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Pharmaceutical Pricing and Reimbursement Information

SLOVAKIA

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Pharma Profile

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Executive Summary

BACKGROUND

Since the early 1990s, Slovakia's gross domestic product (GDP) has shown a continuous increase that was also reflected in international purchasing power parities (PPP). In 2005, Slovakia's gross domestic product (GDP) was about 876 billion SKK, and gross domestic product (GDP) per capita was 162 585 SKK. The annual growth rate in 2005 was 5.8%. Spending on health care was 6.5% of gross domestic product (GDP) in 2005.

Health insurance covers all aspects of health care, including pharmaceuticals and medical devices, and primary, secondary and tertiary care, according to the health care legislation. This includes: Act No. 140/1998 Coll. on Medicines and Medical Devices; Act No. 576/2004 Coll. on Health Care and Health Care-related Services; Act No. 577/2004 Coll. on Scope of Health Care Services; Act No. 578/2004 Coll. on Health Care Providers, Medical Workers, Professional Organisations in the Health Service; Act No. 579/2004 Coll. on Medical Rescue Service; Act No 580/2004 Coll. on Health Insurance; and Act No 581/2004 Coll. on Health Insurance Companies and Supervision.

In Slovakia, health care is based on a social insurance model. In 1994, a mandatory health insurance system was established on the principles of solidarity, plurality and a non-profit-making ethos. In 2005, there were five health insurance funds, thus representing a major decrease (from 12 health insurance institutions in 1995). The biggest of them, General Health Insurance Company (Všeobecná zdravotná poisťovňa, VŠZP), controls 67% of the market and the Common Health Insurance Company controls 12.9%. These two insurance companies could be described as statutory and the State guarantees their solvency. The other three – Apollo, Sideria and Dovera – are private and thus their solvency cannot be guaranteed. Their market shares are 8.5%, 7.2% and 6.2%, respectively. Another company will enter the market in 2007.

The key health care providers, who have contracts with the social health insurance, are primary care physicians, who are remunerated on a capitation basis and act as gatekeepers to the specialist services; and specialists, who are paid on a fee-for-service basis. Furthermore, polyclinics and hospitals also offer specialist care. Hospitals are remunerated based on bed-days.

PHARMACEUTICAL SYSTEM

The key laws governing the pharmaceutical sector are:

- Act No. 140/1998 Coll. on Pharmaceuticals and Medical Devices. The scope of this Act is to set conditions for the handling of pharmaceuticals and medical devices, for the testing of pharmaceuticals, registration of pharmaceuticals, placing pharmaceuticals on the market, placing medical devices on the market, securing and checking quality, effectiveness and safety of pharmaceuticals and medical devices, and tasks of state administration in the field of pharmacy. This Act also includes paragraphs on the registration of pharmaceuticals and classification into groups (cf. Figure 2.1), and it

defines the tasks of the State Institute for Drug Control (Štátny ústav pre kontrolu liečiv, SUKL). The registration of pharmaceuticals has been brought (almost completely) into line with European Union (EU) legislation.

- Act No. 577/2004 Coll. on Scope of Health Care.

The main authority in the field of pharmaceutical pricing and reimbursement in Slovakia is the Ministry of Health, responsible for submitting bills on all relevant aspects of health care, including strategic planning and the scope of health care, as well as pharmaceuticals reimbursed from public health insurance, etc. The Ministry of Health also sets the end prices for the reimbursed pharmaceuticals in retail pharmacy and the ex-factory prices for pharmaceuticals used in hospitals. The advisory body to the Ministry of Health, the Categorisation Committee, is the essential body in pharmaceuticals reimbursement evaluation. The categorisation of pharmaceuticals is reviewed four times a year.

The State Institute for Drug Control (SUKL) supervises the major functions in terms of pharmaceutical registration, market authorisation, classification (cf. Figure 2.1.), research, trials approval, control and pharmaceutical care. The duration of the market authorisation process is limited to a maximum of 210 days from admission of the application, according to Act 140/1998.

In terms of pharmacy, the higher territorial units also hold powers: they issue approvals for community pharmacy operation, supervise pharmaceutical care providers, organise inspections in pharmacies and decide on correctional or disciplinary measures in cooperation with the State Institute for Drug Control (SUKL).

The Slovak pharmaceutical market has shown substantial growth over the years. Since 2001, sales have increased by almost 43%, reaching SKK 27.865 billion / € 721.7 billion at pharmacy retail price (PRP) level, and SKK 3.233 billion / € 83.7 billion in hospitals. Sales at ex-factory level reached SKK 17.739 billion / € 459 billion in 2006. The share of generics has been relatively stable, representing almost half of the sales in all respective years. Dispensing of pharmaceuticals is organised by pharmacies (retail or hospital). In 2006, approximately 1,500 retail pharmacies were in operation in Slovakia.

PRICING

The legal framework for pricing is set out in Act 18/1996 (14 November 1995 Act on Prices) and the respective Decree of the Ministry of Health (No. 07045/2003 OAP), and its recent changes, in Act 577/2004 (1 November 2004 Act on Scope of Health Care Services).

In 2004 major reforms in the pricing and reimbursement system took place. These reforms included a shift in the decision-making power from the Ministry of Finance to the Ministry of Health. The Ministry of Finance used to set the prices at the manufacturer level, which were “deregulated” in 2004, meaning that now the Ministry of Health sets the pharmacy retail price (PRP) for reimbursed products and the ex-factory price if the product is intended for use in only in hospital settings. The ex-factory price for ambulatory use is still indirectly regulated through the maximum wholesale and pharmacy mark ups.

Statutory pricing refers to pharmaceuticals used in retail pharmacy which are totally or partially reimbursed. For these pharmaceuticals retail statutory pricing is regulated together with the level of reimbursement.

For pharmaceuticals used in hospital-only pharmacy, statutory pricing is carried out at manufacturer level.

In any case, mark ups for wholesalers and pharmacists are regulated.

Over-the-counter (OTC) products or non-reimbursed products on prescription used in retail pharmacy are entitled to free pricing at manufacturer level, but mark ups for wholesale and pharmacy for these products are regulated.

The responsible body for statutory pricing is currently the Ministry of Health, since August 2004.

Hospital management teams initiate tenders for the best price for pharmaceuticals prior to purchase. Insurance companies organise negotiations for the end price of pharmaceuticals for selected diseases and respective hospitals (blood factors, growth hormones, etc.).

External price referencing is taken into account if the ex-factory price is regulated, and to monitor the retail price of a reimbursable product, internal reference pricing is carried out in the reimbursement procedure at Anatomic Therapeutic Chemical classification ATC-4 or ATC-5 levels.

Value-added tax (VAT) for pharmaceuticals is 10%, standard value-added tax (VAT) is 19%.

REIMBURSEMENT

In Slovakia reimbursement of pharmaceuticals is carried out using a combination of different reimbursement categories and a reference price system according to the legal bases listed in Act 577/2004 (1 November 2004 Act on Scope of Health Care Services).

The process of reimbursement may only commence once a maximum retail price has been approved. Then, the Ministry of Health evaluates the application for reimbursement: the Ministry, advised by the Categorisation Committee, decides on the level of reimbursement and on any prescribing or indication limitations. The application needs to include basic information about the pharmaceutical (such as the name of the pharmaceutical, manufacturer and authorisation holder, the pharmaceutical form, pack size and strength), as well as information on the effectiveness of the pharmaceutical and its daily defined dose (DDD) (also called standard therapeutic dose) and number of defined daily doses (DDD) in an applied pharmaceutical pack.

The Ministry of Health of the Slovak Republic issues, by way of an edict, the List of pharmaceuticals. The List of pharmaceuticals is updated at least once per year, but in recent years (since the early 2000s) the List has been issued quarterly.

The Ministry determines: the allocation of pharmaceuticals or a combination of pharmaceuticals to the List of pharmaceuticals; any change to the allocation of a pharmaceutical to the List of pharmaceuticals; and the exclusion of a pharmaceutical from the List of pharmaceuticals by categorisation of pharmaceuticals. For the categorisation of pharmaceuticals, the Ministry has set up a Categorisation Committee for pharmaceuticals as its advisory body. The Categorisation Committee comprises 11 members who are appointed by the Minister of Health; three members at the proposal of the Ministry, five members at the proposal of the health insurance companies and three members at the proposal of the Slovak Chamber of Physicians.

The eligibility criteria and evaluation criteria are listed in Act 577/2004 (Act on Scope of Health Care Services) and the decisions of the reimbursement committee are published regularly on the web site of the Ministry of Health.

In 1995, a reference price system was introduced.

In order to set maximum reimbursement price levels, all pharmaceuticals on the List of pharmaceuticals are clustered into therapeutic groups based on Anatomic Therapeutic Chemical classification levels ATC-5 (same active ingredient) and Anatomic Therapeutic Chemical ATC-4 (therapeutically similar products).

In total, the List of pharmaceuticals comprises 4,967 pharmaceuticals are banded together into 1,648 Anatomic Therapeutic Chemical (ATC) groups at Anatomic Therapeutic Chemical ATC-5 level (this could be differentiated depending on mode of administration or strength of active ingredient).

In each Anatomic Therapeutic Chemical (ATC) group, a list of which is given in Annex 4 of Act 577/2004, at least one pharmaceutical is to be fully covered by public health insurance. In the course of the 2003 reforms, the number of Anatomic Therapeutic Chemical (ATC) groups with at least one pharmaceutical mandatorily fully reimbursed was radically reduced to 122 groups, resulting in more pharmaceuticals in any one group.

RATIONAL USE OF PHARMACEUTICALS

Several responsible bodies participating in pharmaceutical policy and decisions on pricing and reimbursement processes are monitoring the effectiveness of the decisions and use of pharmaceuticals from various levels. The bodies are: the Ministry of Health, the State Institute for Drug Control (SUKL), insurance companies, the Slovak Society for Pharmacoeconomy, and Pharmaceutical Faculty UK. The Ministry of Health, in cooperation with the Central Committee for Rational Pharmacotherapy, is regularly working on guidelines on diagnosis and therapy options for selected diseases. It should be stressed that for the most part these guidelines do not only reflect pharmacoeconomy issues.

Programmes and methods used to evaluate pharmaceutical policies, access to pharmaceuticals and the system in general, as well as its impact on health, are focusing on: measuring direct costs for pharmaceuticals; co-payment of inhabitants; and modelling the direct costs for pharmaceuticals, including new molecules and generics with lower prices which had recently had entered into the reimbursement system. There have been some

attempts to analyse the direct and indirect costs in specific disease areas (diabetes mellitus and oncology), mainly by the Slovak Society for Pharmacoeconomy.

CURRENT CHALLENGES AND FUTURE DEVELOPMENTS

It is a positive trend that almost all up-to-date innovative active ingredients are available in Slovakia, but it is clearly yet to be proven whether the total rising pharmaceutical expenditure (PE) is for the benefit of the patients. The costs, reaching over 35% of the health care budget for pharmaceuticals, is a matter that is constantly being discussed and the search for a systemic approach to limit these costs is ongoing.

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List of abbreviations

ACE	Angiotensin-Converting Enzyme
ADL	Asociácia dodávateľov liekov a zdravotníckych pomôcok / Association of wholesalers of pharmaceuticals and medical devices
AOPP	Asociácia na Ochranu Práv Pacientov / Association for Patient Rights Protection
ATC	Anatomic Therapeutic Chemical classification
DDD	Defined Daily Dose
DG SANCO	Health and Consumer Protection Directorate General
EMA	European Medicines Agency
EU	European Union
EU10	Member States joining the EU on 1 May 2004
EU15	Member States belonging to the EU prior to May 2004
EU25	All EU Member States before the expansion of 2007
GDP	Gross Domestic Product
GENAS	Generická asociácia / Association of Generic Producers
GGE	General Government Expenditure
GP	General Practitioner
HE	Health Expenditure
HiT	Health Systems in Transition
HOM	Hospital-Only Medicine(s)
HPI	Health Policy Institute
INN	International Nonproprietary Name
KDH	Kresťanské Demokratické Hnutie / Cristian Democratic Movement
LS-HZDS	Ludová Strana- Hnutie za Demokratickú Spoločnosť / People's Party – Movement for Democratic Slovakia
Mio.	Million
NCU	National Currency Unit
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
XI	

OECD	Organisation for Economic Co-operation and Development
OPP	Out-of-Pocket Payment
OTC	Over-The-Counter pharmaceuticals
PE	Pharmaceutical Expenditure
POM	Prescription-Only Medicine(s)
PPP	Pharmacy Purchasing Price
PPPa	Purchasing Power Parity
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy Retail Price
QALY	Quality-Adjusted Life Year
SAFS	Slovenská Asociácia Farmaceutických Spoločností / Slovak Association of Researched-based Pharmaceutical Companies
SDKU-DS	Slovenská Demokraticko-kresťanská Únia-Demokratická Strana / Slovak Democratic and Christian Union
SHI	Social Health Insurance
SKK	Slovak crones
SLeK Pharmacists	Slovenská Lekárnická Komora / Slovak Chamber of Pharmacists / Association of Pharmacists
SMER-SD	Smer-Sociálna Demokracia / Smer-Social Democratic Party
SMK	Slovenská Maďarská Koalícia / Slovak-Hungarian Coalition
SNS	Slovenská Národná Strana / Slovak National Party
SUKL	Štátny ústav pre kontrolu liečiv / State Institute for Drug Control
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
USD	United States Dollar
VAT	Value-Added Tax
VHI	Voluntary Health Insurance
VŠZP	Všeobecná zdravotná poisťovňa / General Health Insurance Company

WHO

World Health Organization

Introduction

The Pharmaceutical Pricing and Reimbursement Information (PPRI) project is a 31 month-project (2005-2007) commissioned by the Health and Consumer Protection Directorate-General (DG SANCO) of the European Commission and co-funded by the Austrian Federal Ministry of Health, Family and Youth (Bundesministerium für Gesundheit, Familie und Jugend, BMGFJ). The project was coordinated by the main partner Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG (GÖG/ÖBIG) and the associated partner World Health Organisation (WHO) Regional Office for Europe. The PPRI project has established a network of 46 participating institutions (competent authorities and other relevant organisations) in the field of pharmaceuticals.

The PPRI project seeks to increase transparency and knowledge and facilitate the exchange of experience in the field of pharmaceuticals by

- establishing and maintaining a network of relevant institutions in the field of pharmaceuticals in the enlarged European Union (EU), in order to facilitate a regular exchange of information and allow a process of learning from each other,
- producing country reports on pharmaceutical pricing and reimbursement systems, the “PPRI Pharma Profiles”,
- developing indicators for the comparison of pharmaceutical pricing and reimbursement information,
- providing a comparative analysis on pharmaceutical pricing and reimbursement in the European Union (EU) and,

disseminating the outcomes of the project.

The PPRI Pharma Profiles are country-specific reports that provide detailed descriptions of the countries pharmaceutical systems and policies. The profiles are written by PPRI participants (country experts from competent authorities, Medicines Agencies, Social Insurance Institutions, research institutes) and edited by experts of the PPRI project coordination.

This Pharma Profile is one of the many PPRI Pharma Profiles, which all are available on the PPRI website at <http://ppri.oebig.at>. The information and data provided in the PPRI Pharma Profiles refer, in general, to the year 2006.

In order to improve readability and allow for comparisons between countries, the structure of the Pharma profiles follows a template, which was developed by the project coordination team and the PPRI participants. The template is based on a large needs assessment of both national and international stakeholders. In addition to the template a glossary was developed to facilitate the writing process and the readability. The 70-page PPRI Pharma Profile Template and the PPRI Glossary are available at the PPRI website.

1 Background

1.1 Demography

Slovakia has a population of 5.4 Mio. The land surface area is 49,035 km², which results in an average population density of 109.82 inhabitants per km². The population of the capital, Bratislava, is 425,155 inhabitants, creating a density of 1,157 inhabitants per km². There are 2,891 seats in the Parliament, spread across 138 towns and cities.

The age structure of the population could be characterised as uneven and ageing. The shape of the country's population age pyramid indicates a regressive age structure with a relatively low proportion of children and a high proportion of "postproductive" inhabitants. The birth rate has the greatest impact on the age structure. Inhabitants in the age group least represented, those born after 1990, are currently heading into their productive years, which means that the population will be affected by a drop in numbers of people of productive age in the coming years. The current structure, defined by the basic age groups, shows an ongoing decrease in absolute and relative representation of the proportion of children. The share of children aged up to 15 years has dropped in recent years to the historically lowest value of 16.59% (a 5% loss since the mid-1990s).

Ongoing changes are observed also in the postproductive age group, where the number of inhabitants in this group increased by almost 2% since the mid-1990s, of which the share of women represented three quarters. Changes in the age structure of population, when looking at the main age groups, can be interpreted as population ageing. The average age of population has increased, together with the age index values.

The average life expectancy in Slovakia in 2004 was 74.10 years (below the Organisation for Economic Co-operation and Development (OECD) average of 78.20 years); 70.29 in men (below the Organisation for Economic Co-operation and Development (OECD) average of 75.30 years) and 77.83 in women (below the Organisation for Economic Co-operation and Development (OECD) average of 81.00 years). Life expectancy for men has been considerably lower than life expectancy for women since the mid-1990s. Since then, however, life expectancy has risen by 1.48 years for women and 1.9 years for men.

Table 1.1: Slovakia - Demographic indicators 1995, 2000-2005

Variable	1995	2000	2001	2002	2003	2004	2005
Total population	5,367,790	5,402,547	5,378,951	5,379,161	5,380,053	5,384,822	5,389,180
Population density per km ²	109.47	110.18	109.70	109.70	109.72	109.82	109.90
Population aged 0-14 (as a % of total)	21.66*	19.18	18.72	18.13	17.55	17.06	16.59
Population aged 15-64 (as a % of total)	60.72*	62.75	63.17	63.49	63.77	63.95	64.10
Population aged > 64 (as a % of total)	17.62*	18.07	18.11	18.39	18.67	18.98	19.31
Life expectancy at birth, total	n.a.	73.3	n.a.	n.a.	73.9	74.1	n.a.
Life expectancy at birth, females	76.35	77.22	77.54	77.57	77.62	77.83	77.90
Life expectancy at birth, males	68.39	69.14	69.51	69.77	69.77	70.29	70.11

* = as of 1996 (1995 data not available), n.a. = not available

Sources: OECD, Infostat (Statistical Office of the Slovak Republic), Statistical Yearbook 2003, 2004

Because of population ageing, the Government is starting to boost natality by implementing incentive bonuses for parents. The former Government, as well as creating funds through a system whereby a percentage of social insurance payments is transferred and governed by portfolio managers, also implemented a new pension system. The accumulated interest is used as a supplementary source of finance for pensions. This way, individuals participate actively in the development of their pensions.

The most common causes of mortality in 2004 were: circulatory diseases (47.9% of all deaths in men; 61.3% in women; 54.2% in the total population); malignant neoplasms (24.9% in men; 19.8% in women; 22.5% in the total population); and injuries/poisonings in men (8.8%, which is 3.5 times higher than in women) and respiratory diseases in women (51%), respectively.

In 2004, there were 1,020,587 hospitalisations (including those for childbirth), 433,685 in men (42.5%) and 586,902 in women (57.5%). The number of people hospitalised per 100,000 inhabitants was 18,962.34. The most common reasons for secondary hospital care were: in men – circulatory diseases (77,122), digestive diseases (51,086), injuries/poisoning (50,766); and in women – pregnancy, delivery, puerperium (88,940), circulatory diseases (80,386), factors influencing health status and contact with health services (63,627).

1.2 Economic background

Since the early 1990s, Slovakia's gross domestic product (GDP) has shown a continuous increase that was also reflected in international purchasing power parities (PPPa). In 2005, Slovakia's gross domestic product (GDP) was about 876 billion SKK, and gross domestic product (GDP) per capita was 162 585 SKK. The annual growth rate in 2005 was 5.8%.

