

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?

Medicinal products

The key Polish statute is the Act of 6 September 2001, the Pharmaceutical Law (the ‘Polish Pharmaceutical Law Act’).

At European Union level, the main framework is Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. Additionally, Regulation (EC) 726/2004, laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency and Commission Delegated Regulation (EU) 2016/161 regarding safety features/serialisation and verification.

Medical devices

The directly applicable EU framework is Regulation (EU) 2017/745 (otherwise known as the Medical Device Regulation (MDR)) and Regulation (EU) 2017/746 (for in vitro diagnostic medical devices (IVDR)). It is complemented by the Act of 7 April 2022 on medical devices (the ‘Polish Medical Devices Act’).

Poland is a unitary state, so there is no federal/state division of legislative powers.

Key competent authorities

President of the Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products (*Urząd Rejestracji Produktów Leczniczych* or URPL) is the central regulator in Poland (eg, responsible for supervising the safety of medicinal products and medical devices).

The following authorities are responsible for pharmaceutical inspections (eg, supervising the conditions for the manufacture and import of medicinal products and the trade in medical devices), including:

- the Chief Pharmaceutical Inspectorate (*Główny Inspektorat Farmaceutyczny* or GIF), which is a central authority that issues authorisations for pharmaceutical wholesalers; and
- the Voivodship Pharmaceutical Inspector (WIF), which is a regional authority that issues pharmacy authorisations.

The Minister of Health issues executive acts in regard to healthcare and medicinal products, among other things.

Additionally, in regard to the consumer protection and advertising/marketing aspects of medicinal products, general consumer protection and competition authorities may be involved in practice, but ‘sectoral’ supervision, as outlined above, is the main framework.

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 the conclusion of a premarket review and approval process required by a competent authority?

Therapeutic products in Poland typically includes:

- medicinal products as defined in Article 2(32) of the Polish Pharmaceutical Law Act (a substance or mixture of substances presented as having properties for preventing or treating diseases in humans or animals, or administered for the purpose of making a diagnosis or restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action); and
- medical devices (and, where relevant, in vitro diagnostic devices) governed by the MDR (Article 2(1) MDR), IVDR and the Polish Medical Devices Act.

Certain products under the MDR are also considered medical devices, including devices for controlling conception or for assisting conception.

Medicinal products

As a rule, a medicinal product must have a marketing authorisation, ie, a decision issued by the competent authority confirming that the product may be marketed in Poland.

National procedures are conducted by the President of the URPL, and depending on the product, authorisation may also result from EU procedures (including centralised procedures). National law describes the mutual recognition and decentralised procedures.

Medicinal products are classified as prescription drugs (Rx) and over-the-counter (OTC) drugs. There are also special categories of medicinal products (eg, medicinal products used exclusively in hospital treatment; products containing narcotic drugs or psychotropic substances specified in separate regulations; products issued on prescription for restricted use), which directly affects the sales opportunities and distribution channels available (including restrictions on online sales) (Article 23a of the Polish Pharmaceutical Law Act).

Medical devices

The main focus when it comes to medical devices is not national ‘authorisation’ but the completion of a conformity assessment and CE marking in accordance with the MDR. The level of involvement of the notified body in the conformity assessment of a medical device depends on its risk class. For Class I devices under the MDR, the manufacturer is generally responsible; for Classes IIa/IIb/III, the involvement of a notified body is typically required.

Additionally, in terms of the regulatory requirements (in particular, with regard to advertising), medical devices are divided into those intended for lay users and devices intended for professional users. In the case of the second group, the requirements are much more restrictive.

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 practices, facility standards, personnel-related requirements and insurance or financial guarantees) are attached to them?

Medicinal products (pharmaceutical wholesale)

Wholesale trade includes the procurement, storage, delivery or export of medicinal products, carried out with manufacturers or importers in, or with entrepreneurs engaged in wholesale trade, or with pharmacies, or with other authorised entities, excluding the direct supply to the public. Only pharmaceutical wholesalers may engage in the wholesale trade of medicinal products in Poland (Article 72 of the Polish Pharmaceutical Law Act).

Starting a pharmaceutical wholesale business requires a licence from the GIF.

