ÖBIG

Pharmaceutical Pricing and Reimbursement Information

LITHUANIA

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Pharma Profile

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Executive Summary

The population of Lithuania is approximately 3.4 Mio. It is one of the smallest countries in Europe, except for Latvia, Estonia and Malta. The health care system in Lithuania has been gradually transformed from a centralised Semashko model to a social health insurance (SHI) system after the political changes of the year 1990. Life expectancy of Lithuanian inhabitants is significantly shorter than that of the inhabitants of most of European Union (EU) countries. However, the economic situation is improving and Lithuania shows the one of the highest economic growth trends in the European Union (EU). The pharmaceutical market is in the hands of private owners – most pharmacies and all wholesalers are private. The pharmaceutical market in Lithuania is growing. Pharmaceuticals are reimbursed to socially insured people, regardless of their income, for diseases that are included in a List of Diseases. The relatively short list of pharmaceuticals is reimbursed to retired people and disabled people, regardless of the disease they have. Expenditure on pharmaceutical reimbursement is growing. Chapters 3 and 4 cover the main principles of inclusion of new pharmaceuticals (new International Nonproprietary Names (INN)) to the reimbursement system; calculation of pharmacy retail prices (PRP) of reimbursed pharmaceuticals; reimbursed pharmaceutical product base price calculation; reference pricing; and reimbursement levels that are used in Lithuania. The main principles of pharmaceutical market regulation and methods for controlling the expenditure of the country's State Patient Fund (SPF) are also explained in the profile. Principles of rational use of pharmaceuticals are developed in treatment guidelines, generics policy and other measures. Since 2004, reimbursed pharmaceuticals are prescribed according to International Nonproprietary Name (INN) and pharmacies are obliged to inform the patient about prices and co-payments and to offer the cheapest alternative. The greatest challenge now is the implementation of the new Law on Pharmacy

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List of abbreviations

ATC	Anatomic Therapeutic Chemical classification
CIP	Carriage and Insurance Packaging
CIS	Commonwealth of Independent States
DDD	Defined Daily Dose
EC	European Commission
EU	European Union
GCP	Good Clinical Practice
GDP	Gross Domestic Product
GGE	General Government Expenditure
GMP	Good Manufacturing Practice
GP	General Practitioner
HE	Health Expenditure
INN	International Nonproprietary Name
Mio.	Million
MoH	Ministry of Health
NCU	National Currency Unit
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
OTC	Over-The-Counter (pharmaceuticals)
PhD	Department of Pharmacy
PIL	Patient Information Leaflet
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
SHI	Social Health Insurance
SMCA	State Medicine Control Agency
SPC	Summary of Product Characteristics
SPF	State Patient Fund
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
UN	United Nations
VAT	Value-Added Tax
VHI	Voluntary Health Insurance
WHO	World Health Organization
WTO	World Trade 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

The population of Lithuania is approximately 3.4 Mio. It is one of the smallest countries in Europe aside from Latvia, Estonia and Malta. The number of inhabitants in Lithuania is on the decrease since the mid-1990s. This process is caused by the emigration of the population and negative natural increase. Data are taken from the Department of Statistics under the Government of Lithuania (www.stat.gov.lt).

The land area of Lithuania is 65,300 km^2. The population density is on average 52.6 inhabitants per km^2 (in 2004). However, the distribution is not even. In the capital, Vilnius, the density is much higher than in the other parts of the country. Vilnius has approximately 541,824 inhabitants (2005), Kaunas has 360 637, and Klaipeda has 187 316. The division between urban and rural population is 66.6% and 33.4%, respectively (in 2004).

Life expectancy, which is the most important health indicator, has decreased slightly in 2005. The average life expectancy was 77.42 years for females and 65.36 years for males. A pronounced difference in the average female and male life expectancies is still noticed: males live for 11.4 fewer years than females. A particularly big difference is noticeable among the rural male and female population (12.6 years). Since the early 2000s, life expectancy for males has decreased by 1.41 years and life expectancy for female has increased marginally (by 0.03 years). Life expectancy of Lithuanian women is close to the average of all European Union (EU) Member States (EU25), but life expectancy of Lithuanian men is shorter than the European average. The (total) life expectancy of Lithuanian inhabitants is significantly shorter than that of the inhabitants of most of the European Union (EU) countries. Among all the European Union (EU) Member States (EU25) only Estonian and Latvian inhabitants have a shorter life expectancy than Lithuanians.

The structure of causes of death in Lithuania is similar to that of economically developed countries and has not changed for many years. Most deaths occur as a result of three main causes, i.e. circulatory system diseases, malignant neoplasms and external causes. Diseases of the circulatory system are the most widespread cause of death, resulting in 54.4% of all deaths. The majority (67.1%) of all people dying from diseases of the circulatory system are in the age group 64 years or older. Malignant neoplasms cause 18.4% of all deaths. Male deaths from cancer are 1.2 times more frequent than females, and rural population deaths from cancer are 1.4 times more frequent than those among the urban population. External causes accounted for 8.5% of deaths in 2005, affecting males 3.5 times more than females. Suicides were the most widespread external cause of death (23.7% of all deaths from external causes), while 15.9% died from traffic accidents and 8.2% from alcohol poisoning. The suicide rate in Lithuania is one of the highest in Europe.

Table 1.1: Lithuania - Demographic indicators 1995, 2000, 2003 and 2005

Variable	1995	2000	2003	2005
Total population	3,629,1 00	3,499,500	3,454,200	3,414,300*
Population density per km^2	55.6	53.6	52.9	52.3
Population aged 0-14 (as a % of total)	n.a.	n.a.	n.a.	17.07
Population aged 15-64 (as a % of total)	n.a.	n.a.	n.a.	67.82
Population aged > 64 (as a % of total)	n.a.	n.a.	n.a.	15.09
Life expectancy at birth, total	69.08	72.19	72.19	71.32
Life expectancy at birth, females	75.06	77.45	77.85	77.42
Life expectancy at birth, males	63.27	66.77	66.48	65.36

Sources: Department of Statistics under the Government of Lithuania (http://www.stat.gov.lt); Lithuanian Health Information Centre (http://www.lsic.lt).

1.2 Economic background

In 2003, prior to joining the European Union (EU), Lithuania had the highest economic growth rate amongst all candidate countries and Member States, reaching 8.8% in the third quarter. In 2004, the rate was 7.3%; in 2005 it was 7.6%; and in the second quarter of 2006 the rate of 8.4% growth in gross domestic product (GDP) reflected impressive economic development (http://www.stat.gov.lt/en/). Most of Lithuania's trade is conducted within the European Union (EU).

In 2005 the country's gross domestic product (GDP) grew by 7.5%, and the inflation rate was 3%.

Lithuania is a member of the World Trade Organization (WTO) and the European Union (EU). By United Nations (UN) classification, Lithuania is a country with a high average income. The country boasts a well-developed modern infrastructure of railways, airports and 4-lane highways. It has almost full employment, with an unemployment rate of only 2.9%. According to officially published figures, European Union (EU) membership fueled a booming economy, increased outsourcing into the country, and boosted the tourism sector. The national currency, the Lithuanian litas (LTL), has been pegged to the € since 2 February 2002 at the rate of € 1.00 = LTL 3.4528 (http://www.lb.lt/home/default.asp), and Lithuania is expected to switch to the € on 1 January 2009.

Like other countries in the region (e.g. Estonia, Latvia) Lithuania also has a flat tax rate rather than a progressive scheme. Lithuanian income levels still lag behind the income levels of the European Union (EU) Members States belonging to the EU before May 2004 (EU15), with per-capita gross domestic product (GDP) in 2006 at 56% of the European Union (EU) average.

Lower wages may have been a factor that in 2004 influenced the trend of emigration to the wealthier European Union (EU) countries, something that has been made legally possible as a result of accession to the European Union (EU). In 2006, income tax was reduced to 27% and a further reduction to 24% is expected in October 2007. The country's income tax reduction and a 14% annual wage growth are starting to make an impact, with some emigrants gradually beginning to return to Lithuania. The latest official data show emigration in early 2006 to be 30% lower than the previous year, at 3,483.

Lithuania has one ice-free seaport, Klaipeda, with ferry services to German, Swedish, and Danish ports. There are a few commercial airports; scheduled international services use the facilities at Vilnius, Kaunas, and Klaipeda. The road system is well developed, including the Via Baltica highway passing through Kaunas. Border facilities at checkpoints with Poland were significantly improved with the help of European Union (EU) funds, but long waits are still a frequent phenomenon. Telecommunications have improved greatly since independence as a result of heavy investment. There are currently three large companies providing mobile phone services. The economy of independent Lithuania had a slow start, as the process of privatisation and the development of new companies slowly moved the country from a command economy towards a free market. By 1998, the economy had survived the early years of uncertainty and several setbacks, including a banking crisis, and seemed poised for solid growth. However, the collapse of the Russian ruble in August 1998 shocked the economy into negative growth and forced the reorientation of trade from Russia towards the West. Since the Russian monetary crisis, the focus of Lithuania's export markets has shifted from East to West. In 1997, exports to former Soviet states made up 45% of total Lithuanian exports. In 2005, exports to the east were only 18% of the total, while exports to European Union (EU) Member States amounted to 65%.

Exports to the United States make up 4.7% of all of Lithuania's exports, and imports from the United States comprise 2% of total imports. Foreign direct investment in 2005 was LTL 2.6 billion, which represented an increase of only 4.6% compared to the same period in the previous year.

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

Variable (in NCU or %)	1995	2000	2001	2002	2003	2004	2005
GDP in NCU (Mio.)	25,956	45,674	48,585	51,971	56,804	62,587	71,200
GDP per capita in NCU	n.a.	13,502	13,956	14,981	16,445	18,217	20,854
GDP per capita in PPPa	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Growth rate 1995-2000	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Growth rate 1995-2005	n.a.	4.1	6.6	6.9	10.3	7.3	7.6
GGE (Mio. €)	n.a.	9,468	9,987	11,673	12,489	14,560	17,062
GGE as a % of GDP	n.a.	20.7	20.6	22.5	22.0	23.3	24.0
Exchange rate (NCU per €), annual rate	n.a.	3.6990	3.5849	3.4605	3.4528	3.4528	3.4528

GDP = gross domestic product, GGE = general government expenditure, PPPa = purchasing power parity, NCU = national currency unit (LTL)

Sources: Department of Statistics under the Government of Lithuania (http://www.stat.gov.lt).

1.3 Political context

Since Lithuania declared independence on 11 March 1990, it has kept strong democratic traditions. In the first general elections after independence on 25 October 1992, 56.75% of the total number of voters supported the new Constitution (http://en.wikipedia.org/wiki/Lithuania - _note-8#_note-8). Drafting the Constitution was a long and complicated process. The role of the President fueled the most heated debates. Drawing on interwar experiences, politicians made many different proposals ranging from strong parliamentarism to the United States' model. Eventually a compromise – a semi-presidential system – was agreed upon.

The Lithuanian Head of State is the President, elected directly for a 5-year term; s/he may serve a maximum of two consecutive terms. The post of President is largely ceremonial, including certain functions, e.g. overseeing foreign affairs and national security policy. The President is also the Commander-in-Chief. With the approval of the parliamentary body and the unicameral Lithuanian Parliament (*Seimas*), the President also appoints the Prime Minister and on the latter's nomination, appoints the rest of the Cabinet, as well as a number of other top civil servants and the judges for all courts. The judges of the Constitutional Court (*Konstitucinis Teismas*), who serve for 9-year terms, are appointed by the President (three judges), the Chairman of the Parliament (three judges) and the chairman of the Supreme Court (three judges).

Members of Parliament are elected for a 4-year term in 72 single-member constituencies and one multi-member constituency on the basis of universal and equal suffrage, by secret ballot in direct, mixed-system elections. A total of 141 Members of Parliament are elected: 71 in single-member constituencies and 70 in the multi-member constituency (Central Electoral Committee). Under the Constitution of the Republic of Lithuania of October 1992, the Parliament is com-

posed of 141 Members of Parliament who are elected for a 4-year term in one-candidate or multi-candidate electoral areas on the basis of universal and equal suffrage by secret ballot in direct mixed-system elections.

The Parliament meets annually in two regular sessions: a spring session (10 March-30 June) and an autumn session (10 September-23 December). Extraordinary sessions can be convened by the Chairman of the Parliament upon the proposal of at least 1/3 of all Members of Parliament, or, in cases provided for in the Constitution, by the President of the Republic.

The main powers of the Parliament are to:

- consider, adopt and issue laws, and make amendments to the Constitution;
- approve or reject the candidature of the Prime Minister nominated by the President of the Republic;
- discuss and approve the programme of the Government and supervise its policy;
- approve the state budget, supervise its implementation and establish state taxes;
- announce presidential elections and municipal elections;
- ratify international treaties, and discuss other important issues of foreign policy.

Parliament elects committees from among its members to explore drafts for legislation and to clarify other issues in accordance with the Constitution. Parliamentary commissions (both standing and ad hoc) are formed to carry out short-term or limited assignments.

The *Seimas* Statute (Parliamentary Statute) defines the Members of Parliament's duties and rights and has legal power. The Assembly of Elders composed of members of the *Seimas* Board (Parliamentary Board) and representatives of the Parliamentary Groups considers the work programmes of the Parliament session and approves of the draft agendas of week- or day-long sittings, along with coordinating the organisation of the work of the Parliament.

In Lithuania the political system is a centralised federal system. The local municipalities are responsible for implementing laws. The configuration of the current Government is a coalition of three parties: the Social Democratic Party, the Civil Democracy Party and the Peasants and People's Political Party.

1.4 Health care system

This section provides an overview of the organisation of the Lithuanian health care system and also outlines the main actors, their roles and their decision-making powers within the health care system.

1.4.1 Organisation

The health system of the Republic of Lithuania is regulated by the following legal acts: the Law on the Health System of 19 July 1994, the Law on Health Insurance of 21 May 1996, and the Law on Pharmacy of 22 June 2006. The principles of the Lithuanian health care system, its relevant institutions and their responsibilities are set out in the Law on the Health System.

The Law on Health Insurance establishes the types of health insurance in Lithuania, and the compulsory health insurance system: people covered by compulsory health insurance; principles of the Compulsory Health Insurance Fund formation; and compensation of individual health care service costs with Compulsory Health Insurance Fund resources, etc. It is a state-established system of individual health care and economic measures which guarantee the provision of individual health care services to people covered by compulsory health insurance, and reimbursement of the costs of the services provided, including pharmaceuticals and medical aids in the case of insured events.

People not covered by compulsory health insurance are guaranteed only essential medical assistance. For any other services they have to pay the price set by the Ministry of Health (MoH). The Law on Health Insurance provides for additional (voluntary) health insurance (VHI), but it is not yet popular in Lithuania and is used only by a small number of people with exceptionally high income. Compulsory health insurance is managed by one state institution – the State Patient Fund (along with the five Territorial Patient Funds), under the Ministry of Health (MoH). It provides compulsory health insurance to all residents of Lithuania, irrespective of their nationality. The funds at the disposal of the health sector of the Republic of Lithuania make up approximately 6% of gross domestic product (GDP). The costs of the following individual health care services are covered by the Compulsory Health Insurance Fund budget: preventive medical assistance, medical assistance, medical rehabilitation, nursing, social services attributed to individual health care, compensation for people covered by insurance for the costs of pharmaceuticals and medical aids, etc.

1.4.2 Funding

Health expenditure (HE) is financed primarily through health insurance contributions but also through voluntary health insurance (VHI) and out-of-pocket payments (OPP). The budget for the Compulsory Health Insurance Fund is drawn up each calendar year by the State Patient Fund (SPF). Compulsory health insurance revenue consists of: (1) compulsory health insurance contributions from and for the covered persons; (2) national budget contributions for the covered persons insured with public funds; (3) earnings of the institutions providing compulsory health insurance; (4) additional allocations from the national budget; 5) voluntary contributions from natural and legal persons, etc.

When approving the annual state budget, the Parliament also approves the amount of contributions that are to be transferred to the Compulsory Health Insurance Fund per person insured by public funds (not less than 3.5% of the average monthly income, calculated under the procedure prescribed by the relevant legal acts). The payers of compulsory health insurance contributions, the amounts of the contributions and the procedure for payment are set out in the Law on Com-

pulsory Health Insurance. The amount of compulsory health insurance contributions, depending on the payer, constitutes either: 1.5% (of the minimum monthly wage); 3% (of the wage), 3.5% (of the minimum monthly wage); 10% (of the average monthly wage for the national economy); or 30% (of the calculated amount of income tax).

