CONTENTS

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 to dispense medicines and health insurance companies are also required to immediately notify the State Institute for Drug Control of suspected adverse reactions to the medicinal product of which they learned after its registration. On the

basis of the results of the information from the pharmacovigilance system, the State Institute for Drug Control may change, suspend or revoke the marketing registration of a medicinal product. The State Institute for Drug Control also participates in the pharmacovigilance process in the EU.

With respect to the medical devices, the State Institute for Drug performs supervision over the medical devices and records and evaluates information about reported accidents, defects and malfunction of medical devices.

In general, the Slovak regulatory regime can be deemed comparable with the EU law. The State Institute for Drug Control frequently refers to European Medicines Agency's Guidelines and other related documents. EU and US have entered into a mutual recognition agreement on GMP inspections. The capability of the Slovak Republic to carry out GMP inspections at a level equivalent to the US has not been approved by the FDA yet (transition phase will be in place until July 2019).

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

In general, the State Institute for Drug Control can impose a fine ranging from EUR 300 to EUR 35,000 or Ministry of Health can impose a fine ranging from EUR 500 to 1,000,000 for non-compliance with the Act on Medicinal Products (depending on the breach). In case of a repeated breach, the fines can be doubled (or in certain cases even tripled).

The respective authority which issued the respective authorization may also suspend the activity to the respective authorization holder and order to remove the ascertained failure, revoke the respective authorization, to suspend or to revoke the registration of the medicinal product. With respect to the medical devices, the State Institute for Drug Control can prohibit the clinical testing of the medical device, its placement on the market or operation, its removal from the market or operation.

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

Yes, there is a national healthcare system in Slovakia. The healthcare system in Slovakia is based on the principle of universal accessibility of health care and solidarity, mandatory health insurance, free choice of the respective health insurance company and a basic package of healthcare covered by the public health insurance.

In general, all Slovak residents (subject to exceptions specified by the Act on Health Insurance) must mandatorily participate in the public health insurance system. The Slovak legislation specifies the respective types of healthcare covered by the public health insurance system and the extent of the coverage; basically, the public health insurance system fully covers preventive medical examinations, diagnosis of a disease, and treatment of priority diseases as specified by the Slovak legislation; it also regulates the medicinal products which are fully and partially covered by the public health insurance and the respective conditions thereof.

The Ministry of Health is responsible for the general management of the healthcare system and health insurance system, the price regulation and preparation of the state health policy objectives. Certain responsibilities of the Ministry of Health have been delegated to the regional level (e.g. issuance of authorizations

of certain health care providers). The supervision of the healthcare system is under the scope of the Health Care Surveillance Authority (established by the Act on Health Insurance Companies) whose executive bodies are appointed by the Slovak government based on the proposal of the Minister of Health.

The Health Care Surveillance Authority is the competent authority for the issuance of the authorization for performance of public health insurance to the health insurance company. The health insurance companies are obliged to provide for the healthcare for their clients. They have a key role in the system of the purchase of healthcare services by contracting the respective healthcare providers. The compulsory contributions to the public health insurance system are collected by the health insurance companies and are redistributed according to the system of risk adjustment (the system takes into consideration the groups of the insured persons according to their age, gender, economic activity and pharmacy-based costs).

The Slovak public health insurance system is based on compulsory monthly contributions (largely employment-based contributions) of the subjects to the health insurance system (including the state which pays the insurance payments for socially least favoured individuals, like children, students, pensioners, etc.) to their respective health insurance company (currently only 3 insurance companies have the respective authorization to perform the public health insurance in Slovakia, 1 insurance company is owned by the state). The insurance payments paid by the state are paid by the Ministry of Health from the state budget. The public health insurance system is partially financed also from the budgets of the respective regions and municipalities, and from out-of-pocket payments of patients, e.g. surcharges for the prescribed medicinal products. In comparison with the public health insurance, private health insurance is rather negligible in the Slovak Republic.