The Government spent 258.7 billion SKK on public spending in 2005 (general government expenditure (GGE) represents about 29% of gross domestic product (GDP)).

Table 1.2: Slovakia - Macroeconomic indicators 1995, 2000-2005

Variable (in National Currency Unit (NCU) (SKK) or %)	1995	2000	2001	2002	2003	2004	2005
GDP in billion NCU (SKK) **	576.5	941.3	1,020.596	1,111.484	1,212.665	1,355.144	n.a.
Real GDP per capita in NCU (SKK)	107,399.8	174,295.0	189,737.0	206,634.0	225,444.0	251,786.0	n.a.
GDP per capita in USD PPPa	8,114	10,680	11,371	12,256	n.a.	n.a.	n.a.
Annual growth rate (%)	n.a.	n.a.	4.0	4.6	4.5	5.5	5.8
GGE in billion NCU (SKK)	171.4	241.1	249.7	272.0	289.1	312.7	258.7
GGE as a % of GDP	29.7	34.9	34.8	36.3	36.9	37.8	29.5
Exchange rate (NCU (SKK) per € 1), annual average rate*	38.450	42.589	43.309	42.699	41.491	40.045	38.593

GDP = gross domestic product, GGE = general government expenditure, NCU = national currency unit (SKK), PPPa = Purchasing power parity, USD = United States dollar, n.a. = not available

Source: OECD, Statistical Office of the Slovak Republic, *Slovak National Bank, ** www.finance.sk

1.3 Political context

In 1993, Slovakia (the Slovak Republic), formerly a part of Czechoslovakia, became a new, independent country. Slovakia is a republic with a multi-party parliamentary democracy, with the President as the Head of State. Since May 2004, Slovakia has been a full Member State of the European Union.

The National Council of the Slovak Republic, the legislative authority at national level, has a single chamber of 150 members who are elected directly in the general election for a term of four years. The current President of the Slovak Republic was elected in the 2004 direct presidential election for a period of five years. The President appoints and dismisses the Prime Minister and other members of the Government. The President can return for repeated consideration any legislation passed by the Parliament but if it is passed through Parliament the second time it is adopted automatically. The President can also dismiss the Parliament.

The head of the Government is the Prime Minister. There are four vice prime ministers and eleven ministers, who together hold executive powers and conduct governmental affairs. The last general election was held on 17 June 2006. The present cabinet represents a coalition of three parliamentary parties: the winner of the election, the Social Democratic Party (Smer-Sociálna Demokracia, SMER-SD; 29.1%), the People's Party – Movement for Democratic Slovakia (Ludová Strana- Hnutie za Demokratickú Spoločnosť, ĽS-HZDS; 8.8%) and the Slovak National Party (Slovenská Národná Strana, SNS; 11.7%). Other parliamentary parties include the Slovak Democratic and Christian Union (Slovenská Demokraticko-kresťanská Únia-Demokratická Strana, SDKÚ-DS (chaired by the former PM); 18.3%), the Slovak-Hungarian Coalition (Slovenská Maďarská Koalícia, SMK; 11.7%) and the Christian Democratic Movement (Kresťanské Demokratické Hnutie, KDH; 8.3%).

Since 1996 Slovakia has been divided administratively into 8 regions and 79 districts. In 1999 the Government adopted a new public administration reform strategy aimed at strengthening the dual-element public administration system consisting of state and territorial administration. The state administration currently operates at regional level. The heads of the regional offices that correspond territorially with the self-governing higher territorial units are elected directly by the public.

1.4 Health care system

1.4.1 Organisation

In Slovakia, health care is based on a social insurance model. In 1994, a mandatory health insurance system was established on the principles of solidarity, plurality and a non-profit-making ethos. In 2005, there were five health insurance funds, thus representing a major decrease (from 12 health insurance institutions in 1995). The biggest of them, General Health Insurance Company

(Všeobecná zdravotná poisťovňa, VŠZP), controls 67% of the market and the Common Health Insurance Company controls 12.9%. These two insurance companies could be described as statutory and the State guarantees their solvency. The other three – Apollo, Sideria and Dovera – are private and thus their solvency cannot be guaranteed. Their market shares are 8.5%, 7.2% and 6.2%, respectively. Another company will enter the market in 2007.

In the past, choice of insurance company was based on vocational category. Today, insured persons can choose their insurance company freely. The system is funded through health insurance payroll taxes and state contributions for children, the retired and the unemployed (for financial figures, cf. 1.4.2).

The health insurance provides coverage for all aspects of health care, including pharmaceuticals and medical devices, primary, secondary and tertiary care, according to the health care legislation. This legislation includes: Act No. 140/1998 Coll. on Medicines and Medical Devices; Act No. 576/2004 Coll. on Health Care and Health Care-related Services; Act No. 577/2004 Coll. on Scope of Health Care Services; Act No. 578/2004 Coll. on Health Care Providers, Medical Workers, Professional Organisations in the Health Service; Act No. 579/2004 Coll. on Medical Rescue Service; Act No 580/2004 Coll. on Health Insurance; and Act No 581/2004 Coll. on Health Insurance Companies and Supervision.

In 2004 the legislation brought about a change as regards the scope of reimbursement of health care. It suggested a diagnosis-related reimbursement scheme related to health care services, so that priority diagnoses are fully reimbursed (around 6,700 diagnoses, which represent almost two thirds of World Health Organization (WHO) International Classification of Diseases (ICD-10) diagnoses), and others are partially reimbursed using patient co-payments. The scope of reimbursement is determined by the Categorisation Committee, which consists of health insurance representatives, Ministry of Health representatives and health care professionals.

The key health care providers, who have contracts with the social insurance companies, are primary care physicians, who are remunerated on a capitation basis and act as gatekeepers to the specialist services; and specialists, who are paid on a fee-for-service basis. Furthermore, there are still polyclinics and hospitals offering specialist care.

The Ministry of Health plays a key role in health care organisation. Based on the Act on Health Care, the Ministry of Health is responsible for the regulation of health care providers to ensure that everyone has equitable access to health care services. Through the State Office of Public Health of the Slovak Republic, the Ministry ensures surveillance and control of communicable diseases; food safety; safe and healthy working and living conditions; and other public health functions regulated by the Act on Health Protection. Most surveillance and control activities are carried out by the 36 regional offices of public health.

In the past, almost all in-patient health care facilities were owned and run by the Ministry of Health. In 2003, 44 hospitals were transferred to municipalities and higher territorial units, and another 14 became non-profit-making organisations, managing their finances independently.

Formerly, the Ministry of Health also supervised the health insurance companies. The new legislation passed created the Health Care Supervision Authority, the health care watchdog, which supervises the insurance companies and also takes care of patient complaints regarding health care.

The decentralisation process also shifted the power to initiate doctors' licences from the Ministry of Health to the physicians of the higher territorial units. Authority in the field of pharmacy was delegated to the State Institute for Drug Control (Štátny ústav pre kontrolu liečiv, SUKL), including areas such as registration, market authorisation, clinical trial approval; and to higher territorial units, including the granting of approval to operate a pharmacy.

Municipalities' powers include: establishment of out-patient centres, including first-aid centres and social care facilities; establishment of specialised out-patient facilities, such as polyclinics, type I hospitals, etc.; establishment of home care agencies; participation in health prevention programmes; and approval of working hours in non-state health care facilities.

The self-governing higher territorial units hold even more powers. They establish polyclinics and hospitals with type II polyclinics; issue licences for non-state health care facilities; maintain the register of health care facilities; ensure appropriate health care coverage; participate in health prevention programmes; operate secondary nursing schools; and resolve appeals and complaints against health care facility managers' decisions.

Other bodies in health care include the Slovak Doctors' Association and Slovak Association of Pharmacists (Slovenská Lekárnická Komora, SLeK) and other health care workers' associations.

1.4.2 Funding

A mix of public and private sources funds health care in Slovakia, according to the laws outlined in 1.4.1. Public expenditure on health includes spending from the national budget and contributions to the statutory health insurance. In 2002 health insurance contributions were the most significant source of funding, accounting for over 85.9% of the total expenditure on health. This includes the State's budgetary transfers on behalf of economically inactive individuals, who represented 36.6% of the total health expenditure (THE) in 2002.

Each of the five health insurance companies currently operating in Slovakia's health insurance market collects its own contributions and reports them to a special branch of the state-run General Health Insurance Company (VŠZP) for consolidation and reallocation. The insurance contribution is calculated at the rate of 14% of the assessed income of the individual. The employer pays 10% of basic income; for the contribution calculation this is defined as the tax-relevant income from the previous month for each employee. The employee pays 4% of basic income. Employers of disabled people contribute only 2.6% of their assessed income; the rest is made up by the State. Self-employed individuals pay 14% of their assessed income.

The minimum income liable to contributions is SKK 3,000 / € 77 per month and there is an upper limit on an individual's income from which the contributions are paid. The minimum insurance

contribution is SKK 3,000 / € 77 per month and the maximum insurance contribution is also fixed. E.g. in November 2003 this was set at SKK 32,000 / € 828 per month. This means that the system has a regressive component, as the wealthiest pay a smaller proportion of their income than the majority of the population.

The Government pays premiums as lump sums to the respective health insurance company on behalf of dependent children and their carers. In contrast to most social health insurance systems, non-working family members currently are not co-insured by the contributing family member(s). In addition, the Government transfers lump sums to health insurance companies on behalf of pensioners, job applicants not receiving any allowance, persons receiving disability benefits, and reservists. The social insurance companies finance contributions for people receiving sick pay.

Complementary sources have played a marginal role in financing health care. The national Government finances investments and tertiary care at university hospitals. Municipalities used to play a relatively small role in financing health care. Following the decentralisation of hospitals, the municipalities' role in financing health care has been increasing to a not yet quantifiable degree. Other non-profit-making organisations that support health care do not provide suitable data.

Out-of-pocket payments (OPPs) have become an inevitable part of health care funding. Although the constitution guarantees equal and free access to health care, the legislation introduced several co-payments. These include co-payments for: pharmaceuticals and medical devices (although a fully reimbursed pharmaceutical should be available in every therapeutic group), dental products, spectacle frames, etc. Co-payments for provision-related services were introduced in 2003, as follows: primary care or specialist care consultation SKK 20 / € 0.50; bed and board during hospitalisation SKK 50 / € 1.3 per day (in case of a longer stay only for the first 21 days); prescription fee SKK 20 / € 0.50 per prescription (can contain two different pharmaceuticals in the amounts necessary for treatment), of which SKK 5 / € 0.13 is retained in the pharmacy and SKK 15 / € 0.38 paid to the insurance company; non-emergency patient transport SKK 2 / € 0.05 per km; emergency medical attention fee SKK 60 / € 1.55. The reaction to these co-payments was rather negative on the part of the present coalition parties and the public, and from October 2006 they were abolished, while the prescription fee was reduced to SKK 5 / € 0.13 per prescription (whole sum to be kept by the pharmacy) and the emergency service fee remained at SKK 60 / € 1.55.

Voluntary health insurance (VHI) does not play a role in health care funding in Slovakia at the moment.

The total health expenditure (THE) in 2005 was SKK 93.3 billion / € 2,416 billion or 6.5% of gross domestic product (GDP), which is below the 2004 Organisation for Economic Co-operation and Development (OECD) average of 8.4% of gross domestic product (GDP). Of this sum, 81% represents public health expenditure and 19% private health expenditure (mainly out-of-pocket payments (OPPs)). Table 1.3 outlines health expenditure in recent years.

Table 1.3: Slovakia - Health expenditure, 1995, 2000-2005

Health expenditure (HE)	1995	2000	2001	2002	2003	2004	2005***
THE in billion NCU (SKK)	42.9*	51.6	56.2	62.4	70.9****	n.a.	93.3
THE as a % of GDP	7.5*	5.5	5.5	5.6	5.9	n.a.	6.5
THE per capita in USD PPPa (OECD)	546**	595	641	716	777	n.a.	n.a.
THE per capita in NCU (SKK)	7,992	9,551	10,448	11,600	13,167	n.a.	17,305
Public HE as a % of THE	92.5*	89.4	89.3	89.1	88.3	n.a.	81.0
Private HE as a % of THE	7.5	10.6	10.7	10.9	11.7	n.a.	19.0

GDP = gross domestic product, HE= health expenditure, THE = total health expenditure, NCU = national currency unit (SKK), PPPa = purchasing power parity, USD = United States dollar, OECD = Organisation for Economic Co-operation and Development, n.a. = not available

* as of 1996 (1995 data not available), ** as of 1997 (1995 data not available), *** data by HPI, **** calculated from GDP and THE as a % of GDP

Source: OECD Health Data 2006, Statistic Office of the Slovak Republic, Health Policy Institute

1.4.3 Access to health care

1.4.3.1 Out-patient care

In Slovakia, secondary health care is categorised as in-patient and out-patient specialist care that is financed by different kinds of reimbursement. Primary health care includes all first-contact out-patient care, both preventive and curative, including home visits and emergency health services. The four types of first-contact doctors – general practitioners (GPs) for adults, general practitioners (GPs) for children and adolescents (caring for patients aged 0 to 18), gynaecologist-obstetricians and dentists – were preserved from the socialist health system. In 2002, there were 6,452 primary health care doctors. The vast majority of them (94% or 6,076) ran their own (non-state), single-handed practice or surgery and only 376 ran a state practice or ambulatory facility.

Primary health care physicians carry out basic examinations, diagnoses, interventions and treatment. However, they cannot perform some specialised diagnostic procedures or prescribe some pharmaceuticals and for such cases must refer patients to specialists. General practitioners (GPs) caring for children and adolescents up to the age of 18 are involved in immunisation and screening activities. Gynaecologists carry out family planning functions and provide preventive services and screening for women.

Private primary care physicians are paid directly through contracts with health insurance companies and this reimbursement is their main source of income. From their income, they employ at least one

nurse, rent rooms to carry out their practice and pay other fees. Residents of Slovakia have the right to change their primary health care physician every six months, by contract. The choice of primary health care physician is usually related to place of residence or employment.

All types of primary care physicians are gatekeepers by law, referring patients to specialist out- and in-patient care. But despite primary care doctors' gatekeeping role patients may self-refer, e.g. to an ophthalmologist in cases of eye injury or for prescription of spectacles, and, in some cases, go directly to psychiatrists, geneticists, and specialists in sexually transmitted infections. Moreover, those with chronic illnesses and who are registered at a specialist's clinic have direct access to the appropriate specialist physicians.

In 2002, there were 4,389 specialist doctors working in secondary care, remunerated on a fee-for-service basis. Approximately 55% were operating on a private profit-making basis, based on contracts with insurance companies, while 45% were state specialists employed by a health care facility with a national salary allocated according to a pay scale. In fact, specialists employed in a health care facility are allowed to conduct private practice outside their working hours.

In 2002, there were 66 polyclinics and 43 specialised out-patient care establishments; essentially these are new health centres or polyclinics established by private investors. Polyclinics provide medical services for patients, without beds and with no possibility for in-patient care. Out-patient care establishments are special one-day clinics; patients do not have the possibility of staying overnight. Overall, the privatisation of primary and secondary care providers in out-patient care is considered to have been carried out smoothly, without any negative impact on patients.

Out-of-pocket payments (OPPs) are partially used in primary care, especially in procedures that are not reimbursed from health insurance (such as health documentation processing, ear piercing, check-ups and vaccination, etc.). The consultation fee of SKK 20 / € 0.50 (cf. 1.4.2.) has already been abolished.

Table 1.4: Slovakia – Out-patient care 1995, 2000-2005

Variable	1995 ²	2000	2001	2002	2003	2004	2005
Total number of doctors	21,181*	17,385*	n.a.	16,764*	n.a.	18,644*	approx. 19,500
Number of doctors per 1,000 inhabitants	3.95*	3.1**	n.a.	3.1**	n.a.	3.1**	n.a.
Total number of out-patient doctors	15,803*	11,242*	n.a.	10,981*	n.a.	13,384*	n.a.
of which GPs	3,469* ¹	3,625* ¹	n.a.	3,437* ¹	n.a.	3,398* ¹	n.a.
of which dentists	2,137*	2,556*	n.a.	2,493*	n.a.	2,583*	n.a.
Number of out patient doctors per 1,000	2.94*	2.09*	n.a.	2.04*	n.a.	2.48*	n.a.

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inhabitants							
Number of out-patient clinics departments ("ambulatories")	4,953*	8,817*	n.a.	8,623*	n.a.	8,706*	n.a.

¹ GPs and GPPs specify together, ² all data for 1995 taken from 1996

n.a. = not available, GP = general practitioner

Source: **OECD, * Statistical Yearbook 1996, 2000, 2002, 2004

1.4.3.2 In-patient care

In 2002 Slovakia had 137 public in-patient facilities with 41,365 beds (data on private sector are not available). Of the 7.6 beds per 1,000 population, 6.7 per 1,000 were provided in acute care. Although acute hospital beds were reduced steadily from 7.5 per 1,000 inhabitants in 1995 to 6.7 per 1,000 in 2002, Slovakia still had the highest rate of acute care beds compared to neighbouring countries and all 25 European Union (EU) Member States ((pre-2007) EU25), for which the average was 4.2 per 1,000 (the average for Member States joining the European Union (EU) on 1 May 2004 (EU10) was 6.0 per 1,000). Also, the overall hospital bed capacity (7.7 per 1,000) was higher than both the average for the Member States joining the European Union (EU) on 1 May 2004 (EU10) (6.6 per 1,000, from data for 2001) and the average for Member States belonging to the European Union (EU) before the expansion of May 2004 (EU15) (6.1 per 1,000, from data for 2001).

In 2002, 18 people per 1,000 inhabitants were admitted to acute hospitals. According to the data available, the admission rate was lower than the average for countries joining the European Union (EU) on 1 May 2004 (EU10). In addition, the 8.8-day average length of stay in acute hospitals was above the average for countries joining the European Union (EU) on 1 May 2004 (EU10). Altogether, the 66% bed occupancy rate of acute hospitals ranked among the lowest in the whole of the European Union (EU25).

During the period from 1999 to 2002, the existing capacity and network of health care providers was analysed and the total number of acute beds was reduced; 6,000 beds were removed or transformed into chronic care beds. Moreover, three acute care hospitals were closed and several others transformed into almost exclusively chronic (long-term) care facilities. In two cases hospitals were merged and in many cases excess building capacity was sold.

In 2004, there were 25 type I, 37 type II and 10 type III hospitals. The types of hospital differ from each other according to their territory coverage for inhabitants and the type of health services they provide. Type III hospitals provide more specialised health care services. The number of teaching hospitals increased and currently stands at 13; these hospitals provide the most expensive health care. Specialised hospitals play an important role in the system. While the number of physicians in hospitals increased by 24% from 4,607 in 1990 to 5,697 in 1998, the number of physicians in in-patient facilities decreased by 3.5% between 1998 and 2002.

Despite growing financial problems in the health care sector, the number of highly specialised hospitals has increased in comparison with the situation before 1989. Highly specialised health care facilities have been built extensively in recent years as the Government has prioritised programmes

for dialysis, plasmapheresis, cardiovascular disease and cancer. These specialised hospitals take care of a selection of diseases, e.g., the National Institute of Cardiovascular Diseases takes care of all cardiovascular diseases and transplantations at national level. There are also specific prescription limits set for pharmaceutical categorisation, e.g. for new, financially demanding cytostatics, which can only be administered at the National Institute of Oncology and at a few other specialised facilities. Similarly, there are also psychiatric specialised hospitals, hospitals for tuberculosis and respiratory diseases, etc. The goal is to have a county hospital in every region, and specialised institutions spread evenly, one for two or three regions (although some of them also operate at national level, such as the National Institute of Oncology).

