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?

The main legislative framework governing wholesale distribution, retail sale, import and export of therapeutic products includes the following statutes and regulations:

- Act No. XCVIII of 2006 on general rules for the safe and economical supply and distribution of medicinal products and medical aids;
- Act No. XCV of 2005 on medicinal products for human use and on the amendment of other regulations related to medicinal products;
- Act No. CLIV of 1997 on healthcare;
- Government Decree No. 449/2017 on the authorisation of wholesale and parallel import activities of medicinal products;
- Healthcare Decree No. 53/2004 on wholesale and parallel import activities of medicinal products;
- Healthcare Decree No. 30/2005 on the labelling and patient information leaflets of medicinal products for human use;
- Healthcare Decree No. 4/2009 on medical devices;
- Healthcare Decree No. 8/2003 on in vitro diagnostic medical devices;

The main relevant authority regarding the wholesale distribution, retail sale, import and export of therapeutic products is the National Centre for Public Health and Pharmacy (in Hungarian: *Nemzeti Népegészségügyi és Gyógyszerészeti Központ*; abbreviated to NNGYK).

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 Hungary medicinal products for human use are classified into prescription-only medicinal products, over-the-counter medicinal products and reimbursed medicinal products. Medicinal products must be authorised for the Hungarian or EU market before they are launched in Hungary.

As a main rule, medicinal products are to be sold to patients via pharmacies. Prescription-only medicinal products may be dispensed only by pharmacies against a physician's prescription, while OTC medicinal products may be sold without prescription but still only through licensed pharmacies.

The distribution of 'simple' medical devices is not specifically regulated by Hungarian laws. However, there is a specific regulatory regime regarding medical aids, according to which medical aids can only be sold via medical aid stores or pharmacies.

A 'medical aid' (in Hungarian – *gyógyászati segédeszköz*) can be distinguished from a simple 'medical device' (*orvostechnikai eszköz*). A medical device qualifies as medical aid if the following criteria are met:

- the given device is made available for personal use to patients suffering in a temporary or persistent health impairment or disability;
- the given device is designed for use without the continuous presence of healthcare professionals; and
- personal use shall mean where the device is worn, applied or administered in body cavities with exterior opening, whether natural or artificial, or on the body for diagnostics, therapeutic, rehabilitation or nursing purposes.

There are certain 'technical devices for nursing and caring purposes' (*ápolási technikai eszköz*) which do not fall under the category of medical devices, but qualify as medical aids, provided that the above criteria are met.

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

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 product distribution in Hungary is subject to a wholesale distribution licence issued by the NNGYK.

In order for a company to obtain a wholesale distribution licence, it needs to fulfil detailed personnel and equipment related requirements. Such key requirements include – among others – appropriate quality system, technical equipment and facilities, qualified personnel, standard operating procedures and liability insurance.

A special authorisation issued by the NNGYK is required for the distribution of narcotics and psychotropic drugs.

The distribution of medical devices and in vitro diagnostic medical devices does not require a licence from the NNGYK. Importers and distributors of medical devices and in vitro diagnostic medical devices must comply with the MDR/IVDR.

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?

Retail supply of medicinal products in Hungary is subject to a detailed regulatory regime. Pharmacies must obtain an operating licence from the NNGYK in order for them to sell medicinal products to consumers. The activities and operation of pharmacies are regulated in detail and supervised by the NNGYK.

Public pharmacies offer a full-service medical facility supplying medicinal products directly to the public, led by a qualified pharmacist. The qualified pharmacist, together with other pharmacists working at the pharmacy, shall own more than 50 per cent of the shares of the company operating the given pharmacy.

Subject to a specific licence issued by the NNGYK, certain stores other than pharmacies may engage in pharmaceutical retail activities relating to certain OTC medicinal products. Such products are ones where clear self-diagnosis can be made, error is unlikely or do not entail serious health consequences, and risk of side-effects is not significant even in case of a substantial overdose, and provided that certain specific conditions are fulfilled.

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

Pharmacies are permitted to sell OTC medicinal products online, subject to certain requirements. However, home delivery of OTC medicinal products may only be carried out by a pharmacist or pharmacy assistant. Given the limited number of pharmacy personnel entitled to home deliver OTC medicinal products, home delivery of OTC medicinal products is rare in Hungary; most online pharmacy webshops work on a 'click and collect' basis, where consumers buy the products online and collect them from the pharmacy.

There is no specific regime applicable to the online sales of 'simple' medical devices.

Medical aids may be purchased online and delivered to a consumer's home by a distributor (medical aid store or pharmacy) that meets specific conditions; in case of home delivery of reimbursed medical aids no intermediary can be engaged by the distributor.

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)?

Medicinal products must be authorised for the Hungarian or EU market before they are imported to Hungary.

The import of medicinal products from EEA countries is subject to a wholesale distribution licence issued by the NNGYK. The import of medicinal products from non-EEA countries (third countries) is subject to a manufacturing licence issued by the NNGYK.

Within the EU, customs classification and tariff treatment follow the EU Combined Nomenclature; most medicinal products benefit from zero or reduced customs duty, but VAT and import formalities still apply.

