The Pharma Legal Handbook

Slovakia

Regulatory, Pricing and Reimbursement Overview · Preclinical 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

PHARMA BOARDROOM

Slovakia

The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in Slovakia.
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 Slovakia, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

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- Slovak
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- German
- Czech

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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?

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

4. What are the approximate fees for each authorization?

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

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?

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?

In the Slovak Republic, the main regulatory authorities over medicinal products, biologicals, and medical devices are the State Institute for Drug Control and the Ministry of Health.

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

In the Slovak Republic, the main regulatory framework for the authorization of medicinal products, biologicals, and medical devices is the Act on Medicinal Products and related regulations. As regards the pricing and reimbursement of medicinal products, biologicals, and medical devices, the main regulatory framework is the Act on Reimbursement of Medicinal Products and Medical Devices from the Public Health Insurance System and related regulations.

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

In the Slovak Republic, the handling with medicinal products and medical devices, in particular the production of medicinal products, wholesale distribution of medicinal products and provision of pharmacy services, requires a special license for the respective activity issued under the Act on Medicinal Products.

The authorization for manufacturing of medicinal products is required for manufacturing of medicinal products. The State Institute for Drug Control recognizes the authorization for manufacturing of medicinal products issued by the respective authority of another EEA member state. The authorization for manufacturing of medicinal products is required also for import of medicinal products from non-EEA countries. If the applicant fulfils the respective obligations specified by the Act on Medicinal Products, the State Institute for Drug Control issues the authorization for manufacturing of medicinal products within 90 days following the delivery of the application.

The clinical trials require the approval of the the State Institute for Drug Control. In order to obtain the approval of the State Institute for Drug Control, the respective Ethics Committee must issue a positive opinion to the clinical trial. The State Institute for Drug Control then decided on the application within 60 days (subject to certain exemptions provided in the Act on Medicinal Products) following its delivery.

In order to place the medicinal product on the Slovak market, the marketing authorization of the State Institute for Drug Control is required, except for the authorization issued by the European Commission through the centralized procedure which is then valid for all EEA member states. The State Institute for Drug Control has 210 days for reviewing the application following its delivery. Marketing authorization may be also received within the EEA following

simplified procedures, i.e., the mutual recognition procedure (recognition of an existing national marketing authorization by one or more EEA member states) or the decentralized procedure (the application for marketing authorization is submitted simultaneously in several EEA member states). Still, a separate authorization issued by the State Institute for Drug Control is required.

Please see **Answer No. 22** of **Chapter 3: Marketing, Manufacturing, Packaging & Labeling, Advertising** for the details about the process for obtaining the marketing authorization of new medicinal products and other medicinal products in the Slovak Republic and the requirements for placing medical devices into the Slovak market.

4. What are the approximate fees for each authorization?

The administrative fee for the authorization for manufacturing of medicinal products amounts to EUR 100 if the manufacturer is an individual and EUR 250 if the manufacturer is a legal entity.

The administrative fee for the registration of the manufacturer of a medical device amounts to EUR 700.

The administrative fee for the decision on the approval of the clinical trial amounts to EUR 331.50 with respect to medicinal products and EUR 165.50 with respect to medical devices.

The administrative fees for marketing approval are published at the webpage of the State Institute for Drug Control (**click here**).

The price list of the services provided by the State Institute for Drug Control sets prices for additional activities performed by the State Institute for Drug Control, e.g., issuance of a certificate on compliance with the requirements of the GMP.

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

Marketing authorization of a medicinal product is valid for five years. The State Institute for Drug Control may prolong the validity of the authorization on the basis of a written application submitted no later than nine months before the expiry date of the authorization, and on the basis of the review of the risk-benefit balance of the medicinal product.

Based on reasonable grounds relating to the supervision of medicinal products (including the exposition of a nonsufficient amount of patient to the medicinal product), the State Institute for Drug Control may decide to extend the marketing authorization of a medicine for additional five years. Otherwise, it will issue a decision to extend the marketing authorization for an unlimited period of time.

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

A generic version of a medicinal product requires also the marketing authorization issued by the State Institute for Drug Control. In case of generics, the applicant must prove to the State Institute for Drug Control that the product is bioequivalent to the reference medicinal product which has been registered in at least one EEA member state for at least eight years. In addition, the applicant must provide the State Institute for Drug Control with all information

and documents as required in the case of authorization procedure of a new medicinal product, except for the following. The applicant does not have to submit to the State Institute for Drug Control the results of the toxicological, pharmacological and clinical testing carried out by the applicant for the generic version, as the applicant can submit the results of these testing already carried out in relation to the reference medicinal product.

In the Slovak Republic, there is basically no difference between local manufacturers and foreign-owned manufacturers. However, the applicants for the marketing authorization must have their residency or registered seat in the Slovak Republic or in another EEA member state. In case of medical devices, the procedure differs if the manufacture's place of business or registered seat is outside the Slovak Republic (please see **Answer No. 22** of **Chapter 3: Marketing, Manufacturing, Packaging & Labeling, Advertising** for more details).

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

There is not specific regulation on the combination products. Basically, combination products drug + drug and drug + biologic fall under the regulatory framework of medicinal products and the Act on Medicinal Products should be applicable.

With respect to the combination products drug + device, biologic + device and drug + biologic + device, if the medical device and the medicinal products (the active substance) form an integral product, the medical device is intended only for use in such combination, is not reusable, and fulfils the technical requirements of the safety and effectiveness as specified by specific legal regulations, it shall be tested and approved as a medicinal product. Further, when deciding whether a product is a medicinal product or a medical device, the main effect shall be considered. Also, when deciding whether a product is a medicinal product or a medical device, the main effect shall be considered with respect to the medicinal product, and the main mechanism of the effect by which the purpose of determining specified by the manufacturer is achieved shall be considered with respect to the medical device.

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 performs state supervision over the compliance with the Act on the Medicinal Products and fulfilment of obligations imposed on the basis of its decisions and measurements with respect to specified subjects, including the manufacturer of medicinal products and medical devices, the wholesale distributors. In addition, it carries out inspections in order to ensure compliance with the requirements of GMP, GDP and good clinical practice in the area of human pharmacy.

The State Institute for Drug Control also operates and manages the pharmacovigilance system which is regularly audited by the State Institute for Drug Control. The pharmacovigilance system is also obligatory for the holders of marketing authorization which must also evaluate suspected adverse reactions to the medicinal product and report them to the EudraVigilance database. The physicians, other healthcare providers, persons authorized