Since the introduction of the health insurance scheme, hospitals' payment methods have changed several times, mostly reflecting changes in government. In 1993, the points-based fee-for-service system, similar to that used in the German ambulatory care sector, was introduced for in-patient care in Slovakia. It was replaced with a combined system of payment by bed-days and points, but this was abolished after two months.

From July 1994 the performance-based system was used, with hospitals reimbursed for bed-days. A daily charge for a bed-day was defined for each of the five hospital types, increasing from the first to the fifth. The rates were defined after negotiations between the Ministry of Health, the Ministry of Finance, health insurance companies and hospitals. The Ministry of Finance then issued a decree on bed-day prices and hospitals invoiced the health insurance companies for their services.

In 1999 the retrospective system of payment for hospital services was replaced by a system of prospective total budgets for hospitals. The Ministry of Health based these calculations mainly on historical costs although other indicators were also considered. The prospective budget was divided among the different health insurance companies based on the number of insured individuals treated in a given hospital over the previous months and on the volume of services provided to the insured. While this controlled the expenditures of health insurers, unstructured contracts encouraged health care providers to choose priorities that frequently did not correspond with overall health policy goals.

In response to this situation, in December 2001 a new reimbursement mechanism was introduced. This system, which could be described as a "broadband" form of diagnosis-related groups (DRGs), is based on a fee-for-service system for in-patient care delivered with payments classified according to the type of hospital and specialty. Health insurance companies are obliged to have structured contracts with health care providers and to monitor their performance.

The new system includes incentives for shortening the average length of hospital stay as well as certain stimuli to implement day-treatment procedures, some of which are reimbursed on a fee-for-service basis. Nonetheless, insufficient resources to cover fully the generous scope of services, financial limitations in the contracts with health care providers and the debts outstanding from the health insurance companies resulted in health care providers' arrears reaching SKK 16.2 billion / € 0.42 billion in 2003.

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Table 1.5: Slovakia – In-patient care 1995, 2000-2005

Variable	1995	2000	2001	2002	2003	2004	2005
Number of in-patient doctors ¹	5,378*	6,143	n.a.	5,783	5,471	5,260	n.a.
Number of in-patient doctors per 1,000 inhabitants ²	1.00*	1.14	n.a.	1.08	1.02	0.98	n.a.
Number of hospitals	94*	95	n.a.	92	89	91	n.a.
of which specialised hospitals and institutions	129	140	n.a.	137	144	135	n.a.
Number of acute care beds	40,338 *	36,124	n.a.	35,043	33,035	30,394	n.a.
of which in private sector	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Acute care beds per 1,000 inhabitants ¹	7.5	6.9	n.a.	6.7	6.1	5.9	n.a.
Average length of stay in hospital (days)	11.5	8.9	n.a.	8.3	9.1	7.9	n.a.

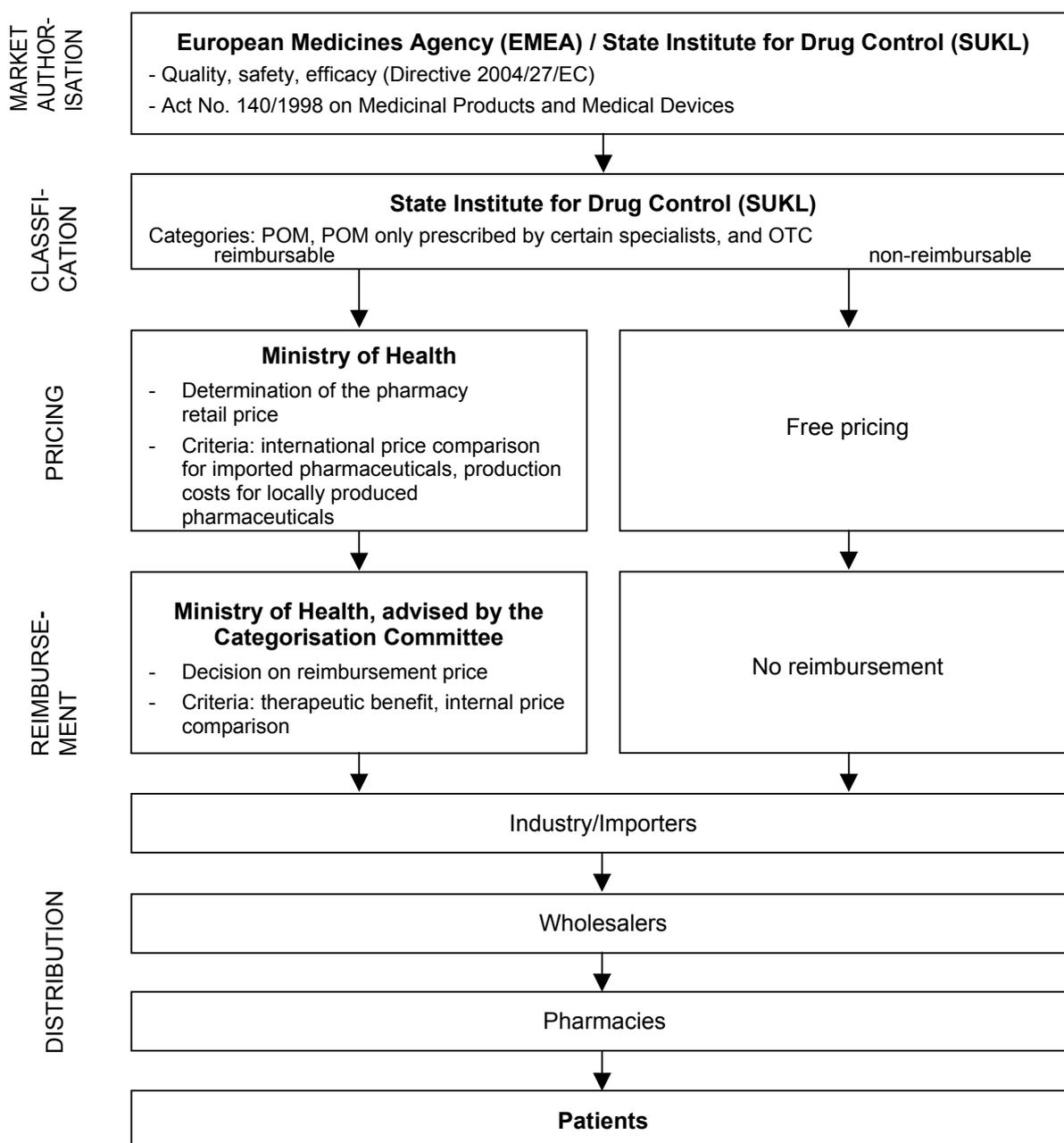
*as of 1996 (1995 data not available), n.a. = not available

Source: Institute of Health Information and Statistics, Statistical Yearbook 2003, 2004

2 Pharmaceutical system

2.1 Organisation

Figure 2.1: Slovakia - Flowchart of the pharmaceutical system 2006



POM = prescription-only medicine(s), OTC = over-the-counter (pharmaceuticals)

Source: SUKL, GÖG/ÖBIG

2.1.1 Regulatory framework

2.1.1.1 Policy and legislation

The key laws governing the pharmaceutical sector are listed here.

- Act No. 140/1998 Coll. on Pharmaceuticals and Medical Devices. The scope of this Act is to set conditions for handling of pharmaceuticals and medical devices, for testing of pharmaceuticals, registration of pharmaceuticals, placing pharmaceuticals on the market, placing medical devices on the market, securing and checking of quality, effectiveness and safety of pharmaceuticals and medical devices and tasks of state administration in the field of pharmacy. This Act also includes paragraphs on registration of pharmaceuticals, classification into groups (as mentioned in Figure 2.1) and defines the tasks of the State Institute for Drug Control (SUKL). The registration of pharmaceuticals has been (almost completely) harmonised to European Union (EU) legislation.
- Act No. 576/2004 Coll. on Health Care and Health Care-related Services,
- Act No. 577/2004 Coll. on Scope of Health Care Services
- Act No. 578/2004 Coll. on Health Care Providers, Medical Workers, and Professional Organisations in the Health Service
- Act. No. 580/2004 Coll. on Health Insurance
- Act No. 581/2004 Coll. on Health Insurance Companies and Supervision
- Decree of the Ministry of Health No. 198/2001 Coll. on Requirements on Good Pharmacy Practice (covers most aspects of pharmaceutical work, dispensation, as well as technical and personal requirements)
- Act No. 139/1998 Coll. on Psychoactive Substances and Preparations

These laws together cover all aspects of providing health care, as well as the scope of health care, and are particularly applicable for pharmacy. The issue of reimbursement of pharmaceuticals from public health insurance is mainly covered by Act No. 577/2004 Coll., detailed above. Act. No. 578/2004 Coll. also introduced a change in the professional body, the Slovak Association of Pharmacists (SLeK).

2.1.1.2 Authorities

The main authority in the field of pharmaceutical pricing and reimbursement in Slovakia is the Ministry of Health, responsible for submitting bills on all relevant aspects of health care, including strategic planning and the scope of health care, as well as pharmaceuticals reimbursed from public health insurance, etc. The Ministry of Health also sets the end prices for the reimbursed

pharmaceuticals in retail pharmacy and the ex-factory prices for pharmaceuticals used in hospitals. The advisory body to the Ministry of Health¹, the Categorisation Committee, is the essential body in pharmaceuticals reimbursement evaluation. The categorisation of pharmaceuticals is reviewed four times a year.

The State Institute for Drug Control (SUKL) supervises the major functions in terms of pharmaceutical registration, market authorisation, classification (cf. Figure 2.1.), research, trials approval, control and pharmaceutical care. The duration of the market authorisation process is limited to a maximum of 210 days from admission of the application, according to Act 140/1998.

In terms of pharmacy, the higher territorial units also hold powers: they issue approvals for community pharmacy operation, supervise pharmaceutical care providers, organise inspections in pharmacies and decide on correctional or disciplinary measures in cooperation with the State Institute for Drug Control (SUKL)².

Table 2.1: Slovakia - Authorities in the regulatory framework in the pharmaceutical system 2006

Name in local language (Abbreviation)	Name in English	Description	Responsibility
Ministerstvo Zdravotníctva (MZ SR)	Ministry of Health	Regulatory body	Regulatory body for pharmaceuticals in charge of policy, reimbursement and pricing
Kategorizačná Komisia (MZ SR)	Categorisation Committee (Ministry of Health)	Advisory body of Ministry of Health	Reimbursement evaluation of pharmaceuticals
Ministerstvo Financíí (MF SR)	Ministry of Finance	Regulatory body, financial policy	Until 2004 set the ex-factory price
Štátny ústav pre Kontrolu Liečiv (SUKL)	State Institute for Drug Control	Medicines Agency (subordinate to the Ministry of Health)	In charge of market authorisation, classification, vigilance, consumption monitoring
Všeobecná Zdravotná Poisťovníňa (VšZP)	General Health Insurance Company	Third-Party Payer, dominates the market	Advisory for Ministry of Health for pricing and reimbursement
Slovenská lekárska komora (SLeK)	Slovak Association of Pharmacists	Professional body	Registers pharmacists – in the past held a lot of power, but at present has less influence (minor role)

Source: SUKL

¹ www.health.gov.sk

² www.sukl.sk

2.1.2 Pharmaceutical market

2.1.2.1 Availability of pharmaceuticals

The total number of available authorised pharmaceuticals in Slovakia has risen since 2002, reaching 29,385 in 2006 (19,693 allopathic pharmaceuticals). This correlates with the increasing presence of generic pharmaceuticals on the market.

In 2006, there were a total of 19,320 pharmaceuticals registered on the market, of which 7,512 were original pharmaceuticals and 6,454 generic pharmaceuticals; as a result of non-specific legislation, 5,354 pharmaceuticals could not be classified into either group. There were 3,024 new registrations and 35 cancellations. Of the 19,693 registered pharmaceuticals, 16,731 were registered nationally and 2,589 centrally within the European Union (EU).

In terms of reimbursement, the number of reimbursable pharmaceuticals has risen, too. The share of totally reimbursed (no co-payment) pharmaceuticals has risen by 3.3% since 2003, reaching a third of all reimbursable pharmaceuticals. The share of pharmaceuticals with no co-payment or a co-payment up to SKK 100 / € 2.59 represented more than three quarters (76%) of reimbursable pharmaceuticals in 2006. There is also a trend towards imposing specialist doctors' prescription requirements and indication limits, as a means of controlling pharmaceutical expenditure (PE).

The number of prescription-only medicine(s) (POM) has fallen and then risen again over the past years, reaching 17,804 in 2006. The number of over-the-counter (OTC) pharmaceuticals reached 1,889 in the same year. The classification is established by the State Institute for Drug Control (SUKL), upon registration, and can be changed if initiated by the company. However, to make a successful switch from prescription to over-the-counter (OTC) pharmaceuticals, the pharmaceutical has to be proven to be safe, efficient, with lots of experience and defined as low risk for the user(s). It must be free from risk of addiction or abuse. The classification in terms of reimbursement and prescription/indication limits is within the remit of the Ministry of Health and its Categorisation Committee.

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Table 2.2: Slovakia - Number of pharmaceuticals 1995, 2000-2006

Pharmaceuticals	1995	2000	2001	2002	2003	2004	2005	2006
Authorised total	25,075	25,425	25,045	22,685	22,951	23,440	26,396	29,385
Authorised excluding homeopathic	16,707	16,554	15,825	13,411	13,648	14,012	16,972	19,693*
On the market	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	19,320
Originals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	7,512
Generics	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	6,454
POM excluding homeopathic	14,276	14,129	13,653	11,534	11,862	12,273	15,230	17,804*
OTCs excluding homeopathic	2,431	2 425	2,172	1,877	1,786	1,739	1,742	1,889*
Reimbursable	n.a.	n.a.	n.a.	n.a.	4,374	4 533	4,562	4,804
Total reimbursement (%)	n.a.	n.a.	n.a.	n.a.	1,334 (30.5)	1,477 (32.6)	1,532 (33.6)	1,622 (33.8)
Co-payment <100 SKK (%)	n.a.	n.a.	n.a.	n.a.	3,241 (74.0)	3,501 (77.2)	3,562 (78.0)	3,650 (76.0)
Specialist POM (%)	n.a.	n.a.	n.a.	n.a.	2,160 (49.4)	2,181 (48.1)	2,189 (48.0)	2,498 (52.0)
Indication limit (%)	n.a.	n.a.	n.a.	n.a.	1,064 (24.4)	1,184 (26.1)	1,331 (29.2)	1,558 (32.4)
Parallel traded	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
Hospital-only	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.

Pharmaceuticals counted per active ingredient in a specific dosage form and pack size. Generics are considered those which are registered with reference to the documentation of already registered pharmaceuticals in Slovakia or the European Union (EU).

*as of November 2006,

POM = prescription-only medicine(s), OTCs = over-the-counter pharmaceuticals, n.a. = not available, n.app. = not applicable

Source: SUKL

2.1.2.2 Market data

The Slovak pharmaceutical market has shown substantial growth over the years. Since 2001, sales have increased by almost 43%, reaching SKK 27.865 billion / € 721.7 billion at pharmacy retail price (PRP) level, and SKK 3.233 billion / € 83.7 billion in hospitals. Sales at ex-factory level reached SKK 17.739 billion / € 459 billion in 2006. The share of generics has been relatively stable, representing almost half of the sales in all respective years.

Table 2.3: Slovakia - Market data 1995, 2000-2005

In Mio. National Currency Unit (NCU) (SKK) / €	1995	2000	2001	2002	2003	2004	2005
<i>Prescriptions</i>							
No. of annual prescriptions by volume in thousands	n.a.	49,216	48,718	49,360	46,737	40,779	43,026
No. of annual prescriptions by value in Mio. NCU (SKK)	n.a.	15,328	17,316	21,449	22,813	23,018	25,593
<i>Pharmaceutical sales</i>							
Sales at ex-factory price level ¹	n.a.	9,661	12,426	14,841	15,837	16,318	17,739
Sales at wholesale price level ¹	n.a.	10,724	13,792	16,474	17,579	18,113	19,691
Sales at PRP level	n.a.	15,176*	19,518	23,313	24,877	25,633	27,865
Sales in hospitals	n.a.	n/a	2,319	2,466	2,313	3,011	3,233
Sales of generics	n.a.	7,477*	8,478*	9,280*	9,746*	9,566*	10,381*
as a % of total*	n.a.	49*	48*	45*	44*	48*	48*
Sales of parallel traded pharmaceuticals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
<i>Exports and imports</i>							
Total pharmaceutical exports	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total pharmaceutical imports	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

¹not inclusive of value-added tax (VAT) (19% in 2006)

NCU = national currency unit, PRP = pharmacy retail price

Source: *SUKL, Pharmadata, NCZI, SUKL

Pharmaceutical consumption reached a level of 150,102,757 packs, representing 27.85 packs per inhabitant in 2005 (updated in 2006). The best-selling pharmaceuticals, by therapeutic group and by active ingredient are outlined in Table 2.4, based on turnover in 2005 and the 2nd quarter of 2006, respectively.

Table 2.4: Top 10 best-selling pharmaceuticals, by Anatomic Therapeutic Chemical (ATC) groups, 2005 and by active ingredient (2nd quarter of 2006) by value

Position	Anatomic Therapeutic Chemical classification 4 – best selling therapeutic groups (2005)	
1	C09AA	ACE inhibitors, plain
2	C10AA	HMG CoA reductase inhibitors
3	M05BA	Bisphosphonates
4	C08CA	Dihydropyridine derivatives
5	R03AK	Adrenergics and other pharmaceuticals for obstructive airway diseases
6	J01FA	Macrolides
7	N05AH	Diazepines, oxazepines and thiazepines (antipsychotics)
8	B03XA	Other antianaemic preparations
9	C07AB	Beta blocking agents, selective
10	L04AA	Selective immunosuppressive agents

Position	Active ingredient, best selling pharmaceuticals (as of 2nd quarter of 2006) by Anatomic Therapeutic Chemical classification 5	
1	B03XA01	Erythropoietin
2	R03AK06	Salmeterol and other pharmaceuticals for obstructive airway diseases
3	C09AA04	Perindopril
4	N05AH03	Olanzapine
5	L01XE01	Imatinib
6	C08CA01	Amlodipine
7	C01EB15	Trimetazidine
8	M05BA07	Risedronic acid
9	C10AA05	Atorvastatin
10	C09AA10	Trandolapril

ATC = Anatomic Therapeutic Chemical (classification), ACE = Angiotensin-Converting Enzyme, HMG CoA = Hydroxymethylglutaryl-coenzyme A

Source: Pharmadata, SUKL

2.1.2.3 Patents and data protection

Patent protection is harmonised under the European Patent Convention and ensures market protection for original pharmaceuticals for 20 years. Under European Union (EU) legislation there is a possible extension for five more years with a Supplementary Protection Certificate.

There is also a limit on the number of years for which the original pharmaceuticals must be registered before generics can be authorised: this currently stands at eight years. Generics can only

be marketed after 10 years from the day of registration of the original pharmaceutical. The 10-year period can also be prolonged by one year, should the pharmaceutical gain another indication (based on relevant trial results)¹.

2.1.3 Market players

2.1.3.1 Industry

After transition to a market economy, Slovakia underwent a privatisation process in the public pharmaceutical production and distribution sector. Consequently, in the late-1980s local production accounted for 80% of the pharmaceutical market, whereas in 2002 it only counted for 18%. The leading Slovakian manufacturer is Zentiva/Slovakofarma³, which mainly produces generics, especially for cardiovascular diseases, gastro-intestinal diseases and analgesics. Zentiva is the outcome of a merger of Slovak-based Slovakofarma and Czech-based Léčiva. The private enterprise Imuna-Pharm in Sarisske Michalany produces, e.g., blood derivatives, physiological infusions and some vaccines. Over recent years, 12 other private companies for mass pharmaceutical production have been established in Slovakia, such as Hoechst-Biotika in Martin, Unimed Pharma, producing ophthalmic products in Bratislava, and Biomin producing mineral supplements in Cífer.

