

The Pharma Legal Handbook

Czech Republic

Regulatory, Pricing and Reimbursement Overview · Pre-clinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms · Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs · Orphan Drugs and Rare Diseases · Localization · Biosimilars and Biologics

Czech Republic

The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in the Czech Republic. It is a must have for any company operating in the country or looking to enter the market.

Prepared in association with PRK Partners, one of the leading law firms in the Czech Republic, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

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A Step Ahead

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01

REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

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6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?

7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?

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01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

The main authorities with jurisdiction over drugs, biologicals, and medical devices in the Czech Republic are the Ministry of Health and the State Institute for Drug Control.

Along with these two main regulatory authorities, the following authorities also possess limited and specific jurisdiction over drugs, biologicals and/or medical devices: the Ministry of the Interior, Ministry of Justice, Ministry of Defense, Ministry of the Environment, Ministry of Agriculture, State Veterinary Administration, Institute for State Control of Veterinary Biologicals and Medicines, State Office for Nuclear Safety, Customs Authorities, District Veterinary Authorities and District Authorities.

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

The authorization, pricing, and reimbursement of drugs, biologicals and medical devices is regulated primarily by the following acts (and related regulations):

- Act No. 378/2007 Coll., on Drugs, as amended (the “**Act on Drugs**”);
- Act No. 48/1997 Coll., on Public Health Insurance, as amended (the “**Public Health Insurance Act**”);
- Act No. 375/2022 Coll., on Medical Devices and In Vitro Diagnostic Medical Devices (the “**Medical Devices Act**”);
- Act No. 526/1990 Coll., on Prices, as amended;
- Regulation (EU) No. 2017/745 on Medical Devices (the “**MD Regulation**”);
- Regulation (EU) No. 2017/746 on In Vitro Diagnostic Medical Devices (the “**IVD Regulation**”); and
- Regulation (EU) No. 536/2014 on Clinical Trials on Medicinal Products for Human Use (the “**Clinical Trials Regulation**”).

3. What are the steps to obtaining authorization to develop, test, and market a product?

In order to conduct testing on drugs that have not yet been registered, it is necessary to obtain clinical trial authorization pursuant to the Clinical Trials Regulation; the State Institute for Drug Control is the relevant authority for the Czech Republic.

To introduce a drug to the market, it is necessary to obtain a registration (marketing authorization). There are three types of registrations: (i) National Registration, (ii) Mutual Recognition Procedure and (iii) Decentralized Procedure. National Registration authorizes the marketing of the product solely in the Czech Republic. The other two authorization types allow for the marketing of the product in other EEA member states as well. In addition, a Centralized Procedure by the European Medicines Agency can also be used; it authorizes the product for all EEA member states. In a limited number of

exceptions (drugs prepared in a pharmacy based on a prescription for an individual patient, drugs for research and development, etc.) the requirement for marketing authorization does not apply.

Manufacturers and distributors of drugs are required to obtain licenses from the State Institute for Drug Control. A manufacturing license is also required to import drugs from non-EEA states. Distribution licenses issued by EEA member states are recognized in the Czech Republic provided that the distributor submits a notification to the State Institute for Drug Control.

4. What are the approximate fees for each authorization ?

The approximate fees for each authorization are:

- Authorization of a clinical trial for a not-yet-registered drug: **approx. EUR 4,000 to approx. EUR 5,100;**
- Authorization of a clinical trial for a not-yet-registered drug manufactured by biotechnological methods: **approx. EUR 4,800 to approx. EUR 6,300;**
- National Registration Procedure: **approx. EUR 3,300 to approx. EUR 11,500;**
- Mutual Recognition Procedure: **approx. EUR 11,500;**
- Decentralized Procedure: **approx. EUR 14,000 to approx. 17,500.**

The above fees as well as fees for other types of proceedings are stipulated in Decree No. 427/2008 Coll.

5. For how long are marketing authorization s/registrations valid? How are marketing authorizations/registrations renewed?

Marketing authorizations are valid for five years after the decision granting the authorization comes into force and effect, provided that the drug is marketed in the Czech Republic.

The State Institute for Drug Control may extend the validity of the authorization on the basis of an application submitted no later than nine months before the expiry of the authorization and after a review of the risk-benefit balance of the drug. If the extension is approved by the State Institute for Drug Control, the authorization will last for an indefinite term, again, provided that the drug is marketed in the Czech Republic. However, if the State Institute for Drug Control finds that there is insufficient pharmacovigilance data (incl. exposure of an insufficient number of patients to the drug concerned), it may choose to extend the validity of the authorization for a new five-year period instead.

6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?

In general, the authorization process is the same for original and generic products. The only difference is that under certain circumstances, the results of preclinical and clinical trials do not have to be submitted in cases where the reference product has been registered in at least one other EEA member state for at least eight years.

The authorization process prescribed by law is the same for local manufacturers as well as foreign-owned manufacturers.

However, applicants for marketing authorization must reside or have their registered seat in the Czech Republic or in another EEA member state.

7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?

Under Czech law, both biologics and drugs are classified as drugs and are subject to the same regulation under the Act on Drugs, while medical devices are regulated separately. Medical devices are regulated under the MD Regulation in combination with the Medical Devices Act while in vitro diagnostic medical devices are regulated under the IVD Regulation in combination with the Medical Devices Act. There are no special regulations for combination products. Therefore, any combination of drugs and biologics is regulated by the MD Regulation provided that the drug has an action that is ancillary to that of the action of the device. However, if the action of the drug is principal and not ancillary to that of the device, the product will be regulated by the Act on Drugs, while the relevant general safety and performance requirements set out in the MD Regulation will apply as far as the safety and performance of the device part are concerned. The same applies if the device and the drug form a single integral product which is intended exclusively for use in the given combination and is not reusable.

8. How is compliance with regulations monitored and evaluated? Is the regulatory regime comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations and requirements?

The State Institute for Drug Control monitors compliance with the legal regulation of drugs and medical devices as well as with the performance of obligations imposed on the basis of its decisions and measures with respect to relevant subjects. This includes manufacturers and distributors of drugs and medical devices. It also carries out inspections to ensure compliance with the requirements of GMP (good manufacturing practice), GDP (good distribution practice) and good clinical practice in the area of human pharmacy. The State Institute for Drug Control also operates and manages a pharmacovigilance system for drugs as well as medical devices and participates in pharmacovigilance processes of the European Union.

The regulatory regime is based on EU regulations and directives and is in line with the European Medicines Agency's requirements.

9. What is the potential range of penalties for noncompliance?

The range of penalties depends on the type of violation and whether it has been committed by a natural person or a legal entity/entrepreneur. Broadly speaking, penalties in the area of drugs range from approx. EUR 4,000 to approx. EUR 830,000. Apart from financial penalties, a prohibition of activity (for up to two years) may be also imposed. In the area of medical devices, penalties range from approx. EUR 8,350 to approx. EUR 1,250,000.

10. Is there a national healthcare system? If so, how is it administered and funded?

Yes, there is a national healthcare system in the Czech Republic. It is regulated primarily by the Public Health Insurance Act and based on the principles of universal accessibility to healthcare, solidarity, mandatory health insurance, freedom to choose a health insurance company, and a basic package of healthcare covered by the public health insurance.

Participation in the public healthcare insurance system is mandatory for every person with permanent residency in the Czech Republic and for every