Pharmaceutical Pricing and Reimbursement Information

LATVIA

November 2008

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Pharma Profile

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Executive Summary

BACKGROUND

Latvia has a national health system based on the residence principle.

Principal laws/acts leading to the implementation of the current health care system are:

- Medical Treatment Law (1997);
- Law on Practice Doctors (1997);
- Pharmaceutical Law (1997);
- Epidemiological Safety Law (1997);
- Sexual and Reproductive Health Law (2002);
- Regulation of the Cabinet of Ministers No. 77 on mandatory requirements for medical treatment institutions and their units (19 February 2002);
- Regulation of the Cabinet of Ministers No. 1046 Procedures for the Organisation and Financing of Health Care (19 December 2006);
- Regulation of the Cabinet of Ministers No. 899 Procedures for the Reimbursement of Pharmaceuticals and Medical Devices for Ambulatory Care (31 October 2006).

The public health care sector is funded from general taxation. The health care budget is based on the state budget subsidy. The current health expenditure (HE) is 6% of gross domestic product (GDP), of which the public share is 63% and the private share is 37% of total health expenditure (THE).

The central organ of the state health care administration is the Ministry of Health (Latvijas Republikas Veselības ministrija (LR VM), MoH), whose main task is to develop and implement the state health policy, draft legislation in health field, and ensure accessibility, cost-efficiency, and quality of health care services.

The process of decentralisation and de-institutionalisation is still developing. The aim is that general practitioner (GP) practices will become the basic unit of health care instead of health care centres or policlinics. Most of the outpatient practices are privately owned, while most inpatient facilities are publicly owned. The main criterion for provision of statutory health care services is an agreement with the Health Compulsory Insurance State Agency (Veselības obligātās apdrošināšanas valsts aģentūra (VOAVA), HCISA), and thus statutory health care services may be provided by both public and private health care service providers.

Citizens of the Republic of Latvia, non-citizens of the Republic of Latvia, foreign nationals who have a residence permit and their family members, citizens of the European Union (EU), the European Economic Area (EEA) and of Switzerland, refugees and persons who have guaranteed alternative status, as well as detained persons, people taken into custody and those sentenced to imprisonment are entitled to health care services covered by the state's health care budget.

A patient receives outpatient care by visiting a primary health care service provider (a GP, a physician's assistant, a nurse, a midwife, a dentist, a dental assistant, a dental nurse, a dental hygienist) or a specialist who provides secondary outpatient health care services at an outpa-

tient medical institution or outpatient department of the hospital. Mainly outpatient care is provided at GP practices, consisting of a GP and nurse or physician's assistant.

A person only receives state-guaranteed secondary and tertiary health care services with a referral from a GP or specialist (except for patients with particular diseases). For the financing of GPs, a mixed capitation model is used.

PHARMACEUTICAL SYSTEM

In Latvia the legislative bases regulating pharmaceutical activities are: (1) The Pharmaceutical Law (1997), which aims to regulate activities of individual and legal persons in the pharmaceutical sector; (2) Law on Procedure for Licit Circulation of Drugs and Psychotropic Substances (1996), which aims to regulate the procedure for the licit circulation of dangerous drugs and psychotropic substances used for medical and research purposes; and (3) Law on Precursors (1996), which aims to regulate the precursors (substances that can be used in the manufacture of pharmaceuticals or psychotropic substances) (cf. http://www.zva.gov.lv).

The Ministry of Health (MoH) of the Republic of Latvia and the Department of Pharmacy within the MoH form a legislative authority in the pharmaceutical sector and are in charge of the overall planning and development of the system.

The State Agency of Medicines (Zāļu valsts aģentūra, SAM) is in charge of market authorisation; classification; vigilance; evaluation of the conformity of pharmaceutical enterprises; ensuring licensing procedures; and issue of import, export, transit and distribution licences for pharmaceuticals.

The State Medicines Pricing and Reimbursement Agency (Zāļu cenu valsts aģentūra (ZCVA), SMPRA) is in charge of implementing the procedures for the reimbursement of pharmaceuticals and updating the list of pharmaceuticals eligible for reimbursement.

The State Pharmaceutical Inspection (Valsts farmācijas inspekcija (VFI), SPI) is in charge of supervision and control of the pharmaceuticals market.

The Health Compulsory Insurance State Agency (HCISA) is in charge of implementing state health care policy and the administration of health care resources.

Total pharmaceutical expenditure (TPE) in 2006 was LVL 150.3 Mio. of which the public expenditure is 57%. Local pharmaceutical manufacturers cover 5.2% of the total consumption of pharmaceutical products in Latvia. In 2007, there were 34 private licensed wholesalers of pharmaceutical products.

There were 799 community pharmacies and 41 closed type (hospital) pharmacies operating in 2007. Pharmacies are mostly privately owned. Only those pharmacies that belong to local governments and public health care institutions have remained in the public sector.

PRICING

Pricing criteria for pharmaceuticals are determined by the Cabinet of Ministers of the Republic of Latvia. For non-reimbursable pharmaceuticals the manufacturer's price is free. The institution responsible for deciding on the inclusion of pharmaceuticals in the reimbursement system and

setting a price for reimbursable pharmaceuticals is the State Medicines Pricing and Reimbursement Agency (SMPRA).

Statutory pricing is not applied, but prices of reimbursable pharmaceuticals may be indirectly influenced via the reference pricing reimbursement system.

Price negotiations are applied for reimbursable products, based on pharmacoeconomic evaluation. Public procurement is applied for particular health care programmes and pharmaceuticals used in the hospital system.

The pricing procedures differ for reimbursable and non-reimbursable pharmaceuticals.

- For non-reimbursable pharmaceuticals the manufacturer's price is free. Before marketing, and in the event that the price is changed, for informative purposes the holder of the market authorisation has to declare the price to the State Agency of Medicines (SAM).
- For reimbursable pharmaceuticals the State Medicines Pricing and Reimbursement Agency (SMPRA) evaluates the price proposed by the holder of the market authorisation. Pricing decisions for reimbursable pharmaceuticals are made on the basis of the assessment of therapeutic value and cost-effectiveness of the product. Internal price referencing is applied for reimbursable pharmaceuticals.

New pharmaceutical products submitted for reimbursement are compared with those included in the Positive List for the same indication in terms of effectiveness and treatment costs. If the treatment costs are higher, the pharmacoeconomic analysis in accordance with the Baltic Guideline for Economic Evaluation of Pharmaceuticals has to be submitted by the holder of the market authorisation.

External price referencing is applied for reimbursable pharmaceuticals. The price submitted for reimbursement should not exceed the price in other Baltic states. If the price for Latvia is higher than in other EU countries, a justification should be submitted.

Wholesalers and pharmacists are remunerated via regressive mark ups. The mark ups are regulated by Regulation of Cabinet of Ministers, specifically according to those listed here.

- For non-reimbursable pharmaceuticals – Regulation of the Cabinet of Ministers of the Republic of Latvia No. 803 of 25 October 2005.
- For reimbursable pharmaceuticals – Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006.

All pharmaceuticals are covered by the regressive mark up scheme, but different mark ups are applied for reimbursable and non-reimbursable pharmaceuticals.

Standard value-added tax (VAT) rate is 18%; VAT for pharmaceutical products is 5%.

REIMBURSEMENT

The pharmaceuticals eligible for reimbursement are listed in the Positive List detailed by the State Medicines Pricing and Reimbursement Agency (SMPRA).

Decisions on reimbursement and price involve a single administrative procedure and this is carried out in compliance with Art. 6 of the Transparency Directive 89/105. Reimbursement decisions comprise two main parts: therapeutic and economic evaluation of the pharmaceutical, which result in reimbursement conditions and the approved price of the product.

The main therapeutic criteria for reimbursement of a pharmaceutical are:

- therapeutic value of a pharmaceutical based on the evidence level from published clinical trials;
- relevance to the treatment schemes and international guidelines for the treatment of the disease;
- position in the treatment scheme of the disease (e.g. first/second-line treatment, specific patient group);
- relevance of the dosage, pharmaceutical form and pack size to the treatment scheme and course of treatment.

The main economic criteria for a pharmaceutical to be reimbursed are:

- justified price, based on comparison with other available treatments and prices in other Baltic and European Union Member States;
- cost-effectiveness data justifying the relevance of pharmaceutical costs, with the expected therapeutic value of the product;
- budget impact.

The reimbursement rates are defined according to the character (chronic nature) and severity of the disease and stated by the Cabinet of Ministers of the Republic of Latvia. Diseases are listed in Appendix No. 1 of the Regulation of the Cabinet of Ministers No. 899 of 31 October 2006.

The following reimbursement rates are applied:

- I category: 100% for chronic, life threatening diseases or diseases causing irreversible disability, where the use of pharmaceuticals ensures and maintains the patient's life functions
- II category: 90% for chronic diseases, where the maintenance of the patient's life functions can be aggravated without use of pharmaceuticals
- III category: 75% for diseases where pharmaceuticals maintain or improve the patient's health
- IV category: 50% for diseases where pharmaceuticals are necessary to improve the patient's health or for reimbursement of vaccines.

All pharmaceuticals for the same indication are reimbursed at the same level.

Reimbursable pharmaceuticals are listed in the Positive List. The Positive List consists of three parts: List A, List B and List C.

- List A is a Reference price list and consists of clusters of interchangeable pharmaceutical products. (Pharmaceutical products are considered to be interchangeable if they: (1) have the same indications; (2) have the same method of administration; (3) have no

clinically significant differences in effectiveness and/or side-effects; (4) are intended for the same patient group.) Products are clustered according to the presentation form, dosage and pack size. Grouping is applied using Anatomic Therapeutic Chemical (ATC) classification at the aggregation levels ATC-3, ATC-4 and ATC-5.

- List B contains pharmaceuticals that are not interchangeable.
- List C contains pharmaceuticals that are not interchangeable and: (1) the cost per patient per year exceeds LVL 3,000 / € 4,270; (2) special medical restrictions cannot be applied to bear the expenditure.

Reimbursable pharmaceuticals can be prescribed by GPs and specialists who have the agreement with the Health Compulsory Insurance State Agency (HCISA) on providing state-covered health services. Reimbursable pharmaceuticals are prescribed using special prescription forms.

Reimbursement is provided through pharmacies. Patients have to pay a co-payment if their condition/ailment has the 90%, 75% or 50% reimbursement rate.

If the prescribed pharmaceutical is not the reference product in the ATC cluster, the patient has to pay the difference between the reference price and the price of the particular product, in addition.

To bear the growing expenditure on pharmaceuticals, the reimbursement system is based on a range of cost-containment measures, detailed here.

Supply-side measures:

- a limited list of reimbursable pharmaceuticals;
- fixed prices for a certain period (two years) for pharmaceuticals included in the Positive List;
- reference pricing mechanism for therapeutically interchangeable products.

Demand-side measures:

- fixed budgets for doctors;
- special reimbursement conditions for very expensive pharmaceutical products, based on evidence-based medicine (EBM), data form clinical trials and cost-effectiveness data;
- patient co-payment according to the reimbursement rate of the disease;
- Rational Pharmacotherapy Guidelines.

Pharmaceuticals for inpatient care are covered by the National Health Service (NHS). The State Medicines Pricing and Reimbursements Agency (SMPRA) elaborates the basic list of hospital pharmaceuticals. There is a Hospital Drug Committee in each hospital responsible for drawing up the additional list of hospital pharmaceuticals. Pharmaceuticals are purchased by hospitals separately, and some purchases are made centrally by the Health Compulsory Insurance State Agency (HCISA).

RATIONAL USE OF PHARMACEUTICALS

The State Medicines Pricing and Reimbursement Agency (SMPRA) elaborates the Rational Pharmacotherapy Guidelines, based on EBM principles. These guidelines are available in published form, as well as on web site of the SMPRA. The guidelines are used by GPs, specialists, hospitals and students of university medical faculties.

Advertisement of pharmaceuticals is regulated by the Regulation of the Cabinet of Ministers of the Republic of Latvia No. 167 of 6 March 2007. Only over-the-counter (OTC) products are eligible for advertisement to the general public. The State Agency of Medicines (SAM) issues permission for advertisements, both for OTC products and prescription products intended for health care professionals.

GPs and specialists are restricted by budget constraints for prescribing reimbursable pharmaceuticals. Budgets are calculated on the basis of the number of registered patients, their age groups and ailments/diseases. At the same time doctors can apply for a budget increase if it is justified by an increase in patient numbers or their treatment costs.

Doctors are encouraged to prescribe cheaper products because of their budget constraints within the reimbursement system and they cannot justify overspending on their budgets if they have not prescribed the cheapest alternatives.

Generic substitution of pharmaceuticals is encouraged. Pharmacists have to inform patients about cheaper alternatives that are available, but in practice generic substitution is voluntary (Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006).

Pharmaceutical consumption data are monitored:

- Total pharmaceutical consumption: data are collected from wholesalers by the SAM;
- Consumption within the reimbursement system: data are collected by the Health Compulsory Insurance State Agency (HCISA) using a special database of reimbursable pharmaceuticals. Pharmacies that have the agreements with the HCISA are responsible for inputting data into the database.

CURRENT CHALLENGES

The main challenges of pharmaceutical system in Latvia include the following points.

- There is continuous growth of pharmaceutical expenditure and limited public resources to cover the growth.
- Pharmaceutical products are marketed at EU prices and at the same time GDP per capita is 6-7 times less than the EU average, thus increasing affordability and equity problems.
- The cost-effectiveness of newly introduced pharmaceuticals needs to be improved, particularly in cases in which the new products fail to prove therapeutic added value, but the treatment costs are considerably higher than currently available therapies.
- There are difficulties in assessing the relative effectiveness of new pharmaceutical products using data from clinical trials, because:

(a) there is lack of point-by-point comparisons in clinical trials;

(b) follow-up is insufficiently detailed, leading to frequent use of modelling techniques based on assumptions or retrospective data;

(c) “surrogate outcomes” used in clinical trials do not provide evidence on improvement in health status.

- There have been cases of irrational use of pharmaceuticals, based on the marketing activities of pharmaceutical companies.
- Limited independent information is available for health care professionals and patients.

Future developments with regard to long-term pharmaceutical policy in Latvia (under implementation) include: (1) further development of the reference pricing system; (2) further development of the economic evaluation of pharmaceuticals; (3) promotion of rational use of pharmaceuticals and providing independent and unbiased information on therapeutic value and cost-effectiveness of pharmaceuticals to the public and to health care professionals.