Overall, there are 40 local pharmaceutical producing companies (mainly generics) and 40 to 50 subsidiaries of international pharmaceutical companies, which are usually not production sites, but trading, marketing and administrative units. Most of them are represented in the Slovak Association of Research-Based Pharmaceutical Companies (Slovenská Asociácia Farmaceutických Spoločností Orientovaných na Výskum a Vývoj, SAFS⁴, including Abbot, Astra Zeneca, Eli Lilly, GlaxoSmithKline, Merck, Novartis, Pfizer, Roche, Sanofi-Aventis, Solvay, etc.

Similarly, there is also the Association of Generic Producers (Generická asociácia, GENAS⁵), which includes Zentiva, Ratiopharm, Sandoz, Stada, Krka, etc.

Table 2.5: Slovakia - Key data on the pharmaceutical industry 1995-2005

Pharmaceutical industry	1995	2000	2001	2002	2003	2004	2005
Total no. of companies	n.a.	n.a.	n.a.	n.a.	n.a.	approx. 120	n.a.
- research-oriented	n.a.	n.a.	n.a.	n.a.	n.a.	40-50	n.a.
- local (generic) producers	n.a.	n.a.	n.a.	n.a.	25*	77*	78*
- biotech	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.

¹ as outlined in the Act No. 140/1998 Coll. on Medicines and Medical Devices

³ <http://www.zentiva.sk>

⁴ http://www.safs.sk/En/index_en.html

⁵ <http://www.genas.sk>

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Number of people employed	n.a.						
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*includes raw materials producers as well as pharmaceutical producers

n.a. = not available, n.app. = not applicable

Source: SUKL

2.1.3.2 Wholesalers

In the past, there was only one wholesaler – MEDIKA. In 1997, the number of wholesalers rose to 260, but has decreased in recent years.

On the wholesale level, Slovakia is organised in a multi-channel system, with mainly private wholesalers operating on the pharmaceutical market. However, 11 wholesale companies dominate the market (95% of pharmaceutical sales). Major wholesalers include Phoenix, Unipharma and Med-Art. Phoenix, the outcome of a merger between Fides, Biama and Drugimpex in October 2004, trades more than 10,000 products in five centres around the country. Unipharma, ranking second on the wholesale market, is a joint stock company whose stakeholders are mostly practising pharmacists.

Pharmaceutical deliveries are carried out several times a day, depending on the requirements/orders, and a fast delivery (within an hour) is possible with some wholesalers (the law requires delivery within 24 hours). No parallel trade is of interest in Slovakia at present.

The professional body of wholesalers is the Association of wholesalers of pharmaceuticals and medical devices⁶ (Asociácia dodávateľov liekov a zdravotníckych pomôcok, ADL), which unites 5 wholesalers, 53 producers and 106 pharmacy operators.

Table 2.6: Slovakia - Key data on pharmaceutical wholesale 1995-2005

Wholesalers	1995	2000	2001	2002	2003	2004	2005
Total number of wholesale companies	n.a.	n.a.	n.a.	n.a.	228	232	236
Total number of outlets	n.a.						

Source: SUKL

2.1.3.3 Pharmaceutical outlets / retailers

Pharmaceuticals in Slovakia are sold through pharmacies and branch pharmacies. Every pharmacy can operate a branch pharmacy. Branch pharmacies can operate in villages where there is no other pharmacy, but they need not work full working hours, provide individual preparation of pharmaceuticals and an emergency 24-hour service.

⁶ <http://www.adl.sk>

2.1.3.3.1 Pharmacies

There were 1,130 pharmacies in 2005 and 1,523 pharmacies in 2006. All of them were private. The rather significant rise (by 34%) in the number of pharmacies can be the result of a relaxing of the criteria for pharmacy operation. As a result, the number of inhabitants per pharmacy dropped by 1,230 people per pharmacy from 2005, reaching 3,539 in 2006. The number of hospital pharmacies (81, serving in-patients only) in 2004 decreased to 74 in 2006 due to mergers or closing of hospital pharmacies.

Privatisation led to a growth in the number of private pharmacies from 500 in 1993 to 1,044 in 2002 and 1,108 in 2004. Hospital pharmacies are operated directly by the hospitals and form an integral part of the hospitals, so ownership depends on the status of the hospital.

Community pharmacies represented 91% (136,074,915 packs) of total pharmaceutical sales in 2005 in terms of total packs (150,102,757 packs), while hospital pharmacies only 9% (14,027,842 packs), and this has been a steady trend since the year 2000.

In terms of value, community pharmacies accounted for 90% (SKK 27,865 billion / € 721.7 billion) of total sales in 2005 (SKK 31,099 billion / € 805 billion), while hospital pharmacies only accounted for 10% (SKK 3,233 billion / € 83.7 billion). Again, this has been a consistent trend since the year 2000.

In the past, only pharmacists were allowed to open and own pharmacies. Multiple ownership of pharmacies was also not allowed. Since 2004, some changes to Act No. 140/1998 Coll. on Medicines and Medical Devices, however, abolished these limits and since June 2004, the ownership of pharmacies is not limited to pharmacists. However, a professionally competent representative has to be employed at all times, in case the owner him/herself is not a pharmacist. Multiple ownership and chain pharmacies are not prohibited. Distance and minimum population per pharmacy limits have also been abolished.

Remuneration of pharmacists is provided through mark ups^{*} on all products and prescription fee payments. The typical mark up is maximum 21% on reimbursable pharmaceuticals, maximum 6% on financially demanding pharmaceuticals (ex-factory price exceeding SKK 10,000 / € 259), maximum 7% on reimbursable vaccines and maximum 15% on non-reimbursable pharmaceuticals including over-the-counter (OTC) pharmaceuticals. The prescription fee at the moment is SKK 5 / € 0.13 per prescription, which is kept by the pharmacy and represents a minor source of income. Rebates (discounts) are not at present allowed by law, for manufacturers, wholesalers or pharmacists.

The main professional body of pharmacists is the Slovak Association of Pharmacists (SLeK). The main goals are to represent and keep the interests of practising pharmacists, provide guidance on professional issues, provide help in case of problems with state administration, operate the register

^{*} as specified by the Act on Scope of Health Care Services No. 759/2004
<http://www.health.gov.sk/redsys/rsi.nsf/0/431913942CAD0217C12570DC004C105E?OpenDocument&ID=PAR759798047640&TYPE=S&LANGUAGE=S&LENGTH=S>

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of pharmacists, supervise compliance with the code of conduct and relevant legislation and participate in legislation in the field of health care. In the past, the Slovak Association of Pharmacists (SLeK) also took part to a large extent in approving licences and moral competence for practising pharmacists, but its role has been diminished, since in the past only pharmacists could own pharmacies, whereas nowadays pharmacies can also be owned by others.

Table 2.7: Slovakia - Retailers of pharmaceuticals 1995, 2000-2006

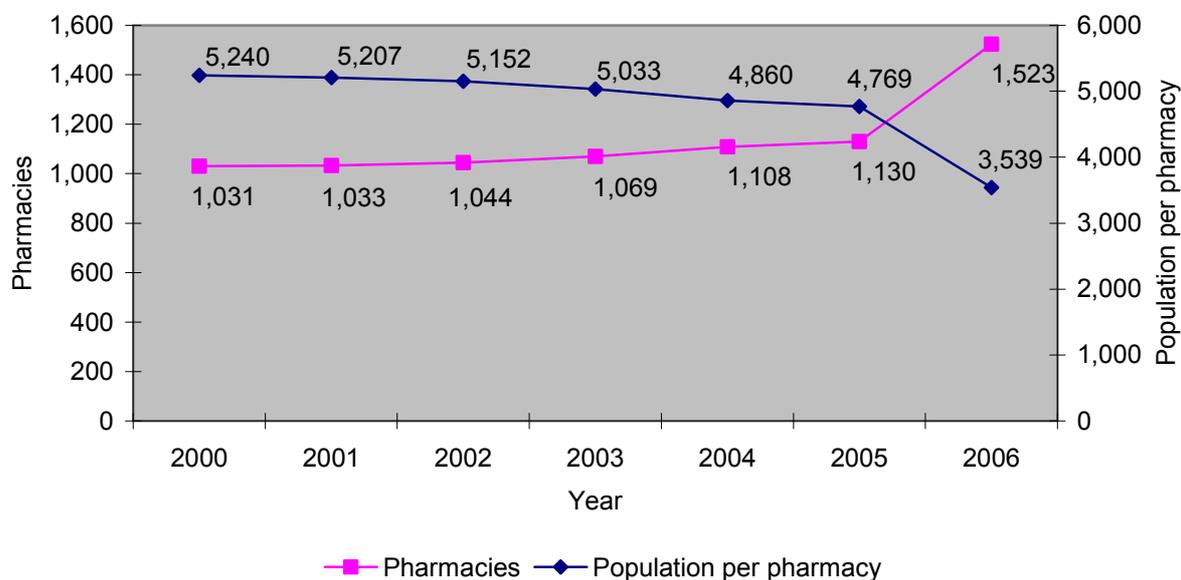
Retailers	1995	2000	2001	2002	2003	2004	2005	2006*
Number of community pharmacies ²	n.a.	1,031	1,033	1,044	1,069	1,108	1,130	1,523
No. of private pharmacies	approx. 500	1,031	1,033	1,044	1,069	1,108	1,130	1,523
No. of public pharmacies	n.a.							
Number of hospital pharmacies for in-patients	n.a.	n.a.	n.a.	n.a.	n.a.	81	n.a.	74
Number of other POM dispensaries:	n.app.							
Total number of POM dispensaries ¹	n.a.	1,031	1,033	1,044	1,069	1,108	1,130	1,523
No. of internet pharmacies	n.app.							
No. of OTC dispensaries, like drugstores	n.a.							

OTC = over-the-counter, POM = prescription-only medicine(s); POM dispensaries = including branch pharmacies, self-dispensing doctors, and other university pharmacies (FIN), polyclinic pharmacies (NL) and hospital pharmacies acting as community pharmacies

² incl. branch pharmacies, *as of Oct 30 2006

Source: SUKL, Statistical Yearbook 2000, 2001, 2002, 2003, 2004

Figure 2.2: Slovakia - Number of retail pharmacies and number of inhabitants per pharmacy 2000-



2006

Source: SUKL, Statistical Yearbook 2000, 2001, 2002, 2003, 2004

The dispensing of pharmaceuticals is only allowed in pharmacies and branch pharmacies.

Some products, such as consumer health care products, herbal products, teas, vitamin mixtures, cosmetics, etc., which are also available in pharmacies, can be marketed in supermarkets, health shops and through similar retailers. However, these are not authorised by the State Institute for Drug Control (SUKL) as pharmaceuticals and require no registration. These are considered dietary supplements and controlled according to food requirements.

2.1.3.3.2 Internet pharmacies

According to Act No. 140/1998, pharmaceuticals can only be dispensed in pharmacies or branch pharmacies, with appropriate consultation and information given. Internet sales of pharmaceuticals are not allowed in Slovakia.

2.1.3.3.3 Dispensing doctors

Dispensing doctors are not authorised in Slovakia; only pharmacies are authorised to dispense pharmaceuticals.

2.1.3.4 Hospitals

As mentioned earlier, in 2006 there were 74 hospital pharmacies. Hospital pharmacies care for the needs of patients in in-patient care. They do not provide pharmaceutical care to out-patients. The recent changes in legislation, however, enabled hospitals to own pharmacies, thus resulting in termination of contracts with community pharmacy owners in/near hospital buildings and in hospitals also providing out-patient care (in a community pharmacy). Surprisingly, the right to provide pharmaceutical care to in-patient care facilities was granted to community pharmacies provided they meet the criteria of Act. No. 140/1998 Coll.

The range of products in hospital pharmacies differs in kind from public pharmacies. Their range includes pharmaceuticals, medical devices and medicinal nutrition products. The range of pharmaceuticals is set in the Hospital Medicines Formulary, which is reviewed at least once a year in cooperation with clinical pharmacists, doctors, the head of the hospital pharmacy and economists and contains the pharmaceuticals available for care in the facility (a selection of pharmaceuticals from the positive list). The hospital pharmacy should provide availability of these pharmaceuticals at all times by ordering appropriate amounts from wholesalers, and the doctors refer to the Formulary when deciding on available care. Financially demanding pharmaceuticals can require tendering at times. However, the mark up for wholesale products delivered to hospital pharmacies is set to be maximum 10% of the ex-factory price (for wholesalers, plus retail pharmacy when delivered via retail pharmacy – in case there is no hospital pharmacy in the hospital).

The role of the Formulary is on the one hand to provide safe and efficient therapy, and on the other to regulate costs of pharmaceuticals, thus creating rational prescription practices, since the costs of pharmaceuticals are part of the hospital budget. Doctors in in-patient care do not use prescription forms (as in out-patient care), but use request forms for the hospital pharmacy.

2.1.3.5 Doctors

Out-patient doctors are free to prescribe any authorised pharmaceutical, provided they have the proper qualification (prescription-only medicine(s) (POM) prescribed by specialist doctors). However, in order to cut down pharmaceutical costs there have been attempts to control doctors by introducing monthly or quarterly prescription budgets (on behalf of health insurance companies), which inevitably leads to increased generics prescription. In some cases, especially when prescribing pharmaceuticals from Category F (financially demanding), approval of a head physician can be required. The free choice of doctor also creates a good environment for pharmaceutical companies' marketing activities.

In-patient doctors should refer to the Hospital Medicines Formulary (cf. 2.1.3.4), unless they run their own out-patient practice.

Doctors are also represented in the Categorisation Committee, when deciding on the scope of reimbursement of pharmaceuticals.

2.1.3.6 Patients

The role of patients in the choice of pharmaceuticals is rather minor and so is their role in pharmaceutical policy-making. Doctors usually inform patients on pharmaceuticals and their prices. Patients also have the opportunity to inform themselves about the pharmaceuticals prices on the General Health Insurance Company (VšZP) web site⁷, and the reimbursement and co-payment details are available in the Law Collection (published after each categorisation), and on the Ministry of Health web site. Pharmacies also inform patients of the co-payment requirements for their desired products. Patients have to pay a fix co-payment of SKK 5 / € 0.13 per prescription (cf. 1.4.2).

There has been a trend, especially in lower income groups, of pressuring doctors to prescribe equivalent generics with no or lower co-payment, in terms of generic substitution. Under circumstances specified in Art. 38b of Act 140/1998 Coll. on Medicines and Medical Devices, pharmacists are allowed to dispense generics, provided the doctor does not clearly prohibit the generic substitution.

The interests of patients are represented in individual associations, such as associations for asthma, allergy and heart diseases, as well as in the Association for Patient Rights Protection (Asociácia na ochranu práv pacientov, AOPP).

2.2 Funding

2.2.1 Pharmaceutical expenditure

Total pharmaceutical expenditure (TPE) has increased significantly since 2000. In 2005, total pharmaceutical expenditure (TPE) reached SKK 31.4 billion / € 0.8 billion, resulting in a total pharmaceutical expenditure (TPE) per capita of SKK 5,825.93 / € 150 billion. Total pharmaceutical expenditure (TPE) has represented approximately a third of total health expenditure (THE) in recent years in Slovakia.

The rising trend in total pharmaceutical expenditure (TPE) is ubiquitous, and can be explained as a result of population ageing, polymorbidity resulting in multiple pharmacies and higher costs of modern pharmaceuticals.

While the public pharmaceutical expenditure (PE) has been kept relatively stable, there has still been a slight rise (of 1.66%) in private pharmaceutical expenditure (PE) as a share of total health expenditure (THE) over the years. This correlates well with the increasing function and responsibility of individuals in terms of health care and health protection, resulting in the introduction of co-payments for most of the common pharmaceuticals, while the co-payments in other aspects of health care are insignificant.

⁷ <http://www.vszp.sk>

Table 2.8: Slovakia - Total pharmaceutical expenditure 1995, 2000-2005

Pharmaceutical expenditure (PE)	1995	2000	2001	2002	2003	2004	2005
TPE in billions of NCU	n.a.*	17.54	19.11	23.28	27.30	28.7**	31.4***
TPE as a % of THE	n.a.*	34.0*	34.0*	37.3*	38.5*	n.a.*	33.6
TPE per capita in NCU	n.a.*	3,246.62	4,327.98	4,327.81	5,074.30	5,319.40	5,825.93
Public PE as a % of THE	n.a.*	n.a.*	28.65	31.40	29.78	n.a.*	26.59
Private PE as a % of THE	n.a.*	n.a.*	5.35	5.90	8.72	n.a.*	7.01
Public PE as a % of TPE	n.a.*	n.a.*	74**	76**	78**	80**	80**
Private PE as a % of TPE	n.a.*	n.a.*	26**	24**	22**	20**	20**

NCU = national currency unit (SKK), GDP = gross domestic product, TPE = total pharmaceutical expenditure, THE = total health expenditure, PE = pharmaceutical expenditure

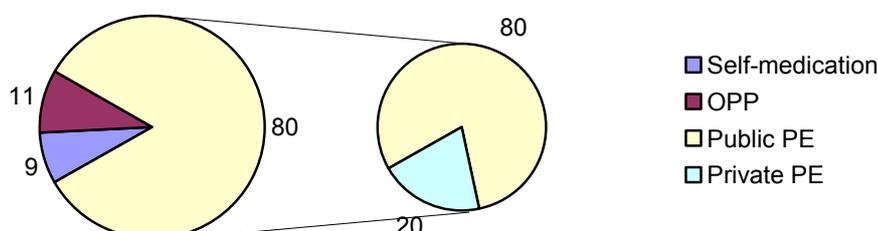
Source: OECD Health Data 2006, **Pharmadata, ***SUKL estimate (prescription-only medicine(s) (POM))

2.2.2 Sources of funds

Funding for pharmaceuticals comes from health care sources, such as health insurance, and out-of-pocket payments (OPPs) (cf. 1.4.2). Since pharmaceutical expenditure (PE) in Slovakia represents a third of total health expenditure (THE), attention is being paid to rational prescription, pricing and reimbursement to regulate these costs. The share of public expenditure on pharmaceuticals has been rising constantly over the last few years, reaching 80% in 2004 and 2005 (cf. 2.2.1).

In 2004 and 2005 alike, private pharmaceutical expenditure (PE) represented about 20% of total pharmaceutical expenditure (TPE). This includes 9% self-medication expenditure and 11% out-of-pocket payments (OPPs), especially co-payments on prescription-only medicine(s) (POM). Voluntary health insurance (VHI) does not play a significant role in Slovakia.

Figure 2.3: Slovakia - Share of private and public pharmaceutical expenditure 2005



OPP = out-of-pocket payment(s), PE = pharmaceutical expenditure

Source: Pharmadata

2.3 Evaluation

The road map for the Slovakian health care system is part of the governmental programme for health care and pharmaceutical policy set out within it by the Ministry of Health⁸.

Responsible bodies participating in pharmaceutical policy are monitoring the effectiveness of decisions on pricing and reimbursement processes from various levels. The bodies are: Ministry of Health, State Institute for Drug Control (SUKL), Insurance companies, Slovak Society for Pharmacoeconomy, and Pharmaceutical Faculty UK.

Programmes and methods used to evaluate pharmaceutical policies, access to pharmaceuticals and the system in general, as well as its impact on health, are focusing on: measuring direct costs for pharmaceuticals; co-payment of inhabitants; and modelling the direct costs for pharmaceuticals, including new molecules and generics with lower prices which had recently had entered into the reimbursement system. There have been some attempts to analyse the direct and indirect costs in specific disease areas (diabetes mellitus and oncology), mainly by the Slovak Society for Pharmacoeconomy.

