ÖSTERREICHISCHES BUNDESINSTITUT FÜR GESUNDHEITSWESEN
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ÖBIG

PHARMACEUTICAL SYSTEMS IN THE NEW EU MEMBER STATES

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COMMISSIONED BY
THE FEDERAL MINISTRY OF HEALTH AND WOMEN AND
THE FEDERATION OF THE AUSTRIAN SOCIAL INSURANCE INSTITUTIONS

Österreichisches Bundesinstitut für Gesundheitswesen
Austrian Health Institute

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Vienna, September 2005

Commissioned by
the Federal Ministry of Health and Women and
the Federation of the Austrian Social Insurance Institutions

ISBN No. 3-85159-081-3
No. 43742-05

Owner and publisher: Österreichisches Bundesinstitut für Gesundheitswesen/Austrian Health Institute (ÖBIG) - responsible editor: Sebastian Kux – secretary: Silvia Laskaridis – design: Renate Weidenhofer – technical production: Ferenc Schmauder – address: A-1010 Vienna, Stubenring 6, phone +43 1 515 61-0, fax no. +43 1 513 84 72, e-mail: lastname@oebig.at

Ecological printing: The paper used for this study has been bleached without the use of chlorine and without optical brightening agents.

Summary

Central and Eastern European countries (CEECs) have undergone major political, economic and social changes during the transition process of the 1990-ties. On 1st of May 2004, eight Central and Eastern European countries (Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia, and Slovenia), together with Cyprus and Malta, acceded to the European Union.

In preparation to the accession, candidate countries had to adjust their legislation to Community law („Acquis Communitaire“). With regard to the pharmaceutical system primarily registration and distribution had to be harmonised. Reimbursement and pricing is basically in the competence of the Member States, while taking into account the overall framework of the EU (e.g. the Transparency Directive). Consequently there are 25 national pharmaceutical systems in the EU which may differ to a great extent. The study “Pharmaceutical Systems in the New EU Member States”, carried out by the Austrian Health Institute (ÖBIG), which was commissioned by the Austrian Federal Ministry of Health and Women and the Federation of Austrian Social Insurance Institutions, describes, in ten country profiles, the underlying health care system, the main players and structures of the pharmaceutical system with a focus on pricing and reimbursement. The ten country profiles are followed by a benchmarking chapter providing a comparative analysis. The 200-pages report, originally published in German, is accompanied by an English version of about 130 pages.

Key conclusions

- Since transition, the health status in the new Member States has improved.

  Life expectancy and other health indicators show a positive trend even if they are still lagging behind in performance compared to the “old” Member States. However, problems known in the “old” Member States such as chronic diseases and unhealthy lifestyle, are increasingly getting acute in the new Member States.

- Within a few years, the organisation of the health care systems has fundamentally changed in the Central and Eastern European countries.

  The health systems in Central and Eastern Europe had formerly been organised on the basis of the Semaskho-model with health services financed and provided in a centralised way by the state, with the focus on the hospital sector. After transition a social insurance system was introduced in most of these countries. At the same time more emphasis was put on primary care by introducing family physician systems with gatekeeping functions in the Central and Eastern European Member States.

- The registration of pharmaceuticals has been – in almost all new Member States – harmonised to EU legislation.

  Before the accession to the EU the candidate countries had to adjust their legislation to Community law. Basically, EU registration procedures are in place; only for “old” pharmaceuticals (i.e. registered some years ago) some Member States requested a transitional period (e.g. Malta, Poland).

- The inclusion of pharmaceuticals into reimbursement is the outcome of a rather strict evaluation with financial considerations being one important criterion.

  Due to tight health budgets the Central and Eastern European Member States left their former health policy of free medication for the whole population. In all new Member States, there are positive lists which, in the CEECs, are linked to reference price systems. Only a range of pharmaceuticals is fully or partially reimbursed, and co-payments, which used to be unthinkable, are nowadays common. Decisions on the inclusion of pharmaceuticals into reimbursement are connected to medical (e.g. therapeutic benefit) and economic criteria (e.g. budgetary restrictions).

- Decisions on reimbursement and pricing of pharmaceuticals are often based on internal price referencing and / or international price comparison.

  Most of the new Member States consider the prices of comparable products in their own country (internal price referencing) as well as prices of the same pharmaceutical in defined reference countries (often neighbouring countries or known “low-price countries”) as criteria for pricing and reimbursement.

- The prices of reimbursable pharmaceuticals are usually set by the state.

  In general, competent authorities (the Ministry of Health or the social health insurance) set the manufacturer or wholesale price of reimbursable pharmaceuticals. The pharmaceutical companies can freely determine the prices of non-reimbursable pharmaceuticals. In most new Member States statutory mark-ups for wholesalers and pharmacies apply to all pharmaceuticals. However, in some countries actors in pharmaceutical distribution do not make use of the maximum mark-ups, especially in the OTC segment, which leads to different retail prices in the pharmacies.

