alternative treatment is available for a particular condition. In this case the medicinal product is delivered via a special order to the relevant hospital.

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?

The sale of therapeutic products to consumers can only be conducted through licensed pharmacies or registered drugstores. The RTA or registration certificate holders can be individuals or legal entities registered as merchants in Bulgaria or in another EU Member State. For the other applicable requirements please refer to the responses to Question 4 and Question 5.

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 importation of medicinal products into Bulgarian territory may be carried out by an individual or legal entity registered under the Law on Commerce or under the legislation of an EU Member State, after obtaining a parallel import authorisation issued by the BDA (Art 213 LMPHM).

A medicinal product authorised in another EU Member State may be subject to parallel import into Bulgaria if it is identical or similar to a medicinal product authorised in Bulgaria under the LMPHM – an identical or similar medicinal product has the same qualitative and quantitative composition in terms of the active substance(s), is offered in the same pharmaceutical form, is offered in the same primary packaging, and has a similar graphic design on the packaging (Art 214 LMPHM). If there are differences (in the composition of excipients and others) between the medicinal product for parallel import and the medicinal product authorised for use in Bulgaria, it must be proven that these do not affect the therapeutic qualities of the medicinal product for parallel import, and they must be indicated on the packaging and in the patient information leaflet (Art 215(3) and (4) LMPHM). If the repackaging and/or labelling of the medicinal product in Bulgarian language is carried out on the territory of Bulgaria, a manufacturing authorisation by

the BDA is required (Art 215(5) LMPHM). The products subject to parallel import may only be used under the MA's conditions of the medicinal product in Bulgaria (Art 215(6) LMPHM).

Parallel import authorisation is not automatically terminated when the MAH of the medicinal product placed on the market in Bulgaria withdraws it for reasons unrelated to a public health risk (Art 216(7) LMPHM).

The import authorisation holder must notify the MAH of the medicinal product placed on the market in Bulgaria of its intention to carry out parallel importation and, on request, provide a sample of the parallel imported medicinal product (Art 217(1) LMPHM).

The LMD does not regulate the parallel import of medical devices.

EXPORT

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

The export of medicinal products may be carried out by a WDA or a manufacturing authorisation holder, with the latter only permitted to export medicinal products which it has manufactured (Art 217a(1) and (2) LMPHM).

Medicinal products included in the Positive Drug List (PLD) for which a shortage has been established may not be exported for the period during which they are included in the list (Art 217a(4) LMPHM). The BDA maintains a Specialised electronic system for monitoring and analysis of medicinal products included in the PLD through which shortages are identified (Art 217b LMPHM). The customs authorities are provided with a list of the medicinal products for which shortage is established (Art 217c(7) LMPHM).

In cases of epidemics, the Minister of Healthcare can ban the export of certain medicinal products for which shortages are established (Art 217d LMPHM).

The LMD does not regulate the export of medical devices.

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 MA is not required for medicinal products only designated for export (Art 8(6) LMPHM). However, a manufacturing authorisation is still required (Art 146(2) LMPHM) and the conditions and requirements thereof apply and the manufacturing operations should comply with the Good Manufacturing Practice.

Further, the manufacturing authorisation holder has to: keep records of the measures it has undertaken to use only active substances and excipients that have been manufactured in accordance with the relevant Good Manufacturing Practices; store samples and documentation relating to the medicinal products and active substances manufactured by it; store information about each transaction concluded for a period of five years – including the date, name of the medicinal product, quantity supplied, name and address of the recipient, and batch number; maintain a system for blocking and recalling medicinal products which are not compliant with the quality requirements; to attach the safety features to the outer or immediate packaging of the medicinal products (Art 160 LMPHM).

The LMD does not regulate the export of medical devices.

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?

The packaging of a medicinal product must consist of primary and/or secondary packaging and a package leaflet for the patient (Art 168 – 170 LMPHM). Its information must fully correspond to the summary of product characteristics as approved by the BDA, and one of the languages in which it is provided must be Bulgarian, the language used should be understandable to the patient, shall be legible and indelible.

The secondary packaging – or in the absence of such, the primary packaging – must provide a unique identifier as a safety feature enabling wholesale and retail distributors to verify the authenticity of the medicinal product and to identify individual packs, as well as a device allowing verification as to whether the packaging of the medicinal product has been tampered with. The secondary packaging shall include a marking for separate collection and recycling, as well as the name, pharmaceutical form and the strength of the active substance per dosage unit of the medicinal product in Braille.

Products containing narcotic substances, as well as products that are still subject to additional monitoring according to Article 23 of EU Regulation 726/2004, must be indicated accordingly.

Packaging of prescription only drugs must include safety features, where that is not required for OTC drugs, except where they are included in a list determined by the European Commission after being assessed as being at risk of falsification.

The package leaflet must include standard wording encouraging patients to report any suspected adverse drug reactions and should be designed in such a way as to be clear and comprehensible.