However, the focus of analysis remains on pharmaceuticals consumption, broken down by groups of pharmaceuticals, as well as prescribed pharmaceuticals themselves, price trends of prescription pharmaceuticals and development of co-payment levels by patient category.

The Ministry of Health and the State Institute for Drug Control (SUKL) provide the analysis on pharmaceuticals consumption from:

⁸ www.government.sk

- regular wholesaler reports to the State Institute for Drug Control (SUKL);
- regular detailed information on pharmaceutical consumption from pharmacies (electronic data sent from every pharmacy to insurance companies and for over-the-counter (OTC) pharmaceuticals to the National Institute for Statistics – compulsory for over-the-counter (OTC) pharmaceuticals reports from pharmacies from 2006).

Specific programmes have been routinely used for modelling the consumption prospectively by the Ministry of Health and the State Institute for Drug Control (SUKL).

Insurance companies provide analysis on pharmaceuticals consumption by diagnosis, by doctor and by dose of the prescribed pharmaceuticals. These analyses are used to various extents, differing from one insurance company to other, to monitor the prescribing habits of specific doctors and to set prescription limits to enable comparison of the prescribing habits of various doctors. Quality indicators are being considered, based on selected criteria, for provision of care in the Slovakian health care system. In pharmaceutical policy, e.g. generics vs originals, the ratio of prescribed pharmaceuticals to generics is monitored by insurance companies in order to promote the use of generics, where possible.

Guidelines for the registration of pharmaceuticals are specified within the Transparency Directive regarding pricing and reimbursement, and these have been (almost completely) brought in line with European Union (EU) legislation. Deadlines for pricing and reimbursement decisions have been observed and Slovakia does not have any special cases or face legal action in this respect.

3 Pricing

3.1 Organisation

Since autumn 2004 the Ministry of Health, advised by the Categorisation Committee, has been setting the pharmacy retail prices for reimbursable pharmaceuticals (original products as well as generics). There is free pricing at manufacturer level for non-reimbursable pharmaceuticals. For wholesalers and pharmacies, there are maximum mark ups for all pharmaceuticals; the last change in the mark-up values is from July 2005.

There are no special regulations on pricing for generics. In reality the prices of generics are 20% to 80% lower than the original product.

The legal framework for pricing is set out in Act 18/1996 (14 November 1995 Act on Prices) and the respective Decree of the Ministry of Health (No. 07045/2003 OAP), and its recent changes, in Act 577/2004 (1 November 2004 Act on Scope of Health Care Services).

In 2004 major reforms in the pricing and reimbursement system took place. These reforms included a shift in the decision-making power from the Ministry of Finance to the Ministry of Health. The Ministry of Finance used to set the prices at the manufacturer level, which were “deregulated” in 2004, meaning that now the Ministry of Health sets the pharmacy retail price (PRP) for reimbursed products and the ex-factory price if the product is intended for use in only in hospital settings. The ex-factory price for ambulatory use is still indirectly regulated through the maximum wholesale and pharmacy mark ups.

3.2 Pricing policies

Price regulation (pharmacy retail price (PRP) or ex-factory price) depends on whether the pharmaceutical is used in the in-patient or out-patient sector.

There are a number of options for pricing regulation in Slovakia.

- When a pharmaceutical is intended for reimbursement in retail, manufacturers have to submit an application for a maximum pharmacy retail price (PRP) to the Ministry of Health together with application for a reimbursement level to be allocated.
- The application for ex-factory pricing for hospital-only products has to also be submitted to the Ministry of Health
- Pharmaceuticals not reimbursed (over-the-counter (OTC), or on prescription) are entitled to free pricing at the manufacturer level. Mark ups for wholesalers and pharmacies are regulated.

Pricing applications for use of reimbursable pharmaceuticals in ambulatory settings can be submitted continuously. These price proposals are then published monthly on the web site of the

Ministry of Health⁹. Two weeks after publishing, the pharmaceutical companies submit another price proposal, which can be the same as the first one or a lower price. In a strategic move (e.g. as a result of competitors' published price proposals), pharmaceutical companies very often lower their second price proposal. No further adjustments are allowed after the second round. The Categorisation Committee then sets the maximum retail prices (which correspond to the reimbursement prices) according to the "agreed" prices. In the event that the price of a pharmaceutical is too high, the Categorisation Committee decides either not to reimburse the pharmaceutical or to reimburse only partially. After the maximum pharmacy retail price (PRP) has been set, manufacturers may apply for reimbursement. The Categorisation Committee then decides on the level of reimbursement.

During the course of the cost-containment measures implemented in 2003, the Ministry of Health put in place the above-mentioned concept of an "agreed" price.

For indirect ex-factory price control (reimbursable pharmaceuticals) or for direct ex-factory price setting (hospital-only products), the manufacturer has to provide different data for the application depending on whether the pharmaceutical is imported or locally produced¹⁰.

- For *locally* produced pharmaceuticals the production costs are the basis for the price calculations.
- For *imported* pharmaceuticals the pharmaceutical company has to submit price data from nine selected European countries: the country of manufacture, Czech Republic, France, Hungary, Austria, Germany, Spain, Italy and Poland. In reality a special focus is given to Poland, Czech Republic and Hungary. If data for one country are not available, then that country is not considered in the price comparison. The Ministry of Health asks the pharmaceutical companies for official proof of the accuracy of the data. The maximum price corresponds to the average of the prices of the three cheapest pharmaceuticals plus a mark up of 10%.

This pricing system is only applicable for reimbursable pharmaceuticals used in retail (indirect ex-factory price regulation, via retail price regulation and maximum mark ups for wholesaler and pharmacy) or in hospital use (direct ex-factory price regulation). Prices of generics are set in the same way; there is no special regulation for generics prices.

Manufacturers can submit applications to increase the ex-factory price of hospital-only pharmaceutical once a year. The application needs to be justifiable, taking into account an increase in production costs or changes in exchange rates of more than 5%. Even if a price change seems justified, the Ministry of Health is under no obligation to grant the requested adjustment.

⁹ <http://www.health.gov.sk/>

¹⁰ Act on Scope of Health Care Services No. 759/2004
<http://www.health.gov.sk/redsys/rsi.nsf/0/431913942CAD0217C12570DC004C105E?OpenDocument&ID=PAR759798047640&TYPE=S&LANGUAGE=S&LENGTH=S>

There are tenders for hospital-only pharmaceuticals after prices are statutorily set at the manufacturer level.

Table 3.1: Slovakia - Ways of pricing of pharmaceuticals

	Manufacturer level	Wholesale level	Pharmacy level
Free pricing at manufacturer level	Non-reimbursable pharmaceuticals (mostly OTC)		
Statutory pricing	- Retail reimbursable pharmaceuticals ¹ only indirectly regulated via mark ups and retail price - Hospital-only directly regulated	All pharmaceuticals regulated via a maximum mark-up scheme	All pharmaceuticals regulated via a maximum mark-up scheme
Public procurement	Tenders are organised after statutory price setting is carried out at manufacturer level. Statutory price setting is the responsibility of the Ministry of Health and tenders are organised by hospital management teams, or price negotiations for specified hospitals are submitted from reimbursement companies.		Not applied
Price/volume agreements, discounts/rebates	No	No	No
Institution in charge of pricing	MZ SR (Ministry of Health) Criteria: international price comparison for imported pharmaceuticals, production costs for locally produced pharmaceuticals		
Legal basis	Act No 18/1996 Coll. on prices, Decree of Ministry of Health No. 07045/2003 OAP and its recent changes on prices, Act No. 577/2004 Coll. on the scope of health care covered by public health insurance and on settlements for health care-related services		

¹ Including the possibility for the manufacturer to deliver a second (lower) price proposal within two weeks ("agreed prices")

OTC = over-the-counter (pharmaceuticals)

Source: Ministry of Health, SUKL

If the process of determining prices:

- is combined with setting the reimbursement level, the decision is made in 180 days according to the Transparency Directive (cf. 3.2);
- is for hospital-only use, ex-factory price has to be determined within 90 days from the submission of the application.

3.2.1 Statutory pricing

Statutory pricing refers to pharmaceuticals used in retail pharmacy which are totally or partially reimbursed. For these pharmaceuticals retail statutory pricing is regulated together with the level of reimbursement.

For pharmaceuticals used in hospital-only pharmacy, statutory pricing is carried out at manufacturer level.

In any case, mark ups for wholesalers and pharmacists are regulated.

Over-the-counter (OTC) products or non-reimbursed products on prescription used in retail pharmacy are entitled to free pricing at manufacturer level, but mark ups for wholesale and pharmacy for these products are regulated.

The legal framework for pricing is set out in Act 18/1996 (14 November 1995 Act on Prices) and the respective Decree of the Ministry of Health (No. 07045/2003 OAP), and its recent changes, in Act 577/2004 (1 November 2004 Act on Scope of Health Care Services).

The responsible body for statutory pricing is currently the Ministry of Health, since August 2004.

Hospital management teams initiate tenders for the best price for pharmaceuticals prior to purchase. Insurance companies organise negotiations for the end price of pharmaceuticals for selected diseases and respective hospitals (blood factors, growth hormones, etc.).

If the process of determining prices:

- is combined with setting the reimbursement level, the decision is made in 180 days according to the Transparency Directive (cf. 3.2);
- is for hospital-only use, ex-factory price has to be determined within 90 days from the submission of the application.

3.2.2 Negotiations

Manufacturers or wholesalers negotiate their delivery price through tenders, but only for hospital-only used pharmaceuticals. Tenders are organised after the statutory maximum ex-factory price has been set by the Ministry of Health. During the tendering process, the purchasing price is the selection criteria for hospitals. Tenders are organised by hospital management teams and are mandatory when the purchasing price for the pharmaceutical reaches the value listed in Act No 25/2006 (Act on Public Purchasing). These tenders are organised each year, mainly in specified centres (National Institute of Oncology, Institute of Cardiovascular Diseases) for medical devices or for pharmaceuticals with a yearly purchasing value above the limit listed in Act No 25/2006.

Price negotiations for certain hospitals are carried out for special pharmaceuticals (blood products, growth hormones, etc.), where more than one importer for pharmaceutical is available or where negotiation is intended to cover the delivery of an expensive pharmaceutical for an extended period.

In these cases insurance companies are responsible for the price negotiations. Price negotiations are based on the purchasing price for specific hospitals. This procedure takes place in specific cases and is actually only for a very limited number of pharmaceuticals.

3.2.3 Free pricing

There is free pricing at manufacturer level for over-the-counter (OTC) products or non-reimbursable pharmaceuticals. Mark ups are regulated for wholesalers and pharmacies.

The legal framework for pricing is set out in Act 18/1996 (14 November 1995 Act on Prices) and the respective Decree of the Ministry of Health (No. 07045/2003 OAP), and its recent changes, in Act 577/2004 (1 November 2004 Act on Scope of Health Care Services).

The current legislation for pricing was introduced in autumn 2004 and the last change on mark ups was introduced in July 2005.

3.2.4 Public procurement / tendering

Generally, tendering is performed in hospitals with larger territory coverage (National Institute of Oncology, Institute of Cardiovascular Diseases) and is organised by hospital management teams according to Act No. 25/2006 (Act on Public Purchasing) (cf. 3.2.2).

Price negotiations are organised after maximum ex-factory price setting has been achieved by Ministry of Health. Negotiations by insurance companies are ongoing for specific pharmaceuticals (blood factors, growth hormones, etc.). Once these negotiations are complete, these products are then delivered, with negotiated prices, to selected hospitals. This procedure takes place in specific cases and is actually only carried out for a very limited number of pharmaceuticals.

3.3 Pricing procedures

External price referencing takes place for imported pharmaceuticals used in hospitals in Slovakia (cf. 3.2), applied for ex-factory prices. The ex-factory prices are compared with those of nine European countries (cf. 3.2). External price referencing is also applied for reimbursable pharmaceuticals in the out-patient sector. Nevertheless, external price referencing for ex-factory prices of reimbursable pharmaceuticals is only a support mechanism for the pharmaceutical pricing process (cf. 3.3.1).

For locally produced pharmaceuticals, the production costs (and profit control) are the basis for the ex-factory price calculations.

The legal framework for pricing is set out in Act 18/1996 (14 November 1995 Act on Prices) and the respective Decree of the Ministry of Health (No. 07045/2003 OAP), and its recent changes, in Act 577/2004 (1 November 2004 Act on Scope of Health Care Services).

Internal price referencing is the principal method for determining the reimbursement price of pharmaceuticals in Slovakia. A mix of therapeutic referencing is applied (e.g. comparisons of similar pharmaceuticals at Anatomic Therapeutic Chemical ATC-4 level and comparisons at Anatomic Therapeutic Chemical ATC-5 level (= active ingredient) (cf. 0)).

Table 3.2: Slovakia - Pricing procedures

Pricing procedure	In use: Yes / No	Level of pricing	Scope
Internal price referencing	YES	Pharmacy retail price	Reimbursable pharmaceuticals
External price referencing	YES	Ex-factory price	- Hospital imported pharmaceuticals - Reimbursable pharmaceuticals in the out-patient sector <u>but only as support</u> for regulating PRP
Cost-plus pricing	YES	Ex-factory price	Locally produced pharmaceuticals
Other, e.g. "agreed" price	YES	Ex-factory price	Reimbursable pharmaceutical in the out-patient sector in addition to external price referencing

PRP = pharmacy retail price

Source: SUKL, Act 18/1996 (from 14 November 1995 Act on Prices) and the respective Decree of the Ministry of Health No. 07045/2003 OAP and its recent changes; Act 577/2004 (1 November 2004 Act on Scope of Health care Services).

3.3.1 External price referencing

External price referencing is applied for hospital-only pharmaceuticals; applicants need to indicate external ex-factory prices of nine European countries in their applications for setting ex-factory prices.

External price referencing is also relevant for certain reimbursable pharmaceuticals in the out-patient sector as a support mechanism; applicants have to indicate external ex-factory prices in their reimbursement application for regulating pharmacy retail price (PRP).

For imported hospital pharmaceuticals the pharmaceutical company has to submit price data from nine selected European countries: the country of manufacture, Czech Republic, France, Hungary, Austria, Germany, Spain, Italy and Poland. In reality there is a special focus on Poland, Czech Republic and Hungary. If data for one country is not available, then that country is not considered in the price comparison. The Ministry of Health asks the pharmaceutical companies for official proof of

the accuracy of the data. The maximum price corresponds to the average of the prices of the three cheapest pharmaceuticals, plus a mark up of 10%.

This pricing system is only applicable for reimbursable pharmaceuticals used in retail (indirect ex-factory price regulation, via retail price regulation and maximum mark ups for wholesalers and pharmacies) or in hospital use (direct ex-factory price regulation). Prices of generics are set in the same way; there is no special regulation for generics prices.

The price information is provided by the pharmaceutical industry, and price comparisons are not reviewed on a regular basis.

The legal framework for pricing is set out in Act 18/1996 (14 November 1995 Act on Prices) and the respective Decree of the Ministry of Health (No. 07045/2003 OAP), and its recent changes, in Act 577/2004 (1 November 2004 Act on Scope of Health Care Services).

3.3.2 Internal price referencing

Internal price referencing applies for retail pharmaceuticals (used in retail pharmacy) which are reimbursed and is applied for the retail price. Internal price referencing is the principal method for determining the reimbursement price of pharmaceuticals in Slovakia. A mix of therapeutic referencing is applied (e.g. comparisons of similar pharmaceuticals on Anatomic Therapeutic Chemical ATC-4 level and comparisons on Anatomic Therapeutic Chemical ATC-5 level (= active ingredient) (cf. 0)).

Pharmaceutical companies have to submit certain information in their application for reimbursement, including at least: information on the proposed ex-factory price and/or pharmacy retail price (PRP); information on the defined daily dose (DDD) for the active substance(s); number of defined daily doses (DDD) in the pack; daily treatment costs in comparison with therapeutic alternatives at Anatomic Therapeutic Chemical ATC-4 level; the proposed level of reimbursement; and arguments, e.g., if this level differs from that which has been defined for an already existing active substance, or if it is a completely new active substance.

3.3.3 Cost-plus pricing

For locally produced pharmaceuticals, the production costs (and profit control) are the basis for the ex-factory price calculations for new products.

The legal framework for pricing is set out in Act 18/1996 (14 November 1995 Act on Prices) and the respective Decree of the Ministry of Health (No. 07045/2003 OAP), and its recent changes, in Act 577/2004 (1 November 2004 Act on Scope of Health Care Services).

3.3.4 (Indirect) Profit control

There is no profit control for the pharmaceuticals already on the market, neither those imported nor those locally produced.

3.3.5 Price competition for the “agreed” price

Price proposals for reimbursable pharmaceuticals in ambulatory use can be submitted continuously. These price proposals are then published monthly on the web site of the Ministry of Health. Two weeks after publishing, the pharmaceutical companies submit another price proposal, which can be the same as the first one or a lower price. In a strategic move (e.g. as a result of competitors' published price proposals), pharmaceutical companies very often lower their second price proposal. No further adjustments are allowed after the second round. The Categorisation Committee then sets the maximum retail prices (which correspond to the reimbursement prices) according to the “agreed” prices. This system is something like tenders for the best price – which here is the lowest price for the pharmaceuticals in the interchangeable group (mostly at Anatomic Therapeutic Chemical ATC-5 level for the active substance with the same administration method and strength).

3.4 Exceptions

3.4.1 Hospitals-only

In the in-patient sector the system of charges for patient beds (therapy in hospital) covers all the costs that are incurred during acute hospital care, excluding investment costs, but including pharmaceuticals. Every hospital has the autonomy to purchase the necessary medical products by tendering, or (in case of special conditions, or over a certain value) by public procurement. However, they always have to take into consideration the rational management of public resources.

Tenders are organised after the statutory maximum ex-factory price has been set by the Ministry of Health. During the tendering process the purchasing price is the selection criteria for hospitals. Tenders are organised by hospital management teams and are mandatory when the purchasing price for the pharmaceutical reaches the value listed in Act No 25/2006 (Act on Public Purchasing).

Hospital-only medicine(s) (HOM) are also included in the positive list, which can differ from hospital to hospital.

Information concerning the prices of pharmaceuticals in hospitals is collected in the reports from hospital pharmacies. Reports are to be sent to the relevant health insurance company. The Slovak Association of Pharmacists (SLeK) in hospital pharmacies also deals with hospital-only medicine(s) (HOM) consumption on a yearly basis.

3.4.2 Generics

Prices of generics are set in the same way as originals; there is no special regulation for generics prices. However, in practice the prices of generics are 20% to 80% lower (cf. 3.3.5).

Pricing applications for reimbursable pharmaceuticals in ambulatory use can be submitted continuously. Two weeks after publishing, the pharmaceutical companies submit another price proposal, which can be the same as the first one or a lower price. In a strategic move (e.g. as a

result of competitors' published price proposals), pharmaceutical companies very often lower their second price proposal. No further adjustments are allowed after the second round. The Categorisation Committee then sets the maximum retail prices (which correspond to the reimbursement prices) according to the "agreed" prices. In the event that the price of a pharmaceutical is too high, the Categorisation Committee decides either not to reimburse the pharmaceutical or to reimburse only partially. After setting of the maximum pharmacy retail price (PRP), the reimbursement level is set by the Categorisation Committee.

The procedure of price competition for agreed price pharmaceuticals is exploited, in particular for generics, with lower prices being sought in order to achieve the best position in the reimbursed Anatomic Therapeutic Chemical (ATC) cluster.

