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 import, wholesale distribution, retail sale, and export of pharmaceuticals is regulated under Czech law by Act No. 378/2007 Coll., on Pharmaceuticals (Pharmaceuticals Act), which implements the relevant EU law, including Directive 2001/83/EC and Regulation (EC) No 726/2004.

The import, wholesale distribution, retail sale, and export of medical devices is governed by Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), both are implemented by Act No. 375/2022 Coll., on Medical Devices (Act on Medical Devices).

The competent national regulatory authorities for pharmaceuticals and medical devices are the State Institute for Drug Control (SÚKL) and the Ministry of Health (MoH). At the European Union level, the competent regulatory authority is the European Medicines Agency.

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?

Pharmaceuticals

Pharmaceuticals are divided into the following main categories under Czech law:

1. prescription-Only Medicines (Rx);
2. prescription medicines with restrictions – prescribed by specialists for treatments requiring hospital diagnosis or supervision due to serious side effects;
3. non-prescription medicines with restrictions – available without prescription but may pose health risks without pharmacist consultation;
4. over-the-counter (OTC) medicines; and
5. designated OTC medicines *(vyhrazené léčivé přípravky)* – may be sold outside pharmacies (eg, at supermarkets, petrol stations etc).

Premarket authorisation is required, as a pharmaceutical product may not be placed on the Czech market unless it has been granted a national marketing authorisation by SÚKL (for human pharmaceuticals), the Institute for State Control of Veterinary Biologicals and Medicines (for

veterinary pharmaceuticals), or a marketing authorisation granted under an applicable centralised EU procedure.

Certain pharmaceutical products are exempt from marketing authorisation requirements. These include products prepared in pharmacies, those intended exclusively for research and development purposes, advanced therapy pharmaceuticals used under the hospital exemption, or certain radiopharmaceuticals prepared for immediate use in healthcare facilities.

Medical devices and in vitro medical devices

Under applicable EU and Czech law, taking into account the intended purpose of the medical devices and their inherent risks, medical devices are classified into risk classes I, IIa, IIb and III. In vitro diagnostic medical devices are classified into risk classes A to D.

Under applicable EU and Czech law, conformity assessment is mandatory and must be carried out before placing a medical device on the market or putting it into service, in accordance with the applicable procedures under the MDR/IVDR. The only limited exception concerns certain class I medical devices/class A in vitro medical devices, where conformity is declared by the manufacturer without the involvement of a notified body, subject to the conditions set out in the MDR.

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?

Pharmaceuticals

As a general rule, the only pharmaceuticals that may be distributed are those duly authorised under Czech law. In limited cases, unauthorised pharmaceuticals may also be distributed, in particular where they are authorised in another EU Member State (subject to restrictions on placing them on the Czech market), or where their distribution, prescription or use is explicitly permitted under Czech law (eg, within special treatment programmes, compassionate use or specific veterinary authorisations).

Pharmaceuticals may only be distributed by persons holding a distribution authorisation granted by SÚKL, or State Control of Veterinary Biologicals and Medicines for veterinary products. A distributor authorised in another EU Member State is entitled to the same rights and obligations in the Czech Republic as a distributor authorised in the Czech Republic. A distribution authorisation does not in itself entitle the holder to import pharmaceuticals from third countries (ie, non-EU countries), unless a manufacturing authorisation for such import has been granted.

A distribution authorisation is granted provided that: the applicant has appropriate and adequate premises, installations and equipment to ensure the proper storage and distribution of pharmaceuticals; has ensured the services of qualified personnel, including a qualified person responsible for ensuring that pharmaceuticals are distributed in compliance with applicable law; and demonstrates the ability to comply with the statutory obligations applicable to distributors.

Medical devices

The distribution of medical devices in the Czech Republic requires prior notification of the distributor's activity to SÚKL. This requirement does not apply to distributors supplying exclusively class I medical devices or class A in vitro diagnostic medical devices, or to distributors supplying devices exclusively to users who are not healthcare service providers.

