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 Law on Pharmacies of the Republic of Lithuania (the 'LoP') is the principal regulatory framework governing the trade and distribution of medicinal products. The Ministry of Health of the Republic of Lithuania (the 'MoH') is responsible for forming state policy in respect of therapeutic products and issues. However, most of the relevant implementing legislation under the LoP empowers the State Medicines Control Agency under the MoH (the 'SMCA') to serve as the competent authority responsible for licensing pharmaceutical activities and supervising compliance.

With respect to medical devices, the principal requirements for placing medical devices on the Lithuanian market are set out in the Law on the Health System of the Republic of Lithuania (the 'LoHS'). Pursuant to the LoHS, medical devices placed on the market must comply with Regulation (EU) 2017/745 (the 'Medical Device Regulation' or 'MDR'), and in vitro diagnostic (IVD) medical devices must comply with Regulation (EU) 2017/746 (the 'In Vitro Diagnostic Medical Devices Regulation' or 'IVDR'). Accordingly, the provision of medical devices to the Lithuanian market must fully comply with the requirements set forth in the MDR/IVDR (including, but not limited to, labelling, quality and safety requirements etc). Regulatory oversight and market monitoring of medical devices is carried out by the State Accreditation Service for Healthcare Activities under the MoH (the 'SASHCA').

2. How are therapeutic products classified for regulatory purposes (eg, prescription-only, over-the-counter, hospital-use and risk classes for devices) 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?

The LoP classifies medicinal products into two main categories: (1) prescription; and (2) non-prescription (ie, over-the-counter) (Article 10 of the LoP). The classification of a medicinal product as a prescription medicinal product is confirmed by the SMCA or the European Medicines Agency.

Both prescription and non-prescription medicinal products may be sold to consumers by licensed pharmacies, and to pharmacies and hospitals by wholesalers. Hospital-use medicinal products are dispensed by hospitals; that is, hospitals may stock and dispense these products according to standard pharmacy and hospital pharmacy rules under the LoP. Non-prescription medicinal products may additionally be sold directly to consumers by medicinal product retail companies (only in respect of an approved list of non-prescription medicinal products).

Only non-prescription medicinal products may be advertised to the general public; prescription medicinal products may only be advertised to healthcare professionals (HCPs). Such advertising may appear either via promotional events or in publications intended for healthcare and pharmacy professionals and on specialised websites, which must not be available to the general public (Articles 50 and 51 of the LoP).

With respect to pre-market review and approval, it is not a medicinal product's classification as prescription or non-prescription that is decisive, but rather its marketing authorisation, as medicinal products may be placed on the Lithuanian market only if they are registered in the Lithuanian Register of Medicinal Products, the Union Register of Medicinal Products or the List of Parallel-Imported Medicinal Products (ie, registered medicinal products) (Article 8 of the LoP).

Medical devices are classified by risk in accordance with the rules under Annex VIII of the MDR into Classes I, IIa, IIb and III. IVD medical devices are classified by risk in accordance with the rules under Annex VIII of the IVDR into Classes A, B, C and D.

The notified body number (a four-digit number) must be indicated next to the CE conformity marking if: (1) the medical device is a Class IIa, IIb or III medical device, or if an IVD medical device is a Class B, C or D medical device; and (2) the medical device is a Class I sterile device or a device with a measuring function, or the IVD medical device is a Class A sterile device.

The risk classification of medical devices under the MDR/IVDR is relevant for determining the applicable conformity, authorisation and registration procedures.

Requirements for advertising medical devices in Lithuania are specified in the Law on Advertising (the 'LoA'), according to which the advertisement must not use the name, surname or image of a patient, or refer to the recommendations of healthcare institutions, HCPs or their professional organisations (Article 15 of the LoA) (eg, it is not permitted to use the image of an HCP referring to a medical device in an advertisement). Advertising that does not comply with the provisions of the MDR/IVDR is also prohibited.

LICENSING, AUTHORISATIONS AND DISTRIBUTION CHANNELS

3. Which licences, authorisations, registrations or other official permissions are required for businesses to engage in the wholesale distribution of therapeutic products, and what key conditions (such as Good Distribution Practice, facility standards, personnel, insurance or financial guarantees) attach to them?

In Lithuania, the wholesale distribution of medicinal products constitutes a licensed pharmaceutical activity. Accordingly, any legal entity, established in Lithuania, seeking to engage in such activity must obtain a wholesale distribution licence from the SMCA (Article 19 of the LoP). Wholesalers, established in other European Union Member States and having respective licences may engage in wholesale distribution in Lithuania.