The legal framework for pricing is set out in Act 18/1996 (14 November 1995 Act on Prices) and the respective Decree of the Ministry of Health (No. 07045/2003 OAP), and its recent changes, in Act 577/2004 (1 November 2004 Act on Scope of Health Care Services).

3.4.3 Over-the-counter pharmaceuticals

There is free pricing for over-the-counter (OTC) products at manufacturer level. Mark ups are regulated for wholesalers and pharmacies (cf. 3.5).

The legal framework for pricing is set out in Act 18/1996 (14 November 1995 Act on Prices) and the respective Decree of the Ministry of Health (No. 07045/2003 OAP), and its recent changes, in Act 577/2004 (1 November 2004 Act on Scope of Health Care Services).

The current method of pricing was introduced in autumn 2004 and the last change on mark ups was introduced in July 2005.

3.4.4 Parallel traded pharmaceuticals

According to information from the Slovak Chamber of Pharmacists (Slovenská Lekárnická Komora, SLeK) and according to personal experiences (anecdotal evidence), parallel imported products are of no relevance in Slovakia.

In general terms, if there are parallel traded pharmaceuticals in Slovakia, the marketing authorisation process for such pharmaceuticals is regulated by Act No 140/1998 (Act on Pharmaceuticals). Parallel trade is not taken into account in the decision on reimbursement status.

3.4.5 Other exceptions

Responsibility for approving delivery on a patient-name basis (non-authorised pharmaceuticals) rests with the Ministry of Health according to Act 140/1998. Social insurance institutions then make the decision on reimbursement of these pharmaceuticals, after approval by the Ministry of Health. Patient-name approvals and deliveries mainly take place in oncology treatment and are of minor importance from the budget point of view. There are no special pricing conditions and procedures

for these pharmaceuticals; after price approval by the Ministry of Health they are mostly reimbursed by insurance companies.

Insurance companies can cover the costs for non-reimbursed pharmaceuticals (authorised or non-authorised but approved by the Ministry of Health). Such exceptions are based mostly on the social status of the patient and are of minor importance in terms of the budget.

3.5 Margins and taxes

Table 3.3: Slovakia - Regulation of wholesale and pharmacy mark ups 2005 and 2006

Wholesale mark up			Pharmacy mark up		
Regulation (Yes/No)	Content	Scope*	Regulation (Yes/No)	Content	Scope*
YES	Specific mark ups for different pharmaceuticals	All pharmaceuticals	Yes	Specific mark ups for different pharmaceuticals	All pharmaceuticals

* Regulations concerning mark ups do not always apply to all pharmaceuticals. For over-the-counter (OTC) pharmaceuticals there is free manufacturing pricing but mark ups are regulated.

Source: SUKL, The legal framework for pricing is set out in Act 18/1996 (14 November 1995 Act on Prices) and the respective Decree of the Ministry of Health (No. 07045/2003 OAP), and its recent changes, in Act 577/2004 (1 November 2004 Act on Scope of Health Care Services).

3.5.1 Wholesale remuneration

The Ministry of Health sets maximum wholesale and pharmacy mark ups for all pharmaceuticals. There are different mark ups depending if the pharmaceutical in question is very expensive, or used for vaccination, or non-reimbursable.

The legal framework for pricing is set out in Act 18/1996 (14 November 1995 Act on Prices) and the respective Decree of the Ministry of Health (No. 07045/2003 OAP), and its recent changes, in Act 577/2004 (1 November 2004 Act on Scope of Health Care Services).

Discussion on regressive mark ups is ongoing and has been for a long period. Possible changes could be expected in this respect during 2007.

Table 3.4: Slovakia - Wholesale mark-up scheme 2006

Ex-factory price in € (example)	Maximum mark up as a % of ex-factory price	Wholesale price in €	Scope*
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PPRI – Pharma Profile
Slovakia

20	11	22.2	Reimbursable pharmaceuticals available in retail pharmacy (reimbursement categories I,S, A – cf. 4.2.2) and pharmaceuticals on prescription but not reimbursed
250	4	260.0	Reimbursable pharmaceuticals available in retail pharmacy – “very expensive” (mostly above € 250) (reimbursement category F – cf. 4.2.2)
20	5	21.0	Reimbursed vaccines available in retail pharmacy (reimbursement category V – cf. 4.2.2)
20	5	21.0	OTC pharmaceuticals
20	10	22.0	HOM (wholesalers share mark up with retail pharmacy, if delivery to hospital is carried out via retail pharmacy)

*Regulations concerning mark ups apply to specific pharmaceuticals defined in Decree of the Ministry of Health No. 07045/2003 OAP and its recent changes

HOM = hospital-only medicine(s), OTC = over-the-counter

Source: SUKL, Act 18/1996 (14 November 1995 Act on Prices) and respective Decree of the Ministry of Health No. 07045/2003 OAP and its recent changes.

3.5.2 Pharmacy remuneration

In Slovakia, the Ministry of Health sets the pharmacy mark ups (cf. 3.5.1). The pharmacy mark ups are added on to the wholesale price. Table 3.5 gives an overview of the pharmacy mark ups. Moreover, a system is in place whereby a flat fee is charged per prescription (maximum of two pharmaceuticals in one prescription from which at least one has to be reimbursed). From 2004 this flat fee was SKK 20 / € 0.50, but from October 2006 only SKK 5 / € 0.13 is charged in practice. A proportion (25%) of the flat fee is kept for the pharmacy, while 75% goes to the relevant insurance company.

The legal framework for pricing is set out in Act 18/1996 (14 November 1995 Act on Prices) and the respective Decree of the Ministry of Health (No. 07045/2003 OAP), and its recent changes, in Act 577/2004 (1 November 2004 Act on Scope of Health Care Services).

Discussion on regressive mark ups is ongoing and has been for a long period. Possible changes in this respect could be expected in 2007.

Table 3.5: Slovakia - Pharmacy mark-up scheme 2006

Pharmacy purchase price	Pharmacy mark up as a % of ex-factory	Pharmacy retail price without value-	Scope*
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PPRI – Pharma Profile
Slovakia

(PPP) from wholesaler in €	price	added tax (VAT) in €	
22.2	21	26.4	Reimbursable pharmaceuticals available in retail pharmacy (mode of reimbursement I,S, A – cf. 4.2.2) and pharmaceuticals on prescription but not reimbursed
260	10	275	Reimbursable pharmaceuticals available in retail pharmacy – “very expensive” (mostly above € 250) (mode of reimbursement F – cf. 4.2.2)
21	7	22.4	Reimbursed vaccines available in retail pharmacy (mode of reimbursement V – cf. 4.2.2)
21	15	24	OTC pharmaceuticals
–	10	–	HOM (wholesalers share mark up with retail pharmacy, if delivery to hospital is carried out via retail pharmacy)
Average mark up	21	–	Reimbursable pharmaceuticals and pharmaceuticals on prescription

*Regulations concerning mark ups apply to specific pharmaceuticals defined in Decree of the Ministry of Health No. 07045/2003 OAP and its recent changes

HOM = hospital-only medicine(s), OTC = over-the-counter

Source: SUKL, Act 18/1996 (14 November 1995 Act on Prices) and respective Decree of the Ministry of Health No. 07045/2003 OAP and its recent changes.

3.5.3 Remuneration of other dispensaries

There are no other dispensaries according to legal requirements.

3.5.4 Value-added tax

In the past, the value-added tax (VAT) rate for pharmaceuticals was 14% and the standard value-added tax (VAT) rate was 20%. In 2004 the value-added tax (VAT) rate for pharmaceuticals increased to 19%, which was also the standard value-added tax (VAT) rate in the sense of “flat tax reform”. From 1 January 2007, the value-added tax (VAT) for pharmaceuticals is different from standard value-added tax (VAT) and the rate for pharmaceuticals and selected medical devices is 10%.

3.5.5 Other taxes

There are no other taxes in Slovakia.

3.6 Pricing related cost-containment measures

3.6.1 Discounts / Rebates

There is no legal basis for rebates (discounts). Since July 2006, it is not legally possible to provide discounts to wholesalers or pharmacies. It is also legally forbidden for pharmacies to grant discounts to consumers.

3.6.2 Margin cuts

In July 2005, the mark-up scheme changed from a linear mark up to a scheme with different mark ups according to reimbursement status and the scope of the pharmaceutical(s).

3.6.3 Price freezes / Price cuts

There have been no price freezes in the recent past in Slovakia. Owing to a stronger position of the SKK against the € or United States dollar (USD), there is some discussion of the possibility of a flat price cut in 2007.

A flat price cut is a general approach to decreasing the retail price by setting a specific percentage that favours the SKK, due to the exchange rate difference between SKK and € or United States dollar (USD) (SKK stronger against € by almost 7% in 2006). From April 2007, a price cut is to be carried out – retail prices to decrease by 6.6%, not including those pharmaceuticals which have already decreased in retail price by this value.

3.6.4 Price reviews

The pharmacy retail price (PRP) for reimbursable pharmaceuticals is evaluated on a regular basis (quarterly) and the reimbursement level is set according to the cheapest price offered for the pharmaceutical at Anatomic Therapeutic Chemical ATC-5 level (i.e. the same active ingredient).

As the pharmacy retail price (PRP) is set in SKK, the exchange rate for SKK vs foreign currency is evaluated, especially for imported pharmaceuticals. The Ministry of Finance carried out such an evaluation several years ago. The Ministry of Health is discussing such an evaluation again for the year 2007.

The pharmacy retail price (PRP) for over-the-counter (OTC) pharmaceuticals had been evaluated in 2005 after deregulating the ex-factory prices for these pharmaceuticals. The Ministry of Health carried out the evaluation in cooperation with the Slovak Chamber of Pharmacists (SLeK). There were no consequences of the evaluation (i.e. no action was taken as a result).

4 Reimbursement

In Slovakia reimbursement of pharmaceuticals is carried out using a combination of different reimbursement categories and a reference price system according to the legal bases listed in Act 577/2004 (1 November 2004 Act on Scope of Health Care Services).

The process of reimbursement may only commence once a maximum retail price has been approved. Then, the Ministry of Health evaluates the application for reimbursement: the Ministry, advised by the Categorisation Committee, decides on the level of reimbursement and on any prescribing or indication limitations. The application needs to include basic information about the pharmaceutical (such as the name of the pharmaceutical, manufacturer and authorisation holder, the pharmaceutical form, pack size and strength), as well as information on the effectiveness of the pharmaceutical and its daily defined dose (DDD) (also called standard therapeutic dose) and number of defined daily doses (DDD) in an applied pharmaceutical pack.

4.1 Organisation

The Ministry of Health, advised by the Categorisation Committee, is responsible for reimbursement decisions.

Until 1995, all pharmaceuticals were fully reimbursed. This had led to a tremendous increase in pharmaceutical expenditure (PE). Therefore the Act 577/2004 (1 November 2004 Act on Scope of Health care Services), which is the legal basis for reimbursement, was reformed in 1995 and then again in 2004. In the course of these reforms, positive lists for both the out-patient and in-patient sectors were implemented. In the past, the positive lists were published as an annex of the Act on Scope of Health Care Services; nowadays, the positive list for the out-patient sector is published in the form of ministerial decrees, as well as regularly on the web site of the Ministry of Health¹¹ and the web site of the General Health Insurance Company (VšZP)¹².

According to Act 577/2004, public health insurance is to fully cover pharmaceuticals administered as part of in-patient care, within the budget of hospitals.

Public health insurance is to fully or partially cover pharmaceuticals administered as part of out-patient care or in pharmacies stipulated in the list of pharmaceuticals, and pharmaceuticals fully covered or partially covered by public health insurance and prescribed pursuant to the prescribing and indication restrictions stipulated in this list. At least one pharmaceutical from each of the Anatomic Therapeutic Chemical classifications (Anatomic Therapeutic Chemical (ATC) groups) – a list of which is given in Annex 4 of Act 577/2004 – is to be fully covered by public health insurance.

¹¹ <http://www.health.gov.sk/redsys/rsi.nsf/0/E065D3D228E53288C125724800038FB6D?OpenDocument>

¹² <http://www.vszp.sk/showdoc.do?docid=81>

The Ministry of Health of the Slovak Republic issues, by way of an edict, the List of pharmaceuticals. The List of pharmaceuticals is updated at least once per year, but in recent years (since the early 2000s) the List has been issued quarterly.

The Ministry determines: the allocation of pharmaceuticals or a combination of pharmaceuticals to the List of pharmaceuticals; any change to the allocation of a pharmaceutical to the List of pharmaceuticals; and the exclusion of a pharmaceutical from the List of pharmaceuticals by categorisation of pharmaceuticals. For the categorisation of pharmaceuticals, the Ministry has set up a Categorisation Committee for pharmaceuticals as its advisory body. The Categorisation Committee comprises 11 members who are appointed by the Minister of Health; three members at the proposal of the Ministry, five members at the proposal of the health insurance companies and three members at the proposal of the Slovak Chamber of Physicians.

Part of the categorisation of pharmaceuticals, upon allocation to the List of pharmaceuticals or upon a change of allocation in the List of pharmaceuticals, is the determination of:

- pharmacy retail price;
- the standard dose (defined daily dose (DDD)) of the pharmaceutical;
- the maximum level of payment by a health insurance company for a defined daily dose (DDD) of the pharmaceutical (set by the Categorisation Committee).

Part of the categorisation of pharmaceuticals may comprise:

- indication restrictions
- prescription restrictions.

Pharmaceutical categorisation criteria, as listed in Act 577/2004, are: a pharmaceutical may be allocated to the List of pharmaceuticals if clinical tests demonstrate that administration of the pharmaceutical will:

- save life
- cure diseases
- prevent the onset of serious health complications
- prevent deterioration of the severity of a disease or its transition to a chronic state
- serve as active prophylaxis
- mitigate the symptoms of disease.

Generally, over-the-counter (OTC) pharmaceuticals and pharmaceuticals with “supportive effect” on disease with no clinical evidence are not covered by public funds.

A pharmaceutical may be excluded from the List of pharmaceuticals if:

- there is no pharmaceutical containing the pertinent pharmaceutical in the List of pharmaceuticals and no application has been made to include a pharmaceutical containing the pertinent pharmaceutical in the List of pharmaceuticals;

- treatment using the pharmaceutical (considering indications, side effects, dosages and the projected duration of treatment required to attain the desired curative effect) is highly costly, or moreover, where concurrently the List of pharmaceuticals includes (an)other comparable pharmaceutical(s) of the same generation of Anatomic Therapeutic Chemical (ATC) classification with lower treatment cost(s).

When categorising pharmaceuticals, the following considerations are taken into account:

- the effectiveness of the pharmaceutical
- the benefit of the pharmaceutical in reducing morbidity and mortality
- comparison of pharmaceuticals in terms of:
 - indications and contraindications
 - the incidence of side effects
 - treatment doses for the given indication
 - doses of the pharmaceutical
 - interaction with other pharmaceuticals
 - curative benefit of the pharmaceutical
 - the level of patient acceptance of treatment
- improvement of treatment compared with existing treatment options.

An application for reimbursement and an official determination of the price of the pharmaceutical has to be submitted to the Ministry of Health by the market authorisation holder or authorised representative. The application for reimbursement must contain detailed identification details regarding the applicant, the specified pharmaceutical and its therapeutic indication, posology, standard therapeutic dose or defined daily dose (DDD) (if determined by the World Health Organization (WHO)) and the number of defined daily doses (DDD) or standard therapeutic doses in one package (unit). Moreover, detailed information is required on the ex-factory price (cf. 3.2 and 3.3.1) and price proposal (pharmacy retail price (PRP)), which can be submitted as the “agreed” price in two rounds, on a monthly basis (cf. 3.2).

Other defining information has to be part of the application, including:

- pharmaceutical(s) that has/have so far not been allocated into the current List of pharmaceuticals;
- a new pharmaceutical form, a new manner of administration, new quantity of pharmaceutical or new dosage of pharmaceutical included in the List of pharmaceuticals;
- the proposed maximum level of payment coverage by a health insurance company, the proposed prescription restrictions to a specialised field of doctor or dentistry, and the proposed indication restrictions for a disease or a target group of people;
- a summary of characteristic properties, details of the treatment strategy of the pharmaceutical, details of the curative position of the pharmaceutical, details on the benefits of the pharmaceutical in treatment practice, and the pharmaco-economic analysis of the pharmaceutical.

The details of the pharmacoeconomic analysis of a pharmaceutical are set out in binding legal regulation issued by the Ministry of Health.

An electronic system of submitting the application, including price proposals, is in use and the Ministry of Health deals with the electronic versions of applications and price proposals. Price proposals are regularly published on the web site of the Ministry of Health (cf. 3.2). The Categorisation Committee holds meetings quarterly and the decisions and results – minutes from Categorisation Committee meetings – are published regularly on the web site of the Ministry of Health¹³.

In recent years the evaluation process has been carried out quarterly, based mainly on frequent price proposals, where generics companies have proposed agreed prices every quarter, allowing savings on public costs in the Anatomic Therapeutic Chemical (ATC) cluster with pharmaceuticals under competition (the same active substance for which internal reference pricing is in practice). In 2007, a re-evaluation process (twice yearly) is expected to be carried out, and in between the input of new pharmaceuticals to the existing system is expected. Besides the evaluation twice a year, pharmaceuticals also may enter into the reimbursement system in this way.

4.2 Reimbursement schemes

The legal framework for the reimbursement process, application form and decision criteria on the reimbursement of pharmaceuticals is set out in Act 577/2004 (Act on Scope of Health Care Services) and stipulates a “minimum coverage from public funds” by the health insurance for the whole territory and for all insurance companies. Insurance companies can exceed this, but have to keep their economic balance and contribute at least the minimum required by the reimbursement scheme.

The process of setting the reimbursement level is combined with setting the pharmacy retail price (PRP) (indirectly ex-factory price) (cf. 3.2). The decision takes place within 180 days of application. The re-evaluated List of pharmaceuticals is issued quarterly.

4.2.1 Eligibility criteria

The factors that determine whether a pharmaceutical qualifies for reimbursement or not are listed in Act 577/2004 (Act on Scope of Health Care Services). The decision is made by the Ministry of Health and its advisory board, the Categorisation Committee.

A pharmaceutical may be allocated to the List of pharmaceuticals if clinical tests demonstrate that administration of the pharmaceutical will:

- save life;

¹³ <http://www.health.gov.sk/kategorizacia>

- cure diseases;
- prevent the onset of serious health complications;
- prevent deterioration in or worsening of the severity of a disease or its transition to a chronic state;
- serve as active prophylaxis;
- mitigate the symptoms of disease.

Generally, over-the-counter (OTC) pharmaceuticals, oral contraceptives, herbal medicines and pharmaceuticals having a “supportive effect” on disease with no clinical evidence are not covered by public funds.

A pharmaceutical may be excluded from the List of pharmaceuticals if:

- there is no pharmaceutical in the List of pharmaceuticals and no application has been submitted to include a pharmaceutical containing the pertinent pharmaceutical to the List of pharmaceuticals; or
- treatment using the pharmaceutical (considering indications, side effects, dosages and the projected duration of treatment required to attain the desired curative effect) is highly costly, or moreover, where concurrently the List of pharmaceuticals includes (an)other comparable pharmaceutical(s) of the same generation of Anatomic Therapeutic Chemical (ATC) classification with lower treatment cost(s).

When categorising pharmaceuticals, the following details are taken into account:

- the effectiveness of the pharmaceutical
- the benefit of the pharmaceutical in reducing morbidity and mortality
- comparison of pharmaceuticals in terms of:
 - indications and contraindications
 - the incidence of side effects
 - treatment doses for the given indication
 - doses of the pharmaceutical
 - interaction with other pharmaceuticals
 - curative benefit of the pharmaceutical
 - the level of patient acceptance of treatment
- improvement of treatment compared with existing treatment options.

