Slovak Republic

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Legislation and regulation constitute important elements in any drug policy. The legal framework must take into account not only policy objectives but also the administrative, social and health infrastructure, the available manpower and other resources.

Drug legislation and regulation address the rights and responsibilities of the different parties concerned with drugs and pharmaceutical products, including medical practitioners, pharmacists, importers, manufacturers and distributors. Legislation and regulation play an important role in ensuring that pharmaceutical products are safe, effective and of good quality.

The drug legislative and drug regulatory system has been in existence for 75 years in Czechoslovakia and for 40 years in Slovakia. The transitional process has brought a new socioeconomic environment and the drug legislative and regulatory system does not correspond with this new situation. Consequently, the drug legislative system and the role of drug regulatory authorities are being changed, especially in the field of drug registration, pricing and reimbursement.

COUNTRY DESCRIPTION

Slovakia is located in Central Europe with an area of 49,000 square kilometers. About 60 percent of the whole area consists of highlands represented by a mountainous arc—The Carpathians (300 to 2655 metres above sea level).

The Slovak Republic has a population of approximately 5.3 million of whom 2.7 million are women. The number of children born alive is about 74,000 (14.1 percent per 1,000 inhabitants); annual deaths are about 53,000 (10.1 per 1,000 inhabitants); the natural population increase is about 21,000 persons (4 per 1,000).

Children up to 14 years old comprise 25 percent; productive age are 58 percent; and post-productive age are 17.3 percent of the population.

The average density of inhabitants is 108 per square kilometer and is highest in the western part of Slovakia. The ethnic nationality breakdown of population is: 85.6 percent Slovak; 10.8 percent Hungarian; 1 percent Czech; 1.5 percent Romanian; and 1.1 percent other.

The health of the Slovak population compares significantly unfavourably to developed countries. This is the result of the devastation of life environment, unhealthy life styles and the stagnation of the healthcare services. The Slovak Republic has one of the highest mortality rates and life expectancy is stagnant. In the last five years the indicators of health condition of the population have changed (life expectancy, mortality, morbidity, etc.). In developed countries these indicators have improved; in Slovakia they have deteriorated. The leading diseases have become chronic noninfectious diseases, which are more typical for the younger groups of population. Cardiovascular diseases represent the most serious health problems for the entire population. Oncological diseases have also increased. Last but not least, chronic respiratory tract diseases and drug abuse (cocaine, heroin, cannabis, etc.) are all serious health threats. Although the negative development of "civilisation diseases" has been postponed or reduced in developed countries, in the Slovak Republic this development is going on and the social and economical environment does not allow positive changes. This statement is based on following indicators:

- Life expectancy in Slovakia (5 to 7 years less than in developed countries):
  - 66.5 years for males
  - 75.3 years for females
- There are high mortality in the middle age group of population.
- Mortality attributed to cardiovascular diseases has rapidly increased compared with the rate in developed countries.
- Alcohol consumption has increased.

This analysis has been the source of State (National) Health Policy, which was introduced in 1994 and innovated in 1995. It consists of long and short term state activities designed to improve health conditions of the population. Those activities should be provided by cooperating governmental and nongovernmental organisations.

The State (National) Health Policy is derived from the Constitution of the Slovak Republic, the World Health Organisation (WHO) Programme "Health for all by the year 2000", the Declaration of Life Environment and Development (Rio de Janeiro 1992) and the European Chart on Life Environment and Health (Frankfurt 1989). This policy is provided by the State through the government in cooperation with

nongovernmental organisations. One of the most important measures taken was changing the healthcare system directly governed and supported by the State to a relatively independent social and health insurance system. After the split from the Czech Republic the national insurance (general health insurance [GHI]) was created to be responsible solely for healthcare. Since January 1995 other branch health insurances were created and some private companies were given licence. The GHI covers about 85 percent of insured people; 9 other health insurance companies cover 15 percent, but they represent only 5 percent of health expenditures. This problem is compensated by the system of solidarity—transfer 60 percent of income to special fund of the GHI. The new law has been in force since 1 January 1996. According to this law, the licence for health insurance activity can be given with the requirements:

- There must be 100,000 clients in order to start.
- There must be more than 300,000 clients within 2 years.