- Privatisation and liberalisation resulted in major changes in the structure of the pharmaceutical market.

  Before transition, the production and distribution of pharmaceuticals (wholesale, pharmacies) in Central and Eastern Europe were in the hands of the state. Thereafter international research-based pharmaceutical companies came into the market; and the main distribution actors were privatised and had to face competition through other providers. In some of the new Member States – especially in urban regions – pharmacy chains are now very common.

- Reforms are the answer of the new Member States to react to the challenges in the pharmaceutical systems.

  Latvia and Slovenia, along with some other Member States, introduced Medicines Agencies, which act as advisory bodies to the Ministry of Health. Furthermore, pharmacoeconomic instruments (e.g. the Baltic Guideline for Economic Evaluation of Pharmaceuticals) are another common reform measure.

What is, in the field of pharmaceuticals, the difference between the new Member States and the “old” ones? All EU Member States have to provide their population with effective, safe and innovative medicines within limited budgetary resources. However, the new Member States, especially in Central and Eastern Europe, have to meet this challenge with very tight health budgets, which is reflected in low investment in health in general and in a small range

of reimbursable pharmaceuticals. Responses of the new Member States are the introduction of pharmacoeconomic instruments and the exchange of experience with other countries[1].

ÖBIG expertise with price comparison

The report “Pharmaceutical Systems in the New EU Member States”, published in 2005 by ÖBIG, follows a long tradition of the Austrian Health Institute (ÖBIG) to undertake studies on health and pharmaceutical systems. Furthermore, this report falls within the framework of the “Pharma Price Information” (PPI) service, provided by ÖBIG on initiative of the Federal Ministry of Health and Women and the Federation of Austrian Social Insurance Institutions. The PPI service provides up-to-date information on pharmaceutical prices at all price levels in all EU Member States. Since the EU enlargement, the Austrian Health Institute has expanded the PPI service to the new Member States, with this study building the basis for the “enlargement” of the PPI service.

[1] PPRI (Pharmaceutical Pricing and Reimbursement Information) is a project funded by the European Commission, Health and Consumer Directorate-General with the objective to provide knowledge and information on the pharmaceutical systems in the 25 Member States of the European Union. It is coordinated by ÖBIG (Austrian Health Institute) and involves WHO-EURO as well as a network of institutions and organisations from all Member States of the enlarged Union.

Acknowledgement

In order to obtain up-to-date first-hand information on pharmaceutical markets and the regulatory framework in the countries investigated, written communication of, and personal contacts to, a large number of institutions and persons were needed.

We are indebted to our contacts, who have shown vivid interest in this study and were always ready to help us. We wish to thank all of them for providing information and data and for answering our questions over the phone or in personal meetings. Our contact persons in the ten new EU Member States are from Ministries, Social Insurances, Medicines Agencies, the pharmaceutical industry, the wholesale market and the pharmacy sector.

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Abbreviations

AESGP	Association Européenne des Spécialités Pharmaceutiques Grand Public
ALP	Association of Lithuanian Pharmaceutical Wholesalers
AOK	Allgemeine Ortskrankenkassen
ARSZMP	Agencija Republike Slovenije za zdravila in medicinske pripomočke / Agency of Medicinal Products and Mecial Devices (Slovenia)
ATC	Anatomic, therapeutic, chemical classification of the WHO
BMGF	Bundesministerium für Gesundheit und Frauen / Federal Ministry of Health and Women (Austria)
CEEC	Central and Eastern European Countries
CIF	Cost, Insurance and Freight
CIP	Cost, Insurance and Packaging
CY	Cyprus
CZ	Czech Republic
DRG	Diagnosis Related Groups
DTC	Drugs and Therapeutics Committee (Malta)
EC	European Community
ECB	European Central Bank
EEC	European Economic Community
EGA	European Generics Association
EMEA	European Agency for the Evaluation of Medicinal products; in 2004 renamed in: European Medicines Agency
ESKI	Egészségügyi Stratégiai Kutatóintézet / National Institute for Strategic Health Research (Hungary)
EST	Estonia
EU	European Union
EU-10	Member States which acceded to European Union in May 2004
EU-15	Member States of the European Union before May 2004
EU-25	Member States of the enlarged European Union since May 2004
EüM	Egészségügy minisztériumi (Hungary)
FD	Farmacijos Departementas (Lithuania)
GDP	Gross Domestic Product
GIF	Główny Inspektorat Farmaceutyczny (Poland)
GIRP	Groupement International de la Répartition Pharmaceutique Européenne European Wholesale Association
GP	General Practitioner
H	Hungary
HPSS	Healthcare Procurement and Supplies Service (Malