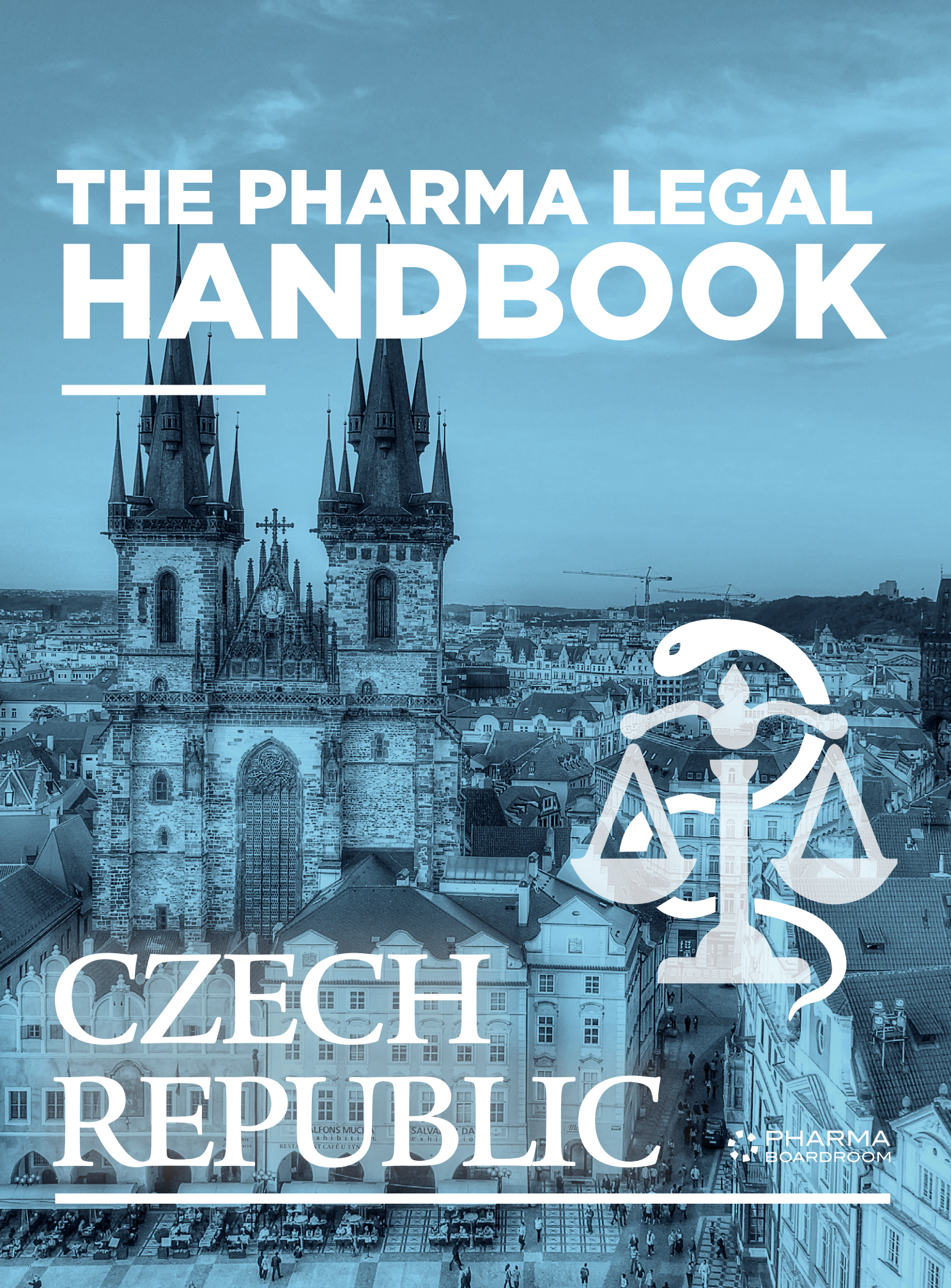
THE PHARMA LEGAL HANDBOOK



CZECH REPUBLIC

PHARMA BOARDROOM

THE PHARMA LEGAL HANDBOOK ANSWERS ESSENTIAL QUESTIONS ABOUT THE LEGAL AND REGULATORY 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.