This legislation partly restricts the creation of the new private health insurance companies, but it was determined that the company could work effectively with a minimum of 250,000 insured persons.

Health providers are paid partly according "points" (value 0.2 Slovakian Currency [SK]) and partly according to the "daily bed count" (value is estimated by the health insurance).

The main problem is that the state has an obligation to pay for nonactive citizens 13.7 percent from minimum salary, but it pays only from 54 percent of minimum salary. This situation leads to an insolvency chain among the state, health insurance, healthcare providers, wholesalers and manufacturers. Per capita health expenditures in Slovakia in 1995 were SK 5,000 (US $172). The GHI's income was circa SK 23 milliarden expenditures SK 25 milliarden. The State should make up the SK 2 milliarden difference. Some measures have been taken in the National Health and Drug Policy, which was issued in 1995 and revised in 1996.

THE SLOVAK PHARMACEUTICAL SECTOR

The opening of the Czech and Slovak pharmaceutical markets to foreign competition in the early 1990s started a process of change that has not yet been completed. A huge loss of market share for domestic companies resulted, which forced them to formulate strategies for the future. For the Slovak pharmaceutical market as a whole, very limited growth and increased competition are expected. As a result, earnings growth for the companies will come only from new product launches and higher exports, with very little help for underlying consumer demand.

The domestic pharmaceutical industry as a whole does not occupy such an important role in the economy in Slovakia as it does in Hungary or Poland. Consequently, authorities have focused more on cost reduction than on the support of domestic companies, resulting in a decreased market share, which was filled by the foreign companies.

After the split of the Czech and Slovak Republics, the combined SPOFA, the domestic association of Slovak pharmaceutical companies, the largest companies (operated in the specific therapeutic groups) had incomplete portfolios. In order to be fully functioning drug companies they restructured their portfolios (which contained too many products of dubious profitability) and improved their production in order to increase profits in a market which seems to be without volume growth. They may make a small profit from the existing reimbursement system, which favours generic drugs, many of which are produced by domestic pharmaceutical companies.

On the other hand the pricing policy negatively affects them with a system of maximum ex-factory prices. The prices for domestic producers are strictly limited (entitled costs plus 30 percent gross profit) for imported drugs. They are established by negotiations. Generally the proposed price is accepted. A lack of resourses for research and development by the domestic manufacturers has resulted from this situation.

Until 1989 Czechoslovakia was 75 percent self-sufficient in drug production; 20 percent of drugs were imported from Communist European Countries (COMECON) and only 5 percent from Western countries. The split of COMECON had a very small impact on the pharmaceutical industry and did not threaten the companies with bankruptcy. During the transitional period, the market situation changed significantly. Now foreign companies have around a 65 percent share of total sales in Slovakia in value but only 31 percent in volume. This situation is mainly caused by the different price level of domestic (including Czech) products and imported drugs.

It is remarkable in the Slovak Republic that total drug expenditures have taken off exponentially (from SK 2.5 billion in 1990 to SK 13,5 billion in 1995) although drug consumption in units has decreased (from 160 million units in 1990 to 147 million units in 1996).

Domestic companies have lost a significant proportion of their market share. They may regain some ground with the reimbursement system which favours generic drugs.

REGULATORY ENVIRONMENT AND REGULATORY AUTHORITIES

The Ministry of Health (MOH) is the central national health authority for healthcare, health protection, curative spas, curative centres, health education and pharmacy care. The "state secretary" has a function as a vice-minister. The MOH consists of the office sections and departments that are responsible for different MOH activities. The MOH directly governs more than 350 hospitals, institutions and healthcare facilities.