In 2003 the State Patient Fund (SPF) spent € 186.8 on average per insured person. Visits to a doctor, treatment at a hospital (including pharmaceuticals) and rehabilitation are fully reimbursed by the Compulsory Health Insurance Fund.

Those who are not insured may apply only for necessary medical assistance, and must pay for other services at the prices set by the Ministry of Health (MoH).

Funds used by the health sector in Lithuania make up approximately 6% of the gross domestic product (GDP).

Additional private health insurance is foreseen in the Health Insurance Law. However, it is still not popular in Lithuania and is only used by a small proportion of the population with high incomes.

The mission of the Ministry of Health (MoH) is to form and implement health policy, overseeing public health, ensuring a high quality of health services and the rational use of resources.

Table 1.3: Lithuania - Health expenditure (HE) 1995, 2000-2005

Health expenditure (HE)	1995	2000	2001	2002	2003	2004	2005
THE in NCU (Mio.)	1242.7	2727.7	2750.3	3063.0	3226.9	3478.2	4065.8
THE as a % of GDP	4.79	5.97	5.66	5.89	5.68	5.56	5.71
THE per capita in NCU	342.4	779.4	790.0	882.9	934.2	1,012.4	1,190.8
Public HE as a % of THE	86.3	72.4	71.7	68.3	69.0	68.2	70.0
Private HE as a % of THE	13.7	27.6	28.3	31.7	31.0	31.8	30.0

GDP = gross domestic product, HE= health expenditure, THE = total health expenditure, NCU = national currency unit (LTL)

Source: Lithuanian Health Information Centre (http://www.lsic.lt/)

1.4.3 Access to health care

1.4.3.1 Out-patient care

There are two main types of out-patient clinic in Lithuania: independent general practitioners (GPs) and integrated practices (where general practitioners (GPs) and first-level specialists are working together). The number of integrated clinics has progressively reduced. All people have access to primary pharmaceutical care by general practitioners (GPs). General practitioners (GPs) decide on any further consultations with specialists. Care for some patient groups (oncology, haematological) can be carried out by specialists. The patient is free to choose the family

doctor and s/he is always free to change doctor. The family doctor (GP) sends the patient to the specialist.

Primary care is provided in private and municipality health centres and polyclinics. Primary care physicians are remunerated on a capitation basis and act as gatekeepers to specialist services. The Ministry of Health (MoH) sets the fees for medical services and all primary care facilities have to offer services at these fees. Almost all hospitals and polyclinics are in public hands.

The majority of general practitioners' (GP) practices are private. The majority of specialists in out-patient care practise publicly (e.g. endocrinologists, cardiologists, etc.). General practitioners (GPs) work as gatekeepers for access to specialists and hospital care. The general practitioner (GP) abilities and competences are described in the Medicinal Standard "Family doctor – rights, functions, competences and responsibility", confirmed by Order of the Minister of Health in 2005. Family doctors are paid by capitation fees from the Compulsory Health Insurance Fund. There is a fixed sum for every patient registered to the family doctor. This sum is administered annually. The specialists' services in out-patient care are paid by the Compulsory Health Insurance Fund according to the number of services provided. There are some out-of-pocket payments (OPP) for medical services in out-patient care (services not covered by compulsory health insurance). The patient must pay if s/he comes to the specialist without referral from a general practitioner (GP).

Table 1.4: Lithuania - Out-patient care 1995, 2000-2005

Variable	1995	2000	2001	2002	2004	2005
Total no. of doctors[1]	14,737	14,034	14,031	13,856	13,397	13,650
No. of doctors[1] per 1,000 inhabitants	4.08	4.02	4.04	4.00	3.91	4.01
Total no. of out-patient doctors	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
of which GPs	n.a.	692	897	1,150	1,665	1,730
of which dentists	1,742	2,446	2,490	2,309	2,272	2,453
No. of out-patient doctors per 1,000 inhabitants[2]	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of out-patient clinic departments ("ambulatories")	n.a.	n.a.	n.a.	n.a.	432	438

[1] excluding retired and non-practising doctors

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

Source: Report of Lithuanian Health Information Centre "The health of citizens of Lithuania and activity of health care institutions in 2005", Vilnius 2006 (Lietuvos Sveikatos informacijos centras "Lietuvos gyventojų svaikata ir sveikatos priežiūros įstaigų veikla 2005 m.", Vilnius 2006".

1.4.3.2 In-patient care

In-patient care institutions are mostly organised as public institutions. There are only few private in-patient care institutions; public non-profit-making health care institutions dominate. There are three different levels of in-patient care services. The highest (third) level of health care services are provided in the biggest hospitals (university and some municipal hospitals). Second-level in-

patient care services are provided in major cities offering specialist care in different medical departments. First-level in-patient care services – the simplest services – can be given in all in-patient health care institutions. Hospitals are spread thorough the country. They have no specialisation, excluding specific hospitals, e.g. tuberculosis treatment hospitals. All in-patient services covered by compulsory health insurance are fully reimbursed. Out-of-pocket payments (OPP) are only paid for services which are not covered by compulsory health insurance, e.g. cosmetic surgery. Doctors are employees of in-patient health care institutions and are paid by hospitals.

Hospitals are remunerated according to the health care services provided to the patients (fee-for-service payments). Hospitals are funded by the Compulsory Health Insurance Fund and can receive money from regional budgets and, for health programmes, from the Ministry of Health (MoH).

Table 1.5: Lithuania - In-patient care 1995, 2000-2005

Variable	1995	2000	2001	2002	2004	2005
No. of in-patient doctors[1]	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of in-patient doctors per 1,000 inhabitants	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of hospitals	195	187	189	188	181	173
No. of acute care beds	40,262	34,145	32,104	31,031	28,972	27,727
of which in private sector	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Acute care beds per 1,000 inhabitants	11.05	9.76	9.24	8.94	8.43	8.12
Average length of stay in hospital	n.a.	11.2	10.9	10.3	10.2	10.2

[1] excluding retired and non-practising doctors

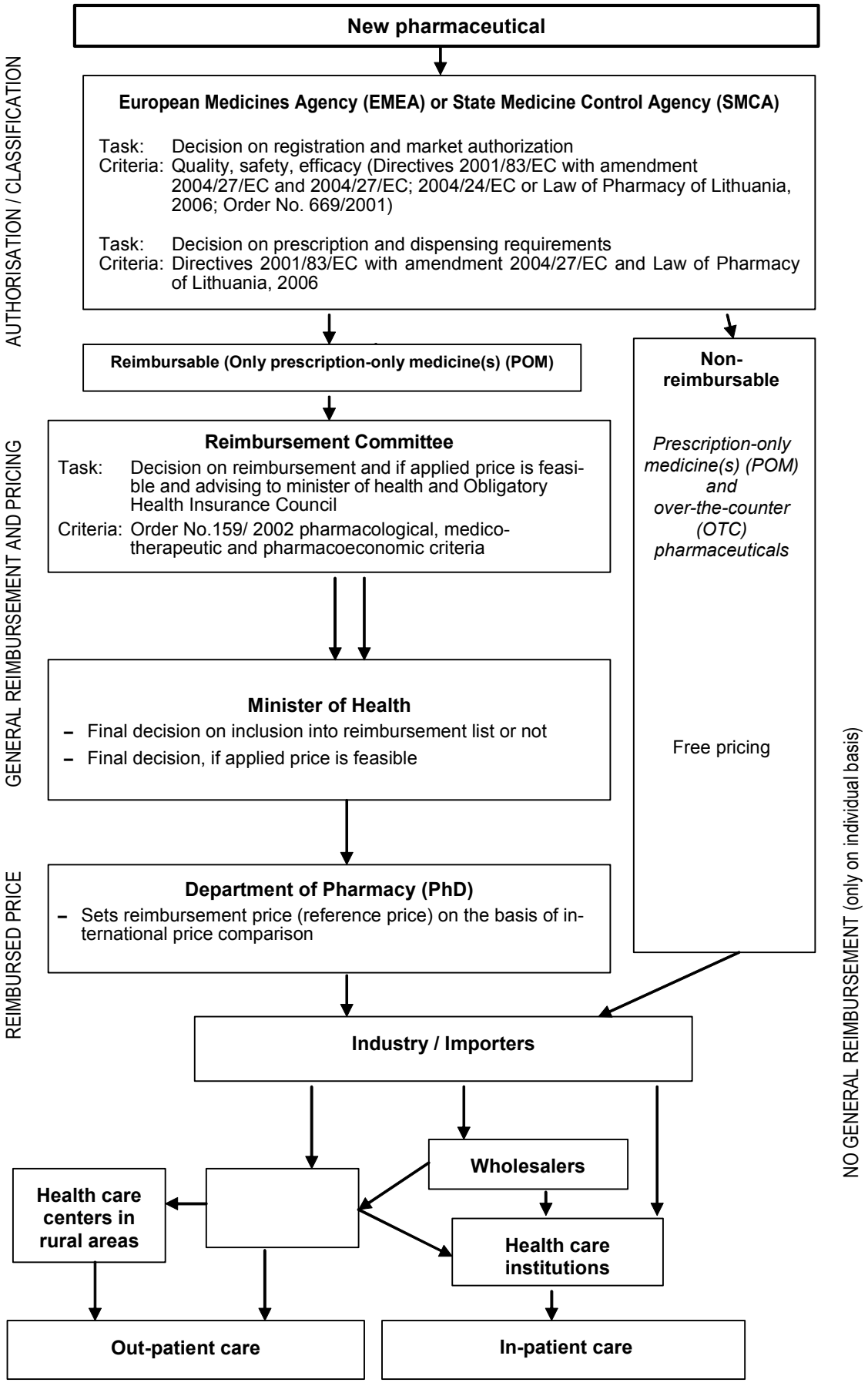
Source: Department of Statistics under Government of Lithuania (http://www.stat.gov.lt); Lithuanian Health Information Centre (http://www.lsic.lt/)

2 Pharmaceutical system

2.1 Organisation

The following section includes a description of the regulatory framework (legal basis, main authorities and their tasks) of the Lithuanian pharmaceutical system and of the country's pharmaceutical market (data, key players, etc.).

Figure 2.1: Lithuania - Flowchart of the pharmaceutical system


New pharmaceutical
AUTHORISATION / CLASSIFICATION
European Medicines Agency (EMEA) or State Medicine Control Agency (SMCA)
Task: Decision on registration and market authorization
Criteria: Quality, safety, efficacy (Directives 2001/83/EC with amendment 2004/27/EC and 2004/27/EC; 2004/24/EC or Law of Pharmacy of Lithuania, 2006; Order No. 669/2001)
Task: Decision on prescription and dispensing requirements
Criteria: Directives 2001/83/EC with amendment 2004/27/EC and Law of Pharmacy of Lithuania, 2006
Reimbursable (Only prescription-only medicine(s) (POM)
Non-reimbursable
GENERAL REIMBURSEMENT AND PRICING
Reimbursement Committee
Task: Decision on reimbursement and if applied price is feasible and advising to minister of health and Obligatory Health Insurance Council
Criteria: Order No.159/ 2002 pharmacological, medico-therapeutic and pharmacoeconomic criteria
Prescription-only medicine(s) (POM) and over-the-counter (OTC) pharmaceuticals
Minister of Health
– Final decision on inclusion into reimbursement list or not
– Final decision, if applied price is feasible
Free pricing
REIMBURSED PRICE
Department of Pharmacy (PhD)
– Sets reimbursement price (reference price) on the basis of international price comparison
NO GENERAL REIMBURSEMENT (only on individual basis)
Industry / Importers
Wholesalers
Health care centers in rural areas
Health care institutions
Out-patient care
In-patient care

Source: Law of Pharmacy 2006, Order of MoH No. 669, 2001, Order of MoH No. 159 (V-91), 2002, Order of MoH No. 459, 2000, Law on Health Insurance, 1996.

2.1.1 Regulatory framework

This section includes a description of the legal framework for pharmaceutical policy, including the principal authorities and the important players in this framework, and their roles.

2.1.1.1 Legislation

Several pieces of legislation regulate pharmaceutical activity in the Republic of Lithuania. The major laws, Government Resolutions and Orders of the Ministry of Health are as follows:

- Law on Pharmacy, 22 June 2006, No. X-709;
- Law on the Health System, 19 July 1994, No. I-552;
- Law on Health Insurance 21 May 1996, No. I-1343;
- Law on the control of narcotic and psychotropic substances, 8 January, 1998, No. VIII – 602);
- Law on the control of precursors of narcotic and psychotropic substances, 1 June 1999, No. VIII – 1207;
- Law on advertising, 18 July 2000, No. VIII – 1871;
- Government Resolution on the rules of licensing of enterprises which engage in pharmacy activity, 30 November 2006, No.1192;
- Government Resolution on the Approval of the Regulations of Issuing Licences to Produce, Import into the Republic of Lithuania and Export from the Republic of Lithuania Narcotic and Psychotropic Substances, to Engage in their Wholesale and Retail trade in the Republic of Lithuania, 28 December 1995, No. 1630;
- Order No. 342/482 of the Minister of Health and Ministry of the Interior on requirements for establishing premises for manufacture and storage of narcotic and psychotropic substances, 25 August 1998;
- Order No. 459 of the Minister of Health on procedure for the calculation and application of prices for pharmaceuticals, active substances and pharmacy goods, 12 August 2000 (being revised at the time of writing);
- Order No. 159 (V-91) of the Minister of Health on modification of the list of diseases and pharmaceuticals reimbursed for their treatment, the list of reimbursed pharmaceuticals and the list of reimbursed medicinal aids, 5 April 2002 (new rules to be confirmed January 2006) (draft prepared 12 February 2007);
- Order No. 669 of the Minister of Health concerning conformation of general regulations for granting market authorisation, 22 December 2001(being revised at the time of writing);
- Order No. 308 (V-596) of the Minister of Health concerning requirements for labelling and packaging leaflets, 29 May 2001(draft prepared 10 June 2007);

- Order No. V-598 of the Minister of Health concerning publications with possibilities for advertising of prescription pharmaceuticals, 8 October 2003;
- Order No. V-268 of the Minister of Health concerning rules of good manufacturing practice for pharmaceuticals, 23 April 2004;
- Order No. 320 of the Minister of Health of the Republic of Lithuania concerning rules of good distribution practice for pharmaceuticals, 5 June 2001;
- Order No. 112 of the Minister of Health concerning writing prescriptions and release (sale) of pharmaceuticals, 8 March 2002;
- Order No. V-7 of the Minister of Health concerning requirements for pharmacies, 7 January 2003;
- Order No V-1128 of the Minister of Health concerning the rules of advertising for pharmaceuticals, 28 December 2006;
- Order No V-1132 of the Minister of Health concerning verification of activities of pharmaceutical enterprises regarding compliance to the requirements of good manufacturing practice for pharmaceuticals, 29 December 2006;
- Order No V-975 of the Minister of Health concerning transportation of pharmaceuticals into Lithuania for personal purposes, 23 November 2006;
- Order No V-1037 of the Minister of Health concerning procedure of information which should be provided by market authorisation holder for promotional expenditure on events (promotional and professional (scientific)) and on health care and pharmacy specialists participating in those events, State Medicine Control Agency (SMCA), 8 December 2006;
- Order No V-1012 of the Minister of Health concerning licensing of pharmacists, 28 November, 2006;
- Order No V-1052 of the Minister of Health concerning registration of pharmacists' assistants, 13 December, 2006;
- Order No V-1011 of the Minister of Health concerning list of products which pharmacies are permitted to sell, 28 December, 2006;
- Order No V-1051 of the Minister of Health concerning storage of pharmaceuticals in hospitals which do not have their own pharmacies, 13 December, 2006;
- Order No V-1053 of the Minister of Health concerning application form for the purpose of obtaining a licence for pharmacy activity,13 December, 2006;
- Order No V-870 of the Minister of Health concerning list of studies with which preparation of pharmaceutical information for advertising is allowed, 23 October, 2006.

Almost all legal acts concerning pharmaceuticals in Lithuania have been updated in compliance with the new Law on Pharmacy (22 June 2006 No. X-709).

2.1.1.2 Authorities

The most relevant player in the Lithuanian pharmaceutical system is the Ministry of Health (MoH), responsible for strategic planning of the pharmaceutical system. Furthermore, the Ministry of Health (MoH) has the final decision on whether a product is reimbursed and at what price.

