Pharmaceutical Pricing and Reimbursement Information

LITHUANIA

September 2008

Pharmaceutical Pricing and Reimbursement Information

LITHUANIA

Pharma Profile

September 2008

PPRI Representatives
Ministry of Health, Department of Pharmacy: Gita Krukiene, Tomas Alonderis

Authors
Ministry of Health, Department of Pharmacy: Gita Krukiene, Tomas Alonderis

Editors
Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG: Simone Morak (Editor-in-Chief)

PPRI Secretariat
Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG

Executive Summary

BACKGROUND

The health system of the Republic of Lithuania is regulated by the following legal acts:

- Law on Health System of 19 July 1994,
- Law on Health Insurance of 21 May 1996, and
- Law on Pharmacy of 22 June 2006.

The principles of the Lithuanian health care system, its relevant institutions and their responsibilities are held in the Law on 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 guarantees 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 case of insured events.

Like other countries in the region (e.g. Estonia, Latvia) Lithuania has a flat tax rate rather than a progressive scheme. Lithuanian income levels still lag behind the rest of the European Union (EU) Member States belonging to the EU before May 2004 (EU 15), with per capita gross domestic product (GDP) in 2006 at 56% of the EU average. GDP grew by 8.8% in 2007, and the inflation rate was 8.1%. In June of 2007 income tax was reduced to 24%. Income tax reduction and 14% annual wage growth is starting to make an impact with some emigrants gradually beginning to come back.

Health expenditure is primarily financed through health insurance contributions but also voluntary health insurance and out-of pocket contributions. 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 (Seimas) also approves the amount of contributions that are to be transferred to the Compulsory Health Care Fund per person insured by public funds (not less than 3.5% of the average monthly income, calculated under the procedure prescribed by relevant legal acts). Payers of compulsory health insurance contributions, the amount of contributions and the procedure of payment are set out in the Law on Compulsory 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 the income tax).

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

In Lithuania health care is organised in a decentralised way. Patients receive health care in regional health care centres and in family doctor clinics. Health care institutions are independent public institutions. University clinics are dependent to the MoH, whereas other health care institutions are either municipal or private.

People who are insured by obligatory health insurance are entitled to an equal level of coverage. Exceptions with regard to pharmaceutical reimbursement exist. For disabled people and children reimbursable pharmaceuticals are reimbursed at a 100% level.

There are two main types of outpatient clinics in Lithuania: independent general practitioners (GPs) and integrated practices (where 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 GPs. 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 GP (family doctor) and s/he is always free to change doctor. The family doctor (GP) refers the patient to the specialist.

PHARMACEUTICAL SYSTEM

Several legal acts regulate pharmaceutical activity in the Republic of Lithuania:

- Law on Pharmacy,
- Law on Health System,
- Law on Health Insurance,
- Law on the Control of Narcotic and Psychotropic substances,
- Government Resolutions on Rules of licensing of the legal entities which prosecute pharmaceutical activity.

Almost all legal acts concerning medicinal products in Lithuania has been updated in compliance with a new Law on Pharmacy (22 June 2006 No. X-709).

The main actors in the pharmaceutical system are the Ministry of Health (MoH), the Department of Pharmacy (PhD), the State Medicine Control Agency (SMCA), and the State Patient Fund (SPF). PhD is responsible for the implementation of pharmaceutical policy and for ensuring the provision of efficient and safe pharmaceuticals at socially acceptable prices. The SMCA, carrying out regulatory and control functions, bears the responsibility of granting marketing authorisation; classification of prescription status; pharmacovigilance; inspecting pharmaceutical industry and pharmaceutical products distribution companies (including pharmacies); controlling the quality and advertisement of pharmaceuticals; approval of clinical trials pharmaceuticals for human use; and performance of good clinical practice (GCP)

inspections. The SPF is in charge of reimbursement along with the procurement via a tendering process of pharmaceuticals with high prices.

There were 19 local pharmaceutical manufacturers registered in 2007 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, biotechnology active pharmaceutical ingredients and medicines, galenas, blood products, and packagers.

In 2007, there were 78 wholesale licenses registered with the SMCA in Lithuania. The wholesale market is in private hands. There were two types of companies holding wholesale licences: 1) full-ranged companies 2) logistic companies that do not have own premises for storing pharmaceuticals (they rent services to storing pharmaceuticals by other companies with the appropriate wholesale licence). Besides a number of smaller companies, there are approximately ten big wholesalers offering more than 2,500 pharmaceuticals in their product range.

In 2007, there were a total of 1,546 pharmacies in Lithuania (including subsidiaries). Most of the community pharmacies are privately owned and just few still are publicly owned. In general, the dispensing of all pharmaceuticals is only allowed in pharmacies. Doctors are not entitled to dispense pharmaceuticals.

The market is growing. In 2007, the sales of pharmaceuticals in Lithuania over the period of the last five years amounted to more than LTL 1.6 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 14.80 (in 2007). State expenditure on pharmaceuticals increased from 10% (in 2000) to 16% (in 2007) of the funds allocated to health care.

PRICING

Manufacturer prices of pharmaceuticals applying for inclusion to the reimbursement list are accepted by the PhD, once the reimbursement procedure for inclusion of new International Non-proprietary Names (INN) is finished. Wholesale and pharmacy retail prices of reimbursed pharmaceuticals are regulated by adding mark ups approved by the MoH. Mark ups are regulated in degressive mark up schemes. Price negotiations are performed for pharmaceuticals with prices exceeding 95% of the average price in reference countries. If the price exceeds the 95% of the average price in reference countries by more than 1 Euro and annual sales of this pharmaceutical is higher than 30,000 Euro negotiations with manufacturers start.

The base price for reimbursement is calculated according to statutorily fixed criteria. Now the calculation of reimbursed price lies within the competence of the government. The new re-

daction of the Law on Health Insurance 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 EU countries (Latvia, Estonia, Poland, Czech Republic, Slovakia, and Hungary).

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) – wholesale price and PRP are regulated via maximum mark ups) and the base price for reimbursement (which only equals to the PRP in case of insulins).

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

In the hospital sector there is free pricing. Expensive hospital pharmaceuticals may be centrally purchased by the SPF.

In Lithuania the standard value-added tax (VAT) is 18% until the 31 December 2008 and will be raised to 19% from 1 January 2009. The reduced VAT rate for pharmaceuticals has been 5% since 2004. From 1 January 2009 a VAT for non reimbursable pharmaceuticals of 19% and for reimbursable pharmaceuticals of 5% will be applied. From 1 July 2009 the VAT will amount to 19% for all pharmaceuticals.

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

REIMBURSEMENT

In Lithuania there are separate reimbursement and pricing procedures. If companies, associations/organisations of doctors, pharmacists, patients, etc. wish to apply for reimbursement of a new active substance, they should submit the application to the PhD for technical evaluation and review of the material. Following this, data is submitted to the Pharmaceuticals Reimbursement Commission, mandated by the Minister of Health. The Pharmaceuticals Reimbursement Commission has six members - representatives of the MoH, SPF, PhD, and SMCA. The Pharmaceuticals Reimbursement Commission makes recommendations for the MoH as to whether or not to reimburse the pharmaceutical(s). The data is then transferred to the Council of Compulsory Health Insurance, which also makes recommendation for the MoH. For the final step of the reimbursement procedure the MoH makes the reimbursement decision and if it is positive, the order to amend the List of Reimbursed Pharmaceuticals accordingly is issued.

Prices are regulated for reimbursed pharmaceuticals only. The price of medicinal pharmaceuticals is part of the evaluation of pharmaceuticals in the Pharmaceuticals Reimbursement Commission.

In Lithuania pharmaceuticals in the outpatient sector are reimbursed according to a list of defined diseases, with the reimbursement category depending on the severity of the disease.

Besides reimbursement according to defined diseases, pharmaceuticals may be reimbursed out of social reasons. The positive list is 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. osteoporoses).

List A includes approximately 250 INN. Reimbursement from the disease-based list accounts to approximately 85% of the country`s total pharmaceutical reimbursement. Under the Law on Health Insurance 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).