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List of abbreviations

AFA	Starptautisko inovatīvo farmaceitisko firmu asociācija / Association of International Research-based Pharmaceutical Manufacturers
ATC	Anatomic Therapeutic Chemical classification
CIP	Cost Insurance Paid
DDD	Defined Daily Dose
DG Sanco	Health and Consumer Protection Directorate-General
€	Euro
EBM	Evidence-Based Medicine
EEA	European Economic Area
EMEA	European Medicines Agency
EU	European Union
GDP	Gross Domestic Product
GGE	General Government Expenditure
GÖG/ÖBIG	Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG
GP	General Practitioner
HE	Health Expenditure
HiT	Health Systems in Transition
HOM	Hospital-Only Medicine(s)
HCISA	Veselības obligātās apdrošināšanas valsts aģentūra (VOAVA) / Health Compulsory Insurance State Agency
ICER	Incremental Cost-Effectiveness Ratio
IMF	International Monetary Fund
INN	International Nonproprietary Name
LVL	Latvia's Lats
Mio.	Million

MoH	Latvijas Republikas Veselības ministrija (LR VM) / Ministry of Health
NATO	North Atlantic Treaty Organisation
NCU	National Currency Unit
NGO	Nongovernmental Organisation
NHS	National Health Service
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
OPP	Out-of-Pocket Payment
OSCE	Organisation for Security and Co-operation in Europe
OTC	Over-The-Counter pharmaceuticals
PE	Pharmaceutical Expenditure
POM	Prescription-Only Medicine(s)
PPP	Pharmacy Purchasing Price
PPPa	Purchasing Power Parity
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy Retail Price
QALY	Quality-Adjusted Life Year
SAM	Zāļu valsts aģentūra (ZVA) / State Agency of Medicines
SD	Self-Dispensing (Doctor(s))
SHI	Social Health Insurance
SMPRA	Zāļu cenu valsts aģentūra (ZCVA) / State Medicines Pricing and Reimbursement Agency of Latvia
SPI	Valsts farmācijas inspekcija (VFI) / State Pharmaceutical Inspection
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
VAT	Value Added Tax
WHO	World Health Organization
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, which are 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 work 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 budgets, 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

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1 Background

1.1 Demography

The resident population of Latvia decreases each year. In 2007 it was 2.28 Mio. The average population density was 35.3 inhabitants per km^2 in 2007. The highest density was registered in the central part of Latvia. In the coming years the highest population density will be observed in Riga (the country's capital), and the Ogre and Bauska districts (central part), and the lowest will be in the western and eastern parts. The resident population has been decreasing mainly due to natural processes, i.e. the number of deaths exceeds the number of births. This also leads to the ageing of society.

On average, women have a higher life expectancy than men. In 2006 the average life expectancy at birth was 71.27 years in Latvia: 65.85 years for males and 76.78 years for females. Morbidity and mortality rates are higher for males than for females. However, life expectancy has been increasing both for males and females since the mid-1990s.

The mortality rate was 14 per 1,000 population in 2006. The main causes of death were diseases of the circulatory system, malignant tumours and external causes. Population health indicators also have not changed significantly. The most prevalent are non-communicable diseases, cardiovascular diseases, mental disorders, malignant tumours and diabetes mellitus.

Table 1.1: Latvia - Demographic indicators, 2000–2007

Variable	2000	2001	2002	2003	*2004*	2005	2006	2007
Total population (annual average population)	2,372,985	2,355,011	2,338,624	2,325,342	2,312,819	2,300,512	2,2879,48	2,275,500 (provisional data)
Total population (at beginning of year)	2,381,715	2,364,254	2,345,768	2,331,480	2,319,203	2,306,434	2,294,590	2,281,305
Population density per km^2	36.9	36.6	36.3	36.1	35.9	35.7	35.5	35.3
Population aged 0-14 (as a % of total)	17.97	17.33	16.65	15.98	15.37	14.80	14.32	13.96
Population aged 15-64 (as a % of total)	67.20	67.43	67.84	68.17	68.44	68.67	68.87	68.95
Population aged >64 (as a % of total)	14.83	15.24	15.51	15.85	16.19	16.53	16.81	17.09
Life expectancy at birth, total	70.74	70.71	71.14	71.37	72.14	71.79	71.27	n.a.
Life expectancy at birth, females	75.98	76.62	76.83	76.86	77.20	77.39	76.78	n.a.
Life expectancy at birth, males	64.93	65.18	65.44	65.91	67.07	65.60	65.85	n.a.

n.a.= not available

Source: Central Statistical Bureau of Latvia

1.2 Economic background

Since re-establishing its independence, Latvia has proceeded with market-oriented reforms. Its freely traded currency, the Lat, was introduced in 1993 and has held steady or appreciated against major world currencies. The International Monetary Fund (IMF) has noted that Latvia's economic performance over the past several years has been among the best of the EU accession countries. Real per-capita gross domestic product (GDP) has approximately doubled compared to its 1995 level. GDP grew by almost 12% in 2006. Inflation, however, has remained high, at 10% in 2007. In the year 2004 Latvian inflation rates were at 6-7%.

Privatisation in Latvia is almost complete. All of the previously state-owned small- and medium-sized enterprises have been privatised, leaving in state hands the electric utility, the Latvian railway company, and the Latvian postal system, as well as state shares in several politically sensitive businesses.

Table 1.2: Latvia - Macroeconomic indicators, 2000–2006

Variable (in NCU=LVL or %)	2000	2001	2002	2003	2004	2005	2006
GDP in thousand NCU (LVL)	4,750,756	5,219,904	5,758,325	6,392,778	7.434.454	9.059.087	11.264.695
GDP per capita in NCU (LVL)	2,002	2,216	2,462	2,749	3,214	3,938	4,923
GDP per capita, PPPa	2,002	2,216	2,462	2,749	3,214	3,938	4,923
Annual economic growth rate in %	1,069	1,080	1,065	1,072	1,087	1,106	1,119
Growth rate 1995-2000	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
Growth rate 1995-2006, at current prices (the previous period=1)	1,114	1,099	1,103	1,110	1,163	1,219	1,243
General government expenditure (GGE) in thousand NCU (LVL)	1,773,893	1,804,561	2,052,529	2,223,637	2,658,950	3,223,641	4,196,359
GGE as a % of GDP	37.3	34.6	35.6	34.8	35.8	35.6	37.3
Exchange rate (LVL per €), annual rate, year average	0.560	0.563	0.583	0.645	0.671	0.703	0.703

GDP = gross domestic product, GGE = general government expenditure, n.app. = not applicable, NCU = national currency unit, PPPa = purchasing power parity

Source: “Macroeconomic indicator of Latvia” 1/2006; Central Statistical Bureau of Latvia, Riga 2006.

1.3 Political context

Latvia is a democratic parliamentary republic. Legislative power is in the hands of a single chamber Parliament – the *Saeima*, consisting of 100 deputies. Parliamentary elections take place every four years. The country’s Head of State is the President, who is elected by the *Saeima* for a period of four years. The President signs laws, chooses the Prime Minister (who heads the Government) and performs representative functions.

Latvia is a member of the EU, the North Atlantic Treaty Organisation (NATO), the United Nations Organisation, the Council of Europe, the World Trade Organisation (WTO), the Organisation for Security and Co-operation in Europe (OSCE), and the Council of the Baltic Sea States, the Euro-Atlantic Partnership Council, among others.

1.4 Health care system

1.4.1 Organisation

Latvia has a national health system based on the residence principle. The public health care sector is funded from general taxation. The health care budget is based on the state budget subsidy. The administration of the health care budget is fulfilled by the Health Compulsory Insurance State Agency (HCISA) and its five regional divisions. The Agency makes annual contracts with the providers of medical services, and covers the expenses of the service providers related to the medical care of the insured under these contracts. The aim of health insurance in Latvia is to cover the costs of health care services provided to insured individuals, as well as to prevent and treat diseases, and to reimburse the costs of certain pharmaceuticals and medical products.

Citizens of the Republic of Latvia, non-citizens of the Republic of Latvia, foreign nationals who have a residence permit and their family members, citizens of the European Union (EU), the European Economic Area (EEA) and Switzerland, refugees and people who have guaranteed alternative status, as well as detained persons, people taken into custody and those sentenced to imprisonment are entitled to health care services covered by the State's health care budget.

The principal laws/acts leading to the implementation of the current health care system are:

- Medical Treatment Law (1997);
- Law on Practice Doctors (1997);
- Pharmaceutical Law (1997);
- Epidemiological Safety Law (1997);
- Sexual and Reproductive Health Law (2002);
- Regulation of the Cabinet of Ministers No. 77 on mandatory requirements for medical treatment institutions and their units (19 February 2002);
- Regulation of the Cabinet of Ministers No. 899 Procedures for the Reimbursement of Pharmaceuticals and Medical Devices for Ambulatory Care (31 October 2006).
- Regulation of the Cabinet of Ministers No.1046 Procedures for the Organisation and Financing of Health Care (19 December 2006).

Several policy documents have been drawn up to solve the existing problems in health care. The "Health Care Development Strategy of Latvia" (1996) includes health-promoting measures with the objective of prolonging the life span of the Latvian population, ensuring a healthy and safe environment as well as prevention and treatment of diseases.

The main objective of the "Public Health Strategy" (2001) and "Public Health Strategy Implementation Action Programme 2004-2010" (2004) is to achieve the improvement of health conditions, approaching the best health indicators of the European Union Member States.

The aim of the "State Out-patient Treatment and Hospital Health Care Structure Plan (Master plan)" (2002) and the "Development Programme of the Out-patient and In-patient Health Care Services" (2004) is to ensure development of the health care system; to optimise the structure

of service providers; to achieve their consolidation and increase the quality of the health care services provided, as well as cost-efficiency and rational access for patients; and to establish the basis for integrated health care system development in every region and in Latvia as a whole.

In order to improve infrastructure and equipment of the emergency medical assistance services, a fundamental approach was set out in the “Development of Emergency Medical Assistance Service” (2005).

On 18 May 2005 the Cabinet of Ministers adopted a fundamental declaration on “Development of Human Resources in Health Care” in order to create long-term human resources development policy, establish priorities concerning human resources development and continue development of a population-oriented, rational, effective and high-quality health care sector.

In 2004 the Cabinet of Ministers accepted the “Development Programme of the Out-patient and In-patient Health Care Services” (Master Plan) and the current government strategy focuses on the rationalisation of secondary and tertiary health care services through the implementation of a Master Plan. The strategy proposes that state hospitals will be consolidated by developing multi-profile hospitals; closing or transforming small hospitals into nursing care hospitals, primary health care centres or social care institutions; and transforming single-profile hospitals into long-term hospitals by moving current services to multi-profile hospitals or out-patient settings. In 2004 and 2005, six hospital unions were carried out, and this process is being successfully continued.

The central organ of the state health care administration is the Ministry of Health (MoH), the main task of which is to develop and implement the state health policy, draft legislation in the health field, and to ensure accessibility, cost-efficiency, and quality of health care services.

The process of decentralisation and deinstitutionalisation is still developing. The aim is that general practitioner (GP) practices will become the basic unit of health care instead of health care centres or policlinics. Most outpatient practices are privately owned, while most inpatient facilities are publicly owned. The main criterion for the provision of statutory health care services is an agreement with the HCISA, and thus statutory health care services may be provided by both public and private health care service providers. Therefore, quality of health care does not depend on ownership (state hospital, municipal hospital or private hospital).

The principles of the health care system have been changed several times since independence. In 1992, the Ministry of Welfare approved the model of primary health care based on the GP structure. Reform of the system was initiated in 1993, and it is based on the principle of primary care provision, with emphasis on prevention. In 1997 inpatient and outpatient health care institution certification was initiated. A patient contribution system was introduced in the early 1990s, and since 1999 the patient contribution amount for visiting a GP has not been changed. In 2003 the MoH was established.

1.4.2 Funding

Sources of health care funding are: state budget subsidy from general taxation, patient co-payment, and private insurance and regional municipal budgets.

The administration of the public health care budget is fulfilled by the HCISA and its five regional divisions. The Agency makes annual contracts with the providers of medical services, and covers the expenses of the service providers related to the medical care of the insured under these contracts, including reimbursement of pharmaceuticals for ambulatory care and pharmaceutical expenditure in hospitals.

Total health expenditure (THE) increases every year. THE as a percentage of the GDP increased from 2000-2004 but has decreased in the years 2005 and 2006. Public health expenditure (HE) as a percentage of THE has steadily increased from 2001. On the contrary private HE decreased from 2001.

Table 1.3: Latvia - Health expenditure, 2000–2006

Health expenditure (HE)	2000	2001	2002	2003	2004	2005	2006
THE in million. NCU (LVL)	285	318	356	389	503	575	679
THE as a % of GDP	6.0	6.1	6.2	6.1	6.8	6.4	6.0
THE per capita[1] in NCU (LVL)	120	135	152	167	217	250	297
Public HE as a % of THE	54.7	51.3	51.8	52.4	58.6	60.5	63.2
Private HE as a % of THE	45.3	48.7	48.2	47.6	41.4	39.5	36.8

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

Source: Ministry of Health, Department of Pharmacy

1.4.3 Access to health care

1.4.3.1 Outpatient care

A patient can receive outpatient care by visiting a primary health care service provider (a GP, a physician's assistant, a nurse, a midwife, a dentist, a dental assistant, a dental nurse, a dental hygienist) or a specialist who provides secondary outpatient health care services at an outpatient medical institution or outpatient department of a hospital. Mainly outpatient care is provided at GP practices consisting of a GP and a nurse or physician's assistant.

Each person has the right to choose a GP and to re-register no more than twice in any calendar year (except for cases where the reason for re-registration is a change of place of residence).

The majority of GP have private practices but most of them are contracted by the HCISA. Almost all dental practices and pharmacies have been privatised.

In Lativia, people can only receive state-guaranteed secondary and tertiary health care services with a referral of a GP or specialist (except patients who have particular diseases).

Outpatient doctors are paid on the basis of fee-for service payments.

In order to receive health care services, a patient must make a contribution, which depends on what level of health care he/she is seeking. For a visit to a GP, the patient contribution is LVL 0.50 / € 0.71; for an outpatient visit to a specialist with a referral, the patient contribution is LVL 2.00 / € 2.85.

The State has ensured that several categories of resident are exempt from paying a patient contribution, e.g. children up to 18 years of age, pregnant women, the poor, etc.

At the same time, in order to limit patient expenditure on health, the State has set patient contribution ceilings.

- The total amount of a patient contribution for each hospitalisation shall not exceed LVL 80 / € 113.83.
- The sum total of patient contributions for outpatient and inpatient health care services within one calendar year shall not exceed LVL 150 / € 213.43.

Most of the voluntary insurance schemes cover patient contribution fees and some insurance companies also cover dentistry, spa treatment, rehabilitation, and pharmaceuticals not reimbursed by the National Health Service (NHS).

61.6% of the state budget resources are intended for payment for inpatient health care services, 32% for outpatient health care services and 6.4% for emergency treatment services. For the financing of GPs, a mixed capitation model is used.

In the years 2004-2006 the total number of doctors in the field of health care has increased and amounted to 8,341. The proportion of GPs as a share of primary health care doctors is increasing, demonstrating the development and consolidation of primary health care in Latvia.

Table 1.4: Latvia - Outpatient care, 2000–2006

Variable	2000	2001	2002	2003	2004	2005	2006
Total no. of doctors (at the end of the year)	8,134	7,744	7,921	7,883	8,087	8,207	8,341
No. of doctors per 1,000 inhabitants (per population at the beginning of the next year)	3.36	3.30	3.40	3.40	3.51	3.58	3.66
Total no. of outpatient doctors (at the end of the year)	3,318	3,519	3,661	3,682	3,854	4,102	4,248
thereof General Practitioners	838	939	999	1,018	1,201	1,243	1,254
thereof dentists	1,036	1,091	1,115	1,145	1,240	1,306	1,418
No. of outpatient doctors per 1,000 inhabitants (per population at the beginning of the next year)	1.40	1.50	1.57	1.59	1.67	1.79	1.86
No. of outpatient clinic departments ("ambulatories")	2,008	2,386	2,589	2,853	2,930	3,075	3,264
of which dentistry institutions	377	452	533	572	592	637	688

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

Source: Data of Health Statistics and Medical Technologies State Agency

1.4.3.2 Inpatient care

Following the Master Plan in 2006 the total number of hospitals decreased by 3, and in 2006 there were 106 hospitals, of which 16 were private hospitals (including health centres). The proportion of physicians employed in private institutions has increased during recent years. This is an indication of the strengthening of the health care institutions' privatisation process.

State institutions have important tasks, e.g. control of tuberculosis, HIV/AIDS, drug abuse and the spread of infectious diseases.