The Slovak Republic has 85 hospitals (including 2 independent delivery hospitals) with 40,000 beds, 107 expert health institutions with 10,000 beds, 44 treatment institutes with 11,000 beds and 30 special children's establishments with 1,726 beds. There are more than 17,000 physicians and surgeons, more than 2,000 pharmacists and 50,000 medium grade health employees.

The central administrative body of drug regulation is the MOH, but other administrative bodies have been established in this regard. The most important is the State Institute for the Control of Drugs. Its main responsibilities are the following:

- Drug registration
- Licencing of manufacturers, wholesalers and pharmacies
- Approval of medical devices
- Control of drugs in laboratories
- Inspection of good manufacturing practice (GMP), good laboratory practice (GLP) and good clinical practice (GCP)
- Postmarketing surveillance and drug safety
- Information
- *Pharmacopoeia* and codex

Decisions in the registration process and licencing of manufacturers, wholesalers and pharmacies are done at the MOH level.

Laboratory control of drugs is concerned with imported drugs, the quality of drugs in manufacturers and wholesaler's facilities, and in pharmacies, hospitals and clinics. The recall system is connected to this control. The Institute is responsible for the recall of drugs which don't meet the requirements for safety, efficacy and quality. Emergency recall is provided by telephone, fax or telegraph, and by the regional "state physicians". Reports about drug quality are regularly published.

On the regional level, regional control laboratories (as a part of the State Institute for Drug Control) are responsible for drug control among wholesalers and pharmacies, especially for pharmacy-compounded drugs.

A very important regulatory function of the State Institute for the Control of Drugs is the inspection of GMP, GLP and GCP. The Inspection Department is responsible for inspecting and supervising the GMP (including good storage and pharmacy practice) among manufacturers, wholesalers and pharmacies. The State Institute is also the national authority for supervising and inspecting GLP. On the regional level, there are inspectors in regional laboratories responsible for inspections in wholesalers' facilities and in the pharmacies. Audit and inspection of GCP is being created.

REGULATORY REQUIREMENTS AND PROCEDURES

The introduction of a new drug on the Slovak market is possible only on the condition that it is registered. During the registration procedure all available data concerning the drug are evaluated, including determining its safety, efficacy and quality. GLP, GMP and GCP are evaluated based on the information obtained. In this

way the essential prerequisite is ensured, i.e., the drug which is on the market must bring the patient more benefit in the treatment of his disease than possible harm.

The State Institute for Drug Control is in charge of the drug registration agenda in the Slovak Republic. The required documentation, corresponding to European Union (EU) standards, should consist of three main parts: pharmaceutical-technological, pharmacological-toxicological and clinical.

Each part is reviewed by an independent expert. Final discussion of the recommendation on drug registration is reserved for the Committee for Drugs, an advisory body of the State Institute for Drug Control. Analytical documentation is verified and reviewed at this institute. The same requirements are applied to both domestic and imported preparations. Registration does not require clinical trials performed in Slovakia. Clinical trials which have been well-organised and carried out abroad can be taken as a reliable basis for drug registration. It depends on the opinion of experts and the Committee for Drugs for each individual case. This Committee consists of experts in different fields of medicine, pharmacy and pharmacology, such as clinical pharmacology, dermatology, anesthesiology, cardiology, etc. There are also specialized drug subcommittees for radiopharmaceutics, synthetic polymers, immunopreparations, dental preparations, phytopharmaceuticals and homeopatics.

An application for registration of a pharmaceutical specialty shall be made by the manufacturer. A foreign manufacturer shall be represented in Slovakia by a domiciled agent (representative) who is empowered to plead the manufacturer's application before the State Institute for Drug Control. Correspondence between the registration authority and the foreign manufacturer usually should be forwarded via the agent.