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

Pharmaceuticals are grouped on the basis of a common (international) name (INN), method of use, form, purpose, and length of action. 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 INN so there is no need to determine dose equivalence. Every generic product of an INN which is approved for the positive list is included in the application for inclusion into the List of Reimbursed Pharmaceuticals.

Dependent on the price of the pharmaceuticals co-payment are applied to all pharmaceuticals except insulins – including the products which are reimbursed at a 100% level. For products of other reimbursement level (90%, 80% or 50%) the patient additionally need to co-pay 10%, 20% or 50% of the base product price.

All pharmaceuticals for patient in hospital are fully reimbursed, i.e. the patient does not need to pay any co-payment for pharmaceuticals when in hospital. The hospital independently purchases pharmaceuticals needed for inpatient treatment, through public competitions. The hospital receives a fixed amount of money from the SPF for the treatment of patients.

There are price-volume agreements with manufacturers for the reimbursement of new chemical entities. There are some agreements in place which are controlled by the SPF.

RATIONAL USE OF PHARMACEUTICALS

The prescription guidelines were drawn up for 27 diseases and include all prescribed pharmaceuticals for the treatment of those diseases. These guidelines are non-obligatory but rather recommended. The initiative of preparing and amending existing guidelines was delegated to doctors associations and universities. The Ministry of Health (MoH) only approves the guidelines.

Information to patients and/or doctors is regulated by the Law on Pharmacy and by order of the MoH No. V-1128 on the rules on advertising of pharmaceuticals. Information of pharmaceuticals is divided into two categories by Law on Pharmacy: pharmaceutical information and promotional information (advertising). Pharmaceutical information is the information which is officially authorised by the SMCA. This is information included in patient information leaflets and summary of product characteristics. Pharmaceutical information is available for everyone.

Annual clinical auditing of doctors is not carried out every year. Experts of the SPF carry out audits of selected doctors for which the prescription quantity/sum is increasing fast, or in cases where the 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 SPF budget in such cases.

Pharmaceutical companies have been required to submit pharmacoeconomic analyses for reimbursement of pharmaceuticals, in accordance with the regulations of the MoH and based on the Baltic Guideline for Economic Evaluation of Pharmaceuticals.

Reimbursed prescriptions are written according to INN. 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. If the doctor prescribes the reimbursed pharmaceutical only according to the brand name, the prescription is not valid. If the patient chooses the product with a higher pharmacy retail price, s/he must pay a higher co-payment.

The SMCA receives information from distribution companies about the amount of all pharmaceuticals being sold.

The SPF collects information about all dispensed reimbursement pharmaceuticals. Data are available for individual consumption monitoring.

CURRENT CHALLENGES AND FUTURE DEVELOPMENTS

Since 2006 when the Law on Pharmacy entered into force almost all legislation relating to pharmaceuticals have been renewed in Lithuania.

Table of contents

List of tables and figures

List of abbreviations

ATC	Anatomic Therapeutic Chemical classification
CIP	Carriage and Insurance Packaging
CIS	Commonwealth of Independent States
DDD	Defined Daily Dose
DG Sanco	Health and Consumer Protection Directorate-General
EC	European Commission
EU	European Union
GCP	Good Clinical Practice
GDP	Gross Domestic Product
GGE	General Government Expenditure
GMP	Good Manufacturing Practice
GÖG/ÖBIG	Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG
GP	General Practitioner
HE	Health Expenditure
HOM	Hospital-Only Medicine
INN	International Non-proprietary Name
LTL	Lithuanian Lita
Mio.	Million
MoH	Ministry of Health
NCU	National Currency Unit
NHS	National Health Service
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
OPP	Out-of pocket Payment

OTC	Over-The-Counter (pharmaceuticals)
PE	Pharmaceutical Expenditure
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 Organisation
WTO	World Trade Organisation

PPRI Pharma Profile Update 2008

Rationale

In the beginning, the Pharmaceutical Pricing and Reimbursement Information (PPRI) project was 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 more than 50 participating institutions (competent authorities and other relevant organisations) in the field of pharmaceuticals (for the list of PPRI members see the PPRI website http://ppri.oebig.at → Network)

Within the course of the PPRI project, country reports on pharmaceutical pricing and reimbursement systems, the "so-called PPRI Pharma Profiles", were produced (see http://ppri.oebig.at → Publications → Country Information. These PPRI Pharma Profiles refer, in general, to the year 2006/2007. The works was mainly under the responsibility of the WHO Regional Office for Europe assisted by the team of the Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG / Austrian Health Institute (GÖG/ÖBIG).

Despite of the official end of the research project in 2007, the PPRI network participants have agreed to continue the network and up-date the PPRI Pharma Profiles.

Outline

The PPRI Pharma Profile consists of six chapters, referring to the situation in 2008:

- Chapter 1 (Background) gives a brief overview of the demographic, economic and political situation and a brief introduction to the health care system.
- Chapter 2 (Pharmaceutical system) provides a description of the pharmaceutical system; the regulatory framework, the pharmaceutical market, the market players and the funding of pharmaceuticals and the methods of evaluating the system.
- Chapter 3 (Pricing) covers a description of the organisation of the pricing system, the pricing policies, the pricing procedures, exceptions to these procedures, as well as a section on margins and taxes and pricing related cost-containing measures.
- Chapter 4 (Reimbursement) covers a description of the organisation of the reimbursement system, the reimbursement scheme including the eligibility criteria, the reimbursement categories and rates and the reimbursement lists. Also described in this chapter is the reference price system, the private pharmaceutical expenditure, the reimbursement in the hospital sector and the reimbursement related cost-containing measures.

- Chapter 5 (Rational Use of Pharmaceuticals) is a description of the methods used to improve rational use of pharmaceuticals including the impact of pharmaceutical budget, prescription guidelines, patient information, pharmaco-economics, generics and consumption.

- Chapter 6 (Current challenges and future developments) is a concluding chapter on the current challenges and future plans for developments in the pharmaceutical sector.

Further deliverables

Besides the PPRI Pharma Profiles and the PPRI network, the PPRI project produced further deliverables, among those:

The **PPRI Glossary**, which is a unique glossary of pharmaceutical terms to establish a common "pharma" terminology within the EU. See http://ppri.oebig.at → Glossary

The **PPRI Conference**, held in Vienna in June 2007. See http://ppri.oebig.at → Conferences → PPRI Conference

The **Set of Core PPRI Indicators** to compare information of different pharmaceutical system. See http://ppri.oebig.at → Publications → Indicators

A comparative analysis, based on the developed indicators, filled with real data from 27 PPRI countries. The PPRI comparative analysis is included in the **PPRI Report** and summed up in the concise report **"PPRI at a Glance"**. See http://ppri.oebig.at → Publications → PPRI Report and http://ppri.oebig.at → Publications → Concise Information

Contact

The PPRI Secretariat is located at Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (GÖG/ÖBIG) which featured as the main partner of the PPRI research project.

Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (GÖG/ÖBIG)
Stubenring 6, 1010 Vienna, Austria
E-Mail: ppri@goeg.at
Fax.: +43 1 5138472
URL: http://ppri.oebig.at

Dr. Sabine Vogler, PPRI Project Manager, E-mail: vogler@goeg.at, Tel.: + 43-1-51561/147

Mag. Claudia Habl, Deputy Project Manager, E-mail: habl@goeg.at, Tel.:+ 43-1-51561/161

Mag. (FH) Christine Leopold, MSc, Communications Officer, E-mail: leopold@goeg.at, Tel.: + 43-1-51561/149

Mag. (FH) Simone Morak, Editor-in-Chief, E-mail: morak@goeg.at, Tel.: + 43-1-51561/241

1 Background

This chapter provides an overview of the country and its health care system as of 2008.