The network of hospitals located in rural territories is very compact and the areas of hospital service overlap recurrently. There are great differences between the numbers of hospital beds and the average length of stay, not only across the country as a whole but also within the framework of individual regions. On the whole medical technologies are concentrated in medical institutions in Riga and several of the larger cities.

Patient contribution for inpatient health care services varies according to the hospital level and it is paid starting on the second hospitalisation day as follows:

- in regional multi-profile hospitals – LVL 5.00 / € 7.11
- in specialised centres and state agencies – LVL 4.00 / € 5.69
- in local multi-profile hospitals – LVL 3.00 / € 4.27
- in specialised hospitals, health centres – LVL 1.50 / € 2.13.

If a patient does not have a referral from a GP or a specialist who is under contract with the HCISA (except for emergency medical assistance), they pay the full price for inpatient health care services. The same categories of residents that were mentioned earlier (cf. section 1.4.3.1) are also exempt from paying a patient contribution for inpatient health care services.

The majority of doctors are employees of hospitals and receive a salary according to their contract with an employer. The State sets the minimum monthly salary and states the particular ratio (an average salary in the economic sector versus an average salary for doctors) that is to be used in order to calculate salaries.

Outpatient doctors are paid on a fee-for service basis and under annual agreements with the HCISA on services provided.

In the years 2004–2006, according to the Master Plan, the number of hospitals has decreased. At the same time the number of inpatient doctors per 1,000 inhabitants has slightly increased. The average length of stay in hospital is decreasing year by year and in 2006 it was 9.6 days.

Table 1.5: Latvia - Inpatient care, 2000-2006

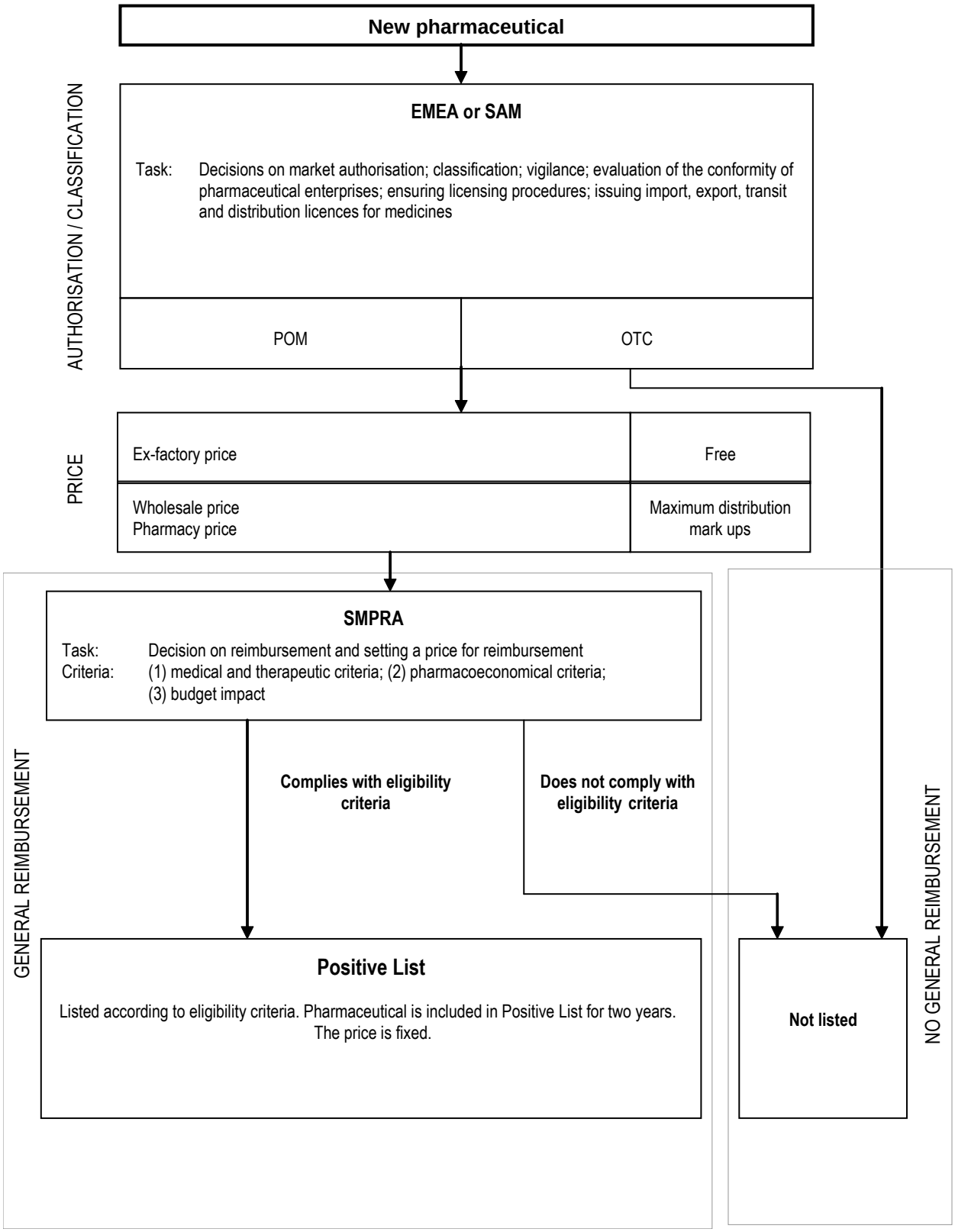
Variable	2000	2001	2002	2003	2004	2005	2006
No. of inpatient doctors *(at the end of the year)*	3,512	3,401	3,445	3,483	3,507	3,505	3,507
No. of inpatient doctors per 1,000 inhabitants *(per population at the beginning of the next year)*	1.49	1.45	1.48	1.50	1.52	1.53	1.54
No. of hospitals *(at the end of the year)*	142	140	129	129	119	109	106
No. of acute care beds *(average number)*	14,494	13,787	13,111	12,955	12,726	12,353	12,214
thereof in private sector	483	489	405	476	485	473	445
Acute care beds per 1,000 inhabitants *(per annual average population)*	6.1	5.85	5.6	5.57	5.5	5.4	5.3
Average length of stay in hospital	11.4	11.3	11.0	10.8	10.6	10.0	9.6

Source: Data of Health Statistics and Medical Technologies State Agency

2 Pharmaceutical system

2.1 Organisation

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



EMEA = European Medicines Agency, SAM = State Agency of Medicines, POM = prescription-only medicine(s), OTC = over-the-counter (pharmaceuticals), SMPRA = State Medicines Pricing and Reimbursement Agency

Source: State Medicines Pricing and Reimbursement Agency (SMPRA)

2.1.1 Regulatory framework

2.1.1.1 Policy and legislation

In Latvia the legislative bases regulating pharmaceutical activities are as follows.

- Pharmaceutical Law: adopted 10 April 1997 (with amendments).[1] The purpose of this law is to regulate the activities of individual and legal persons in the pharmaceutical sector and to ensure the manufacture and distribution of safe, qualitative and effective pharmaceutical products.
- Law on Procedure for Licit Circulation of Drugs and Psychotropic Substances: adopted 9 May 1996 (with amendments).[2] The purpose of this law is to set out the procedure for the licit circulation of dangerous drugs and psychotropic substances used for medical and research purposes.
- Law on Precursors: adopted 9 May 1996. This law regulates the activity of natural and legal persons with precursors (substances that can be used in the manufacture of pharmaceuticals or psychotropic substances) and the aim of this law is to prevent the deviation of these substances into illicit circulation.[3]

2.1.1.2 Authorities

The Ministry of Health (MoH) (Department of Pharmacy) implements the policy of the government in the field of pharmaceuticals, and drafts legislation regulating the operation of the pharmaceutical sector. The purpose of establishing the Advisory Council in the pharmaceutical area was to harmonise the views of public, professional and nongovernmental organisations (NGOs) in the process of drafting legal acts and when formulating policy in the pharmaceutical sector. The Advisory Council has discussed issues related to the development of the reimbursement system and its future prospects; principles for the formulation of the list of reimbursable pharmaceuticals and price formation for pharmaceuticals; mechanisms regulating the number and location of pharmacies, etc.

The process of market authorisation of pharmaceuticals guarantees that they are of the required quality and are safe for administration. Regulation of the Cabinet of Ministers No. 376 on Marketing Authorisation of Medicinal Products (9 May 2006) provides full compliance of the process of market authorisation with requirements established in the EU (http://www.zva.gov.lv). The Medicines Examination Laboratory controls quality of industrially manufactured pharmaceuticals according to the documentation the applicant has submitted to the State Agency of Medicines (SAM).

[1] http://www.zva.gov.lv

[2] http://www.zva.gov.lv

[3] http://www.zva.gov.lv

The SAM provides the registration of the pharmaceuticals within 210 days of the start of the registration process and provides the re-registration (or refusal to re-register) within 90 days of the beginning of the registration process.

Table 2.1: Latvia - Authorities in the regulatory framework within the pharmaceutical system, 2008

Name in local language (Abbreviation)	Name in English (Abbreviation)	Description	Responsibility
Latvijas Republikas Veselības ministrija (LR VM)	Ministry of Health of the Republic of Latvia (MoH)	Regulatory body	Overall planning and legislative authority
Zāļu valsts aģentūra (ZVA)	State Agency of Medicines (SAM)	Subordinate to the MoH Cooperate with public organisations of physicians and pharmacists	In charge of market authorisation; classification; vigilance; evaluation of the conformity of pharmaceutical enterprises; ensuring licensing procedures; issue of import, export, transit and distribution licences for pharmaceuticals
Zāļu cenu valsts aģentūra (ZCVA)	State Medicines Pricing and Reimbursement Agency (SMPRA)	Subordinate to the MoH Cooperate with public organisations of physicians and pharmacists	In charge of implementation of the procedures for pharmaceutical reimbursement and actualisation of the list of pharmaceuticals eligible for reimbursement (Positive List)
Valsts farmācijas inspekcija (VFI)	State Pharmaceutical Inspection (SPI)	Subordinate to the MoH	In charge of supervision and control over the pharmaceutical products market
Veselības obligātās apdrošināšanas valsts aģentūra (VOAVA)	Health Compulsory Insurance State Agency (HCISA)	Subordinate to the MoH	In charge of implementation of state policy for availability of health care services and administration of NHS resources

NHS = National Health Service

Source: Ministry of Health

2.1.2 Pharmaceutical market

2.1.2.1 Availability of pharmaceuticals

The formation of the pharmaceutical market in Latvia is influenced by a range of factors. In general, there are no availability problems and patients have access to the treatments they require. The greatest number of new authorisations issued (1,219) was in the year 2000, in recent years the number has been between 400 and 500. An exception was the year 2006, when the number of annually issued new market authorisations was almost two times fewer than in 2005. This can be explained by the increasing number of centrally registered products.

Table 2.2: Latvia - Number of pharmaceuticals, 2000-2008

Pharmaceuticals	2000	2001	2002	2003	2004	2005	2006	2007	2008
Authorised	1,219	452	360	581	445	579	300	403	n.a.
On the market*	n.a.	3,465	3,585	3,698	3,883	4,031	3,660	5,714	n.a.
POM*	n.a.	2,172	2,265	2,366	2,547	2,646	2,477	2,337	n.a.
Reimbursable **	45	166	189	202	198	226	261	318	316
Generics	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Parallel traded*	n.a.	n.a.	n.a.	n.a.	1	31	36	61	n.a.
Hospital/ Hospital-only*	n.a./ n.a.	2,673/ n.a.	2,811/ n.a.	2,910/ n.a.	3,003/ n.a.	2,891/ 15	2,472/ 11	3,506/ 250	n.a./ n.a.
Others *(please include further lines if necessary)*	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 medicine(s)

* active substances, including pharmaceutical form and strength

** active substances

[1] as of 1 January

Source: State Agency of Medicines. State Medicines Pricing and Reimbursement Agency

Two thirds of all pharmaceuticals available are prescription-only medicine(s) (POM) and one third are over-the-counter (OTC) products. This ratio is reasonable because a higher share of OTC products could lead to a worsening health status of population, increasing the problem of drug resistance, which is rather high in Latvia.

Factors influencing the availability of pharmaceuticals include: the small size of the Latvian market; rather low purchasing power and; subsequently, weak competitiveness in some therapeutic areas. From time to time situations arise in which patients do not have access to the medication they require, particularly in cases in which the product is registered for a very specific indication and is therefore not of interest to the pharmaceutical company because of its small sales volume. The small, restricted market is often mentioned as a reason for Latvia's high pharmaceutical industry prices – even higher than the EU average. From social and economic points of view, products that are priced higher than the EU average cause serious affordability problems.

The reason for the difference between the number of pharmaceuticals registered and the number of pharmaceuticals on the market is the business interests of manufacturers.

There are special names/abbreviations in Latvian for classifications of pharmaceuticals:

1. **PR I** – narcotic drugs and substances in Schedule II of the Convention on Psychotropic Substances of 1971.
2. **PR II** – pharmaceuticals in the outpatient sector and hospital-only medicine(s) (HOM).
3. **PR III** – pharmaceuticals listed in the Convention on Psychotropic Substances of 1971 and narcotic analgesic pharmaceuticals (like as Tramadoli hydrochloride).

The status of a pharmaceutical is defined by the State Agency of Medicines (SAM).

Only some pharmaceuticals (approximately four) have been changed from POM to OTC like Ibuprofen 200mg. The status of the proposed classification depends on the decision of the Ministry of Municipal Affairs and Housing.

2.1.2.2 Consumption

The value of annual prescriptions has grown almost twice from 2003, but annual consumption in packs has been on average 59.500 since 2005.

Table 2.3: Latvia – Annual prescriptions and consumption, 2000–2007

Consumption	2000	2001	2002	2003	2004	2005	2006	2007
No. of prescriptions per year (in volume)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of annual prescriptions in value (in NCU =LVL)	n.a.	n.a.	n.a.	60.22	79.38	91.79	111.31	n.a.
No. of annual consumption in packs	n.a.	n.a.	n.a.	70,099	76,144	60,678	57,790	59,833
No. of annual consumption in DDD	n.a.	n.a.	n.a.	454.33	503.86	515.34	353.37	n.a.

n.a. = not available, DDD = Defined Daily Doses, LVL = Latvia´s Lats, NCU = National Currency Unit

Source: State Agency of Medicines

2.1.2.3 Market data

Table 2.4: Latvia - Market data, 2000–2007

In million NCU = LVL /€	2000	2001	2002	2003	2004	2005	2006	2007
Prescriptions								
No. of annual prescriptions by volume	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of annual prescriptions by value	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
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	72.9/ 104.1	84.3/ 120.4	98.9/ 141.3	111.2/ 158.8	112.7/ 161.0	125.9/ 179.8	148.4/ 211.2	179.6/ 255.5
Sales at PRP level (excluding VAT)	66.7/ 95.3	73.6/ 105.1	80.8/ 115.4	92.8/ 132.5	98.3/ 140.4	105.1/ 150.1	150.4/ 214.0	n.a.
Sales at hospitals (at wholesales price level)	10.4/ 14.8	11.3/ 16.1	14.2/ 20.3	17.8/ 25.4	19.9/ 28.4	21.5/ 30.7	20.8/ 29.6	23.0/ 32.7
Sales of generics	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales of parallel traded pharmaceuticals	n.a.	n.a.	n.a.	n.a.	0.000021	0.002	0.21/ 0.30	0.57/ 0.81
Exports and imports								
Total pharmaceutical exports (domestic manufactures)	16.3/ 23.3	16.8/ 24.0	19.4/ 27.7	23.7/ 33.9	30.2/ 43.1	40.7/ 58.1	54.5/ 77.5	65.4/ 93.0
Total pharmaceutical imports	66.2/ 94.5	77.7/ 111.0	91.8/ 131.1	103.3/ 147.6	104.1/ 151.6	115.5/ 165.0	184.2/ 262.1	219.1/ 311.8

n.a. = not available, VAT = value-added tax, PRP = pharmacy retail price

Source: State Agency of Medicines

Pharmaceutical expenditure (PE) grows each year and had reached LVL 171.2 Mio. in 2006 (sales through pharmacies and hospital expenditure).