The application format is to be harmonised with the EU "Notice to Applicants" (Expert Reports will also be requested). The particulars and documents accompanying an application for marketing authorisation (MA) must be presented in four parts:

Part I: Summary of the Dossier

Part II: Chemical, Pharmaceutical and Biological Documentation (Quality)

Part III: Pharmaco-Toxicological Documentation (Safety)

Part IV: Clinical Documentation (Efficacy)

According to the explanation of the State Language Law, all data which will be the basis for the user's information (physicians, pharmacists and patients) must be submitted in the Slovak language. It means that only the administrative data (I.A) and proposal for packaging, labelling and package insert (I.B2) must be in the Slovak language. The request for Summary of Product Characteristics (SPC) in the Slovak language is under discussion. All other documents are acceptable in English or German.

Pharmaceutical analysis of the samples accompanying the application had been compulsory but now will be carried out only randomly. It will depend on the evaluation of the manufacturer's quality assurance system. The requested clinical trials during the registration process will be very limited.

Recognition Procedure for Centrally Registered Drugs in the EU

The application should be submitted on the official form, the Application for Entry into the Drug Register, in both English (one copy) and in Slovak (in triplicate). An integral part of the application is the Applicant's Declaration and Approval of Information Sharing between the European Medicines Evaluation Agency (EMEA), European Commission and the State Institute for Drug Control.

The documentation submitted for registration relating to the extent must comply with standard requirements for registration documentation and Application for Entry into the Drug Register mentioned previously with the following exemptions and comments.

Part I must to be identical to what is accepted by the EMEA; proposals of Summary of Products Characteristics, package leaflet and warning for the labelling in Slovak should be included.

Part II must to be identical to what is accepted by the EMEA.

Parts III and IV need not be submitted to the full extent. The detailed list of contents is sufficient on condition that individual parts are provided both as original text attached to the decision (in English or German) and as its Slovak version (in triplicate).

The following other materials should be enclosed:

- Consolidated list of comments of Committee on Proprietary Medicinal Products (CPMP)
- Applicant's responses to consolidated list of comments
- Opinion of the CPMP including all annexes
- Assessment report (EPAR)

and either (provided that the application in the Slovak Republic is submitted prior to the final Commission decision):

- Draft Commission decision including all annexes; or
- Commission decision including all annexes (provided that the application in the Slovak Republic is submitted after the final Commission decision).

Mutual Recognition Procedure

Recognition, or the abridged procedure for the drugs registered in the EU according this procedure, was one of the important topics discussed at the Round Table organised in Brussels 27 June 1996. A consensus has not been reached yet, but it is

possible to start this procedure in the Slovak Republic as well. The preliminary requirements for the registration dossier are similar to those for the centralised procedure. The registration procedure can be started after the reference country grants the MA, but the Slovak MA can be granted after the recognition of all EU member country authorities.

Harmonisation With EU Legislation

In 1990 the Slovak Republic passed resolution No. 127 to harmonise legislative regulations with the requirements of the European Community and WHO. This resolution has accelerated the negotiations with the European Commission concerning legislative harmonisation in order to remove obstacles in international trade. The European Commission has prepared the so-called *White Paper* which contains a sector by sector description of the Community "acquis" for the internal market. In all at least 60 areas of legislation will be dealt with. In every area some measures should be taken according to the following criteria:

- The measures concerned provide the overall framework for more detailed legislation.
- The measures concerned address fundamental principles or provide for the basic procedures which govern the sector concerned.
- The measures are in one way or the other a precondition for the effective functioning of the internal market in that sector.

REGULATORY UPDATE

New Drug Regulations

The national drug policy was introduced and approved by the government in 1996 as a "Concept of Drug Policy". Its main goal is to ensure access to safe, effective drugs of high quality and economically acceptable prices for the entire population. An integrated part of this policy is drug legislation, including the drug registration, classification, licencing of manufacturers, wholesalers and pharmacies, clinical trials, GMP, GLP and GCP, etc.

The new drug legislation came about as a result of this document. The "Law of Drugs and Medical Devices" No. 140 was adopted by parliament on 2 April, 1998 and became effective on 1 June. It regulates procedures with drugs and medical devices, drug control and testing, registration, medical device approval, quality assurance of GMP, GLP and GCP and the role of the regulatory authorities. The law's structure can be seen in the following paragraphs.

Definitions

The new Drug Law includes definitions for certain terms such as pharmaceutical care, wholesale, human and veterinary medicinal product (drugs), active ingredient, medical device, drug registration and homeopathic medicinal product.

Rules for Manipulation with Drugs and Medical Devices

The general requirements for subjects such as the manufacturer, wholesaler and pharmacist are described, including the definition and qualification for a "qualified person". The procedures for licencing are regulated in more details.

Testing the Active Ingredients and Medicinal Products

Pharmaceutical testing is described as an analytical procedure for checking the quality and active ingredients of drugs.

Toxicological-pharmacological testing includes preclinical trials for the safety of medicinal products.

Clinical trials are defined in the law (approving efficacy). GCP is the integral part of clinical trials and the separate sub-law regulation (Directive) will be introduced soon. Clinical trials must be approved by the State Institute for Drug Control (SIDC), which has the right for supervising, inspecting and withdrawing the clinical trials.

Drug Registration

All mass-produced drugs have to be registered. Products for research, investigational and testing purposes, products for one patient and one cure, extemporaneously prepared products and antidotes are exempt from registration.

The application for registration can be submitted by the holder of the MA in the country of origin to the SIDC (Foreign manufacturers need the MA from the country of origin.) The MOH defines the applicant as the legal or physical person who has the MA in any country and has the manufacturing authorisation related to the registered product (e.g., contract manufacturing). The content of the dossier is identical with EU regulations.

The proposals for Summary of Product Characteristics, Leaflet and Labelling must be in the Slovak language. The contents are identical with EU regulations. The SIDC evaluates the dossier within 180 days and has the right to a 90 day extension. After the evaluation, the SIDC issues the "binding assessment report" and the application is submitted to the MOH which has a 30 day time limit to grant the MA.

Labelling, Leaflet and Summary of the Product Characterisations

The requirements for the labelling are described in § 24. They respect the EU regulations for outer and inner labelling.

The Patient Information Leaflet (PIL) has to be in the Slovak language. Its content is identical to the EU regulations (§ 25).

Summary of Product Characteristics is defined and described in § 26 and is in conformity with EU requirements.

After granting the MA, the documents have official status and the holder of the MA may change those documents only after the approval of the competent authorities in the process of the variations.

Drug Manufacturing

The natural or legal person can manufacture the medicinal products if the following requirements are met:

- The premises are in accordance with GMP requirements.
- There are "qualified persons".
- The quality assurance system exists.
- Access for inspection by the regulatory authorities is allowed.

Wholesale Distribution

The licence for wholesale distribution can be granted to the natural or legal person if the following requirements are met:

- The premises conform with Good Wholesale Practice.
- There is a "qualified person".
- The quality assurance system exists.

Pharmaceutical Care

Pharmaceutical Care includes the supply, preparation, control, storage and dispensation of medicinal products and medical devices, providing information and consultation for the patient and following the therapy. The licence for pharmaceutical care can only be granted to the natural person with the pharmaceutical qualification.

Supervision

In the process of research and development, manufacturer, wholesale and pharmaceutical care, the quality assurance system has to be introduced with adequate control of the starting materials, intermediates and final products.

Adverse drug reaction (ADR) is defined in the law. The person authorised for the drug prescription, wholesale, dispensation and manufacture is obliged to report an ADR to the SIDC. The SIDC has the right to postpone or withdraw the medicinal products or medical device from the market.