The quality and operational requirements include:

- having facilities that enable the proper conduct of wholesale trade;
- employing a responsible person (a pharmaceutical warehouse manager responsible for running the warehouse in accordance with the regulations and the good distribution practice (GDP) requirements); and
- fulfilling the obligations specified in Article 78 of the Polish Pharmaceutical Law Act, including:
 - sourcing medicinal products exclusively from a marketing authorisation holder, an entrepreneur authorised to manufacture or import or an entrepreneur operating a pharmaceutical warehouse;
 - using only registered intermediaries;
 - supplying medicinal products only to authorised entities;
 - verifying the safety features and withdrawing the unique identifier of the medicinal product before supplying it to specific entities;
 - complying with the GDP requirements;
 - ensuring the continuous supply of an appropriate range of products;
 - submitting information on transactions, stock levels and stock transfers to other pharmaceutical wholesalers to the Integrated System for Monitoring the Trade in Medicinal Products (ZSMOPL); and
 - keeping records of all relevant documentation.

Pharmaceutical law provides for a separate regime for intermediaries involved in the trade in medicinal products, including the requirement to be registered in the National Register of Intermediaries in the Trade in Medicinal Products and to be subject to control measures.

Medical devices (distribution/wholesale)

As a rule, there is no Polish equivalent of a ‘wholesale licence’ like for medicinal products. The pharmaceutical wholesalers referred to above may also engage in the wholesale trade in medical devices. Under the MDR and the Polish Medical Devices Act, certain obligations apply to operators in the supply chain (manufacturer, importer, distributor).

The following requirements apply to distributors in Poland:

- checking the CE marking and EU declaration of conformity, the information provided by the manufacturer (including instructions for use and labels), compliance with the requirements by the importer (if applicable) and the unique device identifier (UDI) code before making the device available on the market;

- ensuring proper storage and transport conditions;
- keeping a register of complaints, non-conformities and withdrawn products;
- cooperating in corrective actions concerning safety and, in the event of a serious risk, immediately notifying the competent authorities;
- obtaining an entry in the national list of distributors kept by the President of the URPL; and
- cooperating with manufacturers or authorised representatives to achieve product traceability.

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 are attached to them?

Medicinal products

Community pharmacies: retail trade in medicinal products for patients is generally conducted within a publicly accessible pharmacy, which is only allowed to operate under a licence. The licence is issued by the WIF.

The Polish Pharmaceutical Law Act provisions stipulate specific requirements, including:

- ownership restrictions, eg, the right to obtain a licence to operate a public pharmacy is held by a licensed pharmacist, a general partnership/professional partnership whose sole business activity is the operation of pharmacies and whose partners are exclusively pharmacists or a university offering education in the field of pharmacy;
- concentration restrictions, including the requirement to specify the number of pharmacies operated by an entity;
- demographic and geographical criteria, which allow for the issuance of a licence if the number of inhabitants in a given municipality, calculated per one publicly accessible pharmacy, is at least 3,000, and the distance from the planned location of the pharmacy to the nearest publicly accessible pharmacy is at least 500 metres; and
- the obligation to appoint a pharmacy manager (ie, the person who runs the pharmacy, guaranteeing its proper operation).

Pharmacy retail points: in addition to pharmacies, pharmacy points may also sell medicinal products. The Polish Pharmaceutical Law Act provisions stipulate specific requirements, including:

- obtaining a licence;
- appointing a person to run the pharmacy point, who is the manager of the pharmacy point, meeting certain requirements (a pharmacist with one year's experience or a pharmacy technician with three years of experience working in a public pharmacy); and
- being located in a rural area, with no publicly accessible pharmacy in the village.

Non-pharmacy retail points: non-pharmacy trade in medicinal products may only be conducted in relation to OTC medicinal products specified in a list published by the Minister of Health.

Non-pharmacy retail points include herbal and medical shops, specialist medical supply shops and shops open to the general public (Article 71(1) of the Polish Pharmaceutical Law Act).

Non-pharmacy retail points must meet specific requirements regarding the premises, product storage and the qualifications of the persons dispensing medicinal products.

Mail order sales of medicinal products may only be conducted by community pharmacies and pharmacy retail points, and only with regard to OTC medicines, with the exception of medicinal products whose sale is restricted by the patient's age.

Medical devices

The sale of medical devices to consumers (including online) is not, in principle, restricted to pharmacies and does not require a ‘pharmacy licence’. Distributors of medical devices must, however, comply with the requirements specified in the answer to Question 3 above.

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

Medicinal products

As indicated in the answer to Question 4 above, online sales of medicines are strictly limited. In Poland, only OTC medicinal products, whose sale is not restricted by the patient’s age, may be sold by mail order, and only by a community pharmacy or a pharmacy retail point.

The entity operating a pharmacy/pharmacy retail point is required to notify the competent WIF of its intention to commence mail order sales at least 14 days prior to commencement, and to keep this information up to date.

Data on pharmacies conducting mail order sales are disclosed in the National Register of Licences to Operate Pharmacies.