Distributors are required to comply with Good Distribution Practice. The MDR/IVDR impose additional obligations on distributors, including ensuring that: medical devices comply with applicable EU requirements; storage and transport conditions are maintained in accordance with the manufacturer's instructions; and distributors cooperate with manufacturers, authorised representatives, importers and competent authorities in connection with corrective actions, vigilance obligations or market withdrawal measures. Under the MDR, importers of medical devices are also required to register as economic operators in the European Database on Medical Devices (EUDAMED).

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?

Pharmaceuticals

In the Czech Republic, pharmaceuticals may primarily be dispensed in pharmacies by licensed pharmacists and, to a limited extent, by pharmacy technicians. A pharmacy is classified as a healthcare facility under Act No. 372/2011 Coll., on Health Services, and may be operated by a natural or legal person only on the basis of an authorisation issued by the competent regional authority. The application for such authorisation must be supported by a number of documents, proving that particular conditions on personnel, premises, equipment, operating rules and compliance with hygiene standards are met.

Outside pharmacies, the direct supply of pharmaceuticals to consumers is generally prohibited, except in narrowly defined statutory cases involving specific categories of pharmaceuticals, such as designated OTC medicines.

Czech law recognises a form of internet pharmacies, namely mail-order dispensing of pharmaceuticals. Mail-order dispensing may only be conducted by an authorised brick-and-mortar pharmacy that holds a valid licence and has physical premises in the Czech Republic. The mail-order activity functions as an extension of the licensed pharmacy's operations and must remain under its direct supervision. Operating an exclusively online pharmacy without a physical location is not permitted.

Medical devices

Medical devices that may be purchased without a medical prescription may be supplied without dispensing restrictions. However, medical devices prescribed on the basis of electronic vouchers may be only dispensed by authorised dispensers, namely pharmacies, optical stores, or other entities that have concluded a contract with a health insurance company. With the exception of Class I devices, dispensing may be carried out only by appropriately qualified professionals, such as pharmacists, pharmacy assistants or, where applicable, orthotists-prosthetists. Devices intended for vision correction may be dispensed exclusively in optical stores and only by qualified optician, optometrist or healthcare professionals.

Apart from medical devices that are freely available without restrictions, Czech law also permits mail-order dispensing of medical devices which are prescribed on the basis of electronic vouchers, provided that such dispensing is carried out exclusively by authorised dispensers.

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

Pharmaceuticals

Only duly registered pharmaceuticals which are not subject to prescription or other dispensing restrictions under their marketing authorisation may be supplied through mail-order sales. A pharmacy must notify SÚKL of the commencement, suspension, or termination of mail-order dispensing within 15 days.

In addition, a pharmacy offering mail-order dispensing must:

- publish clear information about the mail-order service, including the range of pharmaceuticals offered, their prices, and associated delivery costs;
- ensure that packaging and transport preserve the quality of pharmaceuticals, with the pharmacy remaining fully responsible for product quality even where transport is outsourced to a third party;
- dispatch orders within 48 hours of receipt and ensure delivery to the customer within three days, or notify the customer within that period if delivery within three days is not possible (this requirement does not apply to cross-border mail-order dispensing);
- provide a consultation and information service during defined operating hours, delivered by a pharmacist or pharmacy technician, including the receipt and reporting of suspected adverse effects or quality defects; and
- allow customers to return disputed pharmaceuticals at no cost, with such products treated as unusable and dispose of in accordance with applicable legal requirements.

Additional statutory requirements apply to the pharmacy's website, including the publication of SÚKL contact details and the display of the common EU logo for the online sale of pharmaceuticals.

Czech law also permits mail-order dispensing to foreign countries, provided it complies with the legal requirements of the destination country. Such cross-border mail-order dispensing is subject to the same conditions as domestic mail-order dispensing, except for the dispatch and delivery time requirements. In this case, a pharmacy must use foreign-labelled pharmaceuticals and store them separately from those supplied to the Czech market.