1.1 Demography

The population of Lithuania is approximately 3.3 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 51.8 inhabitants per km^2 (in 2007). However, the distribution is not even. In the capital Vilnius the density is much higher than in other parts of the country. Vilnius has approximately 554,409 inhabitants (2007), Kaunas has 358,111, and Klaipeda has 185,936 inhabitants. The division between urban and rural population is 66.7% and 33.2%, respectively (in 2007).

Life expectancy, which is the most important health indicator, has decreased slightly in 2006. The average life expectancy was 77.06 years for females and 65.31 years for males. A pronounced difference in the average female and male life expectancies is still noticed: males live 11.7 years less than females. A particularly big difference is noticeable among the rural male and female population (12.2 years). Since the early 2000s, life expectancy for males has decreased by 1.46 years and life expectancy for females has decreased marginally (by 0.39 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 life expectancy of Lithuanian inhabitants is significantly shorter than that of the inhabitants of most of the EU countries. Among all the 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, 2000–2007

Variable	2000	2001	2002	2003	2004	2005	2006	2007
Total population	3 512 100	3 487 000	3 475 600	3 462 500	3 455 900	3 425 300	3 403 284	3 384 879
Population density per km^2	53.8	53.4	53.2	53.0	52.8	52.3	52.1	51.8
Population aged 0-14 (in % of total)	n.a.	n.a.	n.a.	n.a.	n.a.	17.07	16.47	15.90
Population aged 15-64 (in % of total)	n.a.	n.a.	n.a.	n.a.	n.a.	67.82	68.20	68.52
Population aged > 64 (in % of total)	n.a.	n.a.	n.a.	n.a.	n.a.	15.09	15.33	15.58
Life expectancy at birth, total	72.19	71.78	71.91	72.19	72.06	71.32	71.12	n.a.
Life expectancy at birth, females	77.45	77.58	77.58	77.85	77.75	77.42	77.06	n.a.
Life expectancy at birth, males	66.77	65.95	66.21	66.48	66.36	65.36	65.31	n.a.

n.a. = not available

Source: 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 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 growth rate of 8.4% in gross domestic product (GDP) reflected impressive economic development (http://www.stat.gov.lt/en/). Most of Lithuania's trade is conducted within the EU.

In 2007 the country's GDP grew by 8.8%, and the inflation rate was 8.1%.

Lithuania is a member of the World Trade Organization (WTO) and the 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 4.3% in 2007. According to officially published figures, EU membership fuelled 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 2012.

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

56% of the EU average. Lower wages may have been a factor that the trend of emigration to the wealthier EU countries in 2004 influenced, something that has been made legally possible as a result of accession to the EU. In June 2007, income tax was reduced to 24%. 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 2007 was 13,900 and is lower than in 2005 with 15,571.

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 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 2007, exports to the east were only 24% of the total, while exports to EU Member States amounted to 64%.

Exports to the United States make up 2.5% of all of Lithuania's exports, and imports from the United States comprise 2% of total imports. Foreign direct investment in 2007 was LTL 80.924 million, which represented an increase of 21 % compared to the same period in the previous year.

Table 1.2: Lithuania - Macroeconomic indicators, 2000–2007

Variable (*in LTL (NCU)* or percentage)	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**
GDP in NCU	45,674	48,585	51,971	56,804	62,587	71,200	81,905	96,739
GDP / capita[1] in NCU	13,502	13,956	14,981	16,445	18,217	20,854	24,132	28,615
GDP / capita[1] in PPPa	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Annual economic growth rate in %[2]	4.1	6.6	6.9	10.3	7.3	7.9	7.7	8.8
General government expenditure (GGE)	9,468	9,987	11,673	12,489	14,560	17,062	19,301	22,167
GGE in % of GDP	20.7	20.6	22.5	22.0	23.3	24.0	23.56	22.91
Exchange rate (NCU per €), annual rate	3,6990	3,5849	3,4605	3,4528	3,4528	3,4528	3,4528	3,4528

GDP = gross domestic product, GGE = general government expenditure, n.a. = not available, NCU = national currency unit (LTL), PPPa = purchasing power parity

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 fuelled 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 71 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 composed 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 four parties: the Christian Democrats, Liberal Alliance, Liberals and Centrist Union, Party of National Rise.

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 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 guarantees 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 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 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 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 relevant legal acts). Payers of compulsory health insurance contributions, the amount of the contributions and the procedure of payment are set out in the Law on Compulsory 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 2006 the SPF spent € 297.8 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 MoH.

Funds used by the health sector in Lithuania make up approximately 5.9% of the gross 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 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, 2000–2007

Health expenditure	2000	2001	2002	2003	2004	2005	2006	2007
THE in LTL (NCU)	2727.7	2750.3	3063.0	3226.9	3478.2	4065.8	4832.5	n.a.
THE in % of GDP	5.97	5.66	5.89	5.68	5.56	5.71	5.9	n.a.
THE per capita in NCU	779.4	790.0	882.9	934.2	1012.4	1190.8	1424	n.a.
Public HE in % of THE	72.4	71.7	68.3	69.0	68.2	70.0	72.4	n.a.
Private HE in % of THE	27.6	28.3	31.7	31.0	31.8	30.0	27.6	n.a.

GDP = gross domestic product, HE= health expenditure, n.a. = not available, NCU = national currency unit (LTL), THE = total health expenditure,

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

1.4.3 Access to health care

1.4.3.1 Outpatient care

There are two main types of outpatient clinic in Lithuania: independent GPs and integrated practices (where 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 GPs. 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) refers 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 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 GP practices are private. The majority of specialists in outpatient care practise publicly (e.g. endocrinologists, cardiologists, etc.). GPs work as gatekeepers for access to specialists and hospital care. The GP abilities and competences are described in the Medicinal Standard “Family doctor – rights, functions, competences and responsibility”, confirmed by Order of the MoH 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 outpatient 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 outpatient care (services not covered by compulsory health insurance). The patient must pay if s/he comes to the specialist without referral from a GP.

Table 1.4: Lithuania - Outpatient care, 2000–2007

Variable	2000	2001	2002	2003	2004	2005	2006	2007
Total number of doctors[1]	14,034	14,031	13,856	13,682	13,397	13,650	13,510	n.a.
Number of doctors[1] per 1,000 inhabitants	4.02	4.04	4.00	3.97	3.91	4.01	3.99	n.a.
Total number of outpatient doctors	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
thereof GPs	692	897	1 150	1 500	1 665	1 730	1 792	n.a.
thereof dentists	2,446	2,490	2,309	2,372	2,272	2,453	2,249	n.a.
Number of outpatient doctors per 1,000 inhabitants	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Number of outpatient clinics departments ("ambulatories")	n.a.	n.a.	n.a.	n.a.	432	438	437	n.a.

[1] excluding retired and non-practising doctors

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

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 Inpatient care

Inpatient care institutions are mostly organised as public institutions. There are only few private inpatient care institutions; public non-profit-making health care institutions dominate. There are three different levels of inpatient care services. The highest (third) level of health care services is provided in the biggest hospitals (university and some municipal hospitals). Second-level inpatient care services are provided in major cities offering specialist care in different medical departments. First-level inpatient care services – the simplest services – can be given in all inpatient health care institutions. Hospitals are spread throughout the country. They have no specialisation, excluding specific hospitals, e.g. tuberculosis treatment hospitals. All inpatient services covered by compulsory health insurance are fully reimbursed. OPP are only paid for services which are not covered by compulsory health insurance, e.g. cosmetic surgery. Doctors are employees of inpatient 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 MoH.

Table 1.5: Lithuania - Inpatient care, 2000–2007

Variable	2000	2001	2002	2003	2004	2005	2006	2007
Number of inpatient doctors[1]	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Number of inpatient doctors per 1,000 inhabitants	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Number of hospitals	187	189	188	181	181	173	158	n.a.
Number of acute care beds	34,145	32,104	31,031	29,990	28,972	27,727	27,114	n.a.
thereof in private sector	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Acute care beds per 1,000 inhabitants	9.76	9.24	8.94	8.63	8.43	8.12	8.01	n.a.
Average length of stay in hospital	11.2	10.9	10.7	10.3	10.2	10.2	10.0	n.a.