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

In the Slovak Republic, the public healthcare providers provide mostly the inpatient healthcare services. They are usually profit-making or non-profit-making entities, founded by the Ministry of Health or the respective regional entity or municipality. The public healthcare system constantly faces the lack of finances, material/equipment and personnel. The state determines the minimal network of public healthcare providers with which all health insurance companies have to conclude the agreements in order to preserve the principle of universal accessibility of the public healthcare system.

The outpatient clinics are usually in private hands. There are also few private healthcare providers which provide inpatient healthcare services. The health insurance companies have in place the agreements also with certain private healthcare providers, so certain services provided to the patients by these providers can be fully or partially covered by the public health insurance system.

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

The prices of medicinal products and medical devices are regulated as further described. The competent authority for the price regulation is the Ministry of Health.

The prices of partially or fully reimbursable medicinal products are set as maximal prices using the reference price calculation method of three lowest prices in EU countries. On the basis of individual decisions, the Ministry of Health determines the maximum covered by the public health insurance system, the maximum surcharge paid by the patient and the maximal price of the medicinal product in the pharmacy (this price includes the respective VAT, the wholesale and the pharmacy mark-ups). The list of the reimbursable medicinal products which contains, among others, these maximums, is published by the Ministry of Health. In addition, the price regulation issued by the Ministry of Health contains the regulation of maximal mark-ups for wholesale distributors and pharmacies with respect to medicinal products supplied to inpatient and outpatient clinics and pharmacies (subject to limitations specified in the price regulation). Over-the-counter medicinal products are not subject to price regulation. The similar price regulation of partially or fully reimbursable medicinal products and the regulation of maximal mark-ups for wholesale distributors and pharmacies apply on medical devices.

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

In general, the medicinal products and medical devices are fully reimbursable during inpatient care, if the patient is covered by the public health insurance and the healthcare provider is public or the private healthcare provider has in place the agreement with the health insurance company of the patient which covers the provided services.

In outpatient sector, the medicinal products and medical devices are fully or partially reimbursable, if they are included in the list of reimbursable medicinal products/medical devices on the basis of individual decisions of the Ministry of Health; the list also specifies the amount of the surcharge of the patient (if any). Otherwise, the patient has to pay for the medicinal products and medical devices in full.

In individual cases, the respective insurance company may pay its client the surcharge paid by the client for the partially reimbursable medical products/medical devices, or pay its client a part of the entire amount of the non-reimbursable medical products/medical devices provide (or even the entire amount in exceptional cases) if it is in line with the statutory provisions.

In comparison with the public health insurance, private health insurance is rather negligible in the Slovak Republic.

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

Medicinal products can only be dispensed in the hospital pharmacies, in the public pharmacies and in branches of public pharmacies. Medical devices can be dispensed in the hospital and public pharmacies, in the respective trading places for medical devices, or in optical shops (optical medical devices). The pharmacies and trading places for medical devices must have the authorization for provision of pharmacy services. Operation of optical shops is only subject to a trade license (a positive statement of the State Institute of Drug Control is, however, required).

These dispensers are compensated through the public health insurance system and by payments of patients.

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?

These responsibilities are primarily set out in the Act on Medicinal Products. The holder of the authorization for provision of pharmacy services must, inter alia:

- to secure the purchase of the medicinal products only from the manu facturers of the registered medicinal products, the holders of the marketing authorization, the holders of the authorization for wholesale distribution of the medicinal products;
- provide the pharmacy services in line with the Act on Medicinal Products and comply with the requirements of the good pharmacy practice and the Slovak Pharmaceutical Code;
- to immediately notify the State Institute for Drug Control of suspected adverse reactions to the medicinal products;
- to provide professional information about medicinal products, medical devices, to consult the determination and monitoring of a medical treatment;
- to provide information and counselling in such a way that ensures the effectiveness and safety of the treatment by the medical products and medical devices;
- in case of medicinal products reimbursable from the public health insurance, to inform the patient on the possibility to choose an alternative medicinal product and on the amount of the surcharge for all alternative medicinal products which can be dispensed on the basis of the respective medical prescription.