For medicinal products that are imported from third countries, customs authorities check at the border if the given importer holds a manufacturing licence issued by the NNGYK.

There is no product-specific import licence for medical devices and in vitro diagnostic medical devices. Instead, importers must follow the rules outlined in the MDR/IVDR and ensure that the device bears a valid CE mark, is correctly labelled and is accompanied by a declaration of conformity and UDI information.

Border checks regarding medicinal products and medical devices imported from EEA countries are risk based.

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?

Medicinal products for personal use which are not categorised as ‘narcotic drugs or psychotropic substances’ can be freely imported into Hungary.

Persons undergoing treatment with ‘narcotic drugs or psychotropic substances’ may enter the territory of Hungary if the quantity of such narcotic drugs or psychotropic substances imported in their personal luggage does not exceed the quantity sufficient for three days of treatment, provided that they have an international certificate completed by their treating physician.

Injectable or infusible preparations containing strictly controlled substances sufficient for a period from three to 90 days for personal use may only be imported into Hungary with a specific certificate issued by the competent authority of the country of origin. The traveller is required to present the certificate to the police or customs authorities during inspections.

No specific rules are provided for the import of medical devices for personal use. Such medical devices for personal use can be freely imported into Hungary.

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 online sale of OTC medicinal products directly to consumers via e-commerce may only be undertaken by pharmacies subject to prior notification to the NNGYK.

Foreign pharmacies, whether established within or outside the EU, cannot obtain an authorisation from NNGYK for online sales in Hungary, as Hungarian law does not provide a procedure for foreign pharmacies to apply for such licences.

However, in line with 2001/83 EC Directive, OTC medicinal products may be supplied to Hungary by pharmacies established in any EU Member State, subject to their respective national legislation.

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 possible from EEA countries where the medicinal product also has a marketing authorisation.

The parallel importer shall notify the medicinal product's marketing authorisation holder (MAH) for the Hungarian market, and the NNGYK (in case of centrally authorised medicinal products, the European Medicines Agency) 30 days prior to the planned parallel import activities.

Parallel import activities can be carried out on the basis of a parallel import licence issued by the NNGYK. When assessing the request for parallel import, the NNGYK shall consider whether both the medicinal product to be imported through parallel trade and the medicinal product authorised for the Hungarian market are identical in all aspects.

If the medicinal product to be imported through parallel trade is not identical to the medicinal product authorised for the Hungarian market, the NNGYK shall examine whether the medicinal product to be imported through parallel trade can be classified as a version of the medicinal product authorised for Hungary that can be used identically in therapy, and whether the expected therapeutic and quality differences pose a health risk.

If the medicinal product to be imported through parallel trade needs to be repackaged by the parallel importer in order to ensure that the packaging, label text, and patient information leaflet comply with the marketing authorisation valid for Hungary, then the parallel importer or the third party engaged by the parallel importer for repackaging must obtain a pharmaceutical manufacturing licence.

Parallel trade is also permitted for medical devices and in vitro diagnostic medical devices, within the EEA, subject to MDR/IVDR.

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 to EEA and third countries is subject to a wholesale distribution licence. Where medicinal products are supplied to a third country, the given wholesaler shall ensure that the medicinal products are only supplied to persons authorised or entitled to receive medicinal products for wholesale distribution or retail supply in the third country concerned.

In cases where medicinal products are exported to third countries, the customs authorities check at the border that the exporter holds a wholesale licence or manufacturing licence.

If a wholesale distributor declares to the MAH that certain medicinal products are necessary for satisfying patient care needs in Hungary, the MAH shall satisfy such a wholesale distributor's order. In such cases, the requested medicinal products can only be sold to Hungarian healthcare service providers and may not be exported within the framework of wholesale trading activities.

The MAH shall not be subject to the above obligation to supply medicinal products to the given wholesale distributor if:

- the medicinal product in question is included in the drug shortage list made available by the NNGYK on its website;
- the wholesale distributor made losses during the year prior to the time of placing the order; or
- the wholesale distributor was found guilty by final decision for the unlawful export of medicinal products over a period of five years before the time of placing the order.

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?

In Hungary manufacturers may produce medicinal products for 'export only' purposes. In cases where a manufacturer produces medicinal products for 'export only' purposes, the manufacturer is still required to obtain a manufacturing licence issued by the NNGYK. This means that the manufacturer has to comply with all equipment and personnel related requirements and has to follow the EU Good Manufacturing Practice (GMP).

If a medicinal product is manufactured for 'export only', its labelling should follow the regulation applicable in the importing country.

There is no specific 'export-only' regime for medical devices and in vitro diagnostic medical devices, manufacturers need to comply with MDR/IVDR.

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?

All medicinal products placed on the Hungarian market must be labelled in Hungarian. Medicinal products shall be accompanied by a Hungarian language patient information leaflet, unless the information that should be included in the leaflet is provided on the outer or immediate packaging of the medicinal product.

The patient information leaflet must be written in such a way that the patient can use the medicinal product properly, with the help of a healthcare professional if necessary. The patient information leaflet may be provided in other languages in addition to the Hungarian version, provided that its content is identical in all languages. The NNGYK may waive the requirement of all information being included in Hungarian if the medicinal product is not intended for direct dispensing to patients or if there are serious disruptions in the availability of the given medicinal product.