The main goal of the Ministry of Health (MoH) is to organise the health care system so that accessibility and maximum quality of health care services are ensured by working with existing resources. The strategic goals of the Ministry of Health (MoH) are as follows:

- to ensure public health care by strengthening disease prevention and control;
- to ensure accessible and qualitative health care by improving the performance of health care institutions;
- to ensure that only qualitative, safe, efficacious and cheap pharmaceuticals meeting European Union (EU) requirements are available in the Lithuanian market;
- to ensure effective health care by improving administration and financing of the health care system;
- to ensure effective use of funds allocated to the health care.

Besides its other functions and tasks regarding the health care system, the Ministry of Health (MoH) is to:

- prepare, within its competence, drafts of laws, government resolutions and other legal acts;
- draw up the main guidelines and priorities for the development of the national health care system in Lithuania; license and accredit health care and pharmaceutical activities; issue permits (licences) to engage in treatment, hygienic and pharmaceutical activity; and in the cases provided for by laws also for other professional activities;
- organise and coordinate rational provision of basic pharmaceuticals and medical means to the population of Lithuania; collect and analyse information about pharmaceuticals; compile information on supply and demand of pharmaceuticals; regulate the supply of pharmaceuticals by means of legal measures; register pharmaceuticals; and control the conditions of pharmaceutical activity; and
- establish prices for paid health care services that are provided by health care institutions; establish the mark up when trading in pharmaceuticals, medicinal substances, health care means and costs of the manufacture of pharmaceuticals in pharmacies; control pharmaceutical prices and set norms on acquiring pharmaceuticals in state health care institutions.

The Department of Pharmacy (PhD) is responsible for the implementation of pharmaceutical policy and for ensuring the provision of efficient and safe pharmaceuticals at socially acceptable prices. The main task of the Department of Pharmacy (PhD) is the development of pharmaceutical policy set by the Minister of Health in accordance with the provisions set out in the national laws concerning pharmaceuticals and the health system, as well as the National Programme of Pharmaceutical Policy. The Department of Pharmacy (PhD) carries out the following functions: elaborating of the National Programme of Pharmaceutical Policy; working on the implementation of European Commission (EC) Directives; specialists of Department of Pharmacy (PhD) provid-

ing proposals to the Minister of Health seeking to improve the pharmaceuticals reimbursement system and to reduce expenses related to them; and regularly preparing and publishing pharmaceutical prices in a List of Reimbursed Pharmaceuticals. As commissioned by the Minister of Health, the PhD provides expertise on the legal acts related to pharmaceutical activity and drafted by other state institutions, and provides comments and suggestions within the framework of its competency. Furthermore, the PhD cooperates with the State Medicine Control Agency (SMCA), the State Patient Fund (SPF) and other state authorities and pharmaceutical wholesalers and manufacturers concerning pharmaceutical policy pharmaceutical policy, pharmaceutical advertisement, collection and utilisation of pharmaceutical waste, and non-registered pharmaceuticals (as essential and for individual patient by special prescription), etc. The PhD thus consults the state institutions, pharmaceutical companies and private residents on issues related to pharmaceutical activity.

The State Medicines Control Agency (SMCA) is responsible for controlling pharmaceutical activity in order to ensure the quality, efficacy and safety of pharmaceuticals available in Lithuania, along with pursuing the National Medicines Policy Programme. The State Medicine Control Agency (SMCA) is accountable to the Ministry of Health (MoH). The Director of the State Medicine Control Agency (SMCA) is appointed and dismissed from the position by the Minister of Health. The activities of the State Medicine Control Agency (SMCA) only concern human medicines and products for special medicinal purposes. The control of veterinary medicine and related activities is carried out by the State Food and Veterinary Service of the Republic of Lithuania.

The State Medicine Control Agency (SMCA), carrying out regulatory and control functions, bears the responsibility of granting market authorisation; classification of prescription status; pharmacovigilance; inspecting pharmaceutical industry and pharmaceutical products distribution companies (including pharmacies); controlling the quality of pharmaceuticals and the advertisement of pharmaceuticals; approving clinical trials pharmaceuticals for human use; and performance of good clinical practice (GCP) inspections. According to the new Law on Pharmacy, since 22 June 2006 the State Medicine Control Agency (SMCA) is responsible for the licensing of pharmacy enterprises (manufacturing, distribution and pharmacies) and the licensing of pharmacists. Before this date this task was carried out by a commission at the Ministry of Health (MoH).

The market authorisation process has been fully harmonised in line with European Union (EU) legislation; however, pharmaceuticals that do not conform to European Union (EU) market authorisation requirements may still be marketed in Lithuania until the end of 2006. According to the European Union (EU) Accession Treaty Lithuania has a transitional period for upgrading market authorisations, lasting until 1 January 2007. Therefore, the procedures of market authorisation have been extended. In order to maintain the procedures on time and taking into consideration the workload related to the increasing number of applications, at the beginning of 2007 it the Department of Market Authorisation is to be established (instead of the Market Authorisation Division) involving three Pharmaceuticals Evaluation Divisions divided according to pharmacotherapeutic classes and three Administrative Divisions. It is hoped that this will help to increase the quality of evaluation and also to decrease the timeframe for the procedure.

Market authorisation holders were obliged to submit upgraded documentation for their pharmaceuticals according to the dates indicated in a list issues by the State Medicine Control Agency

(SMCA), so the transitional period is retained. Registration certificates are valid for a period of five years.

The State Medicine Control Agency (SMCA) classifies pharmaceuticals into the categories of prescription-only medicine(s) (POM), with subcategories, and non-prescription medicines (over-the-counter (OTC) pharmaceuticals). There are also categories for homeopathic preparations, food products for special medicinal purposes, and medicated cosmetics. With regard to switching prescription status, the State Medicine Control Agency (SMCA) refers to the European Commission (EC) guidelines, according to which a switch may be initiated by the market authorisation holder or by national authorities.

The registration of homeopathic preparations underlies the general rules of market authorisation for pharmaceuticals; simplified procedures are in place for market authorisation of orally or externally applied preparations without certified therapeutic indications.

The State Patient Fund (SPF) under the Ministry of Health (MoH) is in charge of reimbursement, along with the procurement via a tendering process of pharmaceuticals with high prices.

Patient Funds are independent from the founders of health care institutions (e.g. the Ministry of Health (MoH), counties, municipalities, etc.), which, bearing the responsibility for the health care of the local population, are also responsible for the institutions and personnel working within them. The Patient Funds are responsible for the provision of high-quality medical services to residents and the implementation of the health policy set by the Parliament, Government and Ministry of Health (MoH). Since the Patient Funds have been established, an essential step has been made in striving for more effective management of the system: functions fulfilled by the founders and managers of health care institutions have been separated, and, with the reorganisation of these institutions into public institutions, a system of independent contracts has been developed.

Activities of the State Patient Fund (SPF) are based on provisions of the Law on Health Insurance, laws regulating the state budgetary institutions, and regulations approved by the Ministry of Health (MoH).

The goal of the State Patient Fund (SPF) is to implement the budget of the Compulsory Health Insurance Fund, annually approved by the Parliament of Lithuanian Republic. Main sources of income for the Compulsory Health Insurance Fund’s budget are the following: contributions by the insured to the Compulsory Health Insurance Fund and also contributions paid on their behalf; contributions for the insured payable from the state budget; operational income from institutions engaged in compulsory health insurance activities; subsidies from the state budget as well as voluntary contributions by legal and natural persons. The cost plan for the Compulsory Health Insurance Fund’s budget is implemented by making contracts between the Territorial Patient Funds and providers of services.

The State Patient Fund (SPF) under the Ministry of Health (MoH) coordinates the activities of the five Territorial Patient Funds. The main function of these Territorial Patient Funds is to cover in full or in part the health care services provided to Lithuanian residents, allowing each patient to choose freely a health care institution, and compensating the cost of pharmaceuticals prescribed to the patients. The health care institutions that do not make contracts with the Patient

Funds are not entitled to the resources of the Compulsory Health Insurance Fund budget, and patients receiving medical services at those institutions have to pay for themselves.

An important task of the State Patient Fund (SPF) is defending the interests of patients, so that primary medical assistance is guaranteed to every Lithuanian resident, and so that every taxpayer and state-supported individual receives the services and prescribed pharmaceuticals that the State is currently able to finance.

The Pharmaceuticals Reimbursement Commission, consisting of representatives of the Ministry of Health (MoH), the Department of Pharmacy (PhD), the State Medicine Control Agency (SMCA) and the State Patient Fund (SPF) advises the Minister of Health on reimbursement decisions. If companies or associations/organisations of doctors, pharmacists, patients, etc., wish to apply for reimbursement of a new active substance, they should submit the application to the Department of Pharmacy (PhD) for technical evaluation and review of the related material.

Following this, data are submitted to the Pharmaceuticals Reimbursement Commission, mandated by the Minister of Health. The Pharmaceuticals Reimbursement Commission has six members – representatives of; the Ministry of Health (MoH), the State Patient Fund (SPF), the Department of Pharmacy (PhD) and the State Medicine Control Agency (SMCA). The Pharmaceuticals Reimbursement Commission makes recommendations for the Ministry of Health (MoH) as to whether or not to reimburse the pharmaceutical(s).

The data then come to the Council of Compulsory Health Insurance, which also makes recommendations for Ministry of Health (MoH).

For the final step of the reimbursement procedure, the Minister of Health makes the reimbursement decision and if it is positive, the order is issued to amend the List of Reimbursed Pharmaceuticals accordingly.

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

Name in local language (Abbreviation)	Name in English (Abbreviation)	Description	Responsibility
Lietuvos Respublikos Sveikatos apsaugos ministerija (MoH)	Ministry of Health of the Republic of Lithuania (MoH)	Regulatory body	Overall planning and legislative authority In charge of reimbursement legislation/decisions
Farmacijos departamentas prie Sveikatos apsaugos ministerrijos (FD)	Department of Pharmacy (PhD) under the MoH	Subordinate to the MoH	Legislation, reimbursement lists, price list, pricing procedure
Valstybinė vaistų kontroles tarnyba (VVKT)	State Medicines Control Agency (SMCA)	Subordinate to the MoH	Market authorisation, classification, vigilance, etc., as well as licensing of pharmacy enterprises and pharmacists

Valstybinė ligonių kasa prie Sveikatos apsaugos ministerijos (VLK)	State Patient Fund (SPF) under MoH	Subordinate to the MoH	Reimbursement of pharmaceuticals, pharmaceutical tenders
Ligų ir kompensuojamųjų vaistų sąrašų tikslinimo komisija	Pharmaceuticals Reimbursement Commission	Pharmaceuticals reimbursement committee consisting of representatives of the MoH, the PhD, the SMCA and the SPF	Advising the Minister of Health with regard to reimbursement decisions

Sources: MoH; PhD; SMCA; SPF.

2.1.2 Pharmaceutical market

This section gives an overview of the availability of pharmaceuticals, as well as some market figures.

2.1.2.1 Availability of pharmaceuticals

According to the data as of 22 December 2006 the Register of Pharmaceuticals of Lithuania contained 4,072 nationally authorised pharmaceuticals, including 3,054 pharmaceuticals subject to medical prescription (prescription-only medicine(s) (POM)).

The State Medicines Control Agency (SMCA) is the institution responsible for market authorisation of pharmaceuticals in Lithuania. After joining the European Union (EU), implementation of Community legislation has brought important changes into the regulatory framework as well as applying stricter requirements for market authorisation. Directive 2001/83/EC of the European Parliament (EP) and of the Council (as amended) were fully implemented into national legislation since the Law on Pharmacy of 22 June 2006. The process of market authorisation should not exceed 210 days.

Regarding the new requirements, the number of authorised pharmaceuticals has markedly decreased compared to the period before Lithuania joined the European Union (EU) (Table 2.2). In addition to this, one of the main reasons indicated for the withdrawal of pharmaceuticals was the small Lithuanian market. Moreover, taking into consideration withdrawals and the availability of pharmaceuticals, it should be noted that a lack of essential pharmaceuticals has emerge. Therefore, many of these essential pharmaceuticals are provided by Order of the Ministry of Health as unauthorised products (cf. 5.6).

In accordance with the requirements of the Law on Pharmacy, during the granting of marketing authorisation or evaluating applications to switch classification, the State Medicines Control Agency (SMCA) also classifies authorised pharmaceuticals into pharmaceuticals subject to medical prescription (prescription-only medicine(s) (POM)) and over-the-counter (OTC) pharmaceuticals. The number of authorised pharmaceuticals subject to medical prescription is indicated in Table 2.2.

Classification of pharmaceuticals as reimbursable and non-reimbursable takes place in Lithuania (cf. 4.). There are, however, no exact data on the differences between the number of pharmaceuticals registered and the number of pharmaceuticals on the market; between on-patent and off-patent pharmaceuticals and generics; and between pharmaceuticals in the out-patient sector and hospital-only medicine(s) (HOM).

Parallel trade has been allowed in Lithuania since 2006 according to the Law on Pharmacy, but in practice is not operating at the time of writing. From April 2007 companies may apply for authorisation of parallel trade.

Table 2.2: Lithuania - Number of pharmaceuticals 1995, 2000-2006[1]

Pharmaceuticals	1995	2000	2001	2002	2003	2004	2005	2006
Authorised[2]	n.a.	6,240	5,827	5,494	5,096	4,435	4,435	4,435
On the market	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
POM[2]	n.a.	n.a.	n.a.	4,044	3,723	3,206	3,138	3,054
Reimbursable[2]	2,537	2,143	1,824	1,737	1,483	1,396	1,422	1,565
Generics	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Parallel traded	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Hospital-only	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

POM = prescription-only medicines, n.a. = not available

[1] as of 1 January

[2] method of counting:
incl. different pharmaceutical forms
incl. different pack sizes
incl. different dosages

Source: Data received by written communication with the SMCA.

2.1.2.2 Market data

The State Medicine Control Agency (SMCA) receives information from distribution companies about the amounts of all pharmaceuticals that they have sold. It does not receive information about consumption of any pharmaceuticals from pharmacies. The State Medicine Control Agency (SMCA) only collects data from wholesalers about packs of pharmaceuticals sold to pharmacies and hospitals (without prices). Pharmaceutical consumption is expressed as defined daily doses (DDD) according to the World Health Organization (WHO)-proposed Anatomic Therapeutic Chemical (ATC) classification of pharmaceuticals.

Data about sold packs of pharmaceuticals in Lithuanian market included the following figures (from the State Medicine Control Agency):

- 78,990,046 packs in 2004
- 89,954,496 packs in 2005
- 55,518,108 packs 2006 (1st to 3rd quarters).

The State Patient Fund (SPF) has information on the consumption of reimbursement pharmaceuticals. Public bodies do not collect information on consumption of non-reimbursed pharmaceuticals.

Parallel trade has been allowed in Lithuania since 2006 according to the Law on Pharmacy, but in practice is not operating at the time of writing. From April 2007 companies may apply for authorisation of parallel trade.

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

Pharmaceutical industry in Mio. national currency unit (NCU)	**1995**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**
Prescriptions	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of annual prescriptions by volume	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of annual prescriptions by value	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Pharmaceutical sales							
Sales at ex-factory price level	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales at PRP level	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales of generics	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales of parallel traded pharmaceuticals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Exports and imports							
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.

n.a. = not available, NCU = national currency unit (LTL), PRP = pharmacy retail price

Source: Data received by written communication with SMCA.

Table 2.4: Lithuania - Top 10 best-selling pharmaceuticals, by active ingredient, 2005 or latest available year.

Position	**Pharmaceutical, by active ingredient**
1	Salmeterolum + Flutikazonum

2	Olanzapinum
3	Nebivololum
4	Metoprololum
5	Nicergolinum
6	Budesonidum + Formoterolum
7	Fosinoprilum
8	Clopidogrelum
9	Epoetinum alfa
10	Perindoprilum

Source: Data received by written communication with SPF.

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 it is possible to receive an extension for five more years under a Supplementary Protection Certificate.

Regulations on data protection are introduced in the Law on Pharmacy. According this Law the competent authorities are obliged to apply a data protection period (8+2+1-years) for reference pharmaceuticals. Only after eight years can the State Medicine Control Agency (SMCA) process applications for generic pharmaceuticals under the European Commission (EC) Bolar amendment. However, a generic pharmaceutical authorised according to these provisions may be placed on the market after 10 years have elapsed (provided that by that time the patent has also expired). The authorities may provide for an additional year of data protection (and thereby delay generic market entry) for additional innovative indications (e.g. for paediatric indications).

Product patents have been in place in Lithuania since 1994; before that date “process patents” had been granted to pharmaceutical companies. Under the process patent system, only the process is protected, not the “molecule” itself; therefore, copies could be manufactured if a different process was used.