[1] excluding retired and non-practising doctors

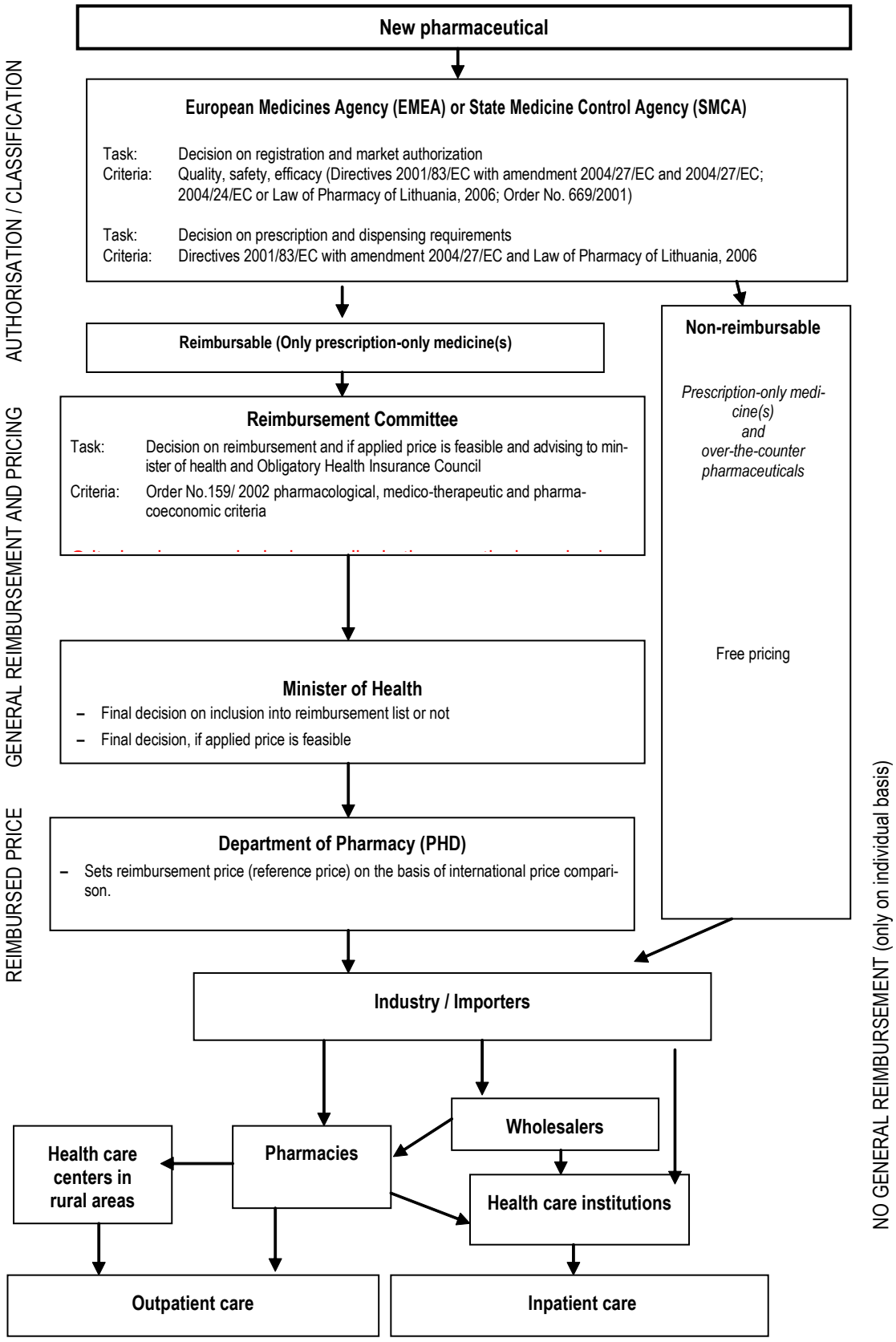
Source: Department of Statistics under Government of Lithuania (http://www.stat.gov.lt); Lithuanian Health Information Centre (http://www.lsic.lt/)

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.) as of 2008.

Figure 2.1: Lithuania - Flowchart of the pharmaceutical system, 2008



Source: Law on Pharmacy 2006, Order of MoH No. 669, 2001, Order of MoH No. V-91, 2007, 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 as of 2008.

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 (MoH) 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;
- Government Resolution on the Approval of the Regulations of determinantion the reimbursed price calculation, 28 May 2008, No. 531;
- Order No. V-949/1V-354 of the Minister of Health and Ministry of the Interior on requirements for establishing premises for manufacture and storage of narcotic and psychotropic substances, 6 October 2008;
- 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 (new redaction is under confirmation process now);
- Order No. 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, 12 February 2007;
- Order No.73 of Ministry of Health concerning grouping of pharmaceuticals, 9 February 2000;
- Order No. V-596 of the Minister of Health concerning conformation of general regulations for granting market authorisation, requirements for labelling and packaging leaflets and other requirements, 10 July 2007 (consolidated order);
- 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 establishing of 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-494 of the Minister of Health concerning requirements of good pharmacy practice, 15 June 2007
- 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 the import and export of medicinal products for personal reasons, receiving and dispatch by post to Lithuania, 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 MoH, responsible for strategic planning of the pharmaceutical system. Furthermore, the MoH has the final decision on whether a product is reimbursed and at what price.

The main goal of the 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 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 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 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 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 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 PhD providing 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 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 SMCA is accountable to the MoH. The Director of the SMCA is appointed and dismissed from the position by the MoH. The activities of the 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 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 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 MoH.

Market Authorisation procedures are compliant with the community legislation. However, SMCA experiences serious difficulties to meet deadlines, especially in National Renewals and Variations. SMCA has two units exclusively assessing National Applications and one unit assessing Mutual Recognition and Decentralised Applications. The latter has been established by the end of 2007 in order to facilitate SMCA's participation in European procedures. SMCA has strong intention to start first procedures in the role of Reference Member State by the end of 2009.

Market authorisation holders were obliged to submit upgraded documentation for their pharmaceuticals according to the dates indicated in a list issues by the SMCA, so the transitional period is retained. Registration certificates are valid for a period of five years.

The SMCA classifies pharmaceuticals into the categories of prescription-only medicines (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 SMCA refers to the 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 SPF under the 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 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 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 SPF are based on provisions of the Law on Health Insurance, laws regulating the state budgetary institutions, and regulations approved by the MoH.

The goal of the 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 SPF under the 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 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 MoH, the PhD, the SMCA and the 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 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 MoH, the SPF, the PhD, and the SMCA. The Pharmaceuticals Reimbursement Commission makes recommendations for the MoH as to whether or not to reimburse the pharmaceutical(s).

The data is then transferred to the Council of Compulsory Health Insurance, which also makes recommendations for 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, 2008

Name in local language (Abbreviation)	Name in English (Abbreviation)	Description	Responsibility
Lietuvos Respublikos Sveikatos apsaugos ministerija (SAM)	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 kompensujamųjų 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 MoH 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 2008 the Register of Pharmaceuticals of Lithuania contained 3,852 nationally authorised pharmaceuticals, including 3,078 pharmaceuticals subject to medical prescription (POM).

The SMCA is the institution responsible for market authorisation of pharmaceuticals in Lithuania. After joining the 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 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 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. section 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 SMCA also classifies authorised pharmaceuticals into pharmaceuticals subject to medical prescription (POM) and 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. section 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 outpatient sector and hospital-only medicine(s) (HOM).

Parallel trade has been allowed in Lithuania since 2006 according to the Law on Pharmacy. From April 2007 companies may apply for authorisation of parallel trade. In September 2008 the first products have been accepted for authorisation of parallel import to Lithuania by the SMCA.