* THIS LEGAL HANDBOOK WAS PUBLISHED IN SEPTEMBER 2019 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.

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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 Defence, 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 mainly regulated 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. 268/2014 Coll., on Medical Devices, as amended (the "**Act on Medical Devices**"); and
- Act No. 526/1990 Coll., on Prices, as amended.

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

In order to conduct testing of drugs, which have not been registered yet, it is necessary to obtain a clinical trial authorization from the State Institute for Drug Control. For the testing of drugs, which have already been registered, it is sufficient to notify the State Institute for Drug Control of the clinical trial.

In order 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 territory of the Czech Republic. The other two authorization types authorize the marketing of the product in other EEA states as well. In addition, the Centralized Procedure by the European Medicines Agency, which authorizes the product for all EEA states, can also be used. The requirement for a marketing authorization does not apply 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.).

Manufacturers and distributors of drugs are required to obtain licenses from the State Institute for Drug Control. A manufacturing license is required also for importing drugs from non-EEA states. Distribution licenses issued by EEA

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 1,750
- Authorization of a clinical trial for a registered drug: approx. EUR 800
- National Registration: approx. EUR 9,000 to approx. EUR 11,000
- Mutual Recognition Procedure: approx. EUR 11,000
- Decentralized Procedure: approx. EUR 16,800

For further details on fees please see: http://www.sukl.eu/sukl/ust-29-version-19

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

Marketing authorizations are valid for 5 years after the decision granting the authorization comes into force and effect. 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 such authorization and 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.

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 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, the applicants for the marketing authorization must have their residency or 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 under the Act on Medical Devices. There is no special regulation aimed at combination products. Therefore, any combination of drugs and biologics is regulated by the Act on Drugs. With respect to combinations of drugs/biologics and medical devices, the part consisting of a drug/biologic is regulated by the Act on Drugs and the part consisting of a medical device is regulated by the Act on Medical Devices, unless the part consisting of a medical device is fully integrated into the product and is for single use only, in which case the product as a whole is considered to be a drug and is regulated solely by the Act on Drugs.

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

The State Institute for Drug Control monitors compliance with the Act on Drugs and the performance of obligations imposed on the basis of its decisions and measures with respect to relevant subjects, including the manufacturers and distributors of drugs and medical devices. It also carries out inspections in order 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 the pharmacovigilance system for drugs as well as medical devices and participates in the pharmacovigilance processes in the EU.

In general, the Czech regulatory regime can be deemed comparable with the one of the European Medicines Agency.

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

The range of penalties is dependent on the type of violation and whether it has been committed by a natural person or a legal entity/entrepreneur. The amounts of the penalties range from approx. EUR 390 to approx. EUR 780,000. Apart from financial penalties, a prohibition of activity (for up to two years) may be also imposed.

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 mainly regulated by the Public Health Insurance Act and is based on the principles of universal accessibility of healthcare and 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 a permanent residency in the Czech Republic and every employee whose employer has a permanent residency or seat in the Czech Republic. The system is funded through mandatory monthly contributions by (i) employees and self-employed persons, (ii) employers and (iii) the state, which pays the insurance contributions for socially least-advantaged individuals, like children, students, pensioners, etc. Contributions are paid to individual health insurance companies (currently, seven health insurance companies hold the authorization to provide public health insurance in the Czech Republic, one health insurance company is owned by the Czech state). Health insurance companies are obliged to ensure healthcare is provided to their clients. They play a key role in the system of purchasing healthcare services by contracting with individual healthcare providers.

Czech legislation specifies the types of healthcare covered by the public health insurance system and the extent of such coverage; basically, the public health insurance system fully covers preventive medical examinations, diagnosis of diseases, and treatment of diseases as specified by applicable Czech law; it also determines the drugs and medical devices which are fully or partially covered by public health insurance and the respective conditions thereof.

In comparison with public health insurance, the share of private health insurance is rather negligible in the Czech Republic.