Because of concerns in the pharmaceutical industry, the European Union (EU) Accession Treaty includes a derogation to limit exports from the new European Union (EU) Member States, when intellectual property rights differed at the time of the market launch of a pharmaceutical. The G10 High Level Group also recommended regulating parallel imports between European Union (EU) Member States. The derogation stipulates that holders of Supplementary Protection Certificates, which had been granted in the European Union (EU) Member States belonging to the European Union before May 2004 (EU15) before product patents were available in the new European Union (EU) Member States (joining on 1 May 2004 – EU10), may prevent exports from the EU10. Furthermore, parallel importers have to notify patent holders of their intention to import a pharmaceutical 30 days prior to their application for a parallel import product licence, thus pharmaceutical companies have the chance to take legal action if they feel that the derogation of the European Union (EU) Accession Treaty is being violated.

2.1.3 Market players

This section describes the key players in the production, distribution, dispensing, prescription and use of pharmaceuticals, besides the authorities which have already been mentioned.

2.1.3.1 Industry

There are 14 local pharmaceutical manufacturers registered in 2006 in Lithuania. The local industry in Lithuania is characterised by small and medium-sized enterprises. There are manufacturers of herbal medicines; of generics in tablets, ampoules and ointments; and of biotechnologically active pharmaceutical ingredients and pharmaceuticals, galenas, blood products, and packagers.

The biggest local producer is Sanitas AB with more than 200 employees. Now Sanitas' range of pharmaceuticals amounts to 67 generic products in various forms (ampoules, tablets, ointments, tinctures and eye drops) for human use. Through various contracts, the company produces 14 different names of pharmaceuticals.

SICOR Biotech UAB develops and manufactures biopharmaceuticals. In 2001 SICOR Biotech became a wholly owned subsidiary of SICOR Inc. (USA). A new good manufacturing practice (GMP)-compliant multipurpose biotech production plant in Lithuania serves for the manufacturing of biopharmaceutical substances to the highest international standards. Today there are more than 150 employees employed at SICOR Biotech.

Four of the Lithuanian manufacturers produce herbal medicines (most of them in the form of herbal teas) – this form of pharmaceutical is popular in Lithuania. In addition, a manufacturer of blood products produces pharmaceuticals from human plasma, by contract with a German company.

Almost all deliveries to public pharmacies are supplied by wholesalers. Direct supply by pharmaceutical manufacturers is allowed (no additional wholesaling licence is needed for their own production). According to the Law on Pharmacy, manufacturing and distribution companies can deliver pharmaceuticals directly to hospitals and polyclinics if the demand is for a limited amount of pharmaceuticals (not more than 14 days' supply).

The main markets for local pharmaceutical industry are, besides Lithuania, the Russian Federation and the countries of the Commonwealth of Independent States (CIS).

Lithuania is ninth in the ranking of pharmaceutical retail markets in central and eastern Europe, with a market share of 2.8% of the leading 12 central and eastern European pharmaceutical retail markets. In 2005, the Lithuanian pharmaceutical market grew approximately 17% in terms of its value compared to the year 2004, and the market is dominated by importers. The generics market share is very high with 72.7% of the market in terms of volume and 41.6% in terms of value (in 2004).

Table 2.5: Lithuania - Key data on the pharmaceutical industry 1995-2005[1]

Pharmaceutical industry	1995	2000	2001	2002	2003	2004	2005
Total no. of companies	n.a.	31	31	30	28	14	13
- research-oriented	n.a.	1	1	1	1	1	1
- generics producers	n.a.	30	30	29	27	13	12
- parallel traders	n.a	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of persons employed[2]	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

n.a. = not available

[1] as of 1 January

[2] counted per head

Source: Data received by written communication with SMCA.

2.1.3.2 Wholesalers

In 2006, there were 74 wholesale licences registered with the State Medicine Control Agency (SMCA) in Lithuania. The wholesale market is in private hands. There were two types of companies holding wholesale licences: (1) full-range companies; and (2) logistics companies that do not have their own premises for storing pharmaceuticals (they rent services to storing pharmaceuticals from other companies with the appropriate wholesale licence).

Besides a number of smaller companies, there are approximately 10 big wholesalers offering more than 2,500 pharmaceuticals in their product range. The five leading wholesalers had a common market share of approximately 70% in 2004. Tamro and Limedika each cover approximately 20% of the market, followed by Medikona, Armila and Mauda. The biggest wholesale companies have own chains of pharmacies.

There are no data available on the number of staff employed in wholesale companies in Lithuania.

Wholesale companies deliver pharmaceuticals to community pharmacies, hospital pharmacies and, according to the new Law on Pharmacy (since June 2006), direct to hospitals and polyclinics if they have a limited demand for pharmaceuticals (not more demand 14 days' supply).

Most of the companies are located in the capital, Vilnius, and in the second largest town, Kaunas. The number of deliveries per day within Vilnius and Kaunas depends on demand. The biggest companies deliver pharmaceuticals to other towns and to the countryside once or twice a day.

The Wholesalers Association of Pharmaceuticals, along with other associations, collaborates with the Ministry of Health (MoH), the Department of Pharmacy (PhD) and the State Medicine Control Agency (SMCA) regarding new regulations concerning pharmaceuticals.

Table 2.6: Lithuania - Key data on pharmaceutical wholesale 1995-2005[1]

Wholesalers	1995	2000	201	2002	2003	2004	2005
Total no. of wholesale companies	n.a.	106	175	92	92	72	72
Total no. of outlets	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

[1] as of 1 January

Source: Data received by written communication with SMCA.

2.1.3.3 Pharmaceutical outlets/retailers

In general, the dispensing of all pharmaceuticals is only allowed in pharmacies. Doctors are not entitled to dispense pharmaceuticals. There are no legal provisions for distance selling or teleshopping of pharmaceuticals, and Internet pharmacy is not allowed.

Besides pharmacies, health care centers may also dispense pharmaceuticals in rural areas, to ensure the supply of pharmaceuticals to patients, although this constitutes a minor share of the country's dispensing arrangements. These health care centers must have a contract with a pharmacy.

2.1.3.3.1 Pharmacies

In 2006 there were a total of 1,426 pharmacy outlets in Lithuania, of which 479 were registered pharmacies and 947 were subsidiaries. There was one pharmacy per 2,386 inhabitants in 2006.

Since the ruling of the Constitutional Court in the year 2002 there are no longer geographic or demographic criteria for the establishment of a new pharmacy. Municipalities grant pharmacy concessions according to criteria set by the Ministry of Health (MoH). The requirements for establishing a community pharmacy and subsidiaries are the same, but if a pharmacy is setting up in a rural area, the premises can be half the size of all other pharmacies. Types of pharmacy include: community pharmacy; community pharmacy carrying out preparation activities (magistrals and officinal's pharmaceuticals); hospital pharmacy; hospital pharmacy carrying out preparation activities (magistrals and officinal's pharmaceuticals); and university pharmacy. University pharmacy activity is the same as community pharmacy or community pharmacy with preparation activity.

There are no requirements for an owner of a pharmacy. Most of the community pharmacies are privately owned and just few still are publicly owned. Pharmacy chains are permitted in Lithuania, of which one of the biggest is *Eurovaistiné*, an international pharmacy chain with approximately 200 outlets. Furthermore, there is vertical integration, with wholesalers owning pharmacies, e.g. a major wholesaler engaged in the retail market in 2003 by establishing its own pharmacy chain *Seimos vaistine*. In 2004, Tamro purchased the pharmacy chain *Farmacijos projektai* with 46 pharmacies and took over a further 13 pharmacy outlets of the *Vogne* chain in 2005. Only approximately 20% of the pharmacies are still independent pharmacies, most of them being in rather non-profitable rural areas.

Every pharmacy can dispense other products besides the full assortment pharmaceuticals, according to a list set by the Ministry of Health (MoH).

According to the Law on Pharmacy (June 2006), pharmacists working either in community pharmacies or in hospital pharmacies should get a licence for pharmacist's practice, issued by the State Medicine Control Agency (SMCA).

There are some associations of pharmacists in Lithuania: the Lithuanian Pharmacy Union; the Union of Lithuanian Pharmacists; and the Trade Union of Lithuanian Pharmacists. There are also some associations of pharmacies in Lithuania: the Association of Independent Pharmaceutical Enterprises; the Association of Provincial Pharmacies; and the Association of Pharmacies named *Provifarma*. Every association has the right to give its opinion on all matters relating to pharmacists or pharmacies.

According to an Order of Ministry of Health (MoH), public pharmacies are remunerated via a maximum mark-up scheme for reimbursement pharmaceuticals (prescription-only medicine(s) (POM)). Pharmacy retail prices (PRP) of reimbursed pharmaceuticals, however, are not uniform throughout the country and can vary from pharmacy to pharmacy.

Prices of non-reimbursed prescription pharmaceuticals and over-the-counter (OTC) pharmaceuticals are not regulated (i.e. these pharmaceuticals are priced freely).

Table 2.7: Lithuania - Retailers of pharmaceuticals 1995, 2000-2006[1]

Retailers	1995	2000	2001	2002	2003	2004	2005	2006
No. of community pharmacies[2]	n.a.	778	1,221	1,350	1,416	1,489	1,459	1,426
No. of private pharmacies	n.a.	767	1,210	1,339	1,406	1,481	1,452	1,422
No. of public pharmacies	11	11	11	11	10	8	7	4
No. of hospital pharmacies for out-patients	n.a.	n.a.	62	68	65	62	61	60
No. of other POM and OTC dispensaries (and *heath care centres*[3])	n.a.	n.a.	n.a.	n.a.	1,040	n.a.	n.a.	959
Total no. of POM dispensaries[1]	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of internet pharmacies	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
No. of OTC dispensaries, e.g. pharmacies	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.

OTC = over-the-counter (pharmaceuticals), POM = prescription-only medicine(s); n.a. = not available

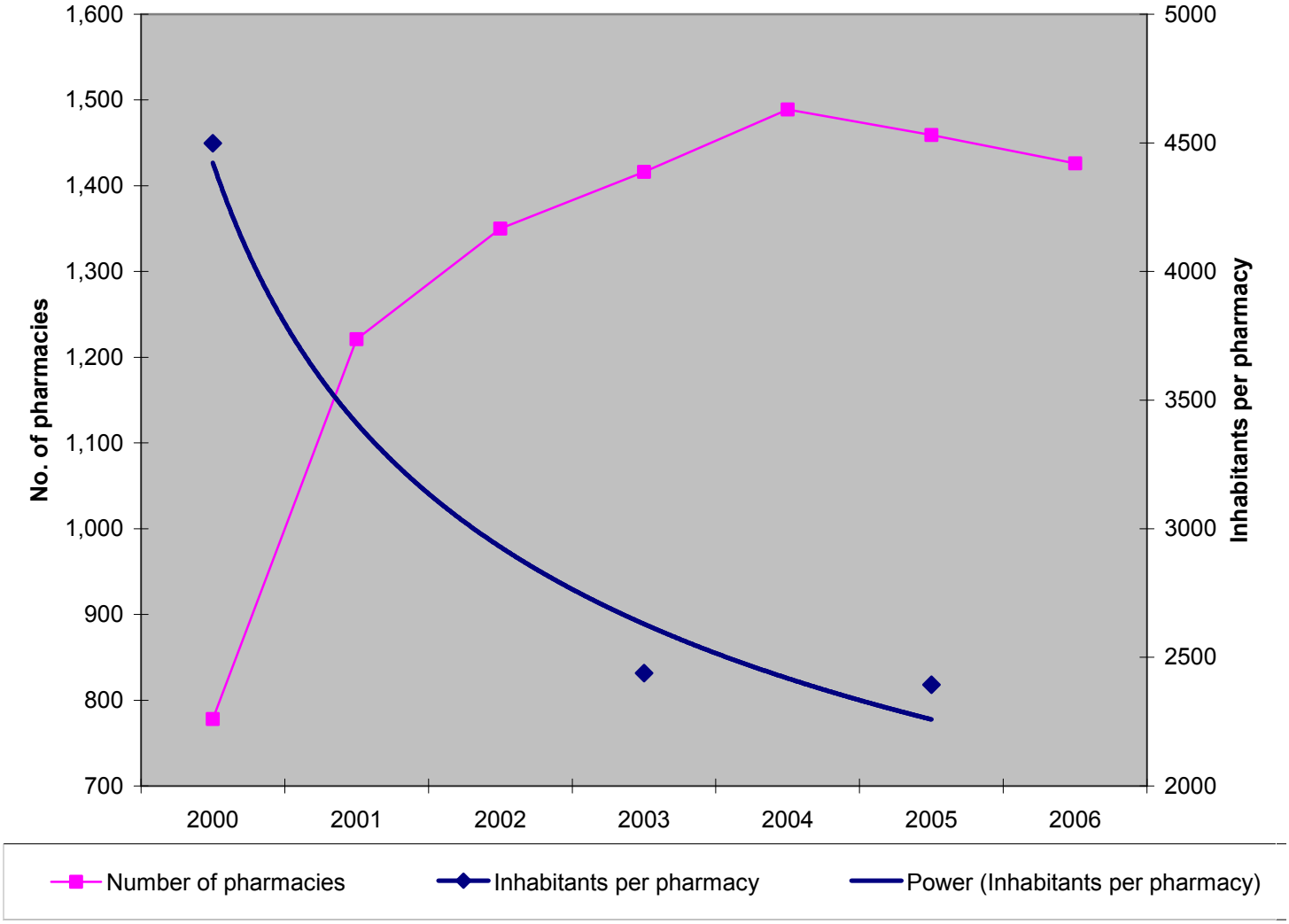
[1] as of 1 January

[2] incl. branch pharmacies

[3] *only in rural areas, minor importance*

Source: Data received by written communication with SMCA.

Figure 2.2: Lithuania - Number of retail pharmacies and number of inhabitants per pharmacy 2000-2006



2.1.3.3.2 Other pharmacy outlets

Health care centres located in rural areas may dispense pharmaceuticals to ensure the supply of pharmaceuticals to patients. These health care centres must have a contract with a pharmacy, which is responsible for the health centre's pharmaceutical activity.

2.1.3.3.3 Internet pharmacies

There are no legal provisions for distance selling or tele-shopping of pharmaceuticals. Doctors are not entitled to dispense pharmaceuticals. Ordering pharmaceuticals by post and Internet pharmacy are not allowed.

2.1.3.3.4 Dispensing doctors

In out-patient care doctors and family nurses are not entitled to dispense pharmaceuticals.

2.1.3.4 Hospitals

Hospital pharmacies are only to be for internal use, set up as a division of a hospital. Hospital pharmacies are not allowed to dispense pharmaceuticals to patients: for this purpose there are ordinary community pharmacies in hospitals and polyclinics.

Hospital pharmacies are only funded by hospitals; there are no other means of funding. Pharmaceuticals are free of charge for in-patients. Hospitals have to confirm the list of pharmaceuticals which they need and purchase pharmaceuticals themselves through a public competition procedure.

2.1.3.5 Doctors

The doctor is the main decision-maker, choosing the pharmaceutical product to be dispensed to the patient. There are 22 treatment guidelines, which are recommendations for doctors. Doctors associations play active role in preparing treatment guidelines and amending existing guidelines. The opinion of the doctors associations is important to the Pharmaceuticals Reimbursement Commission and they are therefore influential in many reimbursement decisions.

2.1.3.6 Patients

In general, the decisions of patients are limited by a framework consisting of a restrictive reimbursement list, a reference price system and non-uniform pharmacy retail prices (PRP) throughout the country.

The importance of self-medication and non-prescription pharmaceuticals is strengthened by a restrictive reimbursement policy. Therefore, patients might be encouraged to choose a pharmacy as their source of information, rather than contacting a doctor.

Patient information on packaging and leaflets has to be confirmed by the State Medicine Control Agency (SMCA). This information has to be clear to the patients. Advertising to patients is only allowed for over-the-counter (OTC) products. In 2005 the Constitutional Court decided that prohibition of advertising prescription-only medicine(s) (POM) to patients via the mass media (radio and television) does not distort competition. Advertising for pharmaceuticals is regulated by law and is under the control of the State Medicine Control Agency (SMCA).

The list of authorised pharmaceuticals, patient information leaflets (PIL) and summary of product characteristics (SPC) are available on the internet. Furthermore, the reimbursement lists are available publicly, stating the maximum pharmacy retail price (PRP) and the base price as the basis for reimbursement.

Since 2004, within the reimbursable sector doctors are obliged to prescribe by International Nonproprietary Name (INN); from 2002 to 2004 doctors were allowed to prescribe by brand

name as well. Pharmacists are obliged to offer the cheapest generic product available to the patient. Thus, the patient has some choice in terms of pharmaceutical selection, at her/his own expense (co-payment).

2.2 Funding

This section provides the reader with an overview of the funding of pharmaceuticals. This includes pharmaceutical expenditure (PE) and the allocation of funds for pharmaceuticals.

2.2.1 Pharmaceutical expenditure

From 2000 to 2005, the sales of pharmaceuticals in Lithuania totalled over LTL 1 billion. The volume of sales over this period of time has been on the increase. However, according to the number of sold packs of pharmaceuticals, the dynamics are negative – a clear downward trend of the market can be observed. Over the given period of time, the average pack of a statistical pharmaceutical remained within the general trend of increasing prices of pharmaceuticals: the prices of pharmaceuticals have increased from LTL 6.20 (in 2000) to LTL 12.90 (in 2005). The costs for pharmaceuticals per resident have also been increasing, except in the year 2002: from LTL 176 in 2000 to LTL 332 in 2005. State expenditure on pharmaceuticals increased from 10% (in 2000) to 15% (in 2005) of the funds allocated to health care.

Table 2.8: Lithuania - Total pharmaceutical expenditure (TPE) 1995, 2000-2005

Pharmaceutical expenditure (PE)	1995	2000	2001	2002	2003	2004	2005
TPE in Mio. NCU	n.a.	618.0	830.0	786.0	852.0	972.0	1,135.0
TPE as a % of THE	n.a.	22.6	30.2	25.7	26.4	27.9	27.9
TPE per capita in NCU	n.a.	176	238	226	246	282	332
Public PE as a % of THE	n.a.	11.2	14.9	11.0	10.9	11.1	11.9
Private PE as a % of THE	n.a.	11.4	15.3	14.7	15.8	16.8	16.0

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

Table 2.9: Lithuania – Prescription-only (POM) and non-prescription (over-the-counter (OTC)) pharmaceutical expenditure (PE) 2000-2005

Prescription-only medicine(s) (POM)/Over-the-counter (OTC) pharmaceuticals	2000	2001	2002	2003	2004	2005
POM, Mio. NCU	438	632	574	600	689	797
OTC, Mio. NCU	181	198	212	251	282	338

POM = prescription-only medicine(s), OTC = over-the-counter (pharmaceuticals), NCU = national currency unit (LTL)

Source: Department of Statistics under Government of Lithuania (http://www.stat.gov.lt); Lithuanian Health Information Centre (http://www.lsic.lt/)

2.2.2 Sources of funds

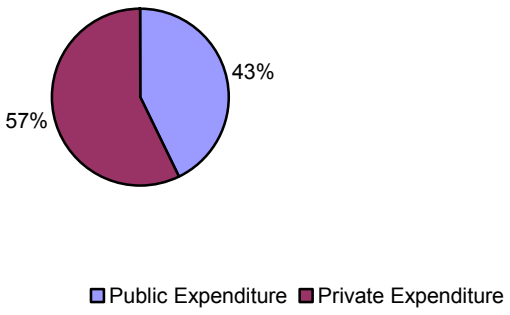
The budget of the Compulsory Health Insurance Fund is also used to reimburse the costs of pharmaceuticals, which have been entered into the List of Reimbursed Pharmaceuticals.

Reimbursement is provided to the groups listed here.

- All insured people that are taken ill with diseases listed in the list of specific diseases.
- Social groups of people (children under the age of 18 years, people with disability, people receiving retirement pensions).

The Law on Health Insurance also provides for additional coverage via (voluntary) health insurance (VHI); however, it is not popular in Lithuania and only used by a small number of people with exceptionally high income. Thus, more extensive information on their expenses for self-medication, additional private insurance expenses and unofficial payments are not available.

Figure 2.3: Lithuania - Share of private and public pharmaceutical expenditure (PE) 2005



Source: Department of Statistics under the Government of Lithuania; Lithuanian Health Information Centre.

3 Pricing

This chapter gives an overview of the pricing system by describing the process and the regulation of pharmaceuticals pricing.

3.1 Organisation

Manufacturer prices of pharmaceuticals applying for inclusion to the reimbursement list are accepted by the Department of Pharmacy (PhD), once the reimbursement procedure for inclusion of new International Nonproprietary Names (INN) is finished. Wholesale and pharmacy retail prices (PRP) of reimbursed pharmaceuticals are regulated by adding mark ups approved by the Ministry of Health (MoH).

Prices of non-reimbursed prescription pharmaceuticals and over-the-counter (OTC) pharmaceuticals are not regulated (i.e. these pharmaceuticals are priced freely at all price levels).

In the hospital sector there is free pricing. Some (very expensive) pharmaceuticals for hospital use or dispensing via hospitals are centrally purchased by the State Patient Fund (SPF).

At the time of writing, the wholesaler mark up is from 5.5% to maximum 14% (c.f. 3.5.1) and the minimum pharmacy retail mark up is 4%, maximum 22%. The mark ups are regulated by digressive mark-up schemes.

In 2006 a List of Reimbursed Medical Aid Products was introduced. Pharmacy retail prices (PRP) of reimbursed medical aids and devices are regulated by adding mark ups, similarly to pharmaceuticals.

In terms of the pricing system of pharmaceuticals in Lithuania, there are two different prices in the reimbursement sector: the prices in the distribution channel (manufacturer price, wholesale price and pharmacy retail price (PRP), where the latter two are regulated via maximum mark ups); and the base price for reimbursement (which is only equal to the pharmacy retail price (PRP) in the case of insulin).

The base price is part of the pharmacy retail price (PRP). The base price for reimbursement is always lower then the pharmacy retail price (PRP), so that patients also have to bear a co-payment in the case of the 100% reimbursement category (except for insulins). For pharmaceuticals where “generic” products exist, the base price is a reference price for the group; for “innovative”, “new” International Nonproprietary Names (INN), where there is no generic alternative, the base price is determined by international price comparison and is still lower than the pharmacy retail price (PRP).

All reimbursed pharmaceuticals are consolidated to groups according the International Nonproprietary Name (INN), method of use, acting duration, purpose and pharmaceutical form. All members of the group have equal reimbursed price according to weight or activity unit (cf. 4.3).

Since the year 2000, patient co-payments have been introduced for all pharmaceuticals, including the cheapest 100% reimbursed pharmaceuticals (with the exception of insulin). Insulins are reimbursed without co-payment. Patient co-payment depends on the price of the pharmaceutical (for the 100% reimbursed, cheapest pharmaceuticals in the group).

Now the calculation of the reimbursed price comes under the expertise of the Government. The new redaction of the Health Insurance Law entered into force in May 2005. This Law was amended by the provision that the reference manufacturing decelerated price should not exceed 95% of the average manufacturer's price in the six reference European Union (EU) countries (Latvia, Estonia, Poland, Czech Republic, Slovakia, Hungary). Otherwise, if the pharmaceutical is not registered in the reference European Union (EU) Member State the reference price is included in the price referencing process. According to the above-mentioned Law, representatives of the foreign pharmaceuticals companies in Lithuania had to provide information about the pharmaceuticals prices in the relevant European Union (EU) countries.

The Government act allows the manufacturer to set the price higher than 95% of the average manufacturer's price in the six reference European Union (EU) countries (Latvia, Estonia, Poland, Czech Republic, Slovakia, Hungary), but in that case the basic (reimbursed price) is calculated not from the manufacturer's declared price but from 95% of the average manufacturer's price in the six reference European Union (EU) countries and difference would be added to the co-payment. In October 2005 a rule was introduced that the next product to be added to an International Nonproprietary Name (INN) group where only one product was included before must have a price 30% lower than that of the product already included. If the price is higher than 70%, the reimbursed price (base price) is set at 70% of the old reimbursed price.

There is no special "Price Committee" in Lithuania. Applications to increase prices of reimbursed pharmaceuticals are discussed in the Pharmaceuticals Reimbursement Commission and a decision is made to grant the price increase or not.

Pricing and reimbursement decisions are separate procedures. The reimbursement decision is implemented by Decree of the Minister of Health. The maximum retail and reimbursed prices of new reimbursed products are calculated and the new product is included in the List of Reimbursed Pharmaceuticals. Prices are determined after the reimbursement decision. The price list is renewed once every three months.

The application for a new product reimbursement is determined in Order No. 159 (V-91) of the Ministry of Health of the Republic of Lithuania, 5 April 2002. The reimbursed price calculation is determined in Decree No. VIII-994 of the Government of the Republic of Lithuania, 13 September 2005 (http://www3.lrs.lt), and Order No. 459 of the Ministry of Health of the Republic of Lithuania, 12 August 2000.

3.2 Pricing policies

The Lithuanian system of pharmaceutical reimbursement involves co-payments for reimbursed pharmaceuticals. As in many European countries, in Lithuania, people are required to pay co-payments for part of the pharmaceutical retail price (PRP). Co-payments were introduced in

1997 when the Health Insurance Law came into force. All pharmacy retail prices (PRP) were reimbursed by the State Social Insurance Fund until 1997. This led to irrational consumption of pharmaceuticals, sizeable expenditure, and debts of the State Social Insurance Fund budget.

According to the Health Insurance Law, regulation of the pricing of pharmaceuticals falls within the remit of the Ministry of Health (MoH). Wholesale and pharmacy retail prices (PRP) of reimbursed pharmaceuticals are regulated by adding mark ups approved by the Ministry of Health (MoH). The Law stipulates that pharmacy retail prices (PRP) of reimbursed pharmaceuticals are not fixed but rather "maximum prices". Pharmacy retail prices (PRP) of reimbursed pharmaceuticals, however, are not uniform throughout the country and can vary from pharmacy to pharmacy. Prices of non-reimbursed prescription pharmaceuticals and over-the-counter (OTC) pharmaceuticals are not regulated (i.e. these pharmaceuticals are priced freely).

Table 3.1: Lithuania - Ways of pricing pharmaceuticals

	Manufacturer level	Wholesale level	Pharmacy level
Free pricing	Non-reimbursable pharmaceuticals Reimbursed pharmaceuticals – Ministry of Health seeks to have prices no higher than 95% of the average manufacturer's price in the six reference European Union (EU) countries (Latvia, Estonia, Poland, Czech Republic, Slovakia, Hungary)	Non-reimbursable pharmaceuticals	Non-reimbursable pharmaceuticals
Statutory pricing	Not applied	Reimbursable pharmaceuticals regulated via a regressive mark-up scheme	Reimbursable pharmaceuticals regulated via a regressive mark-up scheme
Price negotiations	Not applied	Not applied	Not applied
Price–volume agreements, discounts/rebates	No	No	No
Institution in charge of pricing	PhD under MoH		
Legal basis	Order No. 459 of the Minister of Health[1].		

PhD = Department of Pharmacy, MoH = Ministry of Health

Source: Law on Pharmacy 2006[2]

[1] Order No. 459 of the Minister of Health of procedure for the calculation and application of prices for medicinal products, active substances and pharmacy goods, 12 August 2000

[2] Law on Pharmacy 2006, 22 June 2006 No. X-709;

[3] Decree No. VIII-994[2] of the Government of the Republic of Lithuania, 13 September 2005, http://www3.lrs.lt

Non-reimbursed products are freely priced. Prices of reimbursed pharmaceuticals are determined according to Decree No. VIII-994[3].

The current pricing system is implemented according to Decree No. VIII-994[3]. The price setting procedures are the same. It does not depend on the type of pharmaceutical (e.g. me-too pharmaceuticals, generics). Pricing decisions are made at manufacturer level.

3.2.1 Statutory pricing

The base price for reimbursement is calculated according to statutorily fixed criteria. Now the calculation of the reimbursed price falls under the remit of the Government. The new redaction of the Health Insurance Law entered into force in May 2005. This Law was amended by the provision that the reference manufacturing decelerated price should not exceed 95% of the average manufacturer's price in the six reference European Union (EU) countries (Latvia, Estonia, Poland, Czech Republic, Slovakia, Hungary).

According to the Health Insurance Law, regulation of the pricing of pharmaceuticals falls within the remit of the Ministry of Health (MoH). Wholesale and pharmacy retail prices (PRP) of reimbursed pharmaceuticals are regulated by adding mark ups approved by the Ministry of Health (MoH). Prices of non-reimbursed prescription pharmaceuticals and over-the-counter (OTC) pharmaceuticals are not regulated (i.e. these pharmaceuticals are priced freely).

According to the Law on Pharmacy (2006), the Department of Pharmacy (PhD) under the Ministry of Health (MoH) is responsible for pricing procedures for including pharmaceuticals in the List of Reimbursed Pharmaceuticals. The pricing procedure is set out by Order No. 459 of the Minister of Health on the procedure for the calculation and application of prices for pharmaceuticals, active substances and pharmacy goods, 12 August 2000.

3.2.2 Negotiations

Price negotiations are not used in Lithuania as yet. A draft Order on Price Negotiations has already been prepared.

3.2.3 Free pricing

Prices of all non-reimbursed prescription pharmaceuticals and over-the-counter (OTC) pharmaceuticals are not regulated (i.e. these pharmaceuticals are priced freely). Free pricing is used at all price levels. The current method of pricing was introduced in 2002.

3.2.4 Public procurement / tendering

In Lithuania, expensive pharmaceuticals are centrally purchased by the State Patient Fund (SPF) under the Ministry of Health (MoH) (from the Compulsory Health Insurance Fund). This is the only method of reimbursement for expensive pharmaceuticals in Lithuania. Competition is

provided among wholesalers. The State Patient Fund (SPF) monitors delivery and consumption of the expensive pharmaceuticals. These data are collected about every patient.

3.3 Pricing procedures

Table 3.2 gives an overview of the different pricing procedures in Lithuania and in the following subsections the procedures are explained in more detail.

Table 3.2: Lithuania - Pricing procedures

Pricing procedure	In use: Yes / No	Level of pricing[1]	Scope[2]
Internal price referencing	Yes	Reimbursed price	Only reimbursable pharmaceuticals
External price referencing	Yes	Reimbursed price	Only reimbursable pharmaceuticals
Cost-plus pricing	n.app.	n.app.	n.app.
Other, e.g. indirect profit control	Not applied	Not applied	Not applied

[1] Level of pricing = the stage of the pricing process at which the pricing take places (e.g. at the pharmacy retail price (PRP) level)

[2] Scope = A pricing procedure does not always refer to all pharmaceuticals, e.g. the pricing procedure could only refer to reimbursable pharmaceuticals, whereas for over-the-counter (OTC) pharmaceuticals there is free pricing.

Source: Decree No. VIII-994 [1]

3.3.1 External price referencing

External price referencing is regulated in Decree No. VIII-994[1]. External price referencing only applies for all reimbursed pharmaceuticals (prescription-only medicine(s) (POM), generics); it is applied at manufacturer price level and it is only a procedure, but not a criterion. The declared manufacturer price is compared with 95% of the average manufacturer prices in reference countries. There are six reference countries: Latvia, Estonia, Poland, Czech Republic, Slovakia, and Hungary. In the event that there are no data on prices in these countries, the price in the country of manufacture is taken. In the event that there are no data on one or some prices in the reference countries the prices of the rest of reference countries are taken. If the manufacturer price declared in Lithuania exceeds 95% of the average manufacturer prices in the reference countries, the base price is calculated from the average manufacturer prices in the reference countries. The application for inclusion into the List of Reimbursed Pharmaceuticals should contain the prices in € in the reference countries. The exchange rate LTL/€ is fixed at € 1 to LTL 34,528. The manufacturer should provide information about prices in the reference countries to the Ministry of Health (MoH) and the Department of Pharmacy (PhD). The manufacturer should inform

[1] Decree No. VIII-994 of the Government of the Republic of Lithuania, 13 September 2005; Order of ministry of health concerning grouping of pharmaceuticals, No.73, 9 February 2000

the authorities about price changes in the reference countries. The Department of Pharmacy (PhD) is responsible for checking information on the web sites of authorities in the reference countries and if there are any prices that are suspected to be incorrect the company is informed and is required to check the mistake.

3.3.2 Internal price referencing

There are rules for internal price referencing in Lithuania. The rules are determined and the internal price referencing is applied according to Order of the Ministry of Health on grouping of pharmaceuticals, No. 73, 9 February 2000. Companies have to deliver information about trade name, International Nonproprietary Name (INN), and manufacturing price in Lithuania, as well as manufacturing prices in the reference countries. The Department of Pharmacy (PhD) is in charge of the assignment of a pharmaceutical to a group according to a summary of product characteristics (SPC) of the pharmaceutical.

Pharmaceuticals are grouped on the basis of a common (international) name (International Nonproprietary Name (INN)), method of use, form, purpose, and length of action.