Table 2.2: Lithuania - Number of pharmaceuticals, 2000–2008[1]

Pharmaceuticals	2000	2001	2002	2003	2004	2005	2006	2007	2008
Authorised	6,240	5,827	5,494	5,096	4,435	4,435	3,763	3,852	4,067
On the market	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
POM	n.a.	n.a.	4,044	3,723	3,206	3,138	3,054	2,961	3,078
Reimbursable	2,143	1,824	1,737	1,483	1,396	1,422	1,565	1,504	1,501
Generics	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Parallel traded	-	-	-	-	-	-	-	-	4
Hospital-only	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Others	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

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

[1] as of 1 January

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 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 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.

Table 2.3: Lithuania - Annual prescriptions and consumption, 2000–2007

Consumption	2000 - 2003	2004	2005	2006	2007
No. of prescriptions per year (in volume)	n.a.	n.a.	n.a.	n.a.	n.a.
No. of annual prescriptions in value (in NCU =____)	n.a.	n.a.	n.a.	n.a.	n.a.
No. of annual consumption in packs[1]	n.a.	78,807,847	89, 952, 658	68,179,099	86,790,584
No. of annual consumption in DDD	n.a.	n.a.	n.a.	n.a.	n.a.

n.a. = not available, DDD = Defined Daily Doses

[1] amount of sold pharmaceuticals

Source: SMCA

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

2.1.2.3 Market data

There is no data on pharmaceutical sales, exports, and import available in Lithuania.

Table 2.4: Lithuania - Market data, 2000–2007

In million	2000	2001	2002	2003	2004	2005	2006	2007
Pharmaceutical sales								
Sales at ex-factory price level	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales at wholesale price level	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales at pharmacy retail price level	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales at hospitals	n.a.	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.	n.a.
Sales of parallel traded pharmaceuticals	-	-	-	-	-	-	-	-
Exports and imports								
Total pharmaceutical exports **	n.a.	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.

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

Table 2.5: Lithuania - Top 10 best-selling pharmaceuticals, by active ingredient, 2007

Position	Pharmaceutical, by active ingredient
1	Salmeterolum + Flutikazonum
2	Nebivololum
3	Olanzapinum
4	Clopidogrelum
5	Budesonidum + Formoterolum
6	Triptorelinum
7	Risperidonum
8	Insulinum aspartum
9	Interferonum beta 1-a
10	Lercanidipinum

Source: Data received by written communication with SPF

2.1.2.4 Patents and data protection

Patent protection is harmonised under the European Patent Convention and ensures market protection for original pharmaceuticals for 20 years. Under 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 to this Law the competent authorities are obliged to apply a data protection period (8+2+1-years) for reference pharmaceuticals. After eight years the SMCA can process applications for generic pharmaceuticals under the European Commission 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 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 EU Accession Treaty includes a derogation to limit exports from the new 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 EU Member States. The derogation stipulates that holders of Supplementary Protection Certificates, which had been granted in the EU Member States belonging to the EU before May 2004 (EU15) before product patents were available in the new 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 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 were 19 local pharmaceutical manufacturers registered in 2007 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 192 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.

Two 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 2007, the Lithuanian pharmaceutical market grew approximately 13,7% in terms of its value compared to the year 2006, and the market is dominated by importers. The generics market share is very high with 64% of the market in terms of volume and 35% in terms of value (in 2007).

Table 2.6: Lithuania - Key data on the pharmaceutical industry, 2000–2007[1]

Pharmaceutical industry	2000	2001	2002	2003	2004	2005	2006	2007
Total no. of companies	31	31	30	28	14	13	14	19
– research-oriented	1	1	1	1	1	1	1	1
– generic producers	2	2	2	2	2	2	2	2
– biotech	1	1	1	1	1	1	1	1
Number of persons employed[2]	n.a.	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 2007, there were 78 wholesale licences registered with the 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 MoH, the PhD, and the SMCA regarding new regulations concerning pharmaceuticals.

Table 2.7: Lithuania - Key data on pharmaceutical wholesale, 2000–2007[1]

Wholesalers	2000	2001	2002	2003	2004	2005	2006	2007
Total number of wholesale companies	106	175	92	92	72	72	80	78
Total number of importers	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	5
Total number of outlets	-	-	-	-	-	-	-	-

[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 mail order trade for pharmaceuticals. Besides pharmacies, health care centres 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 centres must have a contract with a pharmacy.

2.1.3.3.1 Pharmacies

In 2007 there were a total of 1,546 pharmacy outlets in Lithuania, of which 512 were registered pharmacies and 1,034 were subsidiaries. There was one pharmacy per 2,190 inhabitants in 2007.

Until the year 2006 the MoH issued liccences of pharmaceutical activities (pharmacy activity, wholesale distribution and manufacturig). Since 2006 according to the Law of Pharmacy the licencing is procecuted by the State Medicine Control Agency. 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. 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 (magisterial and officinal's pharmaceuticals); hospital pharmacy; hospital pharmacy carrying out preparation activities (magisterial 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 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 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 MoH, public pharmacies are remunerated via a maximum mark up scheme for reimbursement pharmaceuticals (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 OTC pharmaceuticals are not regulated (i.e. these pharmaceuticals are priced freely).

Table 2.8: Lithuania - Retailers of pharmaceuticals, 2000–2008[1]

Retailers	2000	2001	2002	2003	2004	2005	2006	2007	2008
No. of community pharmacies[2]	778	1,221	1,350	1,416	1,489	1,459	1,426	1,546	1,561
Thereof: No. of private pharmacies	767	1,210	1,339	1,406	1,481	1,452	1,422	1,542	1,557
No. of public pharmacies	11	11	11	10	8	7	4	4	4
No. of hospital pharmacies for inpatients (there are no data about pharmacies in hospital for outpatient)	n.a.	62	68	65	62	61	60	61	61
No. of other POM and OTC dispensaries: *Heath Care Centers*[3]	n.a.	n.a.	n.a.	n.a.	1,040	n.a.	959	959	815
Total no. of POM-dispensaries[1]	-	-	-	-	-	-	-	-	-
No. of internet pharmacies	-	-	-	-	-	-	-	-	-
No. of OTC dispensaries, like drugstores	-	-	-	-	-	-	-	-	-

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

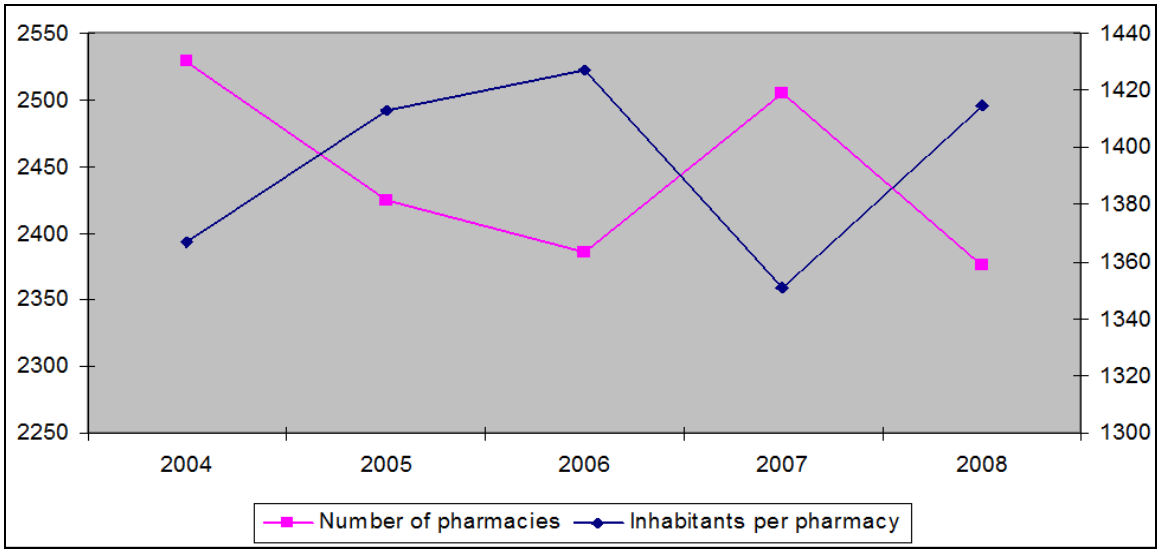
[1] as of 1 January

[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, 2004–2008



POM = prescription-only medicines; All POM-dispensaries = including branch pharmacies, hospital pharmacies acting as community pharmacies and Health care centres in rural areas.