Medical devices

Mail-order dispensing of prescription medical devices is subject to the fulfilment of specific statutory obligations, including the obligation to publish transparent information on the medical devices offered via mail order, delivery timelines, reimbursement under public health insurance, patient co-payments, and delivery costs.

Dispensers must also: ensure appropriate packaging and transport while remaining responsible for the quality of medical devices; ensure timely dispatch of consignments or promptly inform the customer of any delivery delay; and provide an information service during defined operating hours in accordance with statutory requirements.

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)?

Pharmaceuticals

Within the EU internal market, pharmaceuticals lawfully placed on the market in another Member State may be imported into the Czech Republic without customs formalities, subject to compliance with applicable regulatory requirements, including parallel import rules where relevant.

The import of pharmaceuticals into the Czech Republic from non-EU countries is governed primarily by EU legislation, as supplemented by national law.

Import of pharmaceuticals from third countries may be carried out only by a holder of a manufacturing authorisation issued by SÚKL covering the importation of pharmaceuticals. This authorisation is required to be presented to the customs authorities on importation of pharmaceuticals into the Czech Republic. SÚKL maintains the official registration of authorised manufacturers. Border controls and inspections are carried out on a risk-based basis by customs authorities in cooperation with SÚKL.

An application for a manufacturing authorisation for pharmaceuticals may be submitted by a natural or legal person to SÚKL or, in the case of veterinary pharmaceuticals, to the competent veterinary authority.

The application must include: information identifying the applicant and the scope and justification of the requested authorisation; details of the premises where pharmaceuticals are to be manufactured, controlled or imported from third countries (including the relevant products and dosage forms); evidence that the applicant has suitable and adequate premises, technical equipment and control facilities compliant with Good Manufacturing Practice requirements; and proof that the applicant has secured the services of at least one qualified person responsible for manufacturing activities.

Medical devices

The import of medical devices into the Czech Republic is primarily covered by the harmonised EU legislation.

Under the MDR and IVDR importers must register as economic operators in EUDAMED, and ensure that imported devices comply with applicable EU requirements. In particular, importers are responsible for verifying that storage and transport conditions do not compromise compliance with the general safety and performance requirements or the conditions specified by the manufacturer.

Importers must also retain the EU Declaration of Conformity for the required period, maintain records of complaints, non-conforming devices and market withdrawals, and cooperate with manufacturers, authorised representatives and competent authorities in connection with corrective actions or market withdrawals.

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?

Pharmaceuticals

Under Czech law, consumers residing in the Czech Republic may import pharmaceuticals for their personal use only under very limited conditions.

Pharmaceuticals may be ordered from abroad for personal use exclusively through mail-order dispensing from another EU Member State. Importation of pharmaceuticals for personal use from third countries (ie, outside of the EU), whether by mail or otherwise, is not permitted.

Only human pharmaceuticals may be supplied for personal use, provided that they: (1) are duly registered in the Czech Republic or in the EU Member State from which the mail-order dispensing is carried out; (2) are not subject to prescription-only status or other dispensing restrictions in the Czech Republic; (3) are supplied in accordance with the conditions of their marketing authorisation.

Where no authorised pharmaceutical with the same composition or comparable therapeutic properties is available in the Czech Republic, an unregistered pharmaceutical may be prescribed or used by the treating physician for an individual patient. Import from another EU Member State is generally possible without prior approval from SÚKL, whereas import from third countries requires prior consent from SÚKL.

Medical devices

Czech law does not generally prohibit the personal import of medical devices by individuals, and no specific quantitative thresholds are specifically laid down. However, the import must be clearly limited to personal use and must not involve resale or systematic supply.

Personal import by consumers does not relieve manufacturers or economic operators of their obligations under the MDR or IVDR. Devices imported for personal use should still comply with applicable EU safety and conformity requirements.