Name of a group	Pharmaceutical form
Oral (hard)	Dragees, granules (except for granules for suspension), caplets, capsules, powders, tablets (except for instant tablets)
Oral (hard) for children	Doses for children: dragees, granules (except for granules for suspension), caplets, capsules, powders, tablets (except for instant tablets)
Oral (hard) modified-release	Dragees, prolonged-release granules (except for granules for suspension), caplets, capsules, powders, tablets (except for instant tablets)
Oral (liquid)	Extracts, elixirs, emulsions, granules for suspension, drops, mixture, tincture, instant tablets, solution, syrup, suspension, gel
Oral (liquid) for children	Doses for children: extracts, elixirs, emulsions, granules for suspension, drops, mixture, tincture, instant tablets, solution, syrup, suspension, gel
Injected	Solutions for injection, emulsions, suspensions, sterile powders, tablets
Injected (prolonged-release)	Solutions for injection, emulsions, suspensions, sterile powders, tablets
External (soft)	Emulsions, creams, liniments, pastes, ointments, gel
External (liquid)	Lotions

Rectal (vaginal)	Globules, pessaries, vaginal tablets, suppositories
Rectal (liquid)	Enemas
Sticking plasters	Treatment schemes: sticking plasters, bandages
Drops	Ear / eye / nose drops
Aerosols (liquid)	Aerosols, inhalations
Aerosols (powder)	Dust aerosols, dusting powder, and powders

Insulin preparations and Somatropin preparations are grouped on the basis of origin, length of action and specifications related to their use.

3.3.3 Cost-plus pricing

In Lithuania cost-plus pricing procedures have not been applied.

3.3.4 (Indirect) Profit control

There is no direct or indirect profit control in Lithuania.

3.4 Exceptions

In Lithuania, there are some exceptions to the pricing procedures explained above. In the following sections, these exceptions for hospital-only medicines (HOM), generics, over-the-counter (OTC) products and parallel traded pharmaceuticals are explained.

3.4.1 Hospitals-only

Hospitals carry out their own procurement direct from wholesalers. Hospitals must confirm their list of necessary pharmaceuticals. Pharmaceuticals are free of charge to the patient and the cost of pharmaceuticals is included in the price of medical services.

Hospitals are autonomous to purchase the necessary pharmaceuticals by means of a tendering process, according to the Law on Public Procurements, No. I-1491, 13 August 1996, with the exception of private hospitals. To achieve lower prices they negotiate with wholesalers. However, they have to take always into consideration the aspect of rational management of public resources.

Pharmacy purchase prices (PPP) of hospital procurements are not collected centrally; every hospital has its own data.

Expensive pharmaceuticals may be centrally purchased by the State Patient Fund (SPF) (cf. 4.2.2).

3.4.2 Generics

In Lithuania there is no different price setting procedure for generics. There is rule for the inclusion of generics: the manufacturer price of the preparation should be at least 30% below the manufacturing price of the original preparation – if not, the co-payment would be high (Decree No. VIII-994 of the Government of the Republic of Lithuania). This rule is applied to all generics, i.e. both domestic and imported pharmaceuticals.

3.4.3 Over-the-counter pharmaceuticals

Prices of over-the-counter (OTC) pharmaceuticals are not regulated (i.e. these pharmaceuticals are priced freely), according to Order No. 459 of the Ministry of Health of the Republic of Lithuania, 12 August 2000.

3.4.4 Parallel trade pharmaceuticals

Parallel trade is not operating in Lithuania at the time of writing. It is regulated by the Law on Pharmacy and was approved by Order of the Minister of Health of the Republic of Lithuania No. V- 228 on 30 March 2007, entering into force the day after it is published in the Official Journal. Since then, companies may apply for authorisation of parallel trade.

3.4.5 Other exceptions

There are no other exceptions in Lithuania.

3.5 Margins and taxes

This section contains a description of the wholesale and pharmacy mark ups, dispensing fees and sales taxes applied to pharmaceuticals.

In Lithuania reimbursed pharmaceuticals are regulated via maximum mark-up schemes for wholesalers and pharmacies.

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

	Wholesale mark up			Pharmacy mark up		
	Regulation (yes/no)	**Content**	**Scope***	**Regulation (yes/no)**	**Content**	**Scope***
Lithuania	Yes	Mark-up system	All reimbursed pharmaceuticals	Yes	Mark-up system	All reimbursed pharmaceuticals

* Regulations concerning mark ups do not always apply to all pharmaceuticals, , e.g. in the example the pricing procedure only refers to reimbursable pharmaceuticals. For over-the-counter (OTC) pharmaceuticals there is free pricing.

Source: Order No. 459 [1]

3.5.1 Wholesale remunerations

In Lithuania wholesalers are remunerated via maximum mark ups of reimbursable pharmaceuticals (cf. Table 3.4), regulated by Order No. 459[1]. This involves a combination of linear and regressive schemes.

Table 3.4: Lithuania - Wholesale mark-up scheme 2006

Ex-factory price in national currency unit (NCU) / €	Maximum mark up as a % of ex-factory price	Wholesale price in national currency unit (NCU) / €
up to LTL 6.43 / € 1.86	14	-
from LTL 6.44 / € 1.87 to LTL 10.00 / € 2.89	-	LTL 0.90 / € 0.26
from LTL 10.01 / € 2.90 to LTL 19.44 / € 5.63	9	-
from LTL 19.45 / € 5.64 to LTL 25.00 / € 7.24	-	LTL 1.75 / € 0.51
from LTL 25.01 / € 7.25 to LTL 53.57 / € 15.51	7	-
from LTL 53.58 / € 5.52 to LTL 68.18 / € 9.74	-	LTL 3.75 / € 1.09
from LTL 68.19 / € 19.75 to LTL 909.09 / € 263.28	5.5	-
from LTL 909.10 / € 263.29	-	LTL 50.00 / € 14.48

NCU = national currency unit (LTL)

Source: Order No. 459 of the Ministry of Health of the Republic of Lithuania, 12 August 2000

Wholesale mark ups for non-reimbursable pharmaceuticals are not statutorily regulated. Wholesalers are not obliged to grant any discounts to the State Patient Fund (SPF) or other state insti-

[1]Order No. 459 of the Ministry of Health of the Republic of Lithuania, 12 August 2000 (last amended by order No.V-992 on 19 December 2005).

tutions. Discounts granted to pharmacies are without any legal regulation and are subject to negotiations between wholesalers and pharmacies.

3.5.2 Pharmacy margins remunerations

In Lithuania pharmacies are remunerated via maximum mark ups of reimbursable pharmaceuticals (cf. Table 3.4), regulated by Order No. 459[1]. This involves a combination of linear and regressive schemes.

Table 3.5: Lithuania - Pharmacy mark-up scheme 2006

Pharmacy purchasing price (PPP) from … to… in national currency unit (NCU) / €	Maximum pharmacy mark-up coefficient as a % of pharmacy purchasing price (PPP)
up to LTL 8.19 / € 2.37	22
from LTL 8.20 / € 2.38 to LTL 10.00 / € 2.89	LTL 1.80 / € 0.52
from LTL 10.01 / € 2.90 to LTL 15.28 / € 4.42	18
from LTL 15.29 / € 4.43 to LTL 25.00 / € 7.24	LTL 2.75 / € 0.80
from LTL 25.01 / € 7.25 to LTL 27.28 / € 7.90	11
from LTL 27.29 / € 7.91 to LTL 75.00 / € 21.72	LTL 3.00 / € 0.87
from LTL 75.01 / € 21.73 to LTL 500.00 / € 144.81	4
from LTL 500.00 / € 144.81	LTL 20.00 / € 5.79

PPP = pharmacy purchasing price, NCU = national currency unit (LTL)

Source: Order No. 459[1]

As mark ups are at the maximum level, pharmacies may set their prices below the maximum allowed pharmacy retail price (PRP) held in the List of Reimbursed Pharmaceuticals. Mark ups for non-reimbursable pharmaceuticals and over-the-counter (OTC) products are not regulated. Therefore, prices of non-reimbursable pharmaceuticals, but also of some reimbursable pharmaceuticals, might vary between pharmacies.

3.5.3 Remuneration of other dispensaries

There are not any other dispensaries in the out-patient sector. Costs of pharmaceuticals used in in-patient treatment are covered by fee-for-service payments.

3.5.4 Value-added tax

Standard value-added tax (VAT) is 18% in Lithuania. Since 2004 the reduced rate of value-added tax (VAT) for pharmaceuticals is 5% (up to this point a specific level of value-added tax (VAT) for pharmaceuticals was not applied). Value-added tax (VAT) is applicable to all pharmaceuticals irrespective of their reimbursement status. Only products produced from human tissues (blood clotting features) are not taxed with value-added tax (VAT).

3.5.5 Other taxes

There are no other taxes or fees on pharmaceuticals in Lithuania.

3.6 Pricing-related cost-containment measures

This section contains a description of the price control mechanisms currently used in Lithuania.

3.6.1 Discounts / Rebates

All types of discounts are allowed, but there is no legal basis for them.

Thus, neither the pharmaceutical industry nor wholesalers or pharmacies are obliged to grant any discounts, rebates or claw-backs to the State Patient Fund (SPF) or any other public body.

Commercial discounts in the distribution chain are allowed and are commonplace – these discounts are not regulated and are subject to negotiations between the distribution actors. Also, pharmacies may grant discounts to their customers on non-reimbursable pharmaceuticals, but also on reimbursable pharmaceuticals, thus reducing the patient co-payment.

3.6.2 Margin cuts

Wholesale and pharmacy margins on pharmaceuticals are regulated through a regressive mark-up scheme (cf. 3.51 and 3.5.2). In 2002, wholesale and pharmacy mark ups were lowered by Order of the Ministry of Health (MoH). In 2004 wholesale margins were further reduced by Order of the Minister of Health.

3.6.3 Price freezes / Price cuts

Neither price freezes nor price cuts are applied in Lithuania.

3.6.4 Price reviews / evaluations

There is no regular procedure for review and evaluation of pricing procedures. At the time of writing Order No. 459 of the Minister of Health on the procedure for the calculation and application of prices for pharmaceuticals, active substances and pharmacy goods (2000) is being revised. Every individual has the opportunity to ask for a review of pricing procedures.

4 Reimbursement

This chapter gives an overview of the reimbursement system, the reimbursement procedure and the regulation of reimbursement.

4.1 Organisation

The main rules of reimbursement of pharmaceuticals are stated in Art. 10 of the Law on Health Insurance.

100% of the basic price of the reimbursed pharmaceuticals that are included in the List of Diseases and Reimbursed Pharmaceuticals for their Treatment and in the List of Reimbursed Pharmaceuticals and Medical Aid Products included in the List of Reimbursed Medical Aid Products for out-patient treatment are to be reimbursed to (cf. 3.1):

- children under 18 years of age
- disabled people in Group I.

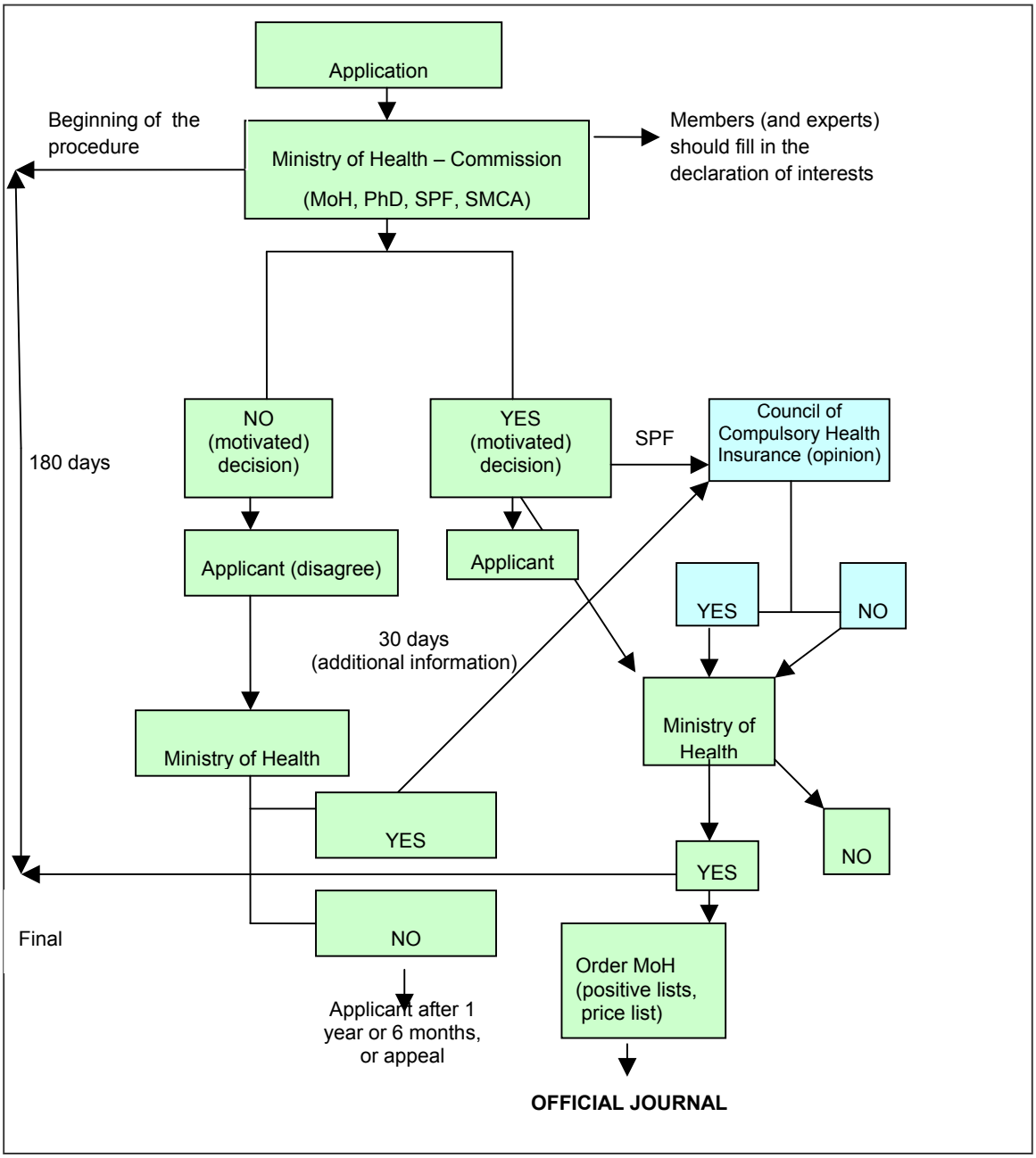
100%, 90%, 80% or 50% of basic price of the reimbursed pharmaceuticals and medical aid products for out-patient treatment are to be reimbursed to the insured who are not mentioned in the above paragraph and who are diagnosed with diseases, syndromes and states included in the List of Diseases and Reimbursed Pharmaceuticals for their Treatment or in the List of Reimbursed Medical Aid Products by the level of reimbursement.

50% of the basic price of the reimbursed pharmaceuticals included in the List of Reimbursed Pharmaceuticals and Medical Aid Products included in the List of Reimbursed Medical Aid Products for out-patient treatment are to be reimbursed for people who receive state social insurance old-age pension and pensions for the disabled people in Group II, as well as the beneficiaries of (social) benefits who are not mentioned in the paragraphs above.

The over-the-counter (OTC) pharmaceuticals or products which can be used only in hospitals are excluded from reimbursement lists.

The reimbursement procedure is as follows: if companies or associations/organisations of doctors, pharmacists, patients, etc., wish to apply for reimbursement of a new active substance, they should submit the application to the Department of Pharmacy (PhD) for technical evaluation and review of the related material. Following this, data are submitted to the Pharmaceuticals Reimbursement Commission, mandated by the Minister of Health. The Pharmaceuticals Reimbursement Commission has six members – representatives of; the Ministry of Health (MoH), the State Patient Fund (SPF), the Department of Pharmacy (PhD) and the State Medicine Control Agency (SMCA). The Pharmaceuticals Reimbursement Commission makes recommendations for the Ministry of Health (MoH) as to whether or not to reimburse the pharmaceutical(s). The data then come to the Council of Compulsory Health Insurance, which also makes recommendations for Ministry of Health (MoH). For the final step of the reimbursement procedure, the Minister of Health makes the reimbursement decision and if it is positive, the order is issued to amend the List of Reimbursed Pharmaceuticals accordingly.

Figure 4.1: Lithuania - New International Nonproprietary Name (INN) reimbursement procedure



MoH = Ministry of Health, PhD = Department of Pharmacy, SPF = State Patient Fund, SMCA = State Medicine Control Agency

In Lithuania there are separate reimbursement and pricing procedures. The policy is the same for the whole country. The requirements for application for reimbursement are listed in Order of the Ministry of Health No. 159 (V-91), 14 April 2002.

The reimbursement status of a pharmaceutical does not change if the patent runs out. The reimbursement status changes in the following cases: if the inclusion of another product into a reimbursement list changes the pharmacoeconomic index of the product which was included into

the list before; if a producer increases the manufacturer price of the product and the Pharmaceuticals Reimbursement Commission decides to recommend to the Minister of Health to exclude this product from the list; if the pharmaceutical loses the status of prescription-only medicine(s) (POM); and if the producer cannot supply the pharmaceuticals to the market.

4.2 Reimbursement schemes

The Transparency Directive is implemented by the Law on Pharmacy[1], Order No. 159 (V-91) of the Ministry of Health[2], and Order No. 459 of the Ministry of Health[3]. The current scheme has been implemented with the purpose of insuring a transparent coverage process, with strict deadlines and forms required by the Directive. The process of reimbursement cannot exceed 180 days.

4.2.1 Eligibility criteria

Lithuania operates a positive list, which contains pharmaceuticals eligible for reimbursement under specified conditions in the out-patient sector. Expensive pharmaceuticals are centrally purchased by the State Patient Fund (SPF).

The Ministry of Health (MoH) decides on the inclusion of pharmaceuticals into the positive list. The Ministry of Health (MoH) is advised by the Pharmaceuticals Reimbursement Commission, which is an interdisciplinary committee consisting of representatives of the Ministry of Health (MoH) (3), the Department of Pharmacy (PhD) (2), the State Medicine Control Agency (SMCA) (1) and the State Patient Fund (SPF) (1) (cf. 4.1).

Criteria for inclusion into the reimbursement list include the budget impact, therapeutic value and safety of the pharmaceutical compared to its therapeutic alternatives, as well as the severity of the disease for which it is intended.

A pharmaceutical is included into the List of Reimbursed Pharmaceuticals for a maximum period of five years; after this period a re-application for reimbursement has to be submitted. In Lithuania pharmaceuticals are reimbursed in the out-patient sector according to a List of Diseases, with the reimbursement category being decided according to the severity of the disease. Besides reimbursement according to defined diseases, pharmaceuticals may be reimbursed for certain social reasons.

All individuals insured with compulsory health insurance are eligible for pharmaceuticals under this system.

[1] Law on Pharmacy 2006, 22 June 2006 No. X-709

[2] Order of Health Ministry No. 159, 14 April, 2002

[3] Order No. 459 of the Ministry of Health of the Republic of Lithuania, 12 August 2000 (last amended by order No.V-992 on 19 December 2005).

Only prescription-only medicine(s) (POM) can be included in the reimbursement system. In general, pharmaceuticals are reimbursed for diseases for which treatment is expensive and lengthy or lifelong. The majority of patients receiving reimbursed pharmaceuticals are pensioners or disabled people. Also, patients who, without treatment are considered to be dangerous to society or to themselves, receive pharmaceuticals from the social health insurance (SHI).

4.2.2 Reimbursement categories and reimbursement rates

Reimbursement categories are determined by Parliament. The principles of the reimbursement levels are determined by the Law on Health Insurance. In Lithuania pharmaceuticals are reimbursed in the out-patient sector according to a List of Diseases, with the reimbursement category being decided according to the severity of the disease. Besides reimbursement according to defined diseases, pharmaceuticals may be reimbursed for certain social reasons. The positive list is therefore made up of two categories.

- List A covers pharmaceuticals which are reimbursed with regard to the severity of the disease at the following levels:
  - 100% (e.g. cancer, asthma, schizophrenia)
  - 90% (a category introduced in 2002)
  - 80% (e.g. hepatitis B and C), or
  - 50% (e.g. osteoporosis).

  List A includes approximately 250 International Nonproprietary Names (INN). Reimbursement from the disease-based list accounts for approximately 85% of the country's total pharmaceutical reimbursement. Under the Health Insurance Law of 2002 the criteria for inclusion of pharmaceuticals in the 100% reimbursement category were revised, and a new reimbursement category of 90% was introduced.
- List B covers all pharmaceuticals, which are reimbursed for social reasons at the following levels:
  - 100% (treatment of children under the age of 18 and severely disabled people), or
  - 50% (retired people and other social groups).

  There is a tendency to include pharmaceuticals reimbursed for social reasons in List A as well, which means that List B is progressively reduced. Approximately 80 International Nonproprietary Names (INN) are covered by List B.

All reimbursement categories correspond to the base price of the pharmaceutical (basis for calculation of reimbursement sum), which is always lower than the pharmacy retail price (PRP). All necessary products in the in-patient care institutions are fully reimbursed. The prices of pharmaceuticals are included in the price of the medical services for in-patient treatment.

Besides the above-mentioned reimbursement categories, patients and doctors may apply for reimbursement of a pharmaceutical on an individual basis. This mainly concerns very expensive pharmaceuticals which are centrally purchased through the State Patient Fund (SPF), and such reimbursement is granted to people in the out-patient sector, only after the approval of three specialists and the head of a hospital.

Patients with swallowing difficulties or children under six years old can receive more expensive pharmaceuticals in a liquid form or soluble tablets. The doctor as to attest in the patient's pharmaceutical history that the patient has swallowing difficulties.

The main rules of reimbursement of pharmaceuticals are stated in the Art. 10 of the Law on Health Insurance.

The proposed reimbursement level for a pharmaceutical is mentioned in the application for reimbursement. During discussions in the Pharmaceuticals Reimbursement Commission the reimbursement level is determined and the recommendation to reimburse the product is discussed in the Council of Compulsory Health Insurance. The final decision on reimbursement of the product and the reimbursement level is made by the Minister of Health. In Lithuania there is no specific or fixed reimbursement price as a prerequisite for inclusion of the pharmaceutical in the reimbursement list.

Table 4.1: Lithuania - Reimbursement of pharmaceuticals

Reimbursement category	Reimbursement rate	Characteristic of category
Fully reimbursed	100% of pharmacy retail price (PRP)	Insulin
Fully reimbursed	100% of basic price	Pharmaceuticals for treatment of life-threatening diseases
Partially reimbursed	90%	Some products for glaucoma treatment
Partially reimbursed	80%	The products for treatment of main chronic diseases (e.g. hypertension)
Partially reimbursed	50%	The products for treatment of diseases which influence quality of life but not longevity

Source: Order of MoH, No. 49, 2000

4.2.3 Reimbursement lists

There are only positive lists in Lithuania. In 2006 there were approximately 250 International Nonproprietary Names (INN) on List A and 80 International Nonproprietary Names (INN) on List B available for out-patient reimbursement. This corresponds to nearly 1,500 brand names including dose and pack size variations included in the reimbursement lists. The lists are administered according to Order of the Minister of Health No. 159, 5 April 2002 (to become V-91, 12 February 2007). (For the administration procedure cf. 4.1.) The lists are updated when new pharmaceuticals are included in or removed from them. On average, this takes place approximately 3-4 times a year.

Only pharmaceuticals registered in Lithuania or the European Union (EU) via a centralised procedure can be included into the List of Diseases and Pharmaceuticals for treatment of registered indications.

The main criteria for inclusion in and/or exclusion from the list(s) are:

- the medical benefit provided by the pharmaceutical;

- the results of the pharmacoeconomic evaluation;
- the impact of reimbursement of the pharmaceutical on the budget of the State Patient Fund (SPF) (estimation is made for each indication submitted for reimbursement).

When determining the medical benefit provided by the pharmaceutical the following characteristics are considered: effectiveness of the pharmaceutical; its safety; its place in the treatment algorithms, in comparison to other reimbursed pharmaceuticals or alternative treatment options; the severity of the disease which the pharmaceutical is intended to treat; pathogenetic, symptomatic or prophylactic effect of the pharmaceutical; and data from published clinical trials.

The Orders of the Minister of Health are published in the Official Journal, available to doctors, pharmacists and patients. Changes are made 3-4 times a year.

Those products that do not completely fulfil the inclusion criteria are rejected from the list in the Pharmaceuticals Reimbursement Commission and can only apply again one year after rejection.

Hospitals and nursing homes can purchase pharmaceuticals independently, according to public competition criteria.

4.3 Reference price system

The reference price system is set by the Government. Government Act No. 994[1] is currently in effect. The reference price system was implemented in 2003 by Parliament, amending the Health Insurance Law. In 2002 the Parliament stipulated that the manufacturer price in Lithuania must not exceed 5% higher than the lowest price in the European Union (EU). After the European Union (EU) enlargement of 2004 the Health Insurance Law was changed and the task of pricing of reimbursed pharmaceuticals was delegated to Government.

Pharmaceuticals are consolidated into groups, as described in 3.3.2.

Pharmaceuticals are grouped on the basis of a common (international) name (International Nonproprietary Name (INN)), method of use, form, purpose, and length of action (for more detail cf. 3.3.2).

The Department of Pharmacy (PhD) is responsible for checking the accuracy of prices given by producers.

Every pack of an original product produced by only one manufacturer has its own reimbursed price.

[1] Decree No. VIII-994[1] of the Government of the Republic of Lithuania, 13 September 2005, http://www3.lrs.lt

The reference price in a group of pharmaceuticals is calculated according to the cheapest price of the product weight or activity unit. All products have the same International Nonproprietary Name (INN), so there is no need to determine dose equivalence.

Every generic product of an International Nonproprietary Name (INN) which is approved for the positive list is included in the application for inclusion into the List of Reimbursed Pharmaceuticals.

Prescribing by International Nonproprietary Name (INN) is obligatory for doctors, and in turn “generic substitution” is permitted by pharmacists, who are obliged to inform patients of the cheapest generic product available.

Parallel trade has been allowed in Lithuania since 2006 according to the Law on Pharmacy, but is not operating in practice at the time of writing. From April 2007 companies may apply for authorisation of parallel trade.

If there are no suitable pharmaceuticals for comparison for the determination of a reference price in Lithuania, comparison is carried out according to the price in the country of manufacture.

4.4 Private pharmaceutical expenses

The rules for reimbursed pharmaceutical pricing are stipulated by Government Order. The private contribution to total pharmaceutical expenditure (TPE) approximately is 20% of total reimbursed pharmaceutical expenditure (PE).

In List B there are 80 International Nonproprietary Names (INN) of pharmaceuticals which are reimbursed to disabled people and pensioners at the 100% and 50% levels. For disabled people and children, all pharmaceuticals from List A and List B are reimbursed at the 100% level, irrespective of the disease.

There are 22 algorithms for treatment of diseases, involving the majority of patients. Co-payments work as an incentive for rational use of pharmaceuticals because pharmaceuticals are not free to patients, but rather they need to pay part of the price.

The increasing revenue of the health sector does not mean that the reimbursement level of pharmaceuticals can also be raised. All additional money is used to cover the growing consumption of reimbursed pharmaceuticals, and for reimbursement of new pharmaceuticals for diseases from List A.

In the year 2002 the reimbursement rates of some diseases were reduced and all non-prescription (over-the-counter (OTC)) pharmaceuticals were removed from the List of Reimbursed Pharmaceuticals and respective price list. The 100% reimbursement category mainly applies to pharmaceuticals used for treatment of diseases which may result in the death of patient in a short time without treatment, as well as diseases which render the status of the patient as dangerous to members of the community.

4.4.1 Direct payments

There are some types of pharmaceuticals that are not covered by social health insurance (SHI): over-the-counter (OTC) are generally not reimbursed. Besides over-the-counter (OTC) pharmaceuticals, the patient has to pay the full amount of the price of the pharmaceutical as a direct payment for all other non-reimbursed pharmaceuticals.

4.4.2 Out-of-pocket payments

Patients must pay a co-payment for reimbursed pharmaceuticals. Only insulin is fully reimbursed and has no co-payment. There is no limit on the total co-payment amount.

4.4.2.1 Fixed co-payment

There are no fixed co-payments in Lithuania. Co-payments are variable according to the reimbursement level and pharmacy retail price (PRP) of the pharmaceutical.

4.4.2.2 Percentage co-payment

Percentage co-payments are applied to all reimbursable pharmaceuticals (cf. 4.2.2). The basic principle is that patients are obliged to pay the difference between the reimbursement sum, calculated according to the base price (cf. 3.1) for reimbursement, the percentage reimbursement category and the pharmacy retail price (PRP). The base price for reimbursement is always lower than the maximum pharmacy retail price (PRP) (with the exception of some insulins).

There is neither a minimum co-payment nor an annual or monthly out-of-pocket maximum.

4.4.2.3 Deductibles

Deductibles are not used in Lithuania.

4.5 Reimbursement in the hospital sector

All pharmaceuticals for patients in hospital are fully reimbursed, i.e. the patient does not pay any co-payment for pharmaceuticals when in hospital. The hospital independently purchases pharmaceuticals needed for in-patient treatment, through public competition. The hospital receives from the State Patient Fund (SPF) for treatment of patients. The price of pharmaceuticals is included in this sum of money.

With in-patient treatment the patient only needs to pay a co-payment in the event that s/he wants more expensive treatment than is included in the social health insurance (SHI)-financed

treatment algorithms. In that case the patient must pay the difference between the standard treatment price and the price for the treatment that s/he wants.

4.6 Reimbursement-related cost-containment measures

This section contains a description of major changes in the reimbursement system, and reviews.

4.6.1 Major changes in reimbursement lists

There are two reimbursement lists in Lithuania: List A (85% of total pharmaceutical reimbursement) is a disease-based list (reimbursement for patients with the listed disease(s)); and List B (progressively reduced), which is for reimbursement for social groups. Since the mid-1990s new reimbursement lists have not been introduced. Reimbursement List B (reimbursed products for social groups) is progressively reduced and products from List B are moving into reimbursement List A (List of Diseases and Reimbursed Pharmaceuticals for their Treatment). List B has not replenished since 2002.

4.6.2 Introduction / review of reference price system

Since the year 2000, patient co-payments have been introduced for all pharmaceuticals, including the cheapest 100% reimbursed pharmaceuticals (with the exception of insulin).

Patient co-payment depends on the price of the pharmaceuticals (for 100% reimbursed cheapest pharmaceuticals in the group). The reimbursed price is not the whole pharmacy retail price (PRP), but part of the price referencing retail price (excluding insulin).

Until 2003 the formula for the calculation of the reference price was set by the Government; between 2003 and 2005, it was set by the Ministry of Health (MoH); and since 2005 it is set by the Government again.

All products with same chemical formula are consolidated into groups and one reference price is calculated and allocated to all the products included in this group.

Since 2003 the reference price is calculated according to the Health Insurance Law.

According to the regulations in Lithuania, reference prices were calculated between 2003 and 2005 using the lowest European carriage and insurance packaging (CIP) price, plus 5%. The co-payment depended on the difference between the lowest European carriage and insurance packaging (CIP) price and the Lithuanian carriage and insurance packaging (CIP) price. If the producer reduced the carriage and insurance packaging (CIP) price, the co-payment reduced too. This regulation was changed in 2005 in line with the enlargement of the European Union (EU), and the reimbursed price is now calculated as not higher than 95% of the average manufacturer prices in six reference countries (Latvia, Estonia, Poland, Czech Republic, Slovakia and

Hungary). The difference between this reference price and the pharmacy retail price (PRP) is paid by the patient in the form of a co-payment.

Parallel trade has been allowed in Lithuania since 2006 according to the Law on Pharmacy, but in practice is not operating at the time of writing. From April 2007 companies may apply for authorisation of parallel trade.

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

Since the year 2000, patient co-payments have been introduced for all pharmaceuticals, including the cheapest 100% reimbursed pharmaceuticals (with the exception of insulin).

Co-payment is calculated according to a special formula which does not allow it to exceed LTL 5. Co-payments are not fixed and depend on the pharmacy retail price (PRP). There are no additional pharmaceutical fees in Lithuania.

The patient co-payment depends on the price of the pharmaceutical (for 100% reimbursed cheapest pharmaceuticals in the group), e.g.:

- if the pharmacy retail price (PRP) is LTL 10, the patient pays LTL 0.83
- if the pharmacy retail price (PRP) is LTL 50, the patient pays LTL 2.38
- if the pharmacy retail price (PRP) is LTL 100, the patient pays LTL 3.17
- if the pharmacy retail price (PRP) is LTL 500, the patient pays LTL 4.55
- if the pharmacy retail price (PRP) is LTL 1,000, the patient pays LTL 4.76.

4.6.4 Claw-backs

There are no claw-backs used in Lithuania.

4.6.5 Reimbursement reviews

Reimbursement decisions are reviewed every five years. The reimbursed pharmaceuticals are evaluated in the Pharmaceuticals Reimbursement Commission. The criteria for review are the same as the inclusion criteria. Doctors, doctors associations, universities, the State Patient Fund (SPF), the State Medicines Control Agency (SMCA), and the Department of Pharmacy (PhD) can apply for reimbursement review. At the time of writing, results are not usually published.

5 Rational use of pharmaceuticals

This chapter gives an overview of the current methods used to promote equitable and efficient use of pharmaceuticals.

5.1 Pharmaceutical budgets

Pharmaceutical budgets are not used in Lithuania at the time of writing.

During the period 2002-2003, pharmaceutical budgets were used as a means to control Statutory Health Fund (State Patient Fund (SPF)) expenditure, and were set according to the actual health care budget. Specific budgets were allocated to health care institutions. The budget amount allocated to every doctor was set by the institution according to the amount of patients treated by that doctor and depending on the products prescribed by this doctor (according to the doctors' specialties). These budgetary limitations were set at national level and were in effect from April 2002 until September 2003. Budgetary limitations were set by Order of the Minister of Health and were enforced by experts of the State Patient Fund (SPF). Possible sanctions for budgetary overspending were set for health care institutions. If doctors did not keep within the budgetary limits the State Patient Fund (SPF) could reduce the amount of money which would be paid to the respective health care institution for medicinal services to insured people. As a further measure the administration of the health care institutions could reduce the salary of doctors who overspent. The sanctions were set by Order of the Minister of Health but were not used in reality. The budgetary restrictions were cancelled in September 2003.

5.2 Prescription guidelines

Prescription guidelines were introduced in July 2002. First, the guidelines were only for reimbursed pharmaceuticals and were confirmed by Order of the Ministry of Health. The main purpose of those guidelines was to create rules for the treatment of 10 diseases, which consumed majority of the Compulsory Health Insurance Fund budget for pharmaceutical reimbursement. During the next few years guidelines were drawn up for 27 diseases and these included all prescribed pharmaceuticals (reimbursed and non-reimbursed) for treatment of those diseases. These guidelines are not obligatory, but rather recommended, and if a doctor judges that a situation requires measures not described in the guidelines s/he should explain her/his actions in the patient's medical history. In 2006 some key principles for preparing the therapeutic guidelines were outlined. The initiative of preparing and amending existing guidelines was delegated to doctors associations and universities. The Ministry of Health (MoH) only approves the guidelines. These principles are set out in Order of the Ministry of Health No. V-395, 17 May 2006.

Annual clinical auditing of doctors is not carried out every year. Experts of the State Patient Fund (SPF) carry out audits of selected doctors for which the prescription quantity/sum is increasing fast, or in cases where the State Patient Fund (SPF) has noticed that doctors are prescribing reimbursed pharmaceuticals for patients for which there contraindications regarding the

use of such pharmaceuticals. Sanctions can be imposed for doctors who prescribe reimbursed pharmaceuticals without indications. As such actions must be treated as detrimental to the Compulsory Health Insurance Fund budget, health care institutions can be refused allocations from the State Patient Fund (SPF) budget in such cases. The State Patient Fund (SPF) receives information about discrepancies just after the patient receives the reimbursed pharmaceutical(s). The health care institution's administration decides how to deal with the doctor that incorrectly prescribed the reimbursed pharmaceutical (request that they pay back all or part of the reimbursed sum or impose other penalties). Prescribing larger pack sizes does not cause any problems because patients do not want to go to the doctor very often to be prescribed a new pack of pharmaceuticals. If the medical audit service determines that a doctor's competence is insufficient the audit service can obligate the doctor to attend an additional refresher course.

Doctors can access the information on prescription guidelines online, in databases, and it is also available in printed form. The first guidelines were introduced in August 2002 and were prepared by working groups of (doctor) specialists and specialists at the Ministry of Health (MoH) and the State Patient Fund (SPF). The guidelines are updated when new pharmaceuticals came onto the market or into the reimbursement system, or when there are changes in treatment. Dose, duration or diagnostic limits are included, along with the range of pharmaceuticals available.

5.3 Information to patients / doctors

Information to patients and/or doctors is regulated by the Law on Pharmacy (22 June 2006), which implements the provisions of Directive 2001/83/EC and Order of the Ministry of Health No. V-1128 on the rules on advertising of pharmaceuticals (28 December 2006). The State Medicine Control Agency (SMCA) is responsible for monitoring the information provided and the advertising of pharmaceuticals.

Information on pharmaceuticals is divided into two categories by the Law on Pharmacy: pharmaceutical information and promotional information (advertising).

Pharmaceutical information is that which is officially authorised by the State Medicine Control Agency (SMCA). This is information included in patient information leaflets (PIL) and in the summary of product characteristics (SPC). Pharmaceutical information is available to everyone.

Promotional information (advertising) is allowed for over-the-counter (OTC) pharmaceuticals in all electronic forms (including media and Internet), but is not allowed for prescription-only medicine(s) (POM).

Regulations and restrictions on the activities of representatives of pharmaceutical companies who visit doctors are stipulated in the rules on advertising of pharmaceuticals. A representative should arrange a visit time with a doctor before visiting her/him. If the representative wishes to provide information during the meeting s/he should get permission of the head of the health care institution.

A representative is allowed to show samples of pharmaceuticals to doctors but s/he is not allowed to leave them. Samples of pharmaceuticals are not allowed to be used. (This provision is put in place by law.)

The market authorisation holder is not allowed to pay for specialist visits (travel, accommodation and others) for promotional events, but for professional (scientific) events this is allowed, according to the Law on Pharmacy.

Since 2007 market authorisation holders should provide information to the State Medicine Control Agency (SMCA) once a year on promotional expenditure for events (promotional and professional (scientific)) and for health care and pharmacy specialists participating at such events, according to Order No. V-1037 of the Ministry of Health, 8 December 2006.

There is no control over the quantity of sales promotion activities undertaken by pharmaceutical companies.

No real action is taken to inform patients on the rational use of pharmaceuticals, except the medication prescription.

5.4 Pharmacoeconomics

Since 1 October 2003 pharmaceuticals companies have been required to submit pharmacoeconomic analyses for reimbursement of pharmaceuticals, in accordance with the regulations of the Ministry of Health (MoH) and based on the Baltic Guideline for Economic Evaluation of Pharmaceuticals.[1]

As the Baltic states share similar social and economic conditions, common guidelines for economic evaluation were developed by a cooperation of the Latvian Pricing and Reimbursement Agency (ZCA), the Estonian Health Insurance Fund (HAIGEKASSA) and the Lithuanian Department of Pharmacy (PhD) for purpose of simplifying the application process for pharmaceuticals companies. The guidelines are oriented towards the pharmaceutical industry and give information on the preferred perspective (health care system); on costs to be included in the analysis and how they are to be established; on discount rates to be used, etc.

Pharmacoeconomic evaluation is one of the criteria for including pharmaceuticals in the reimbursement system. Producers must provide the pharmacoeconomic analysis as part of the reimbursement application.

Pharmacoeconomic analysis results are presented to the Pharmaceuticals Reimbursement Commission and are evaluated at points during reimbursement procedure. Pharmacoeconomic evaluation has been applied since October 2003 and is necessary for all pharmaceuticals applying for reimbursement status. Pharmacoeconomic analysis guidelines are confirmed by Order of the Ministry of Health No. V-26 of 2003. These guidelines are made publicly available to appli-

[1] Baltic Guideline for Economic Evaluation of Pharmaceuticals (pharmacoeconomic analysis); http://www.zca.gov.lv/docs/new2002/doc24-1.pdf

cants on the Internet and in the Official Journal. Since 2003 the guidelines have not been re-evaluated, but all Baltic countries have an annual meeting at which issues relating to pharmacoeconomic evaluation are discussed. In Lithuania there is no determined level of quality-adjusted life year (QALY) price, over which the pharmaceuticals are not reimbursed.

The Department of Pharmacy (PhD) is responsible for conducting the pharmacoeconomic evaluations and submitting them to the Pharmaceuticals Reimbursement Commission.

5.5 Generics

In Lithuania the amount (in value) of generics is approximately 17-20% of total expenditure for pharmaceutical reimbursement. In terms of volume, generics account for approximately 50% of all reimbursed prescriptions.

5.5.1 Generic substitution

Since 1 July 2004 reimbursed prescriptions are written according to International Nonproprietary Name (INN), whereas until 1 July 2004 prescriptions were only written only by brand name. Pharmacies are obliged to inform patients about the pharmacy retail price (PRP), reimbursed price and co-payment of pharmaceuticals, as well as about the option to choose among the products with the same International Nonproprietary Name (INN). They are also obliged to have in stock the cheapest product of every International Nonproprietary Name (INN) that they sell. Doctors can indicate on the prescription that the brand name should be used, but in such cases the doctor is obliged to explain why, e.g. that the patient is sensitive to another product, and to inform the State Medicine Control Agency (SMCA) about this case, indicating this in the patient's medical history. If the doctor prescribes the reimbursed pharmaceutical only according to brand name, the prescription is not valid and the doctor must prescribe the pharmaceutical again correctly. If the patient chooses the product with a higher pharmacy retail price (PRP), s/he must pay a higher co-payment.

As a rule the generic products are cheaper than the original products with the same International Nonproprietary Name (INN), so there is a financial initiative for the patient to choose the generic product with the lower co-payment, because the reimbursed price is determined according to the cheapest product with same International Nonproprietary Name (INN). Pharmacies are allowed to substitute products with the same International Nonproprietary Name (INN), but therapeutic substitution with another International Nonproprietary Name (INN) is not allowed.

Parallel trade has been allowed in Lithuania since 2006 according to the Law on Pharmacy, but in practice is not operating at the time of writing. From April 2007 companies may apply for authorisation of parallel trade.

5.5.2 Generic prescription

Prescriptions were written according to brand name until 1 July 2004.

Since 1 July 2004 reimbursed prescriptions are written according to International Nonproprietary Name (INN). If necessary, the doctor has the option of adding (in brackets) the brand name to prescription, indicating that this is the preferred pharmaceutical to be dispensed, if this is medically indicated (cf. 5.5.1).

5.5.3 Generic promotion

There is no special generic promotion among patients, doctors or pharmacists.

Pharmacists are obliged to offer the cheapest generic product available to the patient. Thus, the patient has some choice in terms of pharmaceutical selection, at her/his own expense (co-payment).

5.6 Consumption

The State Medicine Control Agency (SMCA) receives information from distribution companies about the amounts of all pharmaceuticals that they have sold. It does not receive information about consumption of any pharmaceuticals from pharmacies. The State Medicine Control Agency (SMCA) only collects data from wholesalers about packs of pharmaceuticals sold to pharmacies and hospitals (without prices). Pharmaceutical consumption is expressed as defined daily doses (DDD) according to the World Health Organization (WHO)-proposed Anatomic Therapeutic Chemical (ATC) classification of pharmaceuticals.

Information about consumption of non-reimbursed pharmaceuticals is not collected.

The State Patient Fund (SPF) collects information about all dispensed reimbursement pharmaceuticals. Data are available for individual consumption monitoring.

Patients are provided essential pharmaceuticals (without market authorisation) according to Order No. V-622 of the Ministry of Health on placing onto the market essential pharmaceuticals which do not receive market authorisation, 2 September 2004.

The other way to provide patients pharmaceuticals without market authorisation is according to Order No. V-375 of the Ministry of Health (Bona Fide order), May 2005. This is for use by individual patients under their own direct personal responsibility.

Table 5.1: Lithuania - Trends in consumption 2000-2005

Variable (in Mio. national currency unit (NCU) or as a %)	2000	2001	2002	2003	2004	2005
Total sales *of which*	618	830	786	852	972	1135
POM	438	632	574	600	689	797
OTC	181	198	212	251	282	338
Reimbursable pharmaceuticals*	336	398	337	351	387	452
Non-reimbursable pharmaceuticals	282	432	449	501	585	683
Dispensed in pharmacy	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Dispensed in hospital	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Dispensed in other places	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Patented products	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Off-patent products/generics	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

OTC = over-the-counter (pharmaceuticals), POM = prescription-only medicine(s), NCU = national currency unit (LTL), n.a. = not available

Source: * State Patient Fund; other information is unofficial, from private company “IMS Health”

5.7 Evaluation

The main aim of implementing pharmaceutical budgets was to control budgetary spending. During the period 2000-2002 the expenditure of the Compulsory Health Insurance Fund was growing extremely quickly. Pharmaceutical budgets and reference price calculation were introduced, and therapeutic guidelines were prepared. Since 2003 pharmacoeconomic evaluation of new pharmaceuticals applying for reimbursement has been introduced and an external price reference system has also been implemented over the same period. These policies have not been evaluated. But the objective – the control of budgetary expenditure – has been achieved as a result of these measures.

6 Current challenges and future developments

This chapter covers the most difficult pharmaceutical challenges for the Lithuanian pharmaceutical system and the future plans that are in place to ensure that the country meets these challenges.

6.1 Current challenges

New features of the system introduced by the Law on Pharmacy include the following points.

- The State Medicine Control Agency (SMCA) is responsible for licensing of pharmaceuticals. Previously, a commission of Ministry of Health (MoH) was responsible. The procedure for licensing and licence forms has been changed by the Resolution of the Government on the rules on licensing of enterprises of pharmacy activity, 30 November 2006.
- A pharmacist may only fill the position of a pharmacist at a pharmacy if s/he has a licence for pharmacist's practice. For other activities, i.e. distribution or manufacturing of pharmaceuticals, a licence is not necessary.
- A pharmacist's assistant (pharmacy technician) may fill the position of pharmacist's assistant (pharmacy technician) at a pharmacy if s/he is registered on the list of pharmacists' assistants (pharmacy technicians). Previously, pharmacy assistants also had to obtain a licence.
- The definition of a "pharmaceutical service" is a pharmacist's practice at a pharmacy, including control of doctors' prescriptions; evaluation and choice of non-prescription pharmaceuticals; provision of pharmaceutical information to the public, health care and pharmacy professionals about pharmaceuticals; and consultations. Pharmaceutical services should be based upon selling (dispensing) pharmaceuticals to the general public.
- Information about pharmaceuticals is divided into two groups: pharmacy information and advertising. Pharmacy information is to be consistent with the summary of product characteristics (SPC). The law restricts the people who are allowed to prepare pharmacy information – these must be people who have completed adequate biomedicine studies, the list of which is approved by the Minister of Health: these studies include medicine, odontology and pharmacy.

Since the Law on Pharmacy entered into force (22 June 2006), almost all legislation relating to pharmaceuticals has been renewed in Lithuania.

6.2 Adherence to European Commission Directives

The Department of Pharmacy (PhD) under the Ministry of Health (MoH) is responsible for implementation of the European Commission (EC) Directives.

Directive 2001/83/EC with amendments 2004/27/EC and 2004/24/EC is implemented by the Law on Pharmacy of 2006.

The Transparency Directive is implemented by the Law on Pharmacy and Orders of the Ministry of Health (MoH) No.159 (V-91) and No.459.

6.3 Future developments

Drafts of new redactions of Orders have already been prepared, as listed here.

- Decree No. VIII-9941 of the Government of the Republic of Lithuania, 13 September 2005 (draft prepared at the time of writing).
- Order No. 459 of the Minister of Health on procedure for the calculation and application of prices for medicinal products, active substances and pharmacy goods, 12 August 2000 (draft prepared at the time of writing).
- 2007 m. liepos 10 d. Nr. V-596.

7 Appendixes

7.1 References

Report of the Lithuanian Health Information Centre “The health of citizens of Lithuania and activity of health care institutions in 2005”, Vilnius 2006 (Lietuvos Sveikatos informacijos centras “Lietuvos gyventojų svaikata ir sveikatos priežiūros įstaigų veikla 2005 m.”, Vilnius 2006”.

Monthly journal for pharmacy specialists „Farmacija ir laikas“ Nr.1, 2006.

7.2 Web links

Name	Link
Department of Statistics under the Government of Lithuania	http://www.stat.gov.lt/
Lithuanian Health Information Centre	http://www.lsic.lt
Ministry of Health (MoH) of Lithuania	http://www.sam.lt
Department of Pharmacy (PhD) under Ministry of Health (MoH)	http://www.fd.lt
State Medicine Control Agency (SMCA) under Ministry of Health (MoH)	http://www.vvkt.lt
State Patient Fund (SPF) under Ministry of Health (MoH)	http://www.vlk.lt

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