Source: Data received by written communication with SMCA

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 mail order trade for pharmaceuticals.

Order No.V-494 of Minister of Health concerning Good pharmacy practice (2007) lays down that in case the medicinal product has been ordered by phone or internet it shall be dispensed mandatory by pharmacists together with a pure information about the medicinal product (usage, side effect and etc.). Doctors are not entitled to dispense these pharmaceuticals. Tele-shopping of pharmaceuticals is not allowed.

In order to avoid illegal trade (import and export) the Minister of Health issued the Order No.V-975 (2006) concerning the import and export of medicinal products for personal reasons, receiving and dispatch by post to Lithuania. The Order defines the maximum quantity of medicinal products that might be imported or received by post for personal reasons. The allowed quantity depends on the kind of medicinal product (prescription or non-prescription medicinal product). Export of medicinal products for personal reasons and dispatch by post should be in line with the legislation of the country of destination.

2.1.3.3.4 Dispensing doctors

In outpatient care doctors and family nurses are not entitled to dispense pharmaceuticals.

2.1.3.4 Hospitals

Hospital pharmacies are set up as a division of a hospital for internal use only. Hospital pharmacies are not allowed to dispense pharmaceuticals to patients: for this purpose there are ordinary community pharmacies in hospitals and polyclinics. Not every hospital has a hospital pharmacy for inpatients. However, the majority of hospitals and polyclinics have ordinary community pharmacies in their premises (no precise data is available). The largest hospitals and polyclinics have more then one community pharmacies.

Hospital pharmacies are funded by hospitals only; there are no other means of funding. Pharmaceuticals are free of charge for inpatients. 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 an 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 OTC products. In 2005 the Constitutional Court decided that prohibition of advertising 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 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 PRP and the base price as the basis for reimbursement.

Since 2004, within the reimbursable sector doctors are obliged to prescribe by International Non-proprietary 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 2007, the sales of pharmaceuticals in Lithuania totalled over LTL 1.6 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 14.80 (in 2007). The costs for pharmaceuticals per resident have also been increasing, except in the year 2002: from LTL 176 in 2000 to LTL 475 in 2007. State expenditure on pharmaceuticals increased from 10% (in 2000) to 16.1% (in 2007) of the funds allocated to health care.

Table 2.9: Lithuania - Total pharmaceutical expenditure, 2000–2007

Pharmaceutical expenditure	2000	2001	2002	2003	2004	2005	2006	2007
TPE in NCU (Mio LTL)	618	830	786	852	972	1,135	1,416	1,609
TPE in % of THE	22.6	30.2	25.7	26.4	27.9	27.9	33.5	31.5
TPE per capita in NCU	176	238	226	246	282	332	416	475
Public PE in % of THE	11.2	14.9	11	10.9	11.1	11.9	12	11.7
Private PE in % of THE	11.4	15.3	14.7	15.8	16.8	16	19.4	17.8

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

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

2.2.2 Sources of funds

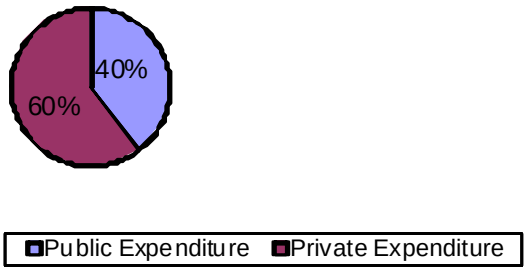
The budget of the Compulsory Health Insurance Fund is also used to reimburse the costs of pharmaceuticals, which have been entered into the List of Reimbursed Pharmaceuticals.

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, 2007



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

2.3 Evaluation

There is no overall evaluation of pharmaceutical policy and the system in Lithuania. The monitoring of prescriptions of reimbursed pharmaceuticals is performed by the SPF. The SPF uses an electronic database program for the monitoring of prescriptions as well as for prescribed and sold reimbursed pharmaceuticals. The SPF publishes reports including statistical data about reimbursed pharmaceuticals and short analysis annually.

The PhD transfers European directives concerning pharmaceuticals (including Transparency directive) into national legislation.

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 in the reimbursement list are accepted by the Department of Pharmacy (PhD), once the reimbursement procedure for inclusion of new International Non-proprietary 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 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 PRP, where the latter two are regulated via maximum mark ups); and the base price for reimbursement (which is only equal to the PRP in the case of insulin).

The base price for reimbursement is always lower than the 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” INNs, where there is no generic alternative, the base price is determined by international price comparison and is still lower than the PRP.

All reimbursed pharmaceuticals are consolidated to groups according the 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. section 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 Law on Health Insurance 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 EU countries (Latvia, Estonia, Poland, Czech Republic, Slovakia, and Hungary). Otherwise, if the pharmaceutical is not

registered in the reference EU Member State the price of the manufacturing country 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 pharmaceutical prices in the relevant 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 EU countries (Latvia, Estonia, Poland, Czech Republic, Slovakia, and Hungary), but in that case the base (reimbursed price) is calculated not from the manufacturer's declared price but from 95% of the average manufacturer's price in the six reference 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 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 either 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. V-91 of the MoH of the Republic of Lithuania, 12 February 2007. The reimbursed price calculation is determined in Decree No. 531 of the Government of the Republic of Lithuania, 28 May 2008, and Order No. 459 of the MoH 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 PRP. Co-payments were introduced in 1997 when the Law on Health Insurance came into force. All 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 Law on Health Insurance, regulation of the pricing of pharmaceuticals falls within the remit of the MoH. Wholesale and PRP of reimbursed pharmaceuticals are regulated by adding mark ups approved by the MoH. The Law stipulates that PRP of reimbursed pharmaceuticals are not fixed but rather "maximum 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 OTC pharmaceuticals are not regulated (i.e. these pharmaceuticals are priced freely).

Table 3.1: Lithuania - Ways of pricing pharmaceuticals, 2008

	Manufacturer level	Wholesale level	Pharmacy level
Free pricing	Non-reimbursable pharmaceuticals Reimbursed pharmaceuticals – MoH allows to have prices higher than 95% of the average manufacturer's price in the six reference 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	Negotiation Committee (PhD; SPF) negotiate with manufacturers	Not applied	Not applied
Price–volume agreements, discounts/rebates	Applied in specific cases	Not applied	Not applied
Institution in charge of pricing	PhD under MoH		
Legal basis	Order No. 459 of the Minister of Health[1]		

EU = European Union, MoH = Ministry of Health, PhD = Department of Pharmacy, SPF = State Patient Fund

[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

Source: Law on Pharmacy 2006, 22 June 2006 No. X-709

Non-reimbursed products are freely priced. Prices of reimbursed pharmaceuticals are determined according to Decree No. 531[1].

The current pricing system is implemented according to Decree No. 531[2]. 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 Law on Health Insurance 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 av-

[1] Decree No. 531 of the Government of the Republic of Lithuania, 28 May 2008

[2] Decree No. 531 of the Government of the Republic of Lithuania, 28 May 2008

erage manufacturer's price in the six reference EU countries (Latvia, Estonia, Poland, Czech Republic, Slovakia, and Hungary).

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

According to the Law on Pharmacy (2006), the PhD under the MoH is responsible for the 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

There were negotiations on 38 pharmaceuticals during the year 2008: prices increased for 17 and decreased for 4 products. For 15 products the prices did not change. Price negotiations are carried out for pharmaceuticals with prices exceeding 95% of the average price in reference countries. If the price exceeds the 95% of the average price in reference countries by more than 1 Euro and annual sales of this pharmaceutical is higher than 30,000 Euro negotiations with manufacturers start. The PhD and SPF are involved in these price negotiations. After the negotiation process the base price for reimbursement is calculated according to the existing pricing procedure. This system was implemented in June 2007 according to the legal Order No V-505 of the Health Minister on negotiations, June 18. In case the negotiation is not successful the Negotiation Committee informs the Reimbursement Committee which then makes a reimbursement decision. The Negotiating Committee decides on price increase according to the medical need of the product, number of patients using this product, the severity of the disease and prices of other pharmaceuticals produced by the same company (e.g. a company increases the price of product A but during the negotiation process the same company offers to reduce the price of product B. In this case the Obligatory Health Insurance Fund can save more money on the product B than increase expenditure on product A. This means that the price of product A increased and price of product B decreased).

3.2.3 Free pricing

Prices of all non-reimbursed prescription pharmaceuticals and 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 SPF under the 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 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, 2008

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

n.appl = applicable, OTC = Over-the-counter, PRP = Pharmacy Retail Price

[1] Level of pricing = the stage of the pricing process at which the pricing take places (e.g. at the 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 OTC pharmaceuticals there is free pricing.

Source: Decree No. 531 of the Government of the Republic of Lithuania, 28 May 2008; Order of ministry of health concerning grouping of pharmaceuticals, No.73, 9 February 2000

3.3.1 External price referencing

External price referencing is regulated in Decree No. 531[3]. External price referencing only applies for reimbursed pharmaceuticals (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 case 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 Euro in the reference countries. The exchange rate LTL/€ is fixed at € 1 to LTL 3.4528. The manufacturer should provide information about prices in the reference countries to the MoH and the PhD. The manufacturer should inform the authorities about price changes in the reference countries. The 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] Decree No. 531 of the Government of the Republic of Lithuania, 28 May 2008

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, INN, and manufacturing price in Lithuania, as well as manufacturing prices in the reference countries. The 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 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, 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 always have to take 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 SPF (cf. section 4.2.2).

3.4.2 Generics

In Lithuania there is no different price setting procedure for generics. There is a 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. 531 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 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 has been allowed in Lithuania since 2006 according to the Law on Pharmacy. From April 2007 companies may apply for authorisation of parallel trade. In 2008 4 products have been accepted for authorisation of parallel import to Lithuania by the SMCA.

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, 2008

	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

Source: 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)

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[4]. This involves a combination of linear and regressive schemes.

Table 3.4: Lithuania - Wholesale mark up scheme, 2008

Ex-factory price in LTL / in €	Maximum mark up as a % of ex-factory price	Wholesale price in LTL / €
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

LTL = Lithuanian Litas

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

[4] 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)

Wholesale mark ups for non-reimbursable pharmaceuticals are not statutorily regulated. The average gross wholesale-margin was 16.5% in 2004, after discounts to the pharmacies the net margin amounted to 9.5%. In the year 2005 the average margin after discounts amounted to 8-9%.

Wholesalers are not obliged to grant any discounts to the SPF or other state institutions. 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[5]. This involves a combination of linear and regressive schemes.

Table 3.5: Lithuania - Pharmacy mark up scheme, 2008

Pharmacy purchasing price in LTL / €	Maximum pharmacy mark up coefficient as a % of pharmacy purchasing price
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

LTL = Lithuanian Litas

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

As mark ups are at the maximum level, pharmacies may set their prices below the maximum allowed PRP held in the List of Reimbursed Pharmaceuticals. Mark ups for non-reimbursable pharmaceuticals and 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 outpatient sector. Costs of pharmaceuticals used in inpatient treatment are covered by fee-for-service payments.

[5] 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)

3.5.4 Value-added tax

In Lithuania the standard value-added tax (VAT) is 18% until the 31 December 2008 and will be raised to 19% from 1 January 2009. The reduced VAT rate for pharmaceuticals has been 5% since 2004. From 1 January 2009 a VAT for non reimbursable pharmaceuticals of 19% and for reimbursable pharmaceuticals of 5% will be applied. From 1 July 2009 the VAT will amount to 19% for all pharmaceuticals. Products produced from human tissues (blood clotting features) are exempt from 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 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. section 3.5.1 and section 3.5.2). In 2002, wholesale and pharmacy mark ups were lowered by Order of the 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 base 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 outpatient treatment are to be reimbursed to (cf. section 3.1):

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

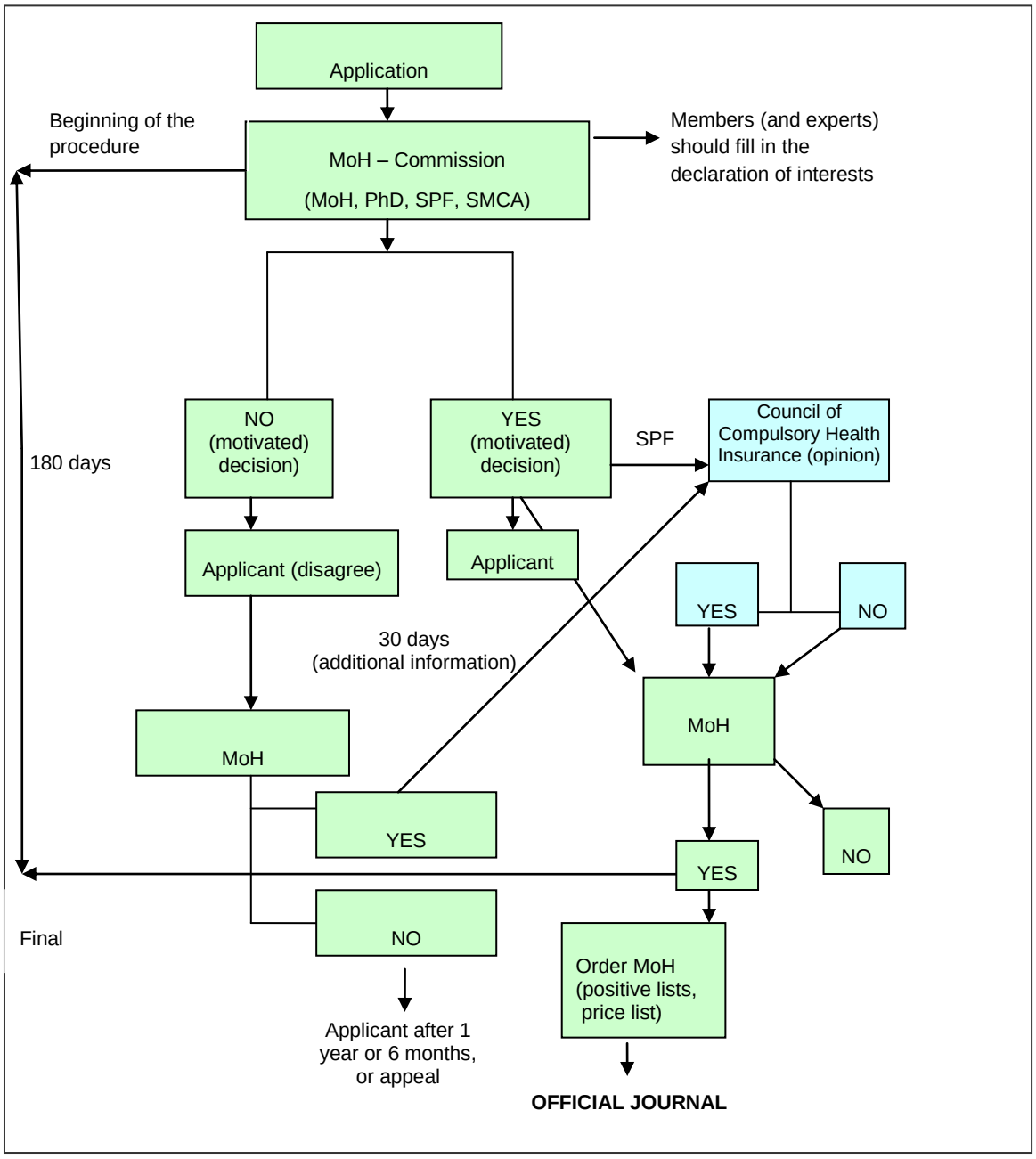
100%, 90%, 80% or 50% of base price of the reimbursed pharmaceuticals and medical aid products for outpatient treatment are to be reimbursed to the insured who are not mentioned in the above paragraph and who are diagnosed with diseases, syndromes and states included in the List of Diseases and Reimbursed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

50% of the base 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 outpatient 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 PhD and the State Medicine Control Agency (SMCA). The Pharmaceuticals Reimbursement Commission makes recommendations for the 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 the 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 - International Non-proprietary Name reimbursement procedure



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

Source: Departmen of Pharmacy

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. V-91, 12 February 2007.