Regulatory Authorities

The regulatory authorities include: the MOH; the Office for Standardisation, Metrology and Testing; the State Institute for Drug Control; and regional authorities.

The State Institute for Drug Control is responsible for supervision in the pharmaceutical sector, medical device approval, the registration process, clinical trial approval, withdrawal of drugs and medical devices, control of advertising and inspection of GMP, GLP and GCP.

Advertising

Drug and medical device advertising is not included in the Drug Law, but the amendment to Advertising Law No. 220/1996 has been adopted. Advertising for the public does not include:

- information for the health professionals
- the SPC and leaflet
- registration documentation

The following cannot be advertised:

- prescription-only medicinal products
- medicinal products containing narcotics and psychotropics
- nonregistered products in the Slovak Republic
- nonprescription medicinal products included in the reimbursement list

The SIDC is responsible for the control of advertising (no preapproval process) and has the right to postpone, withdraw or for penalisation.

Variations and Renewals

As stated in § 23 "Obligations of the Marketing Authorisation Holder" of the new Law No. 140/1998 on medical products and medical devices, the MA holder is obliged to ensure that the properties of the medicinal products registered are in accordance with the documentation submitted with the application for registration. Therefore, the MA holder has to apply for any intended variation concerning the registered product and its documentation, as is customary in the EU. There are no differences between type I and II variations.

Renewal Applications

The decision on registration is valid for 5 years. On the basis of the written application submitted at least 3 months before the expiration date the MOH can extend

the registration for another 5 years. This provision is only valid for MAs granted after 1 June 1998. The amendment of the law allows renewals for existing MAs.

Generic Registration

The registration of generics is not described in the Drug Law. The MOH regulates the process. The applicant may not submit the results of toxicological-pharmacological testing and clinical trials if it is proven that:

- the medicinal product is essentially similar to the medicinal product already registered in the Slovak Republic and consent has been given by an MA holder to refer to its dossier;
- the medicinal product is essentially similar to a medicinal product which has been authorised in the EU for 6 years or registered in the Slovak Republic; and
- the active ingredient(s) has been in therapeutic use for a long time and the safety and efficacy are proven and documented in scientific publications (well established medicinal product).

Essentially similar is the product with the same quantitative and qualitative composition in terms of active principles. The pharmaceutical form is the same, and where necessary, appropriate bioavailability studies have been carried out.

Clinical Trial Procedures

The legislation on the use of pharmaceuticals, including clinical research of investigational products, is based on two laws: The Act of National Council No. 277/1994 and No. 140/1998. The latter act has been in force since 1 June 1998. This legislation brings pharmaceutical usage in closer approximation to the EU law. GCP is mandatory.

Legal Prerequisites for the Conduct of Clinical Trials

Three documents are needed for starting a clinical trial.

- The authorisation from SIDC.
- The approval from institutional ethics committee.
- A contract with healthcare institution.

The clinical trial authorisation from SIDC is needed for all clinical trials in the Slovak Republic.

REGISTRATION PROBLEMS

The drug registration procedure in the Slovak Republic is based more on scientific evaluation than on administrative checking. All steps in this procedure may cause some specific problems because of an overload of applications. Since 1991 there has been an extension of applications for registration—in 1992 about 1,000; in 1993, 1,100; in 1994, 800; in 1995, 700; and in 1996 about 650 applications. Because of very low registration fees, many companies have started to register many products (mainly obsolete) with no intention of placing them on the market. This has caused many of the following problems:

1. The applicant's representative is often not identified, causing problems concerning the identification of the applicant and the MA holder. Many pharmaceutical companies have been sold or merged, making it difficult to identify the right person or right applicant.

2. Administrative checking has discovered that much of the documentation accompanying the application is out of date. There are no analytical validations, an extension of indications is not included in the SPC and the labelling and leaflets are not according to current requirements.

3. Contact and correspondence with the applicant are not very flexible. Very often it is necessary to wait many weeks or months for a response. The answers are sometimes not qualified and unclear. This process leads to the prolongation of the registration process and an ensuing backlog.