The reimbursement level is based on the following criteria: therapeutic benefit of the pharmaceutical, the pharmacy retail price (PRP) of the pharmaceutical and the reimbursed reference price for all comparable pharmaceuticals of the respective Anatomic Therapeutic Chemical (ATC) group with the same active ingredient or active ingredient with similar effectiveness (internal reference pricing comparison).

An affordable co-payment based on the “agreed” price is also considered in the decisions of the Categorisation Committee.

4.2.2 Reimbursement categories and reimbursement rates

Pharmaceuticals in the out-patient sector are subdivided into six categories according to the decisions made by the Categorisation Committee:

- I: full reimbursement – including vital pharmaceuticals (such as cytostatics and basic antibiotics, vital pharmaceuticals for cardiology, respiratory diseases, neurology) and at least one pharmaceutical in each Anatomic Therapeutic Chemical (ATC) group, a list of which is give in Annex 4 of Act 577/2004, shall be fully covered by public health insurance;
- A: full reimbursement – including vital pharmaceuticals (such as cytostatics and basic antibiotics, vital pharmaceuticals for cardiology, respiratory diseases, neurology), and parenteral pharmaceuticals which are to be applied in ambulances working with out-patient services;
- S: partial reimbursement – including some generics or other equivalent original products;
- F full reimbursement – includes reimbursable pharmaceuticals available in retail pharmacies (“very expensive” – mostly above € 250), namely pharmaceuticals restricted to specific oncology diseases, and application needs to be controlled;
- V: full reimbursement – for vaccines available in retail pharmacies, based on the country vaccination programme approved by the Institute of Public Health;
- N: no reimbursement – not included in the List of pharmaceuticals, including over-the-counter (OTC) products, oral contraceptives and pharmaceuticals, where no proof of a therapeutic benefit could be found.

Additionally, there is a “fast-track” reimbursement process for pharmaceuticals with the same active ingredient as a pharmaceutical already included in the positive list. In such cases, the pharmaceutical company accepts a 10% lower pharmacy retail price (PRP) for the pharmaceutical being “fast tracked” and a reduction in the reimbursement level, which may also affect other pharmaceuticals in the Anatomic Therapeutic Chemical (ATC) group with the same active ingredient.

The legal framework for the reimbursement process, application form and decision criteria on the reimbursement of pharmaceuticals is set out in Act 577/2004 (Act on Scope of Health Care Services) and is stipulates a “minimum coverage from public funds” by the health insurance for the whole territory and for all insurance companies. Insurance companies can exceed this, but have to keep their economic balance and contribute at least the minimum required by the reimbursement scheme.

Table 4.1: Slovakia - Reimbursement of pharmaceuticals

Reimbursement category	Reimbursement rate	Characteristic of category
I	Full reimbursement	Vital pharmaceuticals (such as cytostatics and basic antibiotics, vital pharmaceuticals for cardiology, respiratory diseases, neurology) and at least one pharmaceutical in each ATC group, a list of which is given in Annex 4 of Act 577/2004, shall be fully covered by public health insurance.
A	Full reimbursement	Vital pharmaceuticals (such as cytostatics and basic antibiotics, vital pharmaceuticals for cardiology, respiratory diseases, neurology), and parenteral pharmaceuticals which are to be applied in ambulances working with out-patient services.
S	Partial reimbursement	Including some generics or other equivalent original products, depending on certain criteria (cf. 4.2.1) and internal reference pricing. To calculate the reference price for reimbursement in a group, usually the price per DDD of the cheapest available pharmaceutical is taken. For more expensive pharmaceuticals, co-payment is generated as the difference between the retail price of the pharmaceutical and the reimbursement level of the cheapest pharmaceutical in the ATC with the same active ingredient.
F	Full reimbursement	Reimbursable pharmaceuticals available in retail pharmacy “(very expensive” – mostly above € 250), namely pharmaceuticals restricted to specific oncology diseases, and application needs to be controlled.
V	Fully reimbursed vaccines	Based on the country vaccination programme approved by the Institute of Public Health.
N	No reimbursement	Not found in the List of pharmaceuticals, including OTC products, oral contraceptives and pharmaceuticals, where no proof of a therapeutic benefit could be found.

OTC = over-the-counter, DDD = defined daily dose, ATC = Anatomic Therapeutic Chemical

Source: SUKL, Ministry of Health

Table 4.2: Slovakia - Overview of pharmaceuticals in the positive list from January 2007

Reimbursement category	I	V	A	F	S	Total
Fully reimbursed	613	30	794	257		1,694
Co-payment SKK 0-20					628	629
Co-payment SKK 100-150				1	329	330
Co-payment SKK 150 and more				11	766	777
Co-payment SKK 20-50					736	736
Co-payment SKK 50-100				5	796	801
Total	613	30	794	274	3,256	4,967

Source: SUKL, 2006

4.2.3 Reimbursement lists

Until 1995, all pharmaceuticals were fully reimbursed. This had led to a tremendous increase in pharmaceutical expenditure (PE). As a result, Act 577/2004 (1 November 2004 Act on Scope of Health Care Services), which is the legal basis for reimbursement, was reformed in 1995 and then again in 2004. In the course of these reforms, positive lists for both the out-patient and in-patient sectors were implemented. Several years ago, the positive lists were published as an annex of the Act on Scope of Health Care Services; nowadays the positive list for the out-patient sector is published in the form of ministerial decrees, as well as regularly on the web site of the Ministry of Health¹⁴ and the web site of the General Health Insurance Company (VŠZP)¹⁵.

According to Act 577/2004, public health insurance is to fully cover pharmaceuticals administered as part of in-patient care, through the budgets of hospitals.

Public health insurance is to fully or partially cover pharmaceuticals administered as part of out-patient care or in pharmacies stipulated in the list of pharmaceuticals, and pharmaceuticals fully covered or partially covered by public health insurance and prescribed pursuant to the prescribing and indication restrictions stipulated in this list. At least one pharmaceutical from each of the Anatomic Therapeutic Chemical classifications (Anatomic Therapeutic Chemical (ATC) groups) – a list of which is given in Annex 4 of Act 577/2004 – is to be fully covered by public health insurance.

The Ministry of Health of the Slovak Republic issues, by way of an edict, the List of pharmaceuticals. The List of pharmaceuticals is updated at least once per year, but in recent years (since the early 2000s) the List has been issued quarterly.

The Ministry of Health, advised by the Categorisation Committee, is responsible for issuing the detailed List of pharmaceuticals and updating the List, as well as for setting the criteria for inclusion and exclusion (cf. 4.1 and 4.2.1).

4.3 Reference price system

In 1995, a reference price system was introduced.

In order to set maximum reimbursement price levels, all pharmaceuticals on the List of pharmaceuticals are clustered into therapeutic groups based on Anatomic Therapeutic Chemical classification levels ATC-5 (same active ingredient) and Anatomic Therapeutic Chemical ATC-4 (therapeutically similar products).

In total, the List of pharmaceuticals comprises 4,967 pharmaceuticals are banded together into 1,648 Anatomic Therapeutic Chemical (ATC) groups at Anatomic Therapeutic Chemical ATC-5

¹⁴ <http://www.health.gov.sk/redsys/rsi.nsf/0/E065D3D228E53288C125724800038FB6D?OpenDocument>

¹⁵ <http://www.vszp.sk/showdoc.do?docid=81>

level (this could be differentiated depending on mode of administration or strength of active ingredient).

In each Anatomic Therapeutic Chemical (ATC) group, a list of which is given in Annex 4 of Act 577/2004, at least one pharmaceutical is to be fully covered by public health insurance. In the course of the 2003 reforms, the number of Anatomic Therapeutic Chemical (ATC) groups with at least one pharmaceutical mandatorily fully reimbursed was radically reduced to 122 groups, resulting in more pharmaceuticals in any one group.

To calculate the reference price of a group, usually the price per defined daily dose (DDD) of the cheapest available pharmaceutical in the Anatomic Therapeutic Chemical (ATC) classification is taken. The reimbursement price level for pharmaceuticals can occasionally be set at a different level from the reference price, in order to limit additional payments for pharmaceuticals in the same group with price differences.

In the past, the outcomes of the categorisation process have been reviewed on an annual basis. From 2004 on, the Ministry of Health increased the frequency of the categorisation process reviews to four times a year. The quarterly reviews were concentrated on the relevant Anatomic Therapeutic Chemical (ATC) groups (e.g. in the case of a higher reimbursement price and for new pharmaceuticals).

Reference price system in Anatomic Therapeutic Chemical ATC-5 and Anatomic Therapeutic Chemical ATC-4 levels is used to generate a competitive environment for originals and generics in the quarterly re-evaluation process. After setting the maximum pharmacy retail price (PRP) the reimbursement level is set by the Categorisation Committee, based on the internal reference pricing system. To calculate of the reference reimbursement price of a group, usually the price per defined daily dose (DDD) of the cheapest available pharmaceutical is taken. For more expensive pharmaceuticals in group, co-payment is generated as the difference between the retail price of the pharmaceutical and the reimbursement level of the cheapest pharmaceutical in the Anatomic Therapeutic Chemical (ATC) with the same active ingredient. If co-payment for more expensive pharmaceuticals is generated, this co-payment is fixed by law.

The pharmacy retail price (PRP) for generics is set through the procedure of “agreed” price (cf. 3.3.5). Price competition for the agreed price is mostly used for lowering the reimbursement level (retail price for generics is lowered by competition in the Anatomic Therapeutic Chemical (ATC) clusters of the same active substance) and thus saves costs in specific therapeutic groups.

Physicians and pharmacists have to inform the patient of possible co-payments in this respect and they should offer the cheapest pharmaceutical available at Anatomic Therapeutic Chemical ATC-5 level (with the same active ingredient), if patient agrees. This procedure is set out in Act 577/2004 (Act on Scope of Health Care Services).

This procedure has led to competition in the group of substances at Anatomic Therapeutic Chemical ATC-5 level (with the active substance) and the reimbursement level since the early 2000s has been significantly reduced in these cases leading to cost savings and maintaining full

reimbursement for pharmaceuticals at Anatomic Therapeutic Chemical ATC-5 level, where more pharmaceuticals are present.

Afterwards, the internal reference price is compared as differences appear within a group of active substances and the reimbursement levels for pharmaceuticals at Anatomic Therapeutic Chemical ATC-4 level.

4.4 Private pharmaceutical expenses

Among non-reimbursable pharmaceuticals (e.g. over-the-counter (OTC) products) there is free pricing at the ex-factory price level, so the patient has to opt to buy them him/herself. The patient has to pay the full price out of pocket.

In the case of reimbursement, private expenses are variable depending on the reimbursement category, rational use and prescribing habits of the physician, and the role of pharmacists.

In the List of pharmaceuticals, almost 45% of the total 4,967 pharmaceuticals are fully reimbursed or assisted by co-payment up to SKK 20 / € 0.50. Physicians and pharmacists are obliged to inform patients of possible co-payments for pharmaceuticals that are more expensive, as well as their cheaper alternatives. Pharmacists can substitute less expensive instead of more expensive interchangeable products for their patients. However, for the co-payments represented in 2006, close to 13% of costs for pharmaceuticals were covered from public funds (SKK 3 Mio. vs SKK 22.6 Mio. from public funds in 2005).

Over-the-counter (OTC) pharmaceuticals consumption represents approximately 10% of total pharmaceutical costs (SKK 2.3 Mio. / € 0.5 Mio. in 2005). The flat fee per prescription, which was SKK 20 / € 0.50 until October 2006, now stands at SKK 5 / € 0.13 per prescription.

4.4.1 Direct payments

There are no direct payments in Slovakia besides those already mentioned (cf. 4.4). Self-medication is paid directly by patients.

4.4.2 Out-of-pocket payments

Among the non-reimbursable pharmaceuticals (e.g. over-the-counter (OTC) products) there is no control of ex-factory prices, so the patient has to opt to buy them him/herself. The patient has to pay the full price.

In the case of reimbursement, private expenses are variable depending on the reimbursement category. If a pharmaceutical is partially reimbursed, the co-payment above the reimbursement level has to be paid by patient. Moreover, private expenses depend on rational use and prescribing habits of physicians, and the role of pharmacists.

In the List of pharmaceuticals, almost 45% of the total 4,967 pharmaceuticals are fully reimbursed or assisted by co-payment up to SKK 20 / € 0.50. Physicians and pharmacists are obliged to inform patients of possible co-payments for pharmaceuticals that are more expensive, as well as their cheaper alternatives. Pharmacists can substitute less expensive instead of more expensive interchangeable products for their patients. However, for the co-payments represented in 2006, close to 13% of costs for pharmaceuticals were covered from public funds (SKK 3 Mio. vs SKK 22.6 Mio. from public funds in 2005).

Over-the-counter (OTC) pharmaceuticals consumption represents approximately 10% of total pharmaceutical costs (SKK 2.3 Mio. / € 0.5 Mio. in 2005). The flat fee per prescription, which was SKK 20 / € 0.50 until October 2006, now stands at SKK 5 / € 0.13 per prescription.

4.4.2.1 Fixed co-payments

Out-of-pocket payments (OPPs) have become an inevitable part of health care funding. Although the constitution guarantees equal and free access to health care, the legislation introduced several fixed co-payments. These include a pharmaceuticals and medical devices co-payment (although a fully reimbursed pharmaceutical should be available in every therapeutic group), dental products, spectacle frames, etc. Co-payments for provision-related services were introduced in 2003, as follows: primary care or specialist care consultation SKK 20 / € 0.50; bed and board during hospitalisation SKK 50 / € 1.3 per day (in case of a longer stay only for the first 21 days); prescription fee SKK 20 / € 0.50 per prescription (can contain two different pharmaceuticals in amount necessary for the treatment), of which SKK 5 / € 0.13 was retained in the pharmacy and SKK 15 / € 0.38 paid to the insurance company; non-emergency patient transport SKK 2 / approximately € 0.05 per km; emergency medical attention fee SKK 60 / € 1.50.

The reaction to these co-payments was rather negative on the part of the present coalition parties and the public, and from October 2006 they were abolished, while the prescription fee was reduced to SKK 5 / € 0.13 per prescription (whole sum to be kept by the pharmacy) and the emergency service fee remained at SKK 60 / € 1.55.

4.4.2.2 Percentage co-payments

In Act 577/2004 (Act on Scope of Health Care Services), there is a maximum limit on co-payments for pharmaceuticals. In theory, the maximum limit listed in the Act is in the range of approximately 20% of possible co-payments for available pharmaceuticals in the List of pharmaceuticals (in reality the true value is approximately 13%).

No other relevant percentage co-payments than those already discussed exist in Slovakia.

Co-payment is necessary if the reimbursement level is set according to the groups of active substance, and the retail price for the pharmaceutical is over the reimbursement limit. The patient has to pay the difference from his/her pocket.

To limit the maximum co-payment from the List of pharmaceuticals, Act 577/2004 states that the number of co-payments from all pharmaceuticals, expressed as a % of the retail price (calculated from co-payment value, which is the retail price minus the reimbursement level), must not exceed 20%. This is a rather complicated mechanism, but in practice the average percentage of co-payments for all pharmaceuticals and their co-payments stands at 13%.

4.4.2.3 Deductibles

There are no deductibles used in Slovakia.

4.5 Reimbursement in the hospital sector

In Slovakia, reimbursement in the in-patient sector differs from that in the out-patient sector. In the in-patient sector the Slovakian patient-bed financing system covers all costs during acute hospital care (except the investment costs), including pharmaceuticals. The cost content of medical and accommodation services for defined hospital cases is based on a cost assessment study made several years ago. The systematic maintenance of codes and financing parameters is an essential part of the patient-bed financing systems.

The main role in this respect is played by hospital management teams and insurance companies. The contracts are regularly evaluated based on a year-long running period for in-patient services in the selected hospitals.

In chronic care the costs of the pharmaceuticals are covered by the “bed occupancy” days and daily fees. Consequently, the pharmaceuticals are fully reimbursed for in-patient care, making up a significant part of the hospitalisation costs.

The main payers of pharmaceuticals in hospitals are insurance companies, which finance the pharmaceutical costs through the diagnosis-related group (DRG) system (in case of chronic care, the bed occupancy fees) and the hospital management teams ensure the supply of pharmaceuticals (cf. 3.2.2). Often the management teams receive pharmaceuticals free of charge as a gift or sample.

The hospital management teams issue the Hospital Medicines Formulary, the List of pharmaceuticals used in in-patient care in selected hospitals, which should reflect the rational use of pharmaceuticals in in-patient care.

Ideally, the cost content of pharmaceuticals used in diagnosis-related groups (DRGs) is calculated with the price of generics, and protocols have been established regarding utilisation of pharmaceuticals. Besides this, insurance companies provide “very expensive” pharmaceuticals through a special budget. Insurance companies purchase these pharmaceuticals centrally, via tenders (e.g. for haemophilia). There are some efforts to cut down the role of this special budget and to calculate the price of hospital-only medicine(s) (HOM) in diagnosis-related groups (DRGs) (e.g. oncology treatments).

The eligibility criteria for reimbursement of pharmaceuticals in the hospital sector should be the same as in the out-patient sector. The same coverage (policy system) is to be applied for hospital pharmaceuticals with the same procedure, with the only difference being the decision-maker, namely in the case of hospitals, this decision-maker is the management team of the selected hospital.

4.6 Reimbursement-related cost-containment measures

Programmes and methods used to evaluate pharmaceutical policies, access to pharmaceuticals and the system in general, as well as its impact on health, are focusing on: measuring direct costs for pharmaceuticals; co-payment of inhabitants; and modelling the direct costs for pharmaceuticals, including new molecules and generics with lower prices which had recently had entered into the reimbursement system. There have been some attempts to analyse the direct and indirect costs in specific disease areas (diabetes mellitus and oncology), mainly by the Slovak Society for Pharmacoeconomy.

However, the focus of analysis remains on pharmaceuticals consumption, broken down in by groups of pharmaceuticals, as well as and in prescribed pharmaceuticals themselves, price trends ofof prescription pharmaceuticals and development of co-payment levels per by patient category remains the basis in this respect.

The Ministry of Health and the State Institute for Drug Control (SUKL) provide the analysis on pharmaceuticals consumption from:

- regular wholesaler reports to the State Institute for Drug Control (SUKL);
- regular detailed information on pharmaceutical consumption from pharmacies (electronic data sent from every pharmacy to insurance companies and for over-the-counter (OTC) pharmaceuticals to the National Institute for Statistics – compulsory for over-the-counter (OTC) pharmaceuticals reports from pharmacies from 2006).

Specific programmes have been routinely used for modelling the consumption prospectively by the Ministry of Health and the State Institute for Drug Control (SUKL).

Insurance companies provide analysis on pharmaceuticals consumption by diagnosis, by doctor and by dose of the prescribed pharmaceuticals. These analyses are used to various extents, differing from one insurance company to other, to monitor the prescribing habits of specific doctors and to set prescription limits to enable comparison of the prescribing habits of various doctors. Quality indicators are being considered, based on selected criteria, for provision of care in the Slovakian health care system. In pharmaceutical policy, e.g. generics vs originals, the ratio of prescribed pharmaceuticals to generics is monitored by insurance companies in order to promote the use of generics, where possible.

4.6.1 Major changes in reimbursement lists

Since the early 2000s, changes have been introduced in the reimbursement lists. Changes in the organisation of the reimbursement process, reference pricing and other changes relating to eligibility criteria and evaluation have already been described (cf. 4.3).

Besides these changes, the composition of the Categorisation Committee as the advisory board to the Ministry of Health is also worthy of further comment. The representatives of the Categorisation Committee changed in 2003 (as mentioned in Act 577/2004) in favour of payers. Five members of the Categorisation Committee represent insurance companies.