The wholesale distribution of medicinal products must be carried out in accordance with the European Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use of 5 November 2013, and other instructions relayed by the European Commission and the European Medicines Agency (the 'GDP') (Articles 30, 31 and 33 of the LoP). In accordance with GDP requirements, the wholesale distributor must have sufficient suitable premises and equipment to ensure that medicinal products are stored (kept) in accordance with the conditions specified by the manufacturer and distributed appropriately. The distributor must also employ at least one pharmaceutical operations manager (a licensed pharmacist with at least two years of relevant professional experience gained within the last ten years in a legal entity

authorised to carry out the wholesale distribution of medicinal products) (Articles 31, 33 and 34 of the LoP).

The holder of a wholesale distribution or manufacturing licence issued by a competent authority from another European Economic Area (EEA) country wishing to engage in the wholesale distribution of medicinal products or medicinal products manufactured by that person to healthcare institutions and (or) pharmacies must submit a notification of the intended supply to the SMCA no later than 14 working days in advance. The obligations of a wholesale distribution licence holder set out in the LoP apply accordingly to entities included in the list of EEA suppliers.

No separate national wholesale distribution licence is required for medical devices. Rather, the placing of medical devices on the market is subject to compliance with the MDR/IVDR (also, Articles 16 and 59[1] of the LoHS).

The manufacturers of medical devices, and those persons who assemble and/or sterilise procedure packs and/or systems and place them on the market in their own name, must submit documents to the SASHCA with their registered office address, technical data and evidence of conformity of the devices with the MDR or IVDR. Where the manufacturer is not established in an EEA country, the authorised representative established in Lithuania must submit the relevant data. Confirmation of registration by the competent authority and assignment of registration numbers is required before placement on the market. (Article 59[1] of the LoHS).

Manufacturers, authorised representatives, importers and distributors of active implantable medical devices classified as Class IIA, IIB, III or custom-made active implantable medical devices under the MDR must submit their registered office address and data on any devices placed on the Lithuanian market to the SASHCA (no later than 14 working days from the date of placing these devices on the market) (Article 59[1] of the LoHS).

Importers and distributors must ensure appropriate storage, maintain traceability and technical documentation, promptly address non-compliance and cooperate with competent authorities (eg, enable the SASHCA to inspect the storage premises) (Article 59[5] of the LoHS).

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 Lithuania, only pharmacies and medicinal product retail companies (the latter being permitted to sell medicinal products from a limited list of non-prescription medicinal products) may supply medicinal products directly to consumers.

The operation of pharmacies constitutes a licensed pharmaceutical activity. Accordingly, legal entities seeking to operate a pharmacy must obtain a pharmacy activity licence (Article 19 of the LoP). The principal requirements for obtaining such a licence include: (1) having suitable premises and equipment that comply with the requirements established by the MoH; (2) entering into an employment relationship with a pharmaceutical operations manager, who must be a pharmacist holding a valid pharmacist's practice licence; and (3) conducting activities in accordance with the Good Pharmacy Practice rules approved by the MoH (Articles 37 and 40 of the LoP).

Medicinal products may be offered for sale to the public by means of distance selling only by licensed pharmacies and persons established in another EEA country who are legally authorised in that country to offer medicinal products for distance sale (Article 35[1] of the LoP). The key requirements for distance selling are laid out in the answer to Question 5.

A medicinal product retail company may sell directly to the public only non-prescription medicinal products that are included in the List of Medicinal Products approved by the SMCA as authorised for sale at medicinal product retail companies (a restricted list, as inclusion is subject to specific regulatory criteria and not all non-prescription medicinal products qualify) (Article 41[1] of the LoP). In order to engage in such an activity, a medicinal product retail company must be registered in the List of Medicinal Product Retail Companies and meet certain requirements. The activity is subject to strict operational limitations, including a prohibition on selling more than one package of the same medicinal product (by an international non-proprietary name) per transaction; on transporting medicinal products to other business locations; and on sales via self-service areas or vending machines, in non-fixed locations, or to persons under 16 years of age.

With respect to medical devices, all economic operators supplying medical devices to the Lithuanian market must do so in accordance with the requirements under the MDR/IVDR, with sales to end-users not a separately licensed activity under Lithuanian law. Reimbursable medical aid devices are issued to residents by pharmacies or other designated persons.

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

Proposals to sell medicinal products to residents remotely is regulated by the LoP and by implementing Order No V-1491 of the MoH, dated 21 December 2015 'On the Approval of the Procedure for Offering Medicinal Products to Residents Remotely' (Order No V-1491).