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?

Pharmaceuticals

Foreign suppliers may ship pharmaceuticals directly to consumers in the Czech Republic but only to a limited extent. Such shipments are permitted solely in the form of mail-order dispensing from

another EU Member State, provided that the supplier is duly authorised to operate a pharmacy in its home Member State.

Mail-order supply is limited to duly authorised over-the-counter (OTC) pharmaceuticals which are not subject to prescription-only status or other dispensing restrictions in the Czech Republic.

Foreign suppliers are not required to establish a physical presence in the Czech Republic but must comply with applicable EU and Czech requirements. Any sale of pharmaceuticals to Czech consumers via e-commerce platforms, online marketplaces or social media outside this statutory framework is prohibited.

Medical devices

Online sales of medical devices by sellers established in another EU Member State are generally permitted under the principle of free movement of goods, provided that the devices comply with the applicable EU regulatory framework under the MDR/IVDR. However, medical devices that are subject to prescription or reimbursement via a medical voucher under Czech law may only be supplied to Czech consumers by authorised dispensers and, where applicable, only under the regulated mail-order dispensing regime.

Online sales of medical devices from third countries to Czech consumers are subject to EU customs controls and the MDR/IVDR rules on importers as economic operators, as mentioned above. Devices that do not meet EU regulatory requirements may be detained or refused entry by customs authorities.

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?

Pharmaceuticals

A specific authorisation from SÚKL must be obtained to conduct parallel importation of pharmaceuticals into the Czech Republic,. Parallel importation is permitted only where the imported pharmaceutical has the same qualitative and quantitative composition of active substances and the same pharmaceutical form as the reference pharmaceutical authorised in the Czech Republic. It also much have the same therapeutic effects, does not pose a risk to public health, and is used in accordance with the conditions of the Czech marketing authorisation.

From an intellectual-property perspective, parallel importation within the EU is governed by the principle of exhaustion of rights. Once a medicinal product has been lawfully placed on the EU/EEA market by the IP rights holder or with its consent, trademark and other IP rights cannot be relied on to prevent its further distribution within the EU, including by way of parallel imports. In this context, IP rights do not entitle the rights holder to oppose relabelling or repackaging where such measures are objectively necessary to ensure effective access to the Czech market. Consequently, IP rights do not generally prohibit parallel imports as such. However, this does not preclude the application of trademark law in individual cases. It is for the trademark owner to assess whether the relabelled/repackaged product adversely affects the trademark or otherwise infringes applicable trademark legislation.

Medical devices

Unlike medicinal products, Czech and EU law do not recognise a specific regime of 'parallel importation' for medical devices. Once a medical device has been lawfully placed on the EU market in compliance with the MDR or IVDR, it may be freely marketed in other Member States, subject to compliance with applicable regulatory, labelling and post-market obligations.

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?

Pharmaceuticals

Under Czech law, the export of (authorised) pharmaceuticals abroad may be limited in order to safeguard public health and prevent shortages. In particular, where a distributor intends to export a human pharmaceutical included on the statutory list of monitored pharmaceuticals, it must notify SÚKL of its intention in advance. This list covers human pharmaceuticals in respect of which the currently available stock no longer sufficiently covers the current needs of patients in the Czech Republic and where a shortage (ie, insufficient coverage of patient needs) would jeopardise the availability and effectiveness of treatment, with a direct impact on the protection of public health and a significant effect on the provision of healthcare services.

Czech law also recognises the concept of limited availability of pharmaceuticals *(omezená dostupnost)*. Where, on the basis of continuous market monitoring, SÚKL concludes that the quantities of a pharmaceutical available on the Czech market are insufficient to meet patient needs and that such needs cannot be adequately substituted by another pharmaceutical with comparable therapeutic effects, the product may be designated as having limited availability. Failure to comply with this export restriction constitutes an administrative offence, in respect of which the distributor may be subject to the imposition of a fine of up to CZK5m (approx. €205,000).