The basis for dispensing a medicinal product from a community pharmacy or pharmacy retail point as part of the mail order sale of medicinal products is an order. Entities engaged in mail order sales must keep records of orders, which include specified elements (eg, the name and surname of the person placing the order; the name, series and quantity of the medicinal products; the date of order fulfilment). Detailed conditions regarding the mail order sale of medicinal products are additionally specified in the Minister of Health Regulation.

Regardless of the sales process, online marketing activities are subject to Polish regulations on the advertising of medicinal products, in particular, the prohibition on advertising medicinal products to the general public that are only available on prescription, those that contain narcotic drugs and psychotropic substances and those listed on the reimbursement lists.

In addition, the Polish Pharmaceutical Law Act currently prohibits advertising of pharmacies and pharmacy retail points and their activities. However, these regulations are currently being amended in connection with a recent Court of Justice of the European Union (CJEU) ruling (C-200/24) that found them to be too restrictive in relation to EU regulations.

Medical devices

The MDR explicitly provides for a regime for distance sales of medical devices and requires that devices made available to users in the EU comply with the MDR requirements (in particular, that they are compliant, properly labelled and that communication is not misleading).

In addition, there are verification obligations, which we described above (answers to Questions 3 and 4).

Under Article 7 of the Polish Medical Devices Act, service providers are obliged, at the request of the President of the URPL, to immediately provide data concerning the relevant products, systems or treatment sets, as well as services provided with their use, offered or provided electronically, and entities and persons offering such products, systems, treatment kits or services.

The Polish Medical Devices Act introduces a separate, comprehensive advertising regime. It contains detailed requirements and restrictions on marketing activities, primarily a prohibition

whereby advertising directed at the general public may not concern devices intended for use by users other than laypersons.

In addition, public advertising must be formulated in an understandable manner, must not be misleading, is subject to specific restrictions in terms of content and form and must include a mandatory warning. Detailed requirements (eg, how warnings should be presented, the minimum parameters, rules for different formats, namely video/banners/audio/online) also stem from the Minister of Health Regulation of 21 April 2023 on the advertising of medical devices.

Guidelines for good practice are also an important point of reference, including in the area of advertising/communications on medical devices (in particular, via digital channels, influencer marketing, the labelling of advertising content, the separation of education from advertising). These are not sources of generally applicable law but are regarded as industry standards.

IMPORT

6. What requirements are set as part of 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

Poland has three import procedures for medicinal products:

- The General Import Procedure – standard import procedure, regulated in Article 38 of the Polish Pharmaceutical Law Act, under which an authorisation issued by the GIF is required.
- The Target Import Procedure – procedure for unregistered medicines needed to save the life/preserve the health of a patient. A physician submits a request via the Target Import Service System (SOID), which requires confirmation by a provincial or national consultant, followed by approval from the Minister of Health.
- The Parallel Import Procedure – procedure for medicines from EU/European Free Trade Association (EFTA) countries with the same active substance, indications, strength, route of administration and form as a product already authorised in Poland. This procedure requires a permit from the President of the URPL.

Ready-dose or retail-packaged medicines fall under combined nomenclature (CN) code 3004. Many medicines, including generic medicines, have zero per cent customs duty.

Medical devices

No standalone import licence is required to import medical devices. However, EU-based importers bringing medical devices from outside the EU into Poland must:

- register in the European database on medical devices, known as the EUDAMED database; and
- obtain authorisation from the President of the URPL to operate as an importer, which is required under Article 23 of the Polish Medical Devices Act.

Medical devices typically fall under CN codes 3005 and 3006.

7. To what extent may consumers import therapeutic products for personal use (whether by taking the products across the border or receiving them by post), and what quantitative limits, prescription requirements, customs declarations, duties or other restrictions apply?

Medicinal products

Under Article 68(5) of the Polish Pharmaceutical Law Act, an individual may bring up to five packages of a medicinal product for personal use into Poland, provided that the product does not contain narcotic or psychotropic substances. Medicinal products imported for personal use must not be resold or otherwise supplied to third parties.

Where a medicinal product contains narcotic drugs or psychotropic substances, the GIF may issue an authorisation allowing import for personal therapeutic use, based on a medical prescription or relevant medical documentation confirming the necessity of the treatment.

Medical devices

As a rule, there are no specific restrictions on bringing medical devices into Poland for personal use. However, customs authorities may verify the quantity, intended use and value of the devices to assess whether the import genuinely qualifies as personal use rather than a commercial activity.

8. Are foreign suppliers allowed to 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?

Medicinal products

Foreign suppliers can sell or ship OTC medicinal products to Polish consumers via e-commerce or mail order. The shipment of Rx medicines or medicines whose sale is restricted by the patient's age is prohibited. Products must be labelled according to Polish regulatory requirements, including the provision of a Polish language patient information leaflet and packaging compliant with the Polish marketing authorisation.