As noted, only licensed pharmacies and EEA-established entities legally authorised to sell medicinal products remotely may offer them remotely to the public (consumers) in Lithuania (Article 35[1] of the LoP). Both prescription and non-prescription medicinal products may be sold via the internet.

Remote sales are permitted for prescription medicinal products dispensed via electronic prescriptions (excluding those containing narcotic or psychotropic substances), as well as for non-prescription medicinal products.

The key requirements are as follows:

- A pharmacy must notify the SMCA before commencing remote sales.
- Pharmacies must ensure that pharmaceutical services, such as the selection of non-prescription medicinal products, provision of pharmaceutical information and consultation, shall be provided by a pharmacy specialist through communication means (except in cases of persons established in another EEA state).
- The pharmacy website must clearly display the EU common logo and provide the information required by the MoH.
- The pharmacy must draft and approve a description of procedures for remote sales.
- For prescription medicinal products, pharmacies must submit price and product information to the eHealth platform, enabling patients with electronic prescriptions to view participating pharmacies and select the most convenient option.

Remote (online) sales of medical devices are permitted in Lithuania without a separate licence/authorisation for the website or the seller, provided the requirements of the MDR/IVDR are met (Article 59[1] of the LoHS).

Remote sales of reimbursable medical aid devices dispensed on the basis of electronic prescriptions are subject to the same regulatory framework governing the online sale of medicinal products, as established by Order No V-1491.

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 may be placed on the Lithuanian market only if they are registered in the Lithuanian Register of Medicinal Products, the Union Register of Medicinal Products or the List of Parallel-Imported Medicinal Products (ie, registered medicinal products) (Article 8 of the LoP).

A legal entity may import medicinal products from non-EEA countries only upon obtaining a manufacturing licence, which grants the right to manufacture and/or import medicinal products from non-EEA countries (Article 24 of the LoP). Medicinal products imported from non-EEA countries must be manufactured by companies that are authorised by the competent authorities of that country to manufacture medicinal products and whose Good Manufacturing Practice (GMP) standards comply with those established by the EU (Article 24 of the LoP). The holder of such a licence must distribute the imported medicinal products in accordance with all the requirements applicable to the holder of a wholesale distribution licence (Article 27 of the LoP).

A manufacturing licence is also required when medicinal products are manufactured and/or imported from non-EEA countries solely for export purposes.

Import and export permits are required for medicinal products containing narcotic or psychotropic substances (both for third countries and within the EU).

Medical devices and their import are subject to the same regulations across all of the EU (MDR/IVDR). Importers must be established in the EU and only place devices on the EU market that comply with MDR/IVDR (including those obligations regarding conformity, proper labelling and documentation, traceability, storage and transport conditions, post-market vigilance, cooperation with authorities and corrective actions, as set out in Article 13 of the MDR/IVDR).

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?

The procedure for importing and exporting medicinal products into and out of Lithuania, and receiving and sending these by post for the personal use of natural persons, is regulated by a 23 November 2006 decree by the MoH, namely Decree No V-975 'On the approval of the procedure for the import and export of medicinal products into and from the Republic of Lithuania, their receipt and sending by post for the personal needs of natural persons'. The order does not apply for the import of medicinal products containing narcotic or psychotropic substances.

Natural persons may import or receive by mail medicinal products for personal use under the following rules:

- From EU countries, the quantities must be consistent with personal use needs, and the authorities may request proof (eg, prescription or medical certificate) if the amounts are deemed suspicious.
- From third countries, imports are generally limited to the quantities indicated in a valid medical certificate (not exceeding a six-month treatment course).
- Lithuanian law does not establish explicit quantitative limits on the import of medical

devices by individuals for personal use.

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 only ship medicinal products directly to Lithuanian consumers if they fall within the scope outlined in the answer to Question 5, that is, they must be established in an EEA country and legally authorised to sell medicinal products remotely in that country.

Foreign suppliers may not sell medical devices directly to consumers in Lithuania; any entity placing devices on the EU market must be established in the EU and ensure full compliance with MDR/IVDR requirements (see the answers to Questions 5 and 6).

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 relabelling or repackaging, and requirements to maintain original quality, safety and traceability?

The parallel import of a medicinal product means introducing a product into Lithuania authorised in another EEA country, identical or similar to a product already authorised locally, without using the MAH's distribution network (Article 2 of the LoP). Parallel imports into Lithuania are permitted only for medicinal products that have been entered into a List of Parallel Imported Medicinal Products and covered by parallel import authorisation, which may be issued to a legal entity holding a wholesale distribution licence. The authorisation holder must notify the MAH and SMCA in writing at least 15 working days before the first import and, in the case of repackaging, notify the MAH or rights holder at least 15 working days before market supply, providing samples upon request (Article 17 of the LoP).