In line with Article 15 of the LMD the medical devices must have the ‘CE’ marking affixed on them, on the device, in the instructions for use and on its sterile packaging and should be easily legible and indelible. The CE marking shall have a minimum height of 5mm and where the size of the CE marking is different, the proportions of the graphic grid shall be respected. Any other marking attached to the device, its packaging and/or its instructions for use shall not mislead the user regarding the CE marking, nor shall it impair its visibility or legibility. In the case of devices placed on the market in sterile packaging, the CE marking must be attached both to the sterile packaging and to the sales packaging.

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?

A medicinal product may be sold within the territory of the country only after the decision of the NCPRMP approving the ceiling /maximum price has entered into force, or after the price has been registered (Art 261b LMPHM). It cannot be sold for a higher price than the approved/registered.

In order for the medicinal products to be reimbursed, they must be included in the Positive Drug List (PLD), maintained by the NCPRMP (Art 262 LMPHM). The medicines included in the PLD are selected based on evidence of efficacy, therapeutic effectiveness, safety, and an analysis of

pharmacoeconomic indicators (Art 262(4) LMPHM). Certain medicines might be included in the PLD only if the MAH has provided mandatory rebates (Art 262(10) LMPHM).

In the event of discontinuation of sales of a medicinal product included in the PLD, and where no other medicinal product within the same INN is authorised for, the MAH must notify the Ministry of Healthcare and the NCPRMP no later than 18 months prior to the date of sales discontinuation. Until the discontinuation of sales MAH is required to ensure sufficient quantities of the respective medicinal product to meet healthcare needs, except where the discontinuation is due to any of the ground referred to in Article 276 LMPHM (temporary suspension, revocation, termination, or amendment of the marketing authorisation of the medicinal product by the BDA) or Article 277 LMPHM (prohibition of the supply of the medicinal product and ordering its blocking and withdrawal from the market by the BDA).

Medical devices included in a list maintained by the BDA may also be reimbursed (Art 30a LMD), where the State annually determines the ceiling reimbursement values (Art 30b(1) LMD).

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?

The Ministry of Healthcare exercises control over medicinal products. Immediate supervision is exercised by the Chief State Health Inspector, the Chairperson of the NCPRMP, the Executive Director of the BDA, and the Directors of the Regional Health Inspectorates, who act as state inspectors for the control of medicinal products (Art 267 LMPHM). When non-compliance with the Good Manufacturing Practice or the Good Distribution Practice is established, the relevant inspectors issue a statement of non-compliance (Art 269b(2) LMPHM). The relevant inspectors can conduct inspections and, where necessary, issue mandatory instructions or impose coercive administrative measures (Art 270 LMPHM).

Where the manufacturing site does not comply with the conditions under which the manufacturing authorisation was granted, the BDA may temporarily suspend or revoke the marketing authorisation for a group of, or for all, medicinal products. (Art 278(1) LMPHM). The BDA can also apply this measure for import authorisations where the import does not comply with the statutory requirements (Art 278(2) LMPHM). The BDA may also suspend or withdraw the manufacturing authorisation where the statutory manufacturing requirements are not met (Art 278(3) LMPHM).

Additionally, LMPHM envisages administrative sanctions in the form of monetary fines for manufacturing, importation, wholesale or retail of medicinal products without the required authorisation or in breach thereof (Art 284 LMPHM). In such cases the state control authorities can order the suspension of the operation of the establishment; revoke the granted authorisation (Art 293 LMPHM) and order the forfeiture to the State of the medicinal products subject of the infringement (Art 297 LMPHM). When the violations are committed by legal entities or sole merchants, the fines can be triple the amount (Art 291 LMPHM).

Market surveillance of medical devices is carried out by the BDA through inspections or taking samples/specimens of the devices and testing them (Art 87 LMD).

If medical devices are without the ‘CE’ marking or with an expired shelf life, the BDA can order their blocking or recalling from the market (Art 90-92 LMD). If, as a result of sampling, non-compliance with the essential requirements is established, the BDA may order the temporary

suspension of the distribution or use of the device (Art 93-94 LMD). The LMD also provides for different administrative fines in cases of infringement (Art 119-153 LMD).

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?

A bill to amend and supplement the LMPHM has been submitted to the National Assembly in December 2025. Key suggestions for amendments are:

- simplified procedures for supplying the Bulgarian market with medicinal products that are subject to parallel import, allowing parallel import licence holders to obtain licences under an accelerated procedure;
- WDA holders for medicinal products will be required to provide the BDA with daily information on the quantities of medicinal products delivered to the respective natural and legal persons, as well as information on the specific natural and legal persons.
- holders of parallel import permits will be required to notify the BDA of the date of actual placement on the market of the medicinal product; to notify the BDA in writing at least three months before discontinuing sales of a medicinal product, as well as indicate the reasons for discontinuing sales;
- power of the Minister of Healthcare to ban the export of medicinal products in exceptional cases and for reasons related to the protection of public health, provided that the order is issued based on an analysis showing that there are insufficient quantities of medicinal products to meet the needs of the population.

In August 2025, the Minister of Healthcare has issued an order on the basis of Article 217a LMPHM (see response to Question 10, above) banning the export of certain medicinal products for the treatment of diabetes.