Pharmaceutical imports form the greatest part of the pharmaceutical market. Locally produced pharmaceuticals formed 5.2% of the whole market in 2007. At the same time local manufacturers have experienced growth in production and exports.

The level of parallel trade is very low, as the price level in Latvia is below the average of the EU and generic sales are among the highest within the EU Member States.

The consumption of pharmaceuticals in natural units shows that active substances, which are presented by generic products in the Latvian market, form all of the top 10 best-selling products.

Table 2.5: Latvia - Top 10 best selling pharmaceuticals by active ingredient, 2006

Position	Pharmaceutical, by active ingredient
1	Enalapril (30,36)
2	Diclofenac (21.31)
3	Amlodipin (13.92)
4	Omeprazol (13.41)
5	Atorvastatin (10.65)
6	Metoprolol (10.62)
7	Timolol (9.75)
8	Perindopril (9.29)
9	Bisoprolol (8.67)
10	Isosorbidi mononitras (7.92)

Source: State Agency of Medicines

2.1.2.4 Patents and data protection

Latvia has adopted the EU pharmaceutical legislation on patents and data protection. The extension of market exclusivity negatively affects access to pharmaceuticals, due to affordability problems. The high prices set for patented products do not allow these products to be widely used before the end of the market exclusivity period, thus creating equity problems in patient treatment in Latvia in comparison with patients in Member States belonging to the EU before May 2004 (EU15).

2.1.3 Market players

2.1.3.1 Industry

Local manufacturers of pharmaceuticals sell approximately 16% of the manufactured products in Latvia, thus covering 5.2% of the total pharmaceutical market. In 2007, turnover of Latvian manufacturers increased by 17% and exports of pharmaceuticals manufactured in Latvia increased by 20%. Since 2000 the turnover has increased 3.4 times and exports 4 times.

The Association of International Research-based Pharmaceutical Manufacturers (Starptautisko inovatīvo farmaceitisko firmu asociācija, AFA) and the Association of Latvian Chemical and Pharmaceutical Industry form part of the Advisory Council of the pharmaceutical sector. NGOs are involved in policy development by: establishing public opinion; public discussion of their opinion on the political activities that have been undertaken; participating in the assessment of legal acts prior to their final approval by the Government and; using their capacity as cooperation partners (advisors) at the stage in the process at which political activities are formulated.

Table 2.6: Latvia - Key data on the pharmaceutical industry, 2000–2006

Pharmaceutical industry	2000	2001	2002	2003	2004	2005	2006
Total no. of companies	16	15	14	13	13	14	13
- research oriented	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- generics producers	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- biotech	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of persons eployed[2]	1,736	1,740	1,853	1,831	1,700	1,747	1,999

n.a. = not available, No. = number

[1] as of 1 January

[2] counted per head

Source: Ministry of Health, Statistics of Department of Pharmacy on the operation of pharmaceutical enterprises

2.1.3.2 Wholesalers

The number of wholesalers in Latvia has decreased since the mid-1990s. In 2007, there were 34 private licensed wholesalers of pharmaceuticals operating.

A pharmaceutical wholesaler is permitted to distribute means of medical treatment to pharmacies and pharmaceutical wholesalers, as well as to licensed veterinarians and to practising physicians, to enable their work. Pharmaceuticals may be distributed to other institutions, organisations and undertakings only if they have a permit from the MoH. A pharmaceutical wholesaler is liable for the quality of the pharmaceuticals it distributes. It may purchase pharmaceuticals only from pharmaceutical manufacturing undertakings and pharmaceutical wholesalers, at the same time receiving documents that certify the quality of the pharmaceuticals.

The Association of the Latvian Medicine Wholesalers takes part in the Advisory Council in the field of pharmacy.

Table 2.7: Latvia - Key data on pharmaceutical wholesale, 2000–2007

Wholesalers	2000	2001	2002	2003	2004	2005	2006	2007
Total number of wholesale companies	59	50	42	38	37	37	35	34
Total number of importers	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

Source: Ministry of Health, Statistics of Department of Pharmacy on the operation of pharmaceutical enterprises

2.1.3.3 Pharmaceutical outlets / retailers

A pharmacy is an undertaking or an unit of an inpatient medical treatment institution which is engaged in the preparation of pharmaceuticals pursuant to prescriptions and written requests

from medical treatment institutions; in the manufacture of pharmaceuticals; in the storage and distribution of medical treatment products, as well as goods to be used for health care or body care; and in the provision of pharmaceutical care.

The preparation, manufacture and distribution of pharmaceuticals in the Republic of Latvia is only allowed if a special permit (licence) has been issued for the relevant form of entrepreneurial activity. In order that a pharmacy may commence operations it is necessary to provide for premises, equipment, installations and personnel complying with the requirements of regulatory enactments, as well as to – in accordance with the procedures prescribed by the Cabinet of Ministers – obtain a special permit (licence) for the opening (operations) of a pharmacy. Community pharmacies are permitted to distribute pharmaceuticals to medical treatment institutions and social care institutions and to natural persons. A pharmacy may open no more than two branches. The branches may only be opened outside a city where there are no other pharmacies or pharmacy branches within a 5 km radius.

2.1.3.3.1 Pharmacies

Regulation of the Cabinet of Ministers of the Latvian Republic No. 207 Requirements for Opening and Operating of Pharmacies (adopted 22 May 2001) determines the requirements for the opening and operating of pharmacies (except for veterinary pharmacies) and branches of pharmacies.

The Pharmaceutical Law (adopted 10 April 1997, with amendments) Section 36 states that:

> a general type pharmacy (community pharmacy) may be opened only by a pharmacist or – with the permission of the Minister of Health – a local government in its administrative territory. Only a pharmacist or a local government may own a general type pharmacy.

Pharmacies that have received licences for opening (operation), but the operation of which does not conform to the requirements specified in Section 36, Paragraph 1 of this Law, shall reorganise their operations in conformity with these requirements by 31 December 2010. The Pharmacies referred to have the right to receive a licence extension until 31 December 2010.

Pharmacies are mostly privately owned. Only those pharmacies that belong to local governments and public health care institutions have remained in the public sector and constitute 4% of the total number of pharmacies.

In 2006, the turnover of pharmaceuticals of community pharmacies was LVL 117.6 Mio.

The Latvia Pharmacists' Association is a NGO that is active in the field of pharmacy. Approximately 1,000 pharmacists with higher and secondary pharmaceutical education have formed this organisation on voluntary principles. On the basis of common interests the association takes care of the professional growth of its members and the development of their creative potential. The association takes part in the Advisory Council of the pharmaceutical sector.

A pharmacy is only permitted to sell via the internet registered OTC products if the procedures regarding pharmaceutical advertising (determined by the relevant regulatory enactments) are observed, and if the pharmacy has ensured for its clients the possibility of contacting the phar-

macy within a 24-hour period and of receiving from the pharmacy information and consultation without charge (including through the Internet) regarding those pharmaceuticals in conformity with the rules regarding pharmaceutical care. This is specified in the Regulations of the Cabinet of Ministers of the Republic of Latvia No.416 regarding the distribution and quality control of pharmaceuticals (adopted 26 June 2007)

Table 2.8:Latvia - Retailers of pharmaceuticals, 2000-2007[1]

Retailers	2000	2001	2002	2003	2004	2005	2006	2007
No. of community pharmacies[2]	789	868	853	833 +83 branches	838 +93 branches	817 +103 branches	814 +105 branches	799 +100 branches
No. of private pharmacies	763	851	836	820	835	814	812	796
No. of public pharmacies	26	17	17	13	3	3	2	3
No. of closed type pharmacies (hospital pharmacies)	31	40	40	43	44	42	42	41
No. of hospital pharmacies for outpatients	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of other POM dispensaries:	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total no. of POM dispensaries[1]	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of Internet pharmacies	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of OTC dispensaries, e.g. drugstores:	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

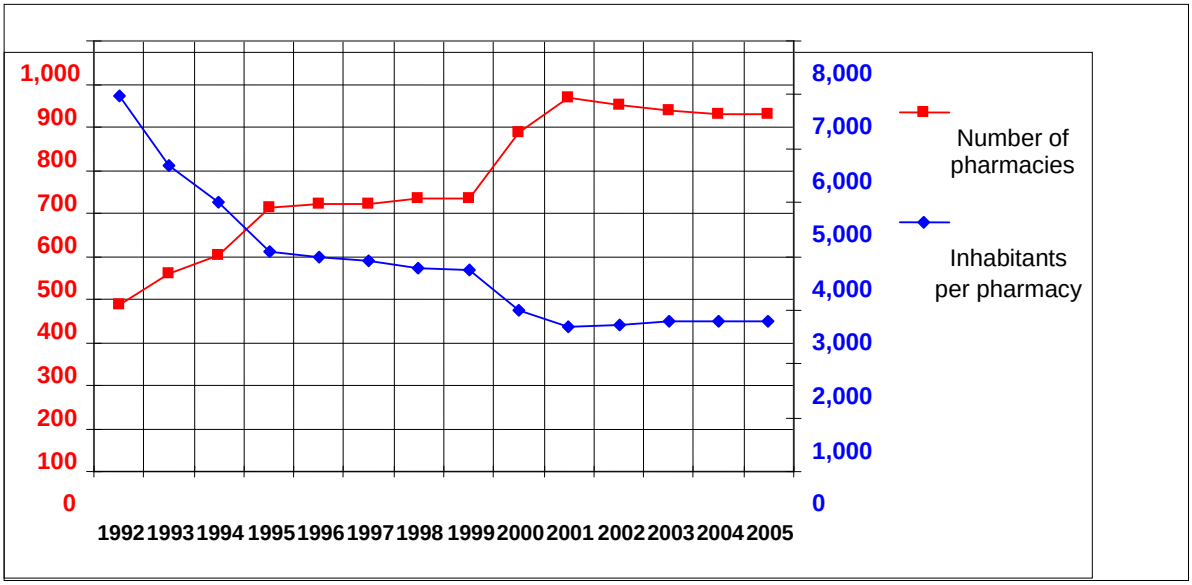
n.a. = not available, OTC = Over-The-Counter Pharmaceuticals, POM = Prescription-Only Medicines; No. = number; POM dispensaries = including branch pharmacies, self-dispensing doctors, and other university pharmacies (FI), policlinic pharmacies (NL) and hospital pharmacies acting as community pharmacies

1 as of 1 January

2 incl. branch pharmacies

Source: Ministry of Health, Statistics of Department of Pharmacy on the operation of pharmaceutical enterprises

Figure 2.2: Latvia - Number of retail pharmacies and number of inhabitants per pharmacy, 1992-2005



Source: Ministry of Health, Statistics of the Department of Pharmacy

It is only allowed to dispense pharmaceuticals in pharmacies or branches of pharmacies.

2.1.3.3.2 Internet pharmacies

Internet pharmacies are not allowed in Latvia.

2.1.3.3.3 Dispensing doctors

Doctors are not allowed to dispense pharmaceuticals.

2.1.3.4 Hospitals

Hospital pharmacies are permitted to package pharmaceuticals in accordance with the requirements of technical standards, prepare pharmaceuticals pursuant to the requests of medical treatment institutions and distribute pharmaceuticals to medical treatment institutions. Hospital pharmacies are not permitted to distribute pharmaceuticals directly to patients.

According to the Regulations of the Cabinet of Ministers of the Republic of Latvia No.220 on purchasing, utilisation, consumption, stocktaking and elimination of the pharmaceuticals in health care institutions and social care institutions (adopted 27 March 2007), there are two lists of pharmaceuticals elaborated for use in the health care institutions:

- basic list of hospital pharmaceuticals for each therapeutic group (Anatomic Therapeutic Chemical (ATC) classifications at the ATC-1 aggregation level);
- additional list of hospital pharmaceuticals.

The pharmaceutical is included into the basic list of hospital pharmaceuticals if:

- it belongs to the pharmacotherapeutic group (ATC classifications at the ATC-3 aggregation level), which is relevant to the treatment schemes, or treatment schemes elaborated by doctors' professional associations, or international treatment guidelines of disease treated in the health care institution;

- it has lower treatment costs compared to other pharmaceuticals, that have the same therapeutic effectiveness and side-effects;

- clinical trials has proved added therapeutic value for certain patient group, compared to alternative treatment, if the treatment costs are higher.

The pharmaceutical is included into the additional list of hospital pharmaceuticals if:

- the pharmaceutical belongs to the ATC group, which is relevant to the health care institution profile, and has proved added therapeutic value in terms of mortality, disability or frequency of complications and remission of the disease for certain patient group;

- clinical trials has proved added therapeutic value for certain patient group, compared to alternative treatment, if the treatment costs are higher.

- the costs of the pharmaceutical are comparable with financial resources of the health care institution.

The responsible institution for elaboration of hospital drug lists is the State Medicines Pricing and Reimbursement Agency (SMPRA), which:

- in cooperation with medical practitioners and representatives from doctors' professional associations elaborates the basic list of hospital pharmaceuticals;

- evaluates and gives the recommendations on the additional list of hospital pharmaceuticals;

- once a year updates the basic list of hospital pharmaceuticals.

Only pharmaceutical, necessary for ensuring its operation, can be acquired by the health care institution. The head of regional and local multi-profile health care institution has to form a Drug Committee, which has the following responsibilities:

- ratify a basic list of hospital pharmaceuticals elaborated by the SMPRA;

- prepare additional list of hospital pharmaceuticals;

- promote the rational use of pharmaceuticals at the health care institution;

- summarise the information on consumption of pharmaceuticals in the health care institution;

- analyse supply and consumption of pharmaceuticals and make recommendations for improvements;
- promote monitoring of side-effects caused by pharmaceuticals;
- ensure opportunities for medical practitioners to receive independent information regarding pharmaceuticals.

In health care institutions with more than 100 beds, a hospital pharmacy shall be established.

2.1.3.5 Doctors

Doctors can prescribe pharmaceuticals by International Non-proprietary Name (INN) or by the name of the product. If the doctor does not wish to allow substitution of the prescribed product by a pharmacist, s/he indicates this on the prescription. If he/she has not done so, the pharmacist is obliged to offer the patient a cheaper product.

The Latvian Association of Physicians unites professional organisations of doctors and its participation in the development of health care processes and in the health system has been prescribed by the Law on Medical Treatment. The Latvian Association of Physicians is represented in the Advisory Council of the pharmaceutical sector. Cooperation between pharmacists and physicians holds an important place in the health care system.

Doctors are not allowed to dispense pharmaceuticals.

2.1.3.6 Patients

When carrying out pharmaceutical care the pharmacist is to inform pharmacy customers of pharmaceuticals and their use, provide pharmacotherapeutic consultations and information on pharmaceuticals and their prices. When providing consultations on pharmaceuticals the pharmacist shall also provide information on the price of the pharmaceuticals and generic substitution, if equivalent pharmaceuticals are available.

Patients' organisations are involved in policy development by establishing public opinion and by public discussion of their opinion about health and pharmacy activities that have been undertaken through participation in the assessment of various draft programmes and legal acts prior to their approval by the government. Two patients' organisations are involved in the work of the Advisory Council of the pharmaceutical sector.