The reimbursement list is re-evaluated quarterly, mainly based on frequent new retail end-price proposals, especially regarding generics. This was the main feature that enabled potential competition from generics to be used to reduce costs in 2004 and 2005, as well as introducing innovative molecules to the list.

4.6.2 Introduction / review of reference price system

Cf. 4.3.

4.6.3 Introduction of new / other out-of-pocket payments

Out-of-pocket payments (OPPs) have become an inevitable part of health care funding. Although the constitution guarantees equal and free access to health care, the legislation introduced several fixed co-payments. These include co-payments for pharmaceuticals and medical devices (although a fully reimbursed pharmaceutical should be available in every therapeutic group), dental products, spectacle frames, etc. Co-payments for provision-related services were introduced in 2003, as follows: primary care or specialist care consultation SKK 20 / € 0.50; bed and board during hospitalisation SKK 50 / € 1.3 per day (in case of a longer stay only for the first 21 days); prescription fee SKK 20 / € 0.50 per prescription (can contain two different pharmaceuticals in amount necessary for the treatment), of which SKK 5 / € 0.13 was retained in the pharmacy and SKK 15 / € 0.38 paid to the insurance company; non-emergency patient transport SKK 2 / approximately € 0.05 per km; emergency medical attention fee SKK 60 / € 1.50.

The reaction to these co-payments was rather negative on the part of the present coalition parties and the public, and from October 2006 they were abolished, while the prescription fee was reduced to SKK 5 / € 0.13 per prescription (whole sum to be kept by the pharmacy) and the emergency service fee remained at SKK 60 / € 1.55.

4.6.4 Claw-backs

There is no system of claw-backs in Slovakia.

4.6.5 Reimbursement reviews

Reimbursement decisions are evaluated by the pharmaceutical departments of insurance companies.

Not only insurance companies, but also pharmaceutical companies, representatives of physicians and the Ministry of Health are entitled to ask for a review of a reimbursement decision or an exclusion of a pharmaceutical from the reimbursement list.

The criteria for such a procedure are listed in Act 577/2004 (Act on Scope of Health Care Services).

In the scope of reduction of the Anatomic Therapeutic Chemical (ATC) groups reimbursement levels, re-evaluation of the reimbursement levels of Anatomic Therapeutic Chemical ATC-4 (therapeutic) pharmaceuticals is expected.

In recent years, reimbursement reviews regarding diabetes pharmaceuticals have been carried out, in particular on: the availability of human insulin products for more of the population; sartans and statins with regard to indication limitation; more demand for body weight control and factors that can be influenced by patients themselves; reimbursement of systemic antibiotics; and vaccine reimbursement schemes.

5 Rational use of pharmaceuticals

Several responsible bodies participating in pharmaceutical policy and decisions on pricing and reimbursement processes are monitoring the effectiveness of the decisions and use of pharmaceuticals from various levels. The bodies are: the Ministry of Health, the State Institute for Drug Control (SUKL), insurance companies, the Slovak Society for Pharmacoeconomy, and Pharmaceutical Faculty UK. The Ministry of Health, in cooperation with the Central Committee for Rational Pharmacotherapy, is regularly working on guidelines on diagnosis and therapy options for selected diseases. It should be stressed that for the most part these guidelines do not only reflect pharmacoeconomy issues.

Programmes and methods used to evaluate pharmaceutical policies, access to pharmaceuticals and the system in general, as well as its impact on health, are focusing on: measuring direct costs for pharmaceuticals; co-payment of inhabitants; and modelling the direct costs for pharmaceuticals, including new molecules and generics with lower prices which had recently had entered into the reimbursement system. There have been some attempts to analyse the direct and indirect costs in specific disease areas (diabetes mellitus and oncology), mainly by the Slovak Society for Pharmacoeconomy.

However, the focus of analysis remains on pharmaceuticals consumption, broken down in by groups of pharmaceuticals, as well as and in prescribed pharmaceuticals themselves, price trends of of prescription pharmaceuticals and development of co-payment levels per by patient category remains the basis in this respect.

5.1 Impact of pharmaceutical budgets

In the course of the reforms of 2003, the Ministry of Health implemented further prescribing controls, such as pharmaceutical budgets (for pharmaceuticals and medical services) for doctors. The sickness funds negotiate monthly or quarterly maximum prescribing limits with the contracted doctors. With the introduction of pharmaceutical budgets along with co-payments and the reference price system, the Ministry of Health is trying to reduce pharmaceutical expenditure (PE).

In hospitals, doctors and management teams are involved in preparing the Hospital Medicines Formulary, the List of pharmaceuticals used in in-patient care in selected hospitals, which should reflect the rational use of pharmaceuticals in in-patient care.

Contracted doctors are monitored according to their prescribing habits as well as being subject to prescription guidelines from the General Health Insurance Company (VšZP).

Prescribing habits of doctors in hospitals, namely in oncology and cardiology, can influence prescriptions in the out-patient sector. This occurs when pharmaceutical companies initiate a course

of therapy (with the respective pharmaceutical) by giving starter packs to hospitals free of charge. Such discounts are therefore strictly controlled by hospital management teams and insurance companies.

5.2 Prescription guidelines

In 1995, the General Health Insurance Company (VšZP)¹⁶ issued the first version of the “guidelines on the prescribing and reimbursement expenditure of medicinal products”.

The Ministry of Health, in cooperation with Central Committee for Rational Pharmacotherapy, is regularly working on guidelines on diagnosis and therapy options for selected diseases. It should be stressed that for the most part these guidelines do not only reflect pharmacoeconomy issues. Guidelines are more informative on the options for diagnosis and therapy for selected diseases and not on the possible therapy steps regarding pharmacoeconomic analysis. There are no “Real Guidelines on Economic Prescribing” but there have been some initial attempts by insurance companies to produce these documents.

The insurance companies monitor to a greater or lesser extent the prescription patterns of their contracted general practitioners (GPs) and specialists, as these individuals are obliged to comply in their prescribing with the budgets for pharmaceuticals and medical services for doctors. The insurance companies negotiate monthly or quarterly maximum prescribing limits with the contracted doctors.

The most common method for insurance companies to monitor contracted doctors is to benchmark the prescription volume of a given doctor to others in the same region, e.g., focusing on the share of generics that doctor prescribes compared to others.

5.3 Information to patients / doctors

Act 140/1998 (Act on Pharmaceuticals) regulates advertising and industry behaviour towards health professionals, which is in line with European Directive 2001/83/EC. The State Institute for Drug Control (SUKL) is the competent institution in charge of supervising pharmaceutical advertising activities.

General requirements for advertising are set out in Act No. 147/2001 (Advertising Act). There is a section on advertising of pharmaceuticals within Act 147/2001 (Advertising Act) and within Act 140/1998 (Act on Pharmaceuticals).

Advertising prescription-only medicine(s) (POM) to the public is not allowed. Representatives of pharmaceutical companies are allowed to promote licensed products in line with the approved

¹⁶ <http://www.vszp.sk/showdoc.do?docid=4>

“Summary of product information” and patient leaflets distributed to health care providers. The State Institute for Drug Control (SUKL) is authorised to control such activities and promotional material.

Samples distributed to doctors free as part of product marketing are limited to units of 3 packs of pharmaceuticals per year and a record of these should be drawn up.

Advertising of over-the-counter (OTC) pharmaceuticals is allowed in all media forms. Public advertising, however, is prohibited for non-prescription pharmaceuticals the brand name of which is the same as that of its prescription-only form, as well as for reimbursable over-the-counter (OTC) products (very rare cases).

There are no measures implemented in order to restrict or control promotional spending of manufacturers.

The ethical regulations of pharmaceutical industry are in practice stipulated by the Association of Pharmaceutical Producers.

5.4 Pharmacoeconomics

Although no real complex pharmacoeconomic evaluation is being carried out in Slovakia, some rules and criteria are fixed in various decrees: Decree of the Ministry of Health No.125/2001 on recent changes on pharmacoeconomic analysis and Decree of the Ministry of Health No. 723/2004 on recent change, as well as decrees on setting the standard dose of pharmaceuticals and on setting the reimbursement level for the standard dose of pharmaceuticals.

These binding legal regulations issued by the Ministry of Health set out the details of the pharmacoeconomic analysis of a pharmaceutical. Requirements are: a comparison of direct costs using a new pharmaceutical and an available biologically identical pharmaceutical or alternative pharmaceutical; the number of patients to be treated by the new pharmaceutical and an estimation of direct costs for the new pharmaceutical; the assumption that quality of life will be improved or indirect costs will be reduced; and the reimbursement level in foreign countries. Information on pharmacoeconomic analysis is to be provided by pharmaceutical companies and is verified by the Categorisation Committee.

In setting reimbursement level, besides the criteria mentioned earlier (cf. 4), pharmacoeconomics is also used.

As already mentioned, the therapeutic value is a ranking based on the pharmaceutical's position in disease therapy, its effectiveness, safety, causality or symptomatic affect on the disease, as well as the abovementioned pharmacoeconomic information (4.2.1). Moreover, the social value is a ranking based on the seriousness of the illness, the risk of misuse of the pharmaceutical (from the point of view of overspending) and the budget impact on insurance costs. These criteria have been valid since 2004 and represent the basic considerations for the Categorisation Committee as an advisory body for the Ministry of Health.

5.5 Generics

The share of generic pharmaceuticals in Slovakia has been rather high for a long time. According to figures from the State Institute for Drug Control (SUKL), the share of generics in term of value rose from 44% in 2003 to almost 50% in 2005. In terms of volume, the generic market shares amounted to 65%. Table 5.1 gives an overview of the market share of generics in volume and value.

Pricing of generics has already been explained (cf. 3.4.2).

According to Act 577/2004 (Act on Scope of Health Care Services), medical doctors and pharmacists are obliged to prescribe the cheapest medically equal effective therapeutic alternatives. Medical doctors and pharmacists are expected to inform the patients of the price of prescribed pharmaceuticals and possible co-payments generated from the reimbursement list. Medical doctors are obliged to inform patients of cheaper identical pharmaceutical (with the same active ingredient), with less or no co-payment. Pharmacists are authorised to offer and substitute interchangeable product (according to the respective Decree of the Ministry of Health) with the same active ingredient, unless this has been prohibited by a medical doctor. Generics are mainly seen as an effective cost-containment tool and are comparable to originals from an effectiveness and safety point of view. Representatives of generics companies, the Ministry of Health and the State Institute for Drug Control (SUKL) promote the use of generics.

The use of generics in the in-patient sector needs still to be increased.

Table 5.1: Slovakia - Development of the generic market in the out-patient sector, 2000-2005

Generic market share (%)	2000	2001	2002	2003	2004	2005
Volume (number of prescriptions per year)	65	63	60	63	65	65
Value	49	48	45	44	48	48

Source: SUKL, Pharmadata

5.5.1 Generic substitution

In Slovakia, generic substitution is allowed as defined in Act 577/2004 (Act on Scope of Health Care Services). Doctors are permitted to prescribe by international nonproprietary name (INN) (active ingredient name); however, this does not often occur in practice, as doctors are not used to this kind of prescription. According to Act 577/2004 (Act on Scope of Health Care Services), medical doctors and pharmacists are obliged to prescribe the cheapest medically equal effective therapeutic alternatives. Medical doctors and pharmacists are expected to inform the patients of the price of prescribed pharmaceuticals and possible co-payments generated from the reimbursement list. Medical doctors are obliged to inform patients of cheaper identical pharmaceutical (with the same active ingredient), with less or no co-payment. Pharmacists are authorised to offer and substitute

interchangeable product (according to the respective Decree of the Ministry of Health) with the same active ingredient, unless this has been prohibited by a medical doctor.

Generic substitution is carried out on a voluntary basis even though it is mentioned in legal regulations.

5.5.2 Generic prescription

When prescribing a pharmaceutical, medical doctors are to inform the patients of the price of prescribed pharmaceutical and possible co-payments generated from the reimbursement list. Medical doctors are obliged to inform patients of cheaper identical pharmaceutical (with the same active ingredient), with less or no co-payment. When dispensing, pharmacists are authorised to offer and substitute interchangeable product (according to the respective Decree of the Ministry of Health) with the same active ingredient, unless this has been prohibited by a medical doctor.

Insurance companies should monitor the prescribing habits of contracted medical doctors in the out-patient sector and one of the indicators for doing this is the ratio of generics to originals that are prescribed.

5.5.3 Generic promotion

Generics are mainly seen as an effective cost-containment tool and comparable to originals from an effectiveness and safety point of view. Representatives of generics companies, the Ministry of Health and the State Institute for Drug Control (SUKL) promote the use of generics.

Generic promotion is enforced by the Association of Generic Producers (GENAS). The process of reimbursement of pharmaceuticals is based on effective use of interchangeable pharmaceuticals with a lower price. Therefore, cheaper pharmaceuticals at Anatomic Therapeutic Chemical ATC-5 level (with the same active ingredient) are in a better position from a co-payment point of view, as more expensive pharmaceuticals in the cluster are reimbursed to the level of the cheaper alternative. Any co-payment that is generated then has to be paid by the patient.

5.6 Consumption

The Ministry of Health and the State Institute for Drug Control (SUKL) provide the analysis on pharmaceuticals consumption from:

- regular wholesaler reports to the State Institute for Drug Control (SUKL);
- regular detailed information on pharmaceutical consumption from pharmacies (electronic data sent from every pharmacy to insurance companies, and for over-the-counter (OTC) pharmaceuticals to the National Institute for Statistics (compulsory for over-the-counter (OTC) pharmaceuticals reports from pharmacies from 2006).

Specific programmes have been routinely used for modelling pharmaceuticals consumption prospectively by the Ministry of Health and the State Institute for Drug Control (SUKL).

Insurance companies provide analysis on pharmaceuticals consumption by diagnosis, by doctor and by dose of the prescribed pharmaceuticals. These analyses are used to various extents, differing from one insurance company to other, to monitor the prescribing habits of specific doctors and to set prescription limits to enable comparison of the prescribing habits of various doctors. Quality indicators are being considered, based on selected criteria, for provision of care in the Slovakian health care system. In pharmaceutical policy, e.g. generics vs originals, the ratio of prescribed pharmaceuticals to generics is monitored by insurance companies in order to promote the use of generics, where possible.

In the List of pharmaceuticals, almost 45% of the total 4,967 pharmaceuticals are fully reimbursed or assisted by co-payment up to SKK 20 / € 0.50.

In total, the List of pharmaceuticals comprises 4,967 pharmaceuticals are banded together into 1,648 Anatomic Therapeutic Chemical (ATC) groups at Anatomic Therapeutic Chemical ATC-5 level (this could be differentiated depending on mode of administration or strength of active ingredient).

In each Anatomic Therapeutic Chemical (ATC) group, a list of which is given in Annex 4 of Act 577/2004, at least one pharmaceutical is to be fully covered by public health insurance. In the course of the 2003 reforms, the number of Anatomic Therapeutic Chemical (ATC) groups with at least one pharmaceutical mandatorily fully reimbursed was radically reduced to 122 groups, resulting in more pharmaceuticals in any one group.

The insurance company is always authorised to make a reimbursement decision outside of the guidance of the List of Pharmaceuticals, on an individual basis.

6 Current challenges and future developments

Costs from public funds increased yearly by more than 10% prior to 2003.

Moreover, from 2003 changes in pharmaceutical policy have been carried out in order to ensure the quality and safety of pharmaceuticals under a limited budget.

Table 6.1: Slovakia - Key figures on pharmaceuticals

Absolute numbers	2000	2001	2002	2003	2004	2005	2006 est.
A. Cost of pharmaceuticals in Mio. SKK (insurance + patients)	16,728	18,463	21,450	22,812	23,046	25,734	27,800
B. Insurance companies from A. in Mio. SKK	15,328	16,935	19,625	20,879	19,951	22,640	24,800
C. Patients from A. in Mio. SKK	1,400	1,528	1,825	1,933	3,095	3,094	3,100
D. Expired pharmaceuticals in pharmacies in kg	25,000	37,823	41,627	40,395	40,087	44,729	n.a.
E. Number of prescriptions (average) in Mio.	49.2	48.8	49.4	45.8	40.6	42.0	44.0
F. Number of reimbursable pharmaceuticals in packs	4,650	4,640	4,600	4,503	4,415	4,533	4,600
G. Number of pharmaceuticals fully reimbursed in packs	1,669	1,368	1,036	1,167	1,362	1,477	1,500

n.a. = not available

Source: Health Information Institute, Slovakia, data from sick funds

However, follow-up action is needed to tackle further challenges in the reimbursement process.

6.1 Current challenges

Current challenges that the Slovakian pharmaceutical system seems to be facing include the new molecules (or rather “innovative pharmaceuticals”), which are very often quite expensive. In the current procedure the decision on whether the pharmaceutical should enter into the List of pharmaceuticals could be made (and this was very often the case in recent years) within 180 days of application, including price setting. However, this needs thorough re-evaluation in terms of the cost–benefit ratio.

It is a positive trend that almost all up-to-date innovative active ingredients are available in Slovakia, but it is clearly yet to be proven whether the total rising pharmaceutical expenditure (PE) is for the benefit of the patients.

Frequent changes in the reimbursement system, quarterly re-evaluation and other fluctuations in the system seem to be confusing for the doctors, patients, pharmacists and wholesalers.

Introducing the transparency reimbursement and coverage policy system was considerable step in the development process.

6.2 Future developments

Future development aims are based on decisions made by the current government.

More sophisticated evaluation of new molecules or new indications (“innovative pharmaceuticals”) is under discussion.

Establishing a new working group under the Categorisation Committee is being considered. This working group “on economic evaluation” is going to be used for alternative evaluation of pharmaceuticals from a purely scientific perspective.

Fast-track entry into the reimbursement system will be retained (cf. 4.2.2), but it will be modified in order that no automatic procedure will decide on the reimbursement level – the Categorisation Committee will decide the reimbursement level.

The frequent publishing of a new List of pharmaceuticals will also be retained – quarterly – but re-evaluation of pharmaceuticals already on the list will take place only twice per year, in order not to confuse health care providers and patients with quarterly changes.

Abolishing fixed co-payments generated in the List of pharmaceuticals (the difference between higher prices and the reimbursement level) is currently being considered. For this to happen, Act 577/2004 needs to be changed. In addition, it is expected that the possibility of providing natural discounts will be reintroduced, by changing Act 140/2004.

7 Appendices

7.1 References

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Until the approval of six reform laws in the Slovak Parliament, MUDr. Rudolf Zajac, 2004.

7.2 Further reading

7.3 Web links

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www.nczisk.sk, www.slaspo.sk, www.slek.sk, www.fpharm.uniba.sk, www.fmed.uniba.sk,

7.4 Authors

Ján Mazag (PharmDr.) graduated from his studies of clinical pharmacy at the Pharmaceutical Faculty of Comenius University in Bratislava, Slovakia in 1983. In 1984, he successfully passed the rigorous examination to become Doctor of Pharmacy. He has worked in pharmaceutical research (Drug Research Institute, Modra), in a pharmaceutical regulatory agency (State Institute for Drug Control (SUKL)), and in the pharmaceutical industry. From 2003, he was appointed as Director General of the pharmaceutical policy section within the Ministry of Health of the Slovak Republic. He has participated in legislative work in the pharmaceutical policy section and has experience in the process of pricing and reimbursement of pharmaceuticals in Slovakia. In March 2006, he was appointed as a General Manager of the State Institute for Drug Control (SUKL). Jan Mazag (PharmDr.) speaks fluent English and Russian. He is a member of the Commission of Human Medicine Products of the European Medicine Evaluation Agency (EMA) and, as an expert in pharmaceutical policy from the Slovak Republic he works with European Union (EU) and Organisation for Economic Co-operation and Development (OECD) representatives on projects dealing with the pharmaceutical evaluation processes.