Medical devices

There is no specific legal regime providing for limited availability status or export restrictions for medical devices, comparable to the regime applicable to pharmaceuticals.

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?

Pharmaceuticals

The export of medicinal products does not require a separate export authorisation, but the distributor must hold a valid distribution authorisation. This applies regardless of whether the products are authorised in the Czech Republic, provided that they are not placed on the Czech market.

Czech law does not explicitly regulate 'dual labelling' as a standalone concept. In practice, the use of additional or multilingual labelling may occur in specific regulatory contexts, such as parallel importation or the manufacture and distribution of pharmaceuticals intended for export, provided that all applicable EU and Czech requirements on labelling, quality, safety and traceability are fully complied with. Czech-language labelling is mandatory for pharmaceuticals placed on the Czech market, while pharmaceuticals intended exclusively for export must comply with the labelling requirements of the country of destination.

Medical devices

There is no specific export-only or dual-labelling authorisation regime for medical devices. Export is enabled through the issuing of a Certificate of Free Sale and compliance with MDR/IVDR, where the device is placed on the EU market. Exports to third countries are generally not restricted.

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?

Pharmaceuticals

Before imported pharmaceuticals may be placed on the Czech market, they must comply with Czech and EU pharmaceutical legislation governing labelling, patient information and traceability.

Imported pharmaceuticals intended to circulate domestically must bear Czech-language labelling and a Czech-language package leaflet, in accordance with the Pharmaceuticals Act and EU Directive 2001/83/EC, unless a specific statutory exception applies (eg, individual patient supply or other exceptional regimes). The labelling and patient information must correspond to the approved marketing authorisation and must not be misleading.

Subject to the EU anti-counterfeiting regime under Directive 2011/62/EU (the Falsified Medicines Directive) and Commission Delegated Regulation (EU) 2016/161, prescription-only pharmaceuticals must comply with serialisation requirements, including the placement of a unique identifier and an anti-tampering device on the packaging. Such pharmaceuticals must be verified through the medicines verification system, comprising the European Medicines Verification System operated by the European Medicines Verification Organisation and its national component in the Czech Republic operated by the Czech Medicines Verification Organisation, prior to dispensing. In addition, full traceability throughout the supply chain must be ensured in accordance with Good Distribution Practice.

By contrast, pharmaceuticals intended solely for export outside the Czech Republic and not placed on the Czech market are not required to comply with Czech-language labelling requirements, provided that they meet the regulatory, labelling and traceability requirements of the destination country and are handled in a manner that prevents their unlawful placement on the Czech market.

Medical devices

Medical devices placed on the Czech market must be accompanied by labelling and instructions for use in the Czech language, as required by national rules adopted pursuant to the MDR and IVDR.

Limited exceptions may apply for devices intended exclusively for healthcare professionals or for export-only devices not placed on the Czech market.

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?

Pharmaceuticals

Price-control and reimbursement

The healthcare system in the Czech Republic is based on a universal public healthcare model, primarily funded through mandatory public health insurance contributions. Within this framework, pharmaceuticals reimbursed from public health insurance are subject to price regulation and reimbursement control, administered by SÚKL.

Maximum prices and reimbursement levels are set by SÚKL through administrative proceedings and may significantly influence market entry, distribution strategies and product availability. SÚKL is also empowered to initiate administrative proceedings to revise reimbursement levels where statutory conditions are met.

The reimbursement system is further structured around reference pricing and internal reimbursement limits, under which therapeutically interchangeable pharmaceuticals are grouped and reimbursement is capped at a reference level. Pharmaceuticals priced above this limit may be supplied only with patient co-payment, which directly influences prescribing and dispensing patterns.