2.2 Funding

2.2.1 Pharmaceutical expenditure

Pharmaceutical expenditure (PE) grows each year by an average of 12% and had reached LVL 150.3 Mio. in 2006 (sales through pharmacies and hospital expenditure). The average consumption of pharmaceuticals in 2006 was LVL 65 / € 92 per capita.

Rather low consumption is influenced by low purchasing power as a result of low income of citizens and public expenditure, which forms only 57% of total pharmaceutical expenditure (TPE).

Public pharmaceutical expenditure as a share of the total health care budget was only 12.7% in 2006.

Table 2.9: Latvia - Total pharmaceutical expenditure, 2000–2006

Pharmaceutical expenditure (PE)	2000	2001	2002	2003	2004	2005	2006
TPE in Mio. NCU = (LVL) in retail prices	77.1	84.9	95.0	110.6	120.0	129.6	150.3
TPE as a % of THE	27	26.7	26.7	28	23.8	22.5	22.1
TPE per capita in NCU (LVL)	32	36	40	47	52	56	65
Public PE in Mio. NCU (LVL)	27.7	37.0	46.5	46.5	58.9	70.0	86.4
Public PE as a % of TPE	36.0	43.6	49.0	42.0	49.0	54.0	57.0
Private PE as a % of TPE	74.0	56.4	51.0	58.0	51.0	46.0	43.0
Public PE as a % of THE	9.9	12.0	13.1	11.9	11.7	12.2	12.7
Private PE as a % of THE	90.1	88.0	86.9	88.1	88.3	87.8	87.3

GDP = Gross Domestic Product, NCU = National Currency Unit, PE = Pharmaceutical Expenditure, THE = total health expenditure, TPE = Total Pharmaceutical Expenditure,
Public PE – reimbursement for outpatients and hospital pharmaceuticals

Source: Ministry of Health, Department of Pharmacy

2.2.2 Sources of funds

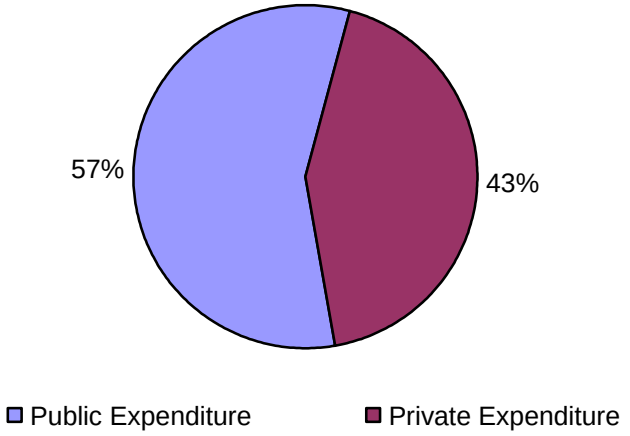
PE is covered by public and private funds. Public funds cover pharmaceuticals for ambulatory care included in the Positive List (reimbursement for treatment of chronic and severe illnesses) and pharmaceuticals in hospitals included in the health care services covered by the National Health Service (NHS).

Sources of private pharmaceutical expenses comprise out-of-pocket payments and private insurance funds.

Private pharmaceutical expenses are made up of:

- expenses for self-medication, OTC pharmaceuticals
- expenses for private (voluntary) health insurance
- co-payments for reimbursable pharmaceuticals
- expenses for non-reimbursable prescription pharmaceuticals.

Figure 2.3: Latvia - Share of private and public pharmaceutical expenditure, 2006



Source: Ministry of Health, Statistics of Department of Pharmacy

3 Pricing

3.1 Organisation

Pricing principles are different for non-reimbursable and reimbursable pharmaceuticals.

- Principles of the pricing of non-reimbursable pharmaceuticals are set out in the Regulation of the Cabinet of Ministers of the Republic of Latvia No. 803 of 25 October 2005. Manufacturers are free to set the prices of non-reimbursable pharmaceuticals regardless of their classification (prescription-only medicine(s) (POM), over-the-counter (OTC)). A manufacturer's price must be declared to the State Agency of Medicines (SAM) when placing the pharmaceutical on the market; further, it must be re-declared twice a year or in the event that the manufacturer's price is changed.
- Principles of the pricing of reimbursable pharmaceuticals as well as general principles of the reimbursement system are set out in the Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006.

Pricing criteria are determined by the Cabinet of Ministers of the Republic of Latvia include the following key points.

- For non-reimbursable pharmaceuticals, the manufacturer's price is free.
- The institution responsible for deciding on the inclusion of a pharmaceutical in the reimbursement system and for setting a price for reimbursement of a pharmaceutical is the State Medicines Pricing and Reimbursement Agency (SMPRA), which is a governmental agency under the Ministry of Health (MoH).

The decision on the price of a pharmaceutical is made along with the reimbursement decision. The institution responsible for deciding on inclusion in the reimbursement system and setting a price for reimbursement of a pharmaceutical is the SMPRA. For pharmaceuticals eligible for reimbursement the decision on inclusion in the reimbursement system and pricing is one procedure.

The price of a pharmaceutical approved by the SMPRA should be adhered to by manufacturers, wholesalers and pharmacies, otherwise the product is switched from the reimbursement scheme.

In 2005 a reference pricing system for therapeutically interchangeable products was introduced.

3.2 Pricing policies

Statutory pricing is not applied in Latvia, but prices of reimbursable pharmaceuticals may be indirectly influenced via the reimbursement system (setting the reimbursement price). Price negotiations are applied for reimbursable products, based on pharmacoeconomic evaluation. Free

pricing is applied for non-reimbursable products. Public procurement is applied for separate health care programmes and hospital pharmaceuticals.

Table 3.1: Latvia - Ways of pricing pharmaceuticals, 2008

	Manufacturer level	Wholesale level	Pharmacy level
Free pricing	For non-reimbursable pharmaceuticals	Regressive wholesale mark up scheme	Regressive pharmacy mark up scheme
Statutory pricing	Not applied, but price of reimbursable pharmaceuticals may be indirectly influenced via the reimbursement system (setting the reimbursement price)	Regressive wholesale mark up scheme	Regressive pharmacy mark up scheme
Price negotiations	For reimbursable pharmaceuticals, based on pharmacoeconomic evaluation	Regressive wholesale mark up scheme	Regressive pharmacy mark up scheme
Price–volume agreements	For reimbursable pharmaceuticals, if: (1) expenditure - exceeds LVL 3,000/€ 4,270 per patient per year; and (2) special medical reimbursement restrictions cannot be applied to bear the expenditure	Regressive wholesale mark up scheme	Regressive pharmacy mark up scheme
Discounts/rebates	n.a.	n.a.	n.a.
Public procurement	➢ For separate health care programmes and hospital pharmaceuticals		
Institution in charge of pricing	➢ SMPRA, for reimbursable pharmaceuticals		
Legal basis	➢ For non-reimbursable pharmaceuticals – Regulation of the Cabinet of Ministers of the Republic of Latvia No. 803 of 25 October 2005 ➢ For reimbursable pharmaceuticals – Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006		

n.a. = not available, SMPRA = State Medicines Pricing and Reimbursement Agency

Source: Regulation of the Cabinet of Ministers of the Republic of Latvia No. 803 of 25 October 2005, Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006

The current pricing system was implemented in 1998. The pricing procedures differ for reimbursable and non-reimbursable pharmaceuticals. Pricing decisions for reimbursable pharmaceuticals are made at wholesale level.

For non-reimbursable pharmaceuticals prices are free. If the manufacturer's price is changed, the manufacturer is to re-declare the price to SAM.

For reimbursable pharmaceuticals, price changes are possible, based on a written application from the manufacturer, containing a justification for the change. The justification should be submitted and the SMPRA evaluates the justification and decides whether the change is to take place.

3.2.1 Statutory pricing

Statutory pricing is not applied in Latvia, but prices of reimbursable pharmaceuticals may be indirectly influenced via the reimbursement system (setting the reimbursement price).

Reimbursable pharmaceuticals are listed in the Positive List. The Positive List consists of three parts – List A, List B and List C.

List A contains clusters of interchangeable pharmaceuticals (pharmaceutical products are considered to be interchangeable if they: (1) have the same indications; (2) have the same method of administration; (3) have no clinically relevant differences in effectiveness and side-effects; (4) are intended for the same patient group). Products are clustered according to the presentation form, dosage and pack size. Then the reference product for each cluster is identified (the cheapest pharmaceutical) and on the basis of the price of the reference product the reimbursement price for each pharmaceutical in the cluster is calculated.

Statutory pricing is carried out at pharmacy retail price (PRP) level by the SMPRA. When calculating the reimbursement price for pharmaceuticals included in List A, an internal pricing procedure is applied. Interchangeable products are clustered according to the presentation form, dosage and pack size. Then the reference product for each cluster is identified (the cheapest pharmaceutical) and on the basis of the price of the reference product the reimbursement price for each pharmaceutical in the cluster is calculated

The current system was implemented in 2005 and the legal framework for it is Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006.

The mechanisms of enforcement are clearly stated principles of collecting the pharmaceuticals into clusters and calculating the respective reimbursement prices.

Only reimbursable pharmaceuticals are replaced by policies in practice other than the ones stated in the law. This includes List A (interchangeable pharmaceuticals).

Decisions on the reimbursement of a pharmaceutical and its price for reimbursement are to be made within 180 days of application.

For information and documentation necessary for applying for reimbursement (cf. section 4.1).

3.2.2 Negotiations

Negotiations take place for reimbursable pharmaceuticals, based on pharmacoeconomic evaluation.

The new pharmaceutical is compared in terms of effectiveness and treatment costs to those included in the Positive List for the same indication. If the treatment costs are higher, the pharmacoeconomic evaluation in accordance with the Baltic Guideline for Economic Evaluation of Pharmaceuticals has to be submitted as justification.

If the pharmacoeconomic evaluation does not justify the high costs of a new pharmaceutical, a price decrease is negotiated between State Medicines Pricing and Reimbursement Agency (SMPRA) and manufacturer.

The negotiating parties (SMPRA and individual manufacturers) agree on the wholesale price and third-party payers are represented by the SMPRA.

Internal price referencing, taking into account costs and therapeutic effectiveness, is used as the basis of the pricing procedures. External price referencing is also used (cf. section 3.3).

3.2.3 Free pricing

Free pricing is applied for non-reimbursable pharmaceuticals at manufacturer price level. Before marketing, and in the event that the price is changed, for informative purposes the holder of the market authorisation has to declare the price to the SAM.

3.2.4 Public procurement / tendering

Tendering is applied to separate health care programmes and for pharmaceutical purchases in hospitals.

3.3 Pricing procedures

Internal price referencing is applied for reimbursable pharmaceuticals.

- For pharmaceuticals included in List A of the Positive List internal price referencing is applied within a cluster of interchangeable pharmaceuticals (cf. section 4.3 and section 3.3.2).
- For pharmaceuticals included in List B and List C of the Positive List internal price referencing is applied taking into account the therapeutic effectiveness.

The new pharmaceutical is compared to those included in the Positive List for the same indication in terms of effectiveness and treatment costs. If the treatment costs are higher, the pharmacoeconomic evaluation in accordance with the Baltic Guideline for Economic Evaluation of Pharmaceuticals has to be submitted as justification.

External price referencing is applied for reimbursable pharmaceuticals.

The price submitted for reimbursement should not exceed the price in other Baltic states. If the price for Latvia is higher than in other EU countries, the justification should be submitted.

Cost-plus pricing and indirect profit control are not applied:

- For non-reimbursable pharmaceuticals – free pricing.
- For reimbursable pharmaceuticals – internal price referencing; external price referencing.

These stipulations are enforced by law. Principles of the pricing of non-reimbursable pharmaceuticals are set out in the Regulation of the Cabinet of Ministers of the Republic of Latvia No. 803 of 25 October 2005. The methodology for calculating the reference price for interchangeable products is stated in Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006.

Pricing principles have not been changed in the past few years, except for the reference pricing system, which was introduced from 1 July 2005.

Table 3.2: Latvia - Pricing procedures, 2008

Pricing procedure	In use: Yes / No	Level of pricing[1]	Scope[2]
Internal price referencing	Yes	Pharmacy price level	Reimbursable pharmaceuticals
External price referencing	Yes	Manufacturer price level and/or wholesale price level	Reimbursable pharmaceuticals
Cost-plus pricing	No	n.a.	n.a.
Other, e.g. indirect profit control	No	n.a.	n.a.

n.a. = not available

1 Level of pricing = at what stage of the pricing process does the pricing take place (e.g. at the retail price level)

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

Source: Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006. Baltic Guideline for Economic Evaluation of Pharmaceuticals.

3.3.1 External price referencing

External price referencing is applied for reimbursable pharmaceuticals at manufacturer price and/or wholesale price level, and is one of the eligibility criteria for reimbursement. External price referencing is carried out as additional information. The price submitted for reimbursement should not exceed the price in other Baltic states. If the price for Latvia is higher than in other EU countries, a justification should be submitted.

The result of the price comparison directly influences pharmaceutical prices since the price submitted for reimbursement should not exceed the price in other Baltic states.

The comparisons are easy due to the fact that socioeconomic factors in Baltic states are comparable; the prices are compared at the manufacturer price level.

Country price information is provided by manufacturers and added to the application for reimbursement. Information is checked on the web sites of relevant institutions.

The product is included in the Positive List for 2 years, 6 months before re-application is submitted. The re-evaluation of a pharmaceutical is performed with regard to the eligibility criteria, including price comparison.

3.3.2 Internal price referencing

Internal price referencing is applied for reimbursable pharmaceuticals at PRP level, when a pharmaceutical is included in List A of the Positive List according to the interchangeability criteria, and the reference price is calculated.

Reimbursable pharmaceuticals are listed in the Positive List. The Positive List consists of three parts – List A, List B and List C.

List A contains clusters of interchangeable pharmaceuticals.

List B contains pharmaceuticals which are considered not to be interchangeable.

List C contains pharmaceuticals which are considered not to be interchangeable and: (1) the cost per patient per year exceeds LVL 3,000 / € 4,270; (2) special medical restrictions cannot be applied to bear the expenditure.

The pharmaceuticals in List A are clustered according to the presentation form, dosage and pack size. The reference product of each cluster is to be identified (the cheapest product). The reimbursement price for each pharmaceutical in the cluster is calculated, based on the price of the reference product.

The methodology for calculating the reference price for interchangeable products is stipulated in Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006.

The pharmaceuticals in List A are grouped in clusters of interchangeable pharmaceutical products.

Grouping is applied using Anatomic Therapeutic Chemical (ATC) classification at the ATC-3, ATC-4 and ATC-5 aggregation levels.

Grouping is applied, if the pharmaceuticals are interchangeable according to four criteria:

1. they have the same indications
2. they have the same method of administration
3. they have no clinically relevant differences in effectiveness and side-effects

4. they are intended for the same patient group.

Products are clustered according to the presentation form, dosage and pack size (cf. section 4.3).

With regard to internal price referencing, manufacturers are to provide the wholesale price of a pharmaceutical as a basis for reimbursement when applying for inclusion in the Positive List.

Internal price referencing is undertaken by the SMPRA.

3.3.3 Cost-plus pricing

Not used in Latvia.

3.3.4 (Indirect) Profit control

Not used in Latvia.

3.4 Exceptions

3.4.1 Hospitals-only

Pharmaceutical expenditure (PE) on inpatient care is covered by the National Health Service (NHS). The State Medicines Pricing and Reimbursements Agency (SMPRA) elaborates the basic list of hospital pharmaceuticals. There is a Hospital Drug Committee in each hospital responsible for drawing up the additional list of hospital pharmaceuticals (cf. section 2.1.3.4). Each hospital is responsible for purchases of pharmaceutical products.

Since 2007 hospitals have to submit information on pharmaceuticals used to the Health Compulsory Insurance State Agency (HCISA).

3.4.2 Generics

The same pricing procedures are applied to generics. Principles of the pricing of pharmaceuticals are set out in the Regulation of the Cabinet of Ministers of the Republic of Latvia No. 803 of 25 October 2005.

Principles of the pricing of reimbursable pharmaceuticals as well as general principles of the pharmaceutical reimbursement system are set out in the Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006.

3.4.3 Over-the-counter pharmaceuticals

The same pricing procedures are applied to OTC pharmaceuticals. Principles of pharmaceutical pricing are set out in the Regulation of the Cabinet of Ministers of the Republic of Latvia No. 803 of 25 October 2005.

OTC pharmaceuticals are not to be included in the reimbursement system according to Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006, stipulating the general principles of the reimbursement system.

3.4.4 Parallel traded pharmaceuticals

The SAM issues import licences for parallel trade products. The system for the pricing of parallel traded pharmaceuticals:

- does not differ from other pricing methods and procedures for non-reimbursable pharmaceuticals;
- differs from other pricing methods and procedures for reimbursable pharmaceuticals.

The wholesale price of parallel traded pharmaceuticals shall be 15% lower than the price of a pharmaceutical included in the Positive List.

Parallel traded pharmaceuticals are treated like generics if they are non-reimbursable. For non-reimbursable pharmaceuticals the pricing principles are the same, regardless of their classification. For reimbursable pharmaceuticals, the wholesale price of parallel traded pharmaceuticals is to be 15% lower than the price of a pharmaceutical included in the Positive List.

The legal basis for this is the Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006, stipulating the general principles of the reimbursement system.

3.4.5 Other exceptions

There are no other exceptions.

3.5 Margins and taxes

Wholesalers and pharmacists are remunerated via regressive mark ups. The mark ups are regulated by Regulation of the Cabinet of Ministers, as shown below.

- For non-reimbursable pharmaceuticals – Regulation of the Cabinet of Ministers of the Republic of Latvia No. 803 of 25 October 2005.
- For reimbursable pharmaceuticals – Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006.

All pharmaceuticals are covered by the regressive mark up scheme, but different mark ups are applied for reimbursable and non-reimbursable pharmaceuticals.

Value-added tax (VAT) is 5% for pharmaceuticals.

Table 3.3: Latvia - Regulation of wholesale and pharmacy mark ups, 2008

	Wholesale mark up			Pharmacy mark up		
	Regulation (yes / no)	**Content**	**Scope***	**Regulation (yes / no)**	**Content**	**Scope***
Latvia	Yes	Regressive mark ups	All pharmaceuticals, but different mark ups are applied for reimbursable and non-reimbursable pharmaceuticals	Yes	Regressive mark ups	All pharmaceuticals, but different mark ups are applied for reimbursable and non-reimbursable pharmaceuticals

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

Source: Regulation of the Cabinet of Ministers of the Republic of Latvia No. 803 of 25 October 2005; Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006

3.5.1 Wholesale remuneration

The wholesalers are remunerated via regressive mark ups. Wholesale margins are different for non-reimbursable and reimbursable pharmaceuticals.

- For non-reimbursable pharmaceuticals – Regulation of the Cabinet of Ministers of the Republic of Latvia No. 803 of 25 October 2005.
- For reimbursable pharmaceuticals – Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006.

All pharmaceuticals are covered by the regressive mark up scheme, but different mark ups are applied for reimbursable and non-reimbursable pharmaceuticals.

The Government regulates the margins by using a regressive scheme. The wholesale price for non-reimbursable pharmaceuticals is calculated by a formula:

$WP = ExFactP \times k + X$

(WP = wholesale price, ExFactP = ex-factory price, k = correction coefficient, X = correction sum)

The regressive mark up scheme for non-reimbursable wholesale pharmaceuticals is shown in Table 3.4.

The wholesale price for reimbursable pharmaceuticals is calculated by applying a mark up to the ex-factory price of a pharmaceutical. The regressive mark up scheme for reimbursable wholesale pharmaceuticals is shown in Table 3.5.

The average wholesale margin on 1 January 2009 for reimbursable pharmaceuticals was 3.4% (in terms of pharmacy purchasing price (PPP)).

Table 3.4: Latvia - Wholesale mark up scheme for non-reimbursable pharmaceuticals, 2008

Ex-Factory Price in LVL / €	Correction coefficient	Correction sum in LVL / €
Up to 2.99 LVL / € 4.25	1.18	0.00 LVL / € 0.00
From 3.00LVL / € 4.26 – 9.99 LVL / € 14.21	1.15	0.09 LVL / € 0.13
Over 10.00 LVL / € 14.22	1.10	0.59 LVL / € 0.84

Source: Regulation of the Cabinet of Ministers of the Republic of Latvia No. 803 of 25 October 2005

Table 3.5: Latvia - Wholesale mark up scheme for reimbursable pharmaceuticals, 2008

Ex-Factory Price in LVL / €	Maximum Mark up in % of Ex-factory price
From 0.01 LVL / € 0.01 – 1.99 LVL / € 2.83	10%
From 2.00 LVL / € 2.84 – 3.99 LVL / € 5.68	9%
From 4.00 LVL / € 5.69 – 7.99 LVL / € 11.37	7%
From 8.00 LVL / € 11.38 – 14.99 LVL / 21.33€	6%
From 15.00 LVL / € 21.34 – 19.99 LVL / € 28.44	5%
Over 20.00 LVL / € 28.45	4%

Source: Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006

3.5.2 Pharmacy remuneration

The pharmacies are remunerated via regressive mark ups. Pharmacy margins are different for non-reimbursable and reimbursable pharmaceuticals.

- For non-reimbursable pharmaceuticals – Regulation of the Cabinet of Ministers of the Republic of Latvia No. 803 of 25 October 2005.
- For reimbursable pharmaceuticals – Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006.

All pharmaceuticals are covered by the regressive mark up scheme, but different mark ups are applied for reimbursable and non-reimbursable pharmaceuticals.

The average pharmacy margin as of 1 January 2008 for reimbursable pharmaceuticals was 19% (in terms of net pharmacy retail price (PRP)) and 25% (in terms of gross pharmacy retail price (PRP)). No changes to the margins are planned.

Pharmacy price for non-reimbursable and reimbursable pharmaceuticals is calculated by the formula:

PP = PPP x n + Y

(PP = pharmacy price, PPP = pharmacy purchasing price, n = correction coefficient, Y = correction sum)

The regressive mark up scheme for non-reimbursable retail pharmaceuticals is shown in Table 3.6.

The regressive mark up scheme for reimbursable retail pharmaceuticals is shown in Table 3.7.

Table 3.6: Latvia - Pharmacy mark up scheme for non-reimbursable pharmaceuticals, 2008

Pharmacy purchase price (PPP) from … to… in NCU / €	Correction coefficient	Correction sum LVL/€
Up to 0.99LVL / € 1.41	1.40	0.00 LVL / € 0.00
From 1.00 LVL / € 1.42 – 1.99 LVL / € 2.83	1.35	0.05 LVL / € 0.07
From 2.00 LVL / € 2.84 – 2.99 LVL / € 4.25	1.30	0.15 LVL / € 0.21
From 3.00 LVL / € 4.26 – 4.99 LVL / € 7.10	1.25	0.30 LVL / € 0.43
From 5.00 LVL / € 7.11 – 9.99 LVL / € 14.21	1.20	0.55 LVL / € 0.78
From 10.00 LVL / € 14.22 – 19.99 LVL / € 28.44	1.15	1.05 LVL / € 1.49
Over 20.00 LVL / € 28.45	1.10	2.05 LVL / € 2.92

Source: Regulation of the Cabinet of Ministers of the Republic of Latvia No. 803 of 25 October 2005

Table 3.7: Latvia - Pharmacy mark up scheme for reimbursable pharmaceuticals, 2008

Pharmacy purchase price (PPP) from … to… in NCU / €	Correction coefficient	Correction sum LVL/€
Up to 0.99 LVL / € 1.41	1.30	0.00 LVL / € 0.00
From 1.00 LVL / € 1.42 – 1.99 LVL / € 2.83	1.25	0.05 LVL / € 0.07
From 2.00 LVL / € 2.84– 2.99 LVL / € 4.25	1.20	0.15 LVL / € 0.21
From 3.00 LVL / € 4.26– 4.99 LVL / € 7.10	1.17	0.30 LVL / € 0.43
From 5.00 LVL / € 7.11– 9.99 LVL / € 14.21	1.15	0.40 LVL / € 0.57
From 10.00 LVL / € 14.22– 14.99 LVL / € 21.33	1.10	0.90 LVL / €1.28
From 15.00 LVL / € 21.34 – 19.99 LVL / € 28.44	1.07	1.35 LVL / € 1.92
From 20.00 LVL / € 28.45 - 49.99 LVL / € 71.13	1.05	1.75 LVL / € 2.49
Over 50.00 LVL / € 71.14	1.00	4.25 LVL / € 6.05

Source: Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006

3.5.3 Remuneration of other dispensaries

There are no self-dispensing doctors, no pharmacies, no non-pharmacy outlets and no special regulations on remuneration of hospital pharmaceuticals.

3.5.4 Value added tax

Standard value added tax (VAT) is 18% and VAT for all pharmaceuticals is 5%. There have been no changes in the VAT in recent years.

However, in the year 2009 it is planned to raise the standard VAT rate to 21% and VAT for pharmaceuticals to 10%.

3.5.5 Other taxes

No further taxes / fees on pharmaceuticals.

3.6 Pricing-related cost-containment measures

3.6.1 Discounts / Rebates

No discounts/rebates are granted in Latvia.

3.6.2 Margin cuts

No margin cuts are used in Latvia.

3.6.3 Price freezes / Price cuts

No price freezes are used in Latvia.

3.6.4 Price reviews

No price reviews are used in Latvia.

4 Reimbursement

4.1 Organisation

General principles of the reimbursement system of pharmaceuticals are stipulated in the Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006.

The reimbursement of pharmaceuticals is to be provided according to the character and severity of the disease for which they are intended. Diseases are listed in Appendix No. 1 of the Regulation No. 899 of 31 October 2006.

The following reimbursement rates are applied according to the character and severity of the disease: 100%, 90%, 75% and 50%.

The pharmaceuticals eligible for reimbursement are listed in the Positive List drawn up by the State Medicines Pricing and Reimbursement Agency (SMPRA).

Reimbursable pharmaceuticals are prescribed by family doctors and certain specialists who have an agreement with the Health Compulsory Insurance State Agency (HCISA).

Reimbursement is provided through pharmacies on the basis of a special reimbursable prescription, patients having to pay only the co-payment in the case of the 90%, 75% or 50% reimbursement levels, or those receiving the pharmaceuticals without payment at the 100% reimbursement level.

A pharmaceutical to be included in the Positive List is to:

- be registered by the State Agency of Medicines (SAM) or by the European Union (EU) Centralised Procedure, or parallel imported according to regulations;
- be classified as “prescription only” (over-the-counter (OTC) products are not reimbursable);
- have an approved indication relevant to diseases listed in Appendix No. 1 of the Regulation No. 899 of 31 October 2006.

Homeopathic products are exempt from reimbursement.

The reimbursement policy covers the whole country.

The decision on the reimbursement of pharmaceutical is the responsibility of the SMPRA, which is a governmental agency under the Ministry of Health (MoH), established by the government in 1998. The main objectives of the SMPRA are to evaluate the therapeutic and economic value of pharmaceutical products as a basis for setting a reasonable price covered by the national health care system and to elaborate the Positive List of reimbursable products.

The tasks, responsibilities and working procedures are set out in Regulation of the Cabinet of Ministers of the Republic of Latvia No. 1007 of 7 December 2004.

For pharmaceuticals eligible for reimbursement the decision on inclusion in the reimbursement system and pricing is one procedure. The decision on price is made along with the reimbursement decision.

To apply for reimbursement of a pharmaceutical the holder of the market authorisation (hereinafter called the applicant) has to submit a written application to the SMPRA.

The following documentation and information is to be included in the application:

- name of the applicant, address, telephone number and fax of the applicant, and name, position and address of the contact person;
- account information;
- trade name of a pharmaceutical product, registration number, registration date;
- name of active substance (International Non-proprietary Name (INN)), Anatomic Therapeutic Chemical (ATC) code;
- concentration, pharmaceutical form, pack size, and recommended daily dosage of a pharmaceutical product;
- manufacturer's cost insurance paid (CIP) price of a pharmaceutical product in currency and LVL, proposal for the price as a basis for reimbursement in LVL;
- information about different trade names of a pharmaceutical product in other countries;
- reimbursement indications/conditions (a special form of application has to be filled out).

The following documentation and information is to be added to the application:

- information on patent or other protection certificate and its expiry date;
- summary of clinical trials for patented products, copies of published clinical trials (with reference to the data source) presenting the therapeutic value of the pharmaceutical product in comparison with other alternative treatments;
- information about manufacturers' prices of the product in the country of origin and other EU Member States;
- pharmacoeconomic analysis in compliance with the Baltic Guideline for Economic Evaluation of Pharmaceuticals (for a new active substance);
- budget impact analysis based on the estimated annual sales volume within the reimbursement system (this analysis, for a new active substance, is a part of the pharmacoeconomic analysis);
- justification of the price increase (in the event of re-application);
- confirmation of the continuous availability of the applicable product on the Latvian market;

- power of attorney of the holder of the market authorisation, if the application is submitted by the authorised person.

The product is to be included in the Positive List for 2 years, 6 months before expiry re-application can be submitted. The re-evaluation of a pharmaceutical is performed by the SMPRA with regard to the eligibility criteria. The reimbursement status of a pharmaceutical can change due to new available information.

4.2 Reimbursement schemes

General principles of the pharmaceuticals reimbursement system are set out in Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006.

The reimbursement of pharmaceuticals shall be provided according to the character and severity of the disease for which they are intended. Diseases are listed in Appendix No. 1 of Regulation No. 899 of 31 October 2006.

The following reimbursement rates are applied, according to the character and severity of the disease: 100%, 90%, 75% and 50%.

The pharmaceuticals eligible for reimbursement are listed in the Positive List drawn up by the SMPRA.

Reimbursable pharmaceuticals are prescribed by family doctors and certain specialists who have an agreement with the HCISA.

Reimbursement is provided through pharmacies on the basis of a special reimbursable prescription, patients having to pay only the co-payment in the case of the 90%, 75% or 50% reimbursement levels, or those receiving the pharmaceuticals without payment at the 100% reimbursement level.

The reimbursement rate is applied to the reimbursement price (reference price for pharmaceuticals in List A; pharmacy price for pharmaceuticals in List B and List C).

The decision on inclusion in the reimbursement system and pricing has to be made within 180 days of application (in compliance with Transparency Directive 89/105/EEC).

4.2.1 Eligibility criteria

The main therapeutic criteria for a pharmaceutical to be reimbursed are:

- therapeutic value of a pharmaceutical based on the evidence level from published clinical trials;
- relevance to the treatment schemes and international guidelines for the treatment of the disease;

- place in the treatment scheme of the disease (e.g. first/second-line treatment, specific patient group);
- relevance of the dosage, pharmaceutical form and pack size to the treatment course.

The main economic criteria for a pharmaceutical to be reimbursed are:

- justified price, based on comparison with other available treatments and prices in other Baltic states and EU Member States;
- cost-effectiveness data; relevance of pharmaceutical expenditure (PE), with expected therapeutic effectiveness;
- budget impact.

There are no patient-specific criteria.

In the event of the application for reimbursement of a pharmaceutical being denied, the applicant has right to appeal to the MoH against the decision of the SMPRA within 30 days after the decision was made. The decision of MoH can later be appealed in court.

4.2.2 Reimbursement categories and reimbursement rates

Reimbursement categories are applied according to the indication. All pharmaceuticals for the same indication are reimbursed at the same rate. The reimbursement rates are based on legal recommendations – the reimbursement rates are defined according to the character and severity of the disease by the Cabinet of Ministers of the Republic of Latvia. Diseases are listed in Appendix No. 1 of the Regulation of the Cabinet of Ministers No. 899 of 31 October 2006.

Table 4.1: Latvia - Reimbursement of pharmaceuticals, 2008

Reimbursement category	Reimbursement rate (%)	Characteristic of category
I category	100	For chronic, life-threatening diseases, or diseases causing irreversible disability, and the use of pharmaceuticals is necessary to ensure and maintain the patient's life functions (e.g. diabetes, cancer, schizophrenia).
II category	90	For chronic diseases, where the maintenance of the patient's life functions can be aggravated without use of pharmaceuticals (e.g. asthma, Parkinson's disease).
III category	75	For diseases, where pharmaceuticals are necessary to maintain or improve the patient's health (e.g. hypertension, acute diseases for children under three years).
IV category	50	For diseases, where pharmaceuticals are necessary to improve the patient's health or for reimbursement of vaccines.

Source: Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006

For reimbursable pharmaceuticals the prices are fixed.

The patient can apply individually for reimbursement of pharmaceuticals which are not included in the Positive List if:

- a diagnosis and the necessity of usage of the pharmaceutical has been approved by the council of doctors;
- the disease is not included in Appendix No. 1 of Regulation of the Cabinet of Ministers No. 899 of 31 October 2006 and the patient's life functions cannot be maintained without use of the respective pharmaceutical;
- the disease is included in Appendix No. 1 of Regulation of the Cabinet of Ministers No. 899 of 31 October 2006 but the pharmaceuticals included in the Positive List for the treatment of this disease are not applicable to maintain the patient's life functions.

4.2.3 Reimbursement lists

The pharmaceuticals eligible for reimbursement are listed in the Positive List, which consists of three parts.

List A – pharmaceuticals are grouped in clusters of interchangeable pharmaceutical products. Pharmaceutical products are considered to be interchangeable if they:

- have the same indications;
- have the same method of administration;
- have no clinically relevant differences in effectiveness and side-effects;
- are intended for the same patient group.

List B – contains pharmaceuticals which are considered not to be interchangeable.

List C – contains pharmaceuticals which are considered not to be interchangeable and: (1) the cost per patient per year exceeds LVL 3,000 / € 4,270; (2) special medical restrictions cannot be applied to bear the expenditure.

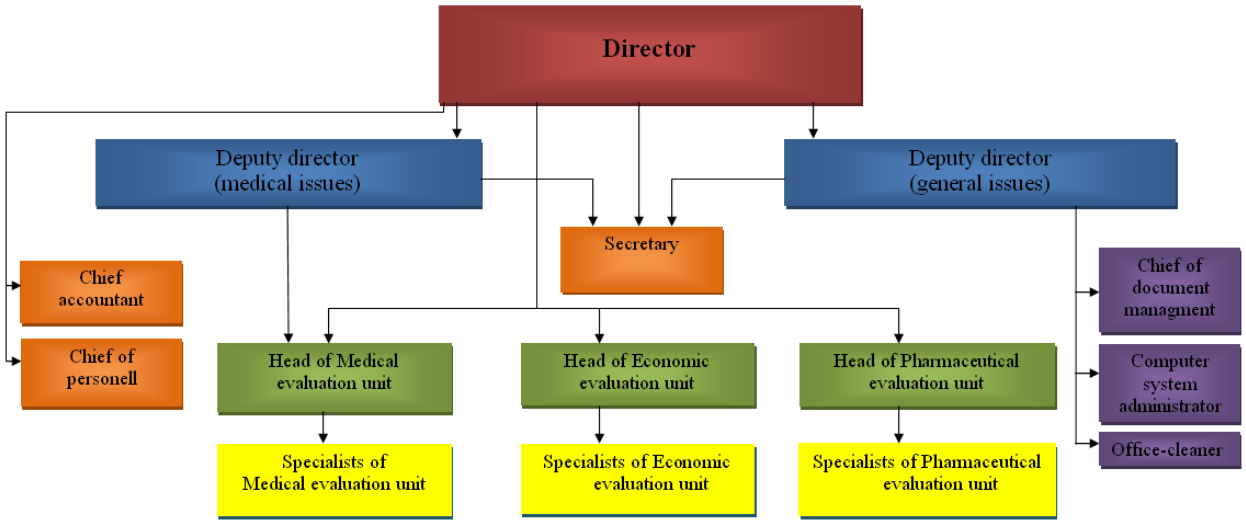
The Positive List is drawn up by the SMPRA. The SMPRA is a governmental agency under the MoH, established by the Government in 1998. Its tasks, responsibilities and working procedures are set out in Regulation of the Cabinet of Ministers of the Republic of Latvia No. 1007 of 7 December 2004.

The main tasks of the SMPRA are:

- to elaborate the Positive List of reimbursable products;
- to decide on reimbursement of pharmaceutical products;
- to set a reasonable price for reimbursement based on comparison of costs within active substance, pharmacotherapeutic group or indication;
- to decide on reimbursement conditions of a pharmaceutical product;

- to draw up the Rational Pharmacotherapy Guidelines based on the evidence data from clinical trials, comparative therapeutic and cost-effectiveness data;
- to conceive and promote projects on the development of the reimbursement system;
- to collaborate with doctors' and pharmacists' professional associations;
- to analyse the information on prescription of reimbursable pharmaceuticals;
- to collaborate with relevant institutions in other countries.

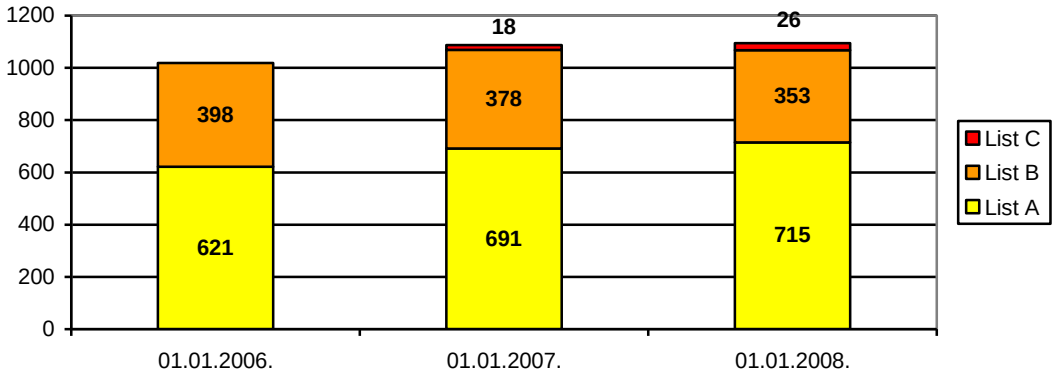
Figure 4.1: Latvia - Composition of the State Medicines Pricing and Reimbursement Agency (SMPRA), 2008



Decisions on the reimbursement of a pharmaceutical and its price for reimbursement are to be made within 180 days of application. The main criteria for a pharmaceutical product to be reimbursed are:

1. burden of disease
2. therapeutic value of the product
3. cost-effectiveness data (cf. section 5.4)
4. impact on the health care budget.

Figure 4.2: Latvia - Development of pharmaceuticals in Reimbursement Lists, 2006-2008*



* Number of pharmaceuticals included in the reimbursement lists

Source: SMPRA

The information on changes to the Positive List is available on the web site of the SMPRA. This information is communicated to doctors and pharmacists through the HCISA and Medicine Information Centre.

Pharmaceuticals used in hospitals are listed in the basic list of hospital pharmaceuticals and the additional list of hospital pharmaceuticals. Pharmaceuticals are purchased by hospitals separately, and some purchases are made centrally by the Health Compulsory Insurance State Agency (HCISA).

4.3 Reference price system

The State Medicines Pricing and Reimbursement Agency (SMPRA) is in charge of the reference price system. The legal basis for the reference price system is Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006, stipulating the general principles of the pharmaceuticals reimbursement system.

The reference price system was implemented gradually, starting from 1 July 2005. The reference pricing principle is applied to the pharmaceuticals listed in List A of the Positive List. The pharmaceuticals are grouped in clusters of interchangeable pharmaceutical products.

Grouping is applied using Anatomic Therapeutic Chemical (ATC) classifications at the ATC-3, ATC-4 and ATC-5 aggregation levels.

Grouping is applied, if the pharmaceuticals are interchangeable according to four criteria:

1. they have the same indications
2. they have the same method of administration
3. they have no clinically relevant differences in effectiveness and side-effects
4. they are intended for the same patient group.

Products are clustered according to the presentation form, dosage and pack size.

Parallel trade pharmaceuticals are included in the reference groups according to criteria of therapeutic interchangeability. The prices of other pharmaceuticals are not to be compared to those of parallel imported products.

The number of pharmaceuticals included in the reference group depends on the number of applications submitted for reimbursement.

The reference price for each cluster is the pharmacy retail price (PRP) of the cheapest product. The reimbursement price for each pharmaceutical is calculated, based on the reference price of the cluster. For this calculation, defined daily doses (DDD) are used within the active substance (grouping is applied at the Anatomic Therapeutic Chemical ATC-5 aggregation level). Within the pharmacotherapeutic group the “dose equivalency” is determined, based on comparative clinical data on relative effectiveness of pharmaceuticals.

The patient has to pay the difference between the actual price of a pharmaceutical and the reference price. When prescribing a pharmaceutical above the reference price, the doctor has to inform the patient.

4.4 Private pharmaceutical expenses

Private pharmaceutical expenditure in 2006 covered approximately 43% of total pharmaceutical expenditure (TPE). Public sources cover hospital pharmaceuticals and pharmaceuticals for ambulatory care included in the Positive List. Private expenditure covers OTC pharmaceuticals, self-medication, homeopathic products, and non-reimbursable POM.

The following principles are applied to protect certain groups of patients.

- Diabetic pregnant women and diabetic children (using an insulin pump or injecting insulin 3-4 times a day) are excluded from co-payment for test strips for diabetes.
- An annual allowance from the State Social Insurance can be requested for low-income individuals.

The objectives of cost-sharing policies are:

- promoting rational use of pharmaceuticals;
- cost-containment of pharmaceutical expenses;
- encouraging the compliance and responsibility of patients.

4.4.1 Direct payments

The following categories of pharmaceuticals have to be paid for by patients:

- OTC pharmaceuticals
- self-medication
- homeopathic products
- non-reimbursable POM.

4.4.2 Out-of-pocket payments

The reimbursement of pharmaceuticals is based on diagnosis. There are four reimbursement rates according to the character and severity of the disease: 100%, 90%, 75% and 50%.

Patients have to pay the respective co-payments for pharmaceuticals at the 90%, 75% and 50% reimbursement levels.

The reimbursement rate is applied according to the reimbursement price (reference price for pharmaceuticals in List A; pharmacy price for pharmaceuticals in List B and List C). If the prescribed pharmaceutical is above the reference price, the patient has to pay the difference between the actual price of a pharmaceutical and the reference price.

Table 4.2: Latvia - Reimbursement rates and patient co-payment rates, 2008

Annual expenses for patients (reimbursement price)	Co-payment rate in %	Reimbursement rate in %
Unlimited	0	100
Unlimited	10	90
Unlimited	25	75
Unlimited	50	50

Source: Regulation of the Cabinet of Ministers No. 899 of 31 October 2006

4.4.2.1 Fixed co-payments

No fixed co-payments are applied.

4.4.2.2 Percentage co-payments

The reimbursement of pharmaceuticals is based on diagnosis. There are four reimbursement rates according to the character and severity of the disease: 100%, 90%, 75% and 50%.

Patients have to pay the respective co-payments for pharmaceuticals at the 90%, 75% and 50% reimbursement levels.

4.4.2.3 Deductibles

No deductibles are applied.

4.5 Reimbursement in the hospital sector

Pharmaceutical expenditure (PE) on inpatient care is covered by the National Health Service (NHS). The State Medicines Pricing and Reimbursements Agency (SMPRA) elaborates the basic list of hospital pharmaceuticals. There is a Hospital Drug Committee in each hospital responsible for drawing up the additional list of hospital pharmaceuticals (cf. section 2.1.3.4). Each hospital is responsible for purchases of pharmaceutical products. Pharmaceuticals are fully reimbursed for inpatient care.

4.6 Reimbursement-related cost-containment measures

To bear the growing expenditure on pharmaceuticals, the reimbursement system is based on a range of cost-containment measures.

Supply-side measures:

- a limited list of reimbursable pharmaceuticals;
- fixed prices for a certain period (two years) for pharmaceuticals included in the Positive List;
- a reference pricing mechanism for therapeutically interchangeable products.

Demand-side measures:

- fixed budgets for doctors;
- special reimbursement conditions for very expensive pharmaceutical products, based on evidence-based medicine (EBM), data from clinical trials and cost-effectiveness data;
- patient co-payments according to the reimbursement rate of the disease/ailment;
- Rational Pharmacotherapy Guidelines.

4.6.1 Major changes in reimbursement lists

Starting from 1 July 2005 the Positive List is gradually being revised in accordance with reference pricing principles, based on the therapeutic interchangeability of products.

4.6.2 Review of reference price system

The pharmaceuticals included in the Positive List have been gradually re-evaluated in compliance with the interchangeability criteria and included in List A or List B. Re-evaluation was implemented according to the ATC classification and the reimbursement rate (in accordance with character and severity of the disease/ailment). The plan for gradual re-evaluation is shaped as follows:

- pharmaceuticals for diseases with reimbursement rates 90%, 75% and 50% – Anatomic Therapeutic Chemical ATC-5 level;
- pharmaceuticals for diseases with reimbursement rate 100% – Anatomic Therapeutic Chemical ATC-5 level;
- pharmaceuticals for diseases with reimbursement rates 90% 75% and 50% – Anatomic Therapeutic Chemical ATC-3, ATC-4 levels.
- Pharmaceuticals for diseases with reimbursement rate 100% – Anatomic Therapeutic Chemical ATC-3, ATC-4 levels.

Criteria for interchangeability – Pharmaceutical products are considered to be interchangeable if they:

- have the same indications
- have the same method of administration
- have no clinically relevant differences in effectiveness or side-effects
- are intended for the same patient group.

No changes in the reference pricing procedures have taken place.

The reference pricing principle is applied to parallel traded pharmaceuticals according to criteria of therapeutic interchangeability. The price of parallel imported pharmaceutical has to be 15% lower than the price of the respective product. The prices of other pharmaceuticals are not to be compared to those of parallel imported products.

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

Since applying the reference pricing principles, patients have to pay the difference between the actual price of a pharmaceutical and the reference price (the price of the cheapest product in the cluster) in the event that the price of the prescribed pharmaceutical is above that of the reference price product.

4.6.4 Claw-backs

Claw-backs are not used in Latvia

4.6.5 Reimbursement reviews

Reimbursement decisions are reviewed and evaluated on a regular basis. The product is included in the Positive List for 2 years, 6 months before expiry re-application can be submitted. The re-evaluation of a pharmaceutical is carried out by the SMPRA with regard to the eligibility criteria and any new available information.

A pharmaceutical company can ask for a review of a reimbursement decision.

The re-evaluation of pharmaceuticals is also performed on a regular basis due to the expiry of their inclusion period in the Positive List.