Repackaging, packaging labelling and packaging leaflet requirements are set out via a 30 March 2007 order by the MoH, namely Order No V-228 'On the approval of the rules for the parallel import of medicinal products', under which the given packaging and leaflet must comply with national requirements. The outer packaging must indicate the parallel importer, the original and repackaged batch numbers, and any differences from the reference medicinal product. The inner packaging must include the two names of the medicinal product, if the names used in the exporting country and those approved by the SMCA are different, and display information related to the safe and proper use of the product (eg, warnings) in Lithuanian, while the leaflet must follow the reference product's leaflet and include relevant additional information. Repackaging may be performed only by a person holding a manufacturing licence established in an EEA country.

No separate national parallel import 'licence' is required for the parallel import of medical devices (but notification is required). The MDR and IVDR impose an obligation on distributors or importers to inform the manufacturer and the competent authority in advance of the placing on the market of a relabelled or repackaged device (Article 16(4) of the MDR/IVDR). As far as the protection of intellectual property rights is concerned, the principles formulated in the field of parallel imports of medicinal products should also apply to parallel imports 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?

No specific export quotas or restrictions apply. However, the suppliers of medicinal products (MAH or its representative) must ensure continuous and sufficient supply to the Lithuanian market of reimbursed medicinal products. In the case of a shortage of a specific reimbursed medicine, such a medicine may be withdrawn from the reimbursement system.

The same is applicable for medical devices. However, the suppliers of reimbursed medical aid devices must ensure the continuous supply of such devices.

Export permits are required for medicinal products containing narcotic or psychotropic substances (both for third countries and within the EU).

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 legal entity that manufactures medicinal products and/or imports them from third countries solely for export must also hold a manufacturing licence (Article 24 of the LoP).

If a wholesale distributor receives medicinal products directly from a non-EEA country for re-export, certain domestic distribution rules do not apply; however, the distributor must ensure that the products are sourced from legally authorised suppliers and are supplied only to those persons entitled to distribute or dispense them under the destination state's law (Article 33 of the LoP).

Under the MDR/IVDR, no separate 'export-only' or dual-labelling applies. A Free Sale Certificate may be issued by the Member State confirming that the device is CE marked and may be sold in the EU.

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?

The packaging of registered medicinal products supplied to the Lithuanian market must be correctly labelled and the package leaflets must be prepared in the Lithuanian language and in accordance with the procedures established by the MoH. The outer packaging must clearly show the product name, dosage, form, usage instructions, warnings, expiry date, manufacturer, batch number and storage information in a way understandable to the user. The package leaflet is prepared on the basis of the SmPC.

The SMCA may temporarily authorise the supply of registered medicinal products in packaging and package leaflets in another EEA language using the Latin alphabet if, due to objective production or supply disruptions or increased demand, the manufacturer cannot ensure a timely supply in Lithuanian-language packaging and, for non-reimbursable products, no adequate Lithuanian-language alternative is available on the market.

The packaging of registered medicinal products must have unique identifiers and protective devices (security measures) that make it possible to verify the authenticity of the medicinal product, identify individual packages and determine whether the outer packaging or, if there is no outer packaging, the inner packaging has been tampered with, in the following cases: (1) if the medicinal product is a prescription medicinal product, except for medicinal products included in the list set out in Annex I to Regulation (EU) 2016/161; and (2), if the medicinal product is a non-

prescription medicinal product included in the list set out in Annex II to Regulation (EU) 2016/161 (Article 8 of the LoP).

Manufacturers, authorised representatives and persons assembling or sterilising procedural kits/systems must: provide the instructions for use and maintenance required under the MDR/IVDR in Lithuanian (or in English if intended for HCPs with recipient consent); deliver local safety notices to users in Lithuanian; and, upon request by the competent authority, provide traceability information across the supply chain (Article 59^5 of the LoP).

Importers and distributors must: supply all manufacturer-provided instructions for use and maintenance in Lithuanian (or English for HCPs, with consent) and, upon request, provide traceability information to the competent authority in accordance with the MDR/IVDR (Article 59^5 of the LoP).

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?

To be reimbursed from the Compulsory Health Insurance Fund (CHIF) budget and administered to patients by HCPs, medicinal products must first be included by their international nonproprietary name (INN) in the List of Diseases and Reimbursable Medicinal Products for the Treatment of Diseases ('List A') and then subsequently by their proprietary name in the Reimbursable Medicinal Products Price List (the 'Price List').