In line with EU Regulation No. 2016/161, medical products shall bear a unique identifier which should be uploaded to a national database operated by a Hungarian non-profit organisation, HUMVO Nonprofit Zrt.

Wholesalers and parallel importers must ensure traceability and safety-feature verification and must report any suspected falsified medicinal products to NNGYK. A manufacturing licence is required if the medicinal product which is imported through parallel trade needs to be repackaged in Hungary in order to ensure that packaging and labelling complies with local requirements. Repackaging outside Hungary may only be carried out in an EEA country.

For medical devices and in vitro diagnostic medical devices, products placed on the Hungarian market must bear a CE mark and be accompanied by instructions for use in the Hungarian language. Devices must carry UDI and economic operators must ensure traceability, registration and vigilance reporting.

PRICING, REIMBURSEMENT, AND MARKET ACCESS

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

In Hungary price-control and reimbursement regimes generally operate independently from trade regulation but in practice, are decisive factors for market access and distribution.

Under Hungarian law, medicinal products authorised for distribution may only be reimbursed if the relevant medicinal product was approved for reimbursement by the National Health Insurance Fund (NEAK) during an official authority procedure. NEAK considers various health policy principles when deciding on including a medicinal product among its list of reimbursement items. These include: (1) consideration of budgetary constraints and financial viability; (2) transparency of interests; (3) needs-based approach; (4) cost-effectiveness; (5) professional soundness etc. Reimbursed medicinal products are subject to statutory price regulation, including maximum wholesale and maximum retail margins.

Medical devices/medical aids may also be reimbursed based on the type and price of the device as well as medical, technical and financial factors.

Wholesale distributors have a general obligation to procure and continuously supply medicinal products to ensure the balanced satisfaction of orders in the framework of ordinary course of business and to satisfy patient care requirements in Hungary.

Hungarian wholesale distributors have certain stock keeping obligations related to specific 'strategic medicinal products' containing certain active ingredients. On its website NNGYK publishes a list of such 'strategic medicinal products' which are available on the Hungarian market.

MAHs shall ensure that Hungarian wholesale distributors collectively have adequate supplies of medicinal products of the above 'strategic medicinal products' available in the required quantity. In cases of reimbursed medicinal products, the MAHs or – where MAHs are not carrying out distribution activities in Hungary – their contracted distributors shall ensure continuous product supply.

In order to control temporary disruptions in the pharmaceutical market, the Hungarian government may order that the price of medicinal products included in contracts between manufacturer and wholesale distributor may not be increased for a maximum of two years.

ENFORCEMENT, COMPLIANCE, AND RECENT DEVELOPMENTS

14. What investigative powers, sanctions, and remedial measures (administrative, civil, or criminal) are available to regulators when they detect non-compliance with trade and distribution rules for therapeutic products, and how are these powers used in practice?

In Hungary the NNGYK is responsible for enforcing the applicable regulations concerning the trade and distribution of therapeutic products.

In cases where the NNGYK finds that the applicable regulations were violated, it may impose the following sanctions:

- order the termination of the infringement; or
- ban the continuation of the infringing conduct; or
- order or initiate the withdrawal from the market of a medicinal product or batch of medicinal products that endangers human life, health or physical integrity; or
- request correction of the deficiencies within a reasonable time limit, or suspend the activity until the deficiencies are remedied; or
- in the event of a repeated or serious violation of public health, it may revoke the licence to continue activity or, in the case of an activity subject to notification, remove the operator from the register.

In cases of violation of product supply obligations, NNGYK may impose a fine up to HUF500m (approx. €1,385). In addition, in cases of violation of supply obligations, the NEAK may exclude the given medicinal product from reimbursement. Exclusion from reimbursement will occur if the medicinal product has not been on the market for longer than six months. In cases where a medicinal product has not been on the market for three continuous years, the NNGYK decides on revoking the marketing authorisation.

If conduct involves import, export or distribution of falsified medicinal products, medical devices or in vitro diagnostic medical devices, it may constitute a criminal offence under the Hungarian Criminal Code.

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 NNGYK regularly inspects wholesale distributors every three-to-five year on an ad hoc basis. In addition, extraordinary inspections may also be carried out (eg, GDP non-compliance, illegal activity, suspected product quality defects). The maximum fine the NNGYK can impose in relation to medicinal product supply-related cases is HUF500m (approx. €1,385).

According to publicly available data, the NNGYK as supervisory authority has initiated 54 proceedings regarding medicinal product promotion and supply over the past decade until 2023. Most of these cases related to medicinal product promotion and two cases related to wholesale distribution activities. In a case which involved public health and drug safety risks, the highest fine of HUF500m was imposed, as well as the withdrawal of the wholesale distribution licence by the predecessor of the NNGYK.[1]

[1] OGYI/2792/2013 – Prompt Pharma Szolgáltató és Kereskedelmi Korlátolt Felelősségű Társaság; https://ogyei.gov.hu/ogyi27922013.