Medicines may only be sold by EU-based, legally authorised pharmacies. The e-commerce platform must also comply with Polish/EU regulations, in particular, it must display the EU common logo for online pharmacies.

Medical devices

Mail order and online sales of medical devices to Polish consumers by suppliers established in other EU Member States are generally permitted, as specified in the answer to Question 4.

9. How is the 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 the product's original quality, safety and traceability?

Medicinal products

Parallel importation is a simplified procedure followed in connection with the import of medicines from EU/EFTA countries, as specified in the answer to Question 6. It can be applied following the granting of authorisation, which requires the entity to demonstrate that the imported product is identical or essentially equivalent to a product authorised for marketing in Poland (ie, it has the same active substance, indications, strength, route of administration and form).

It is based on the principle of the exhaustion of intellectual property rights within the European Economic Area (EEA), under which the rightsholder may not oppose further commercialisation of

a product that has been lawfully placed on the market in the EEA by or with the consent of that rightsholder.

In line with CJEU case law, re-packaging or re-labelling is permitted, in particular, to adapt the packaging and patient information leaflet to the Polish language and regulatory requirements, provided that:

possible objection by the entitled party to re-packaging would contribute to artificial market division;

re-packaging does not affect the original condition of the product inside the packaging;

the packaging clearly states who re-packaged the product and its manufacturer;

the new packaging does not infringe upon the reputation of the trademark placed on it; and

the importer notifies the trademark owner of their intention to sell re-packaged medicines before proceeding to do so.

EXPORT

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

Yes, Poland has a set of legal and administrative mechanisms that restrict the export of therapeutic products in specific circumstances.

Medicinal products

An entrepreneur's basic obligation is to report the export of medicinal products to the ZSMOPL.

The GIF may impose a fine of up to PLN 50,000 for the failure to report to the ZSMOPL.

Medicinal products, medical devices and the FSMP

The Ministry of Health regularly updates the official list of medicines, medical devices and food for special medical purposes (FSMPs) at risk of a supply shortage. Any entity intending to export products featured on the list from Poland must notify the GIF in advance. The GIF has up to 30 days to assess whether the planned export could endanger the availability of the medicine on the Polish market. If such a risk is identified, the GIF may issue an administrative objection, which:

- blocks the export entirely; or
- allows export only up to a specified quantity.

The failure to report the export of medicines at risk of a supply shortage results in a fine of PLN 10,000. It is also punishable by imprisonment for up to five years in the case of the export of medicines or up to two years in the case of medical devices and FSMPs.

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?

Yes, in Poland, there are certain mechanisms allowing for the manufacture and export of therapeutic products not approved for domestic marketing as ‘export only’ products.

Medicinal products

The Polish Pharmaceutical Law Act expressly permits the manufacture of medicinal products exclusively for export outside the EU (Article 51a(1) of the Polish Pharmaceutical Law Act). In particular, the manufacturer must hold a manufacturing authorisation issued by the GIF covering the relevant scope of production and must comply with the obligations set out in Chapter 3 of the Polish Pharmaceutical Law Act, which apply to manufacturers, including the obligation to ensure full compliance with GMP requirements.

The manufacturer is also required to affix the EU export logo to the outer packaging and, where possible, to the immediate packaging, indicating that the product is intended for export to countries outside the EU.

Medical devices

Manufacture on an ‘export-only’ basis is also permitted for medical devices, although this scenario is not expressly regulated either by the MDR or by the Polish Medical Devices Act. The permissibility of such activity results, however, from the scope of application of the MDR and the corresponding Polish implementing legislation. Thus, there is no ‘export-only’ licence issued specifically for medical devices.

To remain outside the MDR and Polish market-access requirements, the medical device must not be placed on the market or made available for use in Poland or any other EU Member State, and the entire supply chain must be structured in a manner that ensures export exclusively to a third country.

With respect to labelling, CE marking must not be affixed, and the device and/or its packaging should be clearly labelled, typically with wording such as ‘For export only – not for sale or use 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?

Medicinal products

Before imported medicinal products can be placed on the Polish market, the outer packaging and, where possible, the immediate packaging must include labelling in the Polish language, and a patient information leaflet (also in the Polish language) must be provided. Mandatory information includes the name of the product, strength, pharmaceutical form, qualitative and quantitative composition, batch number, expiry date, storage conditions, the name and address of the marketing authorisation holder and the marketing authorisation number.

