The Pharma Legal Handbook

Czech Republic

Regulatory, Pricing and Reimbursement Overview · Pre-clinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labelling 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

PHARMA BOARDROOM

Czech Republic

The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in 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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CONTENTS

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 authorisation , pricing, and reimbursement of drugs, biologicals, and medical devices?

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

4. What are the approximate fees for each authorisation ?

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

6. How does the authorisation 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?

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

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

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

11. How does the government (or public) healthcare system function with private sector healthcare?

12. Are prices of drugs and devices regulated and, if so, how?

13. How are drugs and devices used by patients paid for? What roles do public and private payers play?

14. Who dispenses drugs and devices to patients and how are those dispensers compensated?

15. What are the professional and legal responsibilities of those who dispense drugs and devices? What role do they play in providing patient care, information, and safety?

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 authorisation , pricing, and reimbursement of drugs, biologicals, and medical devices?

The authorisation, 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");
- Regulation (EU) No. 2017/745 on Medical Devices (the "MD Regulation");
- Act No. 89/2021 Coll., on Medical Devices (the "Act on Medical Devices");
- Regulation (EU) No. 2017/746 on In Vitro Diagnostic Medical Devices (the "IVD Regulation");
- Act No. 268/2014 Coll., on In Vitro Diagnostic Medical Devices, as amended (the "Act on IVD");
- Regulation (EU) No. 536/2014 on Clinical Trials on Medicinal Products for Human Use (the "Clinical Trials Regulation"); and
- Act No. 526/1990 Coll., on Prices, as amended.

3. What are the steps to obtaining authorisation 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 authorisation from the State Institute for Drug Control. To test drugs that have already been registered, it is sufficient to notify the State Institute for Drug Control of the clinical trial.

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

The approximate fees for each authorisation are:

- Authorisation of a clinical trial for a not-yet-registered drug: **approx. EUR 3,800;**
- Authorisation of a clinical trial for a registered drug: **approx. EUR 800, and EUR 1,700** for accelerated processing;
- National Registration Procedure: **approx. EUR 3,200 to approx. EUR 11,300**;
- Mutual Recognition Procedure: **approx. EUR 11,300**;
- Decentralised Procedure: approx. **EUR 13,000 to approx. 17,300**.

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 authorisation s/registrations valid? How are marketing authorisation s/registrations renewed?

Marketing authorisation are valid for five years after the decision granting the authorisation 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 authorisation on the basis of an application submitted no later than nine months before the expiry of the authorisation 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 authorisation 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 authorisation for a new five-year period instead.

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

In general, the authorisation 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 authorisation process prescribed by law is the same for local manufacturers as well as foreign-owned manufacturers.

However, applicants for marketing authorisation 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 Act on Medical Devices while in vitro diagnostic medical devices are regulated under the IVD Regulation in combination with the Act on IVD. 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 808,000. 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 8,000 to approx. EUR 1,212,000.

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