

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

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, a leading regional-full-service law firm, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

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The firm has a team of lawyers specializing in legislation and other specifics of drugs, biologics, medical devices and related products. They can advise established or start-up firms in life sciences and healthcare on issues ranging from R&D to manufacturing and sale, IP legal issues, data protection, compliance, enforcement, litigation, transactions, public procurement, antitrust and competition issues

The firm has garnered significant international and national awards and has a strong commitment to corporate social responsibility and pro bono work. The firm has been long-term ranked by international ranking agencies of law firms such as Chambers and Partners, The Legal500 or IFLR1000.

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A Step Ahead

CONTENTS

01	REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW	Page 6
02	PRECLINICAL AND CLINICAL TRIAL REQUIREMENTS	Page 16
03	MARKETING, MANUFACTURING, PACKAGING AND LABELING, ADVERTISING	Page 21
04	TRADITIONAL MEDICINES AND OVER-THE-COUNTER PRODUCTS	Page 37
05	PRODUCT LIABILITY	Page 42
06	PATENTS AND TRADEMARKS	Page 48
07	REGULATORY REFORMS	Page 55
08	CANNABINOID DRUGS, MEDICINAL CANNABIS AND OPIOID DRUGS	Page 57
09	ORPHAN DRUGS AND RARE DISEASES	Page 66
10	LOCALIZATION	Page 70
11	BIOSIMILARS AND BIOLOGICS	Page 75

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 (including respective EU regulations which are directly applicable in the Slovak Republic). 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 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 decides 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 proceedings on the approval of the clinical trial varies from EUR 3,500 to EUR 11,000 with respect to medicinal products and EUR 500 with respect to medical devices.

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 300 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, the assessment of the technical documentation in case of the first notification/registration of a medical device/the manufacturer of a medical device.

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. However, 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 manufacturer's place of business or registered seat is outside the Slovak Republic (please see **Question 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 no 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. In addition, the EU Medical Devices Regulation (2017/745) which regulates also these matters fully applies in the Slovak Republic from 26 May 2021.

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

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