Rx medicines manufacturers are also required to place two types of safety features on drug packaging, including:

- a unique identifier (UI) in the form of a 2D DataMatrix code (containing the product code, batch number, expiry date and a unique serial number); and
- an anti-tampering device, allowing verification of whether the packaging has been opened.

Medical devices

Consumer information, including the product name, risk class, intended use, instructions for use, warnings and details of the manufacturer or authorised representative, must be provided in Polish on the label of a medical device. Placing a device on the market also requires affixing CE marking and placing a UDI carrier on the label and packaging.

PRICING, REIMBURSEMENT AND MARKET ACCESS

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

Yes, these include, in particular:

- A regulated pricing and reimbursement system for selected medicinal products and medical devices. The Minister of Health sets maximum official prices for reimbursed medicines and determines the reimbursement conditions through the National Health Fund.
- Public tenders, obligatorily conducted by hospitals and other public healthcare entities, for acquiring medicines and medical devices worth more than PLN 170,000. Tenders may specify minimum or maximum prices, quality requirements, delivery schedules and preferences for domestic products or specific manufacturers.
- Stock levels of medicines, which under Polish law have to be maintained by manufacturers and wholesalers to ensure the continuity of supply, particularly for products critical to public health, specified in the Public Information Journal of the Government Agency for Strategic Reserves.

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?

Medicinal products

Compliance with trade and distribution rules is primarily supervised by the GIS and WIS, mainly through inspections and administrative decisions (orders/bans, licence revocations). The Polish Pharmaceutical Law Act also allocates powers for imposing administrative monetary penalties (fines) between the competent authorities.

As a rule, inspectors may: access business premises of regulated entities (pharmacies, wholesalers and other operators in the distribution chain), request explanations and obtain documentation/data, verify storage/transport conditions, take samples and secure evidence of infringements.

Typical remedial measures (administrative measures) include:

- orders to stop unlawful conduct and to remedy deficiencies;
- suspension/ban of certain activities until compliance is restored; and
- revocation of licences/authorisations (eg, pharmacy/wholesale authorisations) in cases of serious or repeated breaches.

In practice, authorities often start with corrective instructions and escalate to licence measures and/or fines where non-compliance persists.

The Polish Pharmaceutical Law Act provides for administrative monetary penalties imposed by an administrative decision and specifies the competent authority regime. This is a key enforcement

channel for breaches of distribution obligations (including regulated activity requirements and statutory duties applicable to the supply chain).

In addition to the administrative regime, the Polish Pharmaceutical Law Act also provides for criminal offences linked to unlawful trade/distribution (typically, unauthorised activities, breaches of core safety/traceability obligations, etc).

Civil claims may also arise, especially in regard to business-to-business (B2B) disputes, notably under the Act on Combatting Unfair Competition.

Medical devices

Authority and enforcement model: market surveillance and enforcement are largely driven by the President of the URPL.

The Polish Medical Devices Act sets out detailed inspection powers, including visiting facilities and means of transport, requesting explanations and documents, examining documentation and devices, taking samples and verifying implementation of post-inspection recommendations.

The President of the URPL may issue administrative decisions banning or restricting making devices available and/or ordering withdrawal from the market/withdrawal from use, where the entity fails to meet statutory/MDR obligations or does not comply with the authority's requests.

The Act also contains explicit statutory prohibitions on placing on the market/supplying/making available devices in specific situations (eg, expired devices, invalid/suspended certificates, etc).

The provisions set out in the Polish Medical Devices Act provide for a number of administrative monetary penalties imposed by the supervisory authority. However, in recent years the authorities generally apply lower thresholds for monetary penalties (eg, in the area of advertising).

In practice (especially in regard to advertising and communications to consumers), it is possible to investigate cases in parallel under competition and consumer protection procedures (eg, practices infringing collective consumer interests), with administrative sanctions imposed by the President of the Office of Competition and Consumer Protection (UOKiK), in particular, on the basis of the Competition and Consumer Protection Act.

15. Is there any 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?

Legislative developments are ongoing in Poland that may affect the trade, distribution and cross-border movement of therapeutic products.

Poland is currently undergoing a process of pharmaceutical deregulation. As part of this process, an amendment to the Polish Pharmaceutical Law Act, that would remove the obligation for companies to report the planned delivery locations of medicinal products to the national integrated IT system, has been proposed. The aim is to simplify reporting and reduce administrative burdens, potentially facilitating smoother operations for distributors and importers.

The Ministry of Health also regularly updates lists of medicines and medical devices at risk of a supply shortage, which are used to manage supply disruptions and may influence export limitations or stockholding requirements, thereby having a direct impact on distribution strategies and market availability.