Following the determination of maximum prices by SÚKL, marketing authorisation holders negotiate reimbursement conditions with health insurance companies. These reimbursement arrangements determine whether, and under what conditions, pharmaceuticals are covered by public health insurance and therefore have a direct impact on their availability and distribution in the Czech market.

Stock/supply obligations

Where there is a suspicion of a risk to the availability of human pharmaceuticals, SÚKL may issue formal requests for the submission of data to relevant market participants, in particular to marketing authorisation holders, distributors and authorised dispensers.

On the basis of these data and other available information, the MoH, in cooperation with SÚKL, continuously monitors and assesses potential risks to the availability of pharmaceuticals essential for the provision of healthcare services. Where the authorities conclude that future supplies of a

pharmaceutical are unlikely to cover the anticipated patient needs in the Czech Republic, the MoH may include the particular product in the so-called 'reserve stock system' for a period of up to 12 months, with the possibility of repeated extensions. Once a pharmaceutical is included in the reserve stock system, distributors are obliged to maintain reserve stocks of that pharmaceutical in an amount corresponding to one twelfth of the total quantity of the pharmaceutical supplied to authorised dispensers and distributed abroad during the preceding 12 consecutive calendar months.

Medical devices

In the Czech Republic, medical devices are not subject to comprehensive price regulation comparable to that applicable to medicinal products. There is generally no system of administratively set maximum prices for medical devices. However, reimbursement rules and public procurement practices materially influence market access, distribution channels and availability.

Similarly, Czech law does not establish a specific regime of mandatory reserve stocks for medical devices. There are no general statutory supply or export obligations comparable to those imposed on marketing authorisation holders and distributors of pharmaceuticals.

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?

Pharmaceuticals

SÚKL and, in specific cases, the MoH, are vested with investigative, supervisory and enforcement powers to address non-compliance with pharmaceutical trade and distribution rules under the Pharmaceuticals Act.

SÚKL is authorised to conduct regulatory supervision and inspections of marketing authorisation holders, distributors, pharmacies and other entities involved in the pharmaceutical supply chain. These powers include the right to request and collect documents and data, perform on-site inspections, verify compliance with Good Distribution Practice and other regulatory requirements. SÚKL inspectors are vested with extensive immediate remedial powers. For example, inspectors may suspend the validity of authorisations issued under the Pharmaceuticals Act or temporarily seize pharmaceuticals, where there is a reasonable suspicion that a pharmaceutical is being handled by a person not authorised under the Pharmaceuticals Act or where pharmaceuticals are misleadingly labelled.

Breaches of obligations set out in the Pharmaceuticals Act constitute administrative offences. Depending on the nature and seriousness of the infringement, the competent authorities may impose administrative sanctions, most commonly administrative fines, which may reach several million Czech crowns. In more serious cases, the prohibition of activities may be imposed.

Medical devices

Similarly to the above, investigative, supervisory and enforcement powers to address non-compliance with medical device regulation in the Czech Republic are vested in SÚKL. SÚKL is

empowered to sanction administrative offences in the field of medical devices under both Czech law and MDR/IVDR. For breaches of applicable obligations, SÚKL may impose administrative fines, which may reach several million Czech crowns, depending on the nature and severity of the 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?

Proposed amendment to the Medical Devices Act

In December 2025, the Czech Government approved and submitted to the Chamber of Deputies a draft amendment to the Act on Medical Devices introducing new rules on the notification of interruptions or discontinuations of supplies of medical devices, including in vitro diagnostic medical devices. The proposal responds to recent EU regulatory developments and aims to strengthen patient protection when there are potential shortages.

Under the draft amendment, where a risk of shortage arises, the MoH would be empowered to adopt measures temporarily to adjust conditions for placing devices on the market, their distribution or use. The adoption of such measures would be preceded by monitoring activities carried out by SÚKL, based on information on supply disruptions provided by manufacturers.

As the draft legislation is still at an early stage of the parliamentary legislative process, its final wording and timing of entry into force remain uncertain.