4. In the case of generics, there are many controversies with the bioavailability and bioequivalence studies. The comparator is very often not registered in the Slovak Republic or is not the product of the innovator. Some applicants insist that in vitro bioequivalence studies without scientific evaluation and evidence be accepted.

5. Clinical documentation is in many cases not sufficient and not according to GCP requirements. There is a lack of ADR evaluation with the drugs submitted for registration. On the other hand the members of the Drug Commission sometimes request that additional clinical trials be conducted in the Slovak Republic without a serious scientific reason. This is the reason for an enormous delay in the registration process.

6. The other registration problem is reassessing. The requirements for the assessment report are not yet clear. External experts working from case to case for the State Institute for Drug Control are very busy and overloaded with documentation. They are underpaid for the assessment reports and payments are sometimes delayed. The registration fees cannot

be utilised by the Institute for those purposes. The problems could be solved in the following ways:

- Clear rules and a transparent registration procedure should be set up. The new directive will contain the detailed requirements for the registration process for new drugs, for generics (including the rules for accepting some in vitro studies) and for the recognition of the evaluation process of the centralised and mutual recognition EU process. Also, the fees should be higher and should be able to be utilised by the Institute.
- The new Drug Law includes the time limit (210 days) and the clock stop for the applicant in the cases of additional questions and answers. This could speed up the registration process, which would be more transparent.
- The applicants should set their priorities (which product will be seriously launched on the market) and submit the "perfect" documentation. The responses should be on time and qualified. Generally, the EU requirements for the registration documentation shall be respected.
- The representative (person or organisation) shall be clearly identified and empowered for the contact with the Institute. Proper qualification shall be respected. It is necessary to clarify the changes in the company organisation, the new names and the situation in the product licence.

FUTURE TRENDS

Draft for the Amendment of the Medicines Act

The MOH submitted to parliament the draft for the amendment of the Medicines Act. The main proposed changes are:

- The definition of medical device
- The notification procedure for the clinical trials phase IV and its definition
- The definition and responsibility of the monitor
- The classification of over-the-counter (OTC) products
- The updating of the application form
- The harmonisation of the requirements for the documentation
- The generic registration (abridged procedure)

- Data exclusivity
- The definition of "essentially similar"
- Type I and II variations
- Orphan drugs—exemption

These changes will influence greater harmonisation of drug legislation in the Slovak Republic with that of the EU.

CONCLUSION

The drug regulatory system in the Slovak Republic has significantly changed in recent years. National health and drug policies have been introduced and updated. The health and pharmaceutical sectors are one of government's priorities as expressed in the "Concept of Drug Policy" adopted by the government.

The main goal of the government in this sector is to finish health reform and privatisation in order to ensure access to healthcare and drugs for the entire population in accordance with the new socioeconomic environment. This reform shall stop the explosion of health expenditures and better utilise limited resources. In this regard the Drug Regulatory System shall be more flexible, more transparent and harmonised with EU standards and legislation. All mentioned measures have an important impact on the pharmaceutical market, which is becoming more open and transparent.

ABOUT THE AUTHOR

Ludevít Martinec received a PhD in pharmacy from Comenius University in Bratislava. He has taken management courses in the United Kingdom and Belgium and is fluent in English and German. Dr. Martinec has been the director of the Institute of Criminalistics, Ministry of the Interior, Bratislava, director of the Criminalistic and Forensic Institute, Ministry of the Interior, Prague, director and assistant professor of the Criminalistics Institute, Police Academy, Prague, and director of the Drug Research Institute in Modra, Slovakia. He worked as an expert for the State Institute for Drug Control in Bratislava and the Pharmaceutical Factory LECIVA in Prague. He is currently Director of the State Institute for Drug Control in Bratislava and Department Head at the Postgraduate Institute.