5 Rational use of pharmaceuticals

5.1 Impact of pharmaceutical budgets

General practitioners (GPs) and specialists have budgets for prescribing reimbursable pharmaceuticals. Budgets are calculated, taking into account the number of registered patients, as well as the age groups of registered patients and their diseases/ailments.

Administration of financial resources for prescribing reimbursable pharmaceuticals is the responsibility of the Health Compulsory Insurance State Agency (HCISA). If there is a justification based on an increase in patient numbers or the need for more expensive treatments, doctors can apply to the HCISA for their budget increase.

Once a month, doctors receive a report on their budget spending.

5.2 Prescription guidelines

Prescription of pharmaceuticals is targeted by the Rational Pharmacotherapy Guidelines, which are drawn up by the State Medicines Pricing and Reimbursement Agency (SMPRA). The Rational Pharmacotherapy Guidelines are based on the data from clinical trials, and comparative therapeutic and cost-effectiveness data. The scope is the reimbursement system. The principles defined in the Rational Pharmacotherapy Guidelines are included in the Positive List as prescription restrictions related to certain pharmaceuticals.

The following Guidelines[4] have been drawn up:

- Guidelines for treatment of Type 2 Diabetes
- Guidelines for Treatment of Hypertension
- Guidelines for Treatment of Asthma
- Guidelines for Treatment of Epilepsy
- Guidelines for Treatment of Parkinson's Disease
- Guidelines for Insulin Therapy for Patients with Diabetes Mellitus
- Guidelines for Treatment of Malignant Neoplasms of the Prostate
- Guidelines for Treatment of Cerebrovascular Diseases
- Guidelines for Pain Relief
- Guidelines for Treatment of Coronary Heart Disease: Stage 1 – Pharmacotherapy of Dislipidaemia
- Guidelines for Treatment of Coronary Heart Disease

[4] http://www.zca.gov.lv/rekomendacijas.html

- Guidelines for Treatment of Multiple Sclerosis
- Guidelines for Treatment of Chronic Viral Hepatitis C
- Guidelines for Treatment of Nonorganic Enuresis.

These Guidelines have been gradually implemented since 2001 by the SMPRA.

The following prescribing restrictions are defined in the Rational Pharmacotherapy Guidelines:

- prescriber (e.g. certain specialists)
- targeted patient groups
- for special treatment scheme of the disease (e.g. first/second-line treatment).

The HCISA performs monitoring on an ad-hoc basis. Specially appointed doctors (supervisory doctors) check the patients' records with regard to prescribing patterns and adherence to the Guidelines.

Penalties are imposed on doctors if they have not followed the Guidelines, but the pack size of prescriptions is not monitored. A doctor can prescribe a pharmaceutical for a treatment course of up to three months. Doctors receive a report from supervisory doctors but there are no regular (e.g. annual) clinical audits of all doctors.

The Rational Pharmacotherapy Guidelines are available in published format, as well as on the web site of the SMPRA. The Guidelines are drawn up by the SMPRA in collaboration with doctors' professional associations and are updated as necessary. The responsible body for updating the Guidelines is the SMPRA. Information on diagnostics limits, etc. is included and based on evidence-based medicine (EBM) principles and the cost-effectiveness data of pharmaceuticals.

5.3 Information to patients / doctors

The requirements of Directive 2001/83/EC are included in the Regulation of the Cabinet of Ministers of the Republic of Latvia No. 167 of 6 March 2007 regulating advertising of pharmaceuticals. The State Agency of Medicines (SAM) and the State Pharmaceutical Inspection (SPI) are involved in its implementation.

Direct advertising of over-the-counter (OTC) pharmaceuticals to patients is allowed. The advertising of pharmaceuticals on the Internet is allowed and regulated by the Regulation of the Cabinet of Ministers of the Republic of Latvia No. 167 of 6 March 2007.

No measures are implemented in order to restrict or control promotional spending of manufacturers. The restrictions on the activities of representatives of pharmaceutical companies who visit doctors are included in the Regulation of the Cabinet of Ministers of the Republic of Latvia No. 167 of 6 March 2007.

Representatives of pharmaceutical companies shall not supply, offer or promise any kind of goods or values for the prescription of pharmaceuticals.

Expenditure for professional and scientific meetings and arrangements is to be strictly limited, reflecting only the main objective of the arrangements, and used only in a professional capacity.

The restrictions on sending pharmaceutical samples to doctors are included in the Regulation of the Cabinet of Ministers of the Republic of Latvia No. 167 of 6 March 2007.

Free samples of pharmaceuticals are only to be supplied to people qualified to prescribe pharmaceuticals and they are to be supplied in accordance with the considerations listed here.

- The package of the free sample is not to be larger than the smallest presentation on the market.
- The sample is to be marked as “free sample” in accordance with requirements of the regulation on the labelling of the pharmaceuticals.
- A copy of the summary of product characteristics is to be included for each free sample.
- If the pharmaceuticals contain psychotropic or narcotic substances, which are under supervision of the Ministry of Health (MoH), free samples are not to be supplied.
- Free samples are to be supplied by written and dated request.
- The supplier of free samples and recipient is to set up a system for registration and control of free samples.
- In total no more than 1,000 free samples per year of the same prescription-only medicines (POM) are to be supplied to all recipients.
- Free sampling of pharmaceuticals containing isotretinoin is forbidden.

Each year by 31 January a report on all free samples of POM supplied over the previous year is to be submitted to the SAM. The following information is to be included in the report:

- trade name, registration number, pack size of the pharmaceutical(s)
- number of free samples supplied
- names of recipient(s), institution(s) in which they work.

5.4 Pharmacoeconomics

Pharmacoeconomic analysis is part of the application for reimbursement of a new active substance. Pharmacoeconomic analysis is to be performed in accordance with the Baltic Guideline for Economic Evaluation of Pharmaceuticals, included in Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006.

The provision of pharmacoeconomic analyses is necessary for price justification for reimbursable pharmaceuticals, when applying for reimbursement of a new active substance, in order to obtain reimbursement status. Pharmacoeconomic analysis was introduced in 2001, and the

analyses are performed by a manufacturer, as part of the process of applying for reimbursement of a new active substance.

The Baltic Guideline for Economic Evaluation of Pharmaceuticals highlights the main principles for performing pharmacoeconomic analysis, as listed here.

1. Pharmacoeconomic analysis shall be based on published clinical trial data or meta-analysis or clinical trial data performed as a part of the pharmaceutical licensing process.
2. Pharmacoeconomic analysis shall be performed from a health care perspective (incorporating only direct costs and benefits for health care); analysis from a societal perspective (including all costs and benefits outside the health care system) may be presented in addition, if considered relevant by the applicant.
3. Comparison of costs and benefits shall be made between the new pharmaceutical and the most commonly used alternative pharmaceutical within the pharmacotherapeutic group (if the new pharmaceutical belongs to an existing pharmacotherapeutic group) or the most commonly used alternative pharmaceutical for the indication (if the new pharmaceutical belongs to a new pharmacotherapeutic group).
4. The following economic evaluations can be applied:
    - cost-minimisation analysis
    - cost-effectiveness analysis
    - cost-utility analysis (only in addition to the cost-effectiveness analysis).
5. The outcome indicator is the improvement in health resulting from the therapy. The final outcome is the change in the health state (prevention of death, reduced incidence of complications, reduced incidence of side-effects, incidence of well-controlled therapy symptoms, etc.).
6. To identify the differences in the clinical effectiveness of the new pharmaceutical and comparative treatment, absolute risk difference shall be calculated and used for pharmacoeconomic analysis.
7. A summary of the incremental analysis shall be reported, comparing the relevant alternatives. Cost per outcome unit of the new pharmaceutical and alternative treatment shall be reported. To obtain evidence on the differences in costs to achieve an extra unit of benefits, the incremental cost-effectiveness ratio (ICER) shall be calculated. Budget impact and expected sales volumes shall be presented.
8. If the analysis cannot be performed otherwise, modelling techniques can be applied.
9. Economic analysis performed abroad can be applied to the local situation.

5.5 Generics

There are no legal regulations on the use of generics. In practice, generics provide a basis for competition in the pharmaceutical market and there are a relatively high proportion of generics

on the market. Doctors are encouraged to prescribe cheaper therapies because of their limited prescribing budgets within the reimbursement system.

5.5.1 Generic substitution

Generic substitution is allowed in Latvia and generic substitution of reimbursable pharmaceuticals is simultaneously mandatory and voluntary – mandatory, for a pharmacist to inform the patient, in practice, and voluntary, because consent is required from prescribers and patients.

The legal framework for generic substitution is the Regulation of the Cabinet of Ministers of the Republic of Latvia No. 899 of 31 October 2006.

Parallel imports are included in the generic substitution system.

Pharmacies are allowed to substitute a generic for a branded pharmaceutical under the circumstances or conditions listed here.

1. If the doctor has written the prescription indicating only the International Non-proprietary Name (INN) of a pharmaceutical.

2. If the doctor has not indicated in the prescription that the pharmaceutical shall not be substituted. In this case consent from prescribers or patients is required.

The same principles of substituting apply for parallel imported pharmaceuticals.

Doctors are encouraged to prescribe cheaper therapies because of their budget constraints within the reimbursement system and they can not justify overspending on their budgets if they have not prescribed the cheapest pharmaceuticals.

If the prescribed pharmaceutical is reimbursed, when opting for the branded pharmaceutical, the patient has to pay the difference between the actual price of a pharmaceutical and the reference price.
The following incentives are in place for generic substitution:

- regressive margins for pharmacies
- limited prescribing budgets for doctors
- reference pricing principle within the reimbursement system.

5.5.2 Generic prescription

Doctors are not obliged, but are encouraged, to prescribe cheaper therapies because of their budget constraints within the reimbursement system and they cannot justify overspending on their budgets if they have not prescribed the cheapest pharmaceuticals.

Doctors do not profit from prescribing generic pharmaceuticals.

Doctors can prescribe by either the International Non-proprietary Name (INN) or by a “brand name”. Generic prescribing is not readily accepted by doctors in Latvia.

5.5.3 Generic promotion

The use of generics are occasionally promoted among patients, doctors and pharmacists. Reasons for generic substitution:

- cost-containment measures within the reimbursement system
- price decrease due to competition in the pharmaceutical market
- decreased co-payments for patients
- support of local generics manufacturers.

5.6 Consumption monitoring

Individual consumption data are monitored by reviewing total pharmaceutical consumption data, collected from wholesalers by the State Agency of Medicines (SAM). The total pharmaceutical consumption is monitored by the SAM and updated twice a year.

Internet sales of OTC products by pharmacies are included in the total pharmaceutical consumption, monitored by the SAM.

Consumption within the reimbursement system is monitored by reviewing data from the database of reimbursable pharmaceuticals of the Health Compulsory Insurance State Agency (HCISA), as well as by the State Medicines Pricing and Reimbursement Agency (SMPRA) – the data are updated each month and summarised twice a year.

Compliance data are used in decisions regarding individual reimbursement but there is no Essential Drug Policy in place.

6 Current challenges and future developments

6.1 Latest changes

Table 6.1: Latvia - Changes in the pharmaceutical system, 2005–2008

Year	Pricing	Reimbursement	Not attributable to Pricing or Reimbursement
2005	Introduction of reference price system	-	-
2006	-	-	-
2007	-	Changes in the reimbursement categories and rates for separate indications	-
2008	-	-	-

Source: State Medicines Pricing and Reimbursement Agency (SMPRA)

6.2 Current challenges

The main challenges of pharmaceutical system in Latvia are listed here.

- Continuous growth of pharmaceutical expenditure (PE) and limited public resources to cover the growth.
- Pharmaceutical products are marketed at EU prices, and at the same time GDP per capita is 6-7 times less than the EU average, thus increasing affordability and equity problems.
- Analysis of the cost-effectiveness of newly introduced pharmaceuticals in cases in which the new products fail to prove therapeutic added value, but the treatment costs are considerably higher than currently available therapies.
- There are difficulties in assessing the relative effectiveness of new pharmaceutical products using data from clinical trials, because:
    (a) there is a lack of point-by-point comparisons in clinical trials;
    (b) follow-up is insufficiently detailed, leading to frequent use of modelling techniques based on assumptions or retrospective data;
    (c) “surrogate outcomes” used in clinical trials do not provide evidence on improvement in health status.
- There have been cases of irrational use of pharmaceuticals, based on the marketing activities of pharmaceutical companies.
- Limited independent information is available for health care professionals and patients.

6.3 Future developments

Future developments in long-term pharmaceutical policy in Latvia (under implementation) include:

- further development of reference pricing system;
- further development of economic evaluation of pharmaceuticals and broadening the scope to the hospital system, applying economic evaluation to the pharmaceuticals used in hospitals;
- promotion of rational use of pharmaceuticals;
- providing independent and unbiased information on therapeutic value and cost-effectiveness of pharmaceuticals to the public and to health care professionals;
- participation in international collaboration on assessment of the relative effectiveness of pharmaceuticals.

7 Appendixes

7.1 References

List of data sources:

Baltic Guideline for Economic Evaluation of Pharmaceuticals. Available at: http://www.zcva.gov.lv/english/guidelines.html

Central Statistical Bureau of Latvia

Epidemiological Safety Law (1997)

Health Compulsory Insurance State Agency

Health Statistics and Medical Technologies State Agency

Law on Practice Doctors (1997)

Law on Precursors (1996)

Law on Procedure for Licit Circulation of Drugs and Psychotropic Substances (1996)

“Macroeconomic indicator of Latvia” 1/2006; Central Statistical Bureau of Latvia, Riga

Medical Treatment Law (1997)

Ministry of Health

Pharmaceutical Law (1997)

Regulation of the Cabinet of Ministers of the Republic of Latvia No.207 of 22 May 2001 on requirements for opening and operating of pharmacies

Regulation of the Cabinet of Ministers of the Republic of Latvia No.77 of 19 February 2002 on mandatory requirements for health care institutions and their units

Regulation of the Cabinet of Ministers of the Republic of Latvia No.803 of 25 October 2005 on principles of the pricing of pharmaceuticals

Regulation of the Cabinet of Ministers of the Republic of Latvia No.376 of 9 May 2006 on marketing authorisation of medicinal products

Regulation of the Cabinet of Ministers of the Republic of Latvia No.1007 of 7 December 2004 on tasks, responsibilities and working procedures of State Agency of Medicines

Regulation of the Cabinet of Ministers of the Republic of Latvia No.899 of 31 October 2006 on procedures for the reimbursement of pharmaceuticals and medical devices for ambulatory care

Regulation of the Cabinet of Ministers of the Republic of Latvia No.1046 of 19 December 2006 on procedures for the organisation and financing of health care

Regulation of the Cabinet of Ministers of the Republic of Latvia No.167 of 6 March 2007 on regulating advertising of pharmaceuticals

Regulation of the Cabinet of Ministers of the Republic of Latvia No.220 of 27 March 2007 on purchasing, utilisation, consumption, stocktaking and elimination of the pharmaceuticals in health care institutions and social care institutions

Regulation of the Cabinet of Ministers of the Republic of Latvia No.416 of 26 June 2007 on distribution and quality control of pharmaceuticals

Sexual and Reproductive Health Law (2002)

State Agency of Medicines

State Medicines Pricing and Reimbursement Agency

7.2 Web links

Central Statistical Bureau of Latvia: http://www.csb.gov.lv

Health Compulsory Insurance State Agency: http://www.voava.gov.lv

Health Statistics and Medical Technologies State Agency: http://www.vsmtva.gov.lv

Ministry of Health: http://www.vm.gov.lv

State Agency of Medicines: http://www.zva.gov.lv

State Medicines Pricing and Reimbursement Agency: http://www.zcva.gov.lv

State Pharmaceutical Inspection: http://www.farminsp.gov.lv

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