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 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[6], Order No. V-91 of the Ministry of Health[7], and Order No. 459 of the Ministry of Health[8]. 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 outpatient sector. Expensive pharmaceuticals are centrally purchased by the SPF.

The MoH decides on the inclusion of pharmaceuticals into the positive list. The MoH is advised by the Pharmaceuticals Reimbursement Commission, which is an interdisciplinary committee consisting of representatives of the MoH (3), the PhD (2), the SMCA (1) and the SPF (1) (cf. section 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 outpatient 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.

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).

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

[7] Order of Health Ministry No. V-91, 12 February, 2007

[8] 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).

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 outpatient 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 INN. Reimbursement from the disease-based list accounts for approximately 85% of the country's total pharmaceutical reimbursement. Under the Law on Health Insurance 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 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 inpatient care institutions are fully reimbursed. The prices of pharmaceuticals are included in the price of the medical services for inpatient 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 SPF, and such reimbursement is granted to people in the outpatient sector, only after the approval of three specialists and the head of a hospital.

Patients with swallowing difficulties or children under six years of age can receive more expensive pharmaceuticals in a liquid form or soluble tablets. The doctor has 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, 2008

Reimbursement category	Reimbursement rate	Characteristic of category
Fully reimbursed	100% of pharmacy retail price	Insulin
Fully reimbursed	100% of base price	Pharmaceuticals for treatment of life-threatening diseases
Partially reimbursed	90%	e.g. 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 2008 there were approximately 257 INN on List A and 80 INN on List B available for outpatient 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 V-91, 12 February 2007. (For the administration procedure cf. section 4.1) The lists are updated when new pharmaceuticals are included in or removed from them.

Only pharmaceuticals registered in Lithuania or the 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 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. 531[9] 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 be higher than the lowest price in the EU plus 5%. After the EU enlargement of 2004 the Law on Health Insurance was changed and the task of pricing of reimbursed pharmaceuticals was delegated to the Government.

Pharmaceuticals are consolidated into groups, as described in 3.3.2.

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

The 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.

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 INN, so there is no need to determine dose equivalence.

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

Prescribing by 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. In the middle of 2008 parallel traded products became reimbursable.

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.

[9] Decree No. 531 of the Government of the Republic of Lithuania, 28 May 2008

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 INNs 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 (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 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. section 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. section 3.1) for reimbursement, the percentage

reimbursement category and the PRP. The base price for reimbursement is always lower than the maximum 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 inpatient treatment, through public competition. The hospital receives a fixed amount of money from the SPF for treatment of patients. The price of pharmaceuticals is included in this sum of money.

With inpatient 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 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 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 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 Law on Health Insurance.

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 CIP price and the Lithuanian CIP price. If the producer reduced the CIP price, the co-payment reduced too. This regulation was changed in 2005 in line with the enlargement of the EU, and the base price for reimbursement 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 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. From April 2007 companies may apply for authorisation of parallel trade. In the year 2008 4 permissions for parallel trade were issued.

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 if the product is reimbursed 100%. Co-payments are not fixed and depend on the 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 PRP is LTL 50, the patient pays LTL 2.38
- if the PRP is LTL 100, the patient pays LTL 3.17
- if the PRP is LTL 500, the patient pays LTL 4.55
- if the 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 SPF, the SMCA, and the 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, as of 2008.

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 SPF. Possible sanctions for budgetary overspending were set for health care institutions. If doctors did not keep within the budgetary limits the 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 (MoH). 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 MoH only approves the guidelines. These principles are set out in Order of the MoH No. V-395, 17 May 2006.

Annual clinical auditing of doctors is not carried out every year. Experts of the SPF carry out audits of selected doctors for which the prescription quantity/sum is increasing fast, or in cases where the 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 SPF budget in such cases. The SPF re-

ceives 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 MoH and the 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 MoH 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 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 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 MoH, 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 MoH and based on the Baltic Guideline for Economic Evaluation of Pharmaceuticals.[10]

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 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 MoH No. V-26 of 2003. These guidelines are made publicly available to applicants 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 PhD is responsible for conducting the pharmacoeconomic evaluations and submitting them to the Pharmaceuticals Reimbursement Commission.

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

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.

Table 5.1: Lithuania – Development of the generic market in the outpatient sector, 2000–2007

Generic market share	2000	2001	2002	2003	2004	2005	2006	2007
Share of number of generic prescriptions as number of total prescriptions	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Share of expenditure for generics as percentage of total pharmaceutical expenditure	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a

5.5.1 Generic substitution

Since 1 July 2004 reimbursed prescriptions are written according to International Non-proprietary Name (INN), whereas until 1 July 2004 prescriptions were 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 INN. They are also obliged to have in stock the cheapest product of every 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 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 PRP, s/he must pay a higher co-payment.

As a rule the generic products are cheaper than the original products with the same 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 INN. Pharmacies are allowed to substitute products with the same INN, but therapeutic substitution with another INN is not allowed.

Parallel trade has been allowed in Lithuania since 2006 according to the Law on Pharmacy. 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 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. section 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 monitoring

The 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 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 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 MoH 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 MoH (Bona Fide order), May 2005. This is for use by individual patients under their own direct personal responsibility.

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 Latest changes

The most important changes regarding the pharmaceutical system in the last 3–5 years are listed in table 6.1.

Table 6.1: Lithuania - Changes in the pharmaceutical System, 2005–2008

Year	Pricing	Reimbursement	Not attributable to Pricing or Reimbursement
2005	Reference price is 95% of the average manufacturing price in the 6 reference countries		
2006			New Law on Pharmacy
2007	Negotiations on prices	New evaluation criteria for new reimbursed pharmaceutical	
2008		reimbursement of parallel trade pharmaceuticals	

Source: Department of Pharmacy

6.2 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 profes-

sionals 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.

6.3 Future developments

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

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 (new redaction is under confirmation process).

In Lithuania the standard value-added tax (VAT) is 18% until the 31 December 2008 and will be raised to 19% from 1 January 2009. The reduced VAT rate for pharmaceuticals has been 5% since 2004. From 1 January 2009 a VAT for non reimbursable pharmaceuticals of 19% and for reimbursable pharmaceuticals of 5% will be applied. From 1 July 2009 the VAT will amount to 19% for all pharmaceuticals.

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 MoH	http://www.fd.lt
State Medicine Control Agency (SMCA) under MoH	http://www.vvkt.lt
State Patient Fund (SPF) under MoH	http://www.vlk.lt

7.3 Authors

Gita Krukiene – Deputy Director of Department of Pharmacy under Ministry of Health.

Tomas Alonderis – Head of Pharmacoeconomic division of Department of Pharmacy under Ministry of Health.

Other people who contributed Pharma Profile of Lithuania:

Nijolė Ramančiuskaitė - Head of Pricing division of Department of Pharmacy under Ministry of Health.

Liucija kuodienė - Head of Licensing division of State Medicine Control Agency under Ministry of Health.

Irena Vaketaitė - Head of Inspections of good manufacturing practice division of State Medicine Control Agency under Ministry of Health.

Vitalijus Michalkovas - Head of Inspections of distributions enterprises and pharmacies division of State Medicine Control Agency under Ministry of Health.

Loreta Mikucionyte - Head of Coordination subdivision of market authorisation division of State Medicine Control Agency under Ministry of Health.

Liudvikas Lazauskas - Head of Information and monitoring of pharmaceuticals division of State Medicine Control Agency under Ministry of Health.