Medical aid devices (in order to become reimbursable from the CHIF budget) must also be included in the Lists of Reimbursable Medical Aid Devices and the Reimbursable Medical Aid Devices Price List (Articles 58 and 59 of the LoP). Price Lists are approved (updated) twice a year.

The CHIF budget is managed by the National Health Insurance Fund under the Ministry of Health (the 'NHIF'). Consequently, the NHIF prepares the Price Lists, concludes treatment availability improvements and risk-sharing agreements with MAHs, and generally makes key decisions on the reimbursement of medicinal products and medical aid devices.

The base prices and patient co-payments for medicinal products and medical aid devices are governed by specific regulatory provisions set out under applicable laws. Medicinal products and medical aid devices are grouped for base price determinations based on government-approved criteria.

Price regulation applies across the entire supply chain. Reimbursable medicinal products and medical device aids are sold to wholesalers at no more than the price applied by the supplier to Lithuania. These products are supplied to pharmacies and healthcare institutions at a price not exceeding the wholesale price, which is calculated by adding a wholesale mark-up, capped by the MoH, to the supplier's price. Retail prices are determined by adding wholesale and retail mark-ups, capped by the MoH, as well as VAT, to the supplier's price applied in Lithuania. The price of a non-reimbursable medicine applied to Lithuania must be declared to the MoH. Moreover, wholesalers, pharmacies and retail distributors may not apply a higher mark-up than that set by the government. Non-reimbursable medical aids, in turn, are sold at market price (Articles 57 and 59^1 of the LoP).

In Lithuania, the MoH and SMCA oversee and coordinate the uninterrupted supply of essential medicinal products to pharmacies, ensuring that quality, safe and effective medicinal products

remain continuously available. MAHs are obliged to cooperate with distributors to guarantee appropriate and timely supply in line with patient demand (Article 15 of the LoP). Wholesalers holding a distribution licence must also work with MAHs to ensure the sufficient and regular delivery of medicinal products to pharmacies and healthcare institutions (Article 33 of the LoP). For reimbursed medicinal products under agreements with the NHIF, MAHs also commit contractually to maintain uninterrupted supplies to the Lithuanian market and to promptly notify the authorities of any supply disruptions, taking corrective measures as needed.

Regulation (EU) 2024/1860 amending the MDR/IVDR introduced an obligation to provide information in the case of the interruption or discontinuation of supply of certain medical devices. Thus, the relevant economic operators who received information from the manufacturer or another economic operator in the supply chain (eg, importers or distributors) are expected to further share this information 'without undue delay' with other economic operators, health institutions and HCPs to whom they directly supply the given device.

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 cases of non-compliance with the conditions of the licensed activity, the SMCA may suspend or revoke manufacturing, wholesale distribution and pharmacy activity licences, and the right of a medicinal product retail company to sell medicinal products (Articles 19 and 41^5 of the LoP). The SMCA carries out planned periodic and unplanned inspections of entities engaged in activities involving pharmaceutical products and, if necessary, tests samples (Article 62 of the LoP). SMCA inspectors are empowered to conduct on-site inspections of legal entities engaged in pharmaceutical activities; request and obtain documents and information; inspect premises, equipment, inventory and staffing (including personnel qualifications); and carry out test purchases of medicinal products, as well as carry out other investigative actions necessary to verify compliance (Article 63 of the LoP). In certain cases, the SMCA may prohibit the supply of a medicinal product to the market and withdraw it from the market, as well as suspend the manufacture of medicinal products or their import from third countries where a failure to comply with the requirements under the LoP has occurred (Article 67 of the LoP).

Administrative fines imposed under the Code of Administrative Offences (the CoAO) for various violations on responsible persons of legal entities generally range from several hundred euros up to approximately €4,300.

Where unlawful pharmaceutical activities pose a serious threat to human health or life, result in severe injury or cause death, criminal liability may arise under the Criminal Code (CC). The illegal manufacture or disposal of medicinal products without the required authorisations may lead to criminal sanctions ranging from fines and alternative penalties to imprisonment of up to eight years, with liability extending to legal persons (Article 275 of the CC).

For medical devices, the SASHCA may access all information, inspect premises and collect samples related to the manufacture, safety, supply, import, marketing and use of medical devices (Article 59^4 of the LoHS).

Upon identifying infringements, the SASHCA may impose various measures on market operators, such as temporarily suspending the placing of medical devices on the market, or require the withdrawal and/or recall of medical devices (Article 59^6 of the LoHS). In addition, under the CoAO, non-compliance with medical-device laws may result in fines of up to €850 for

managers of legal entities or other responsible persons, and up to €1,500 in the event of a repeated infringement.
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?
No significant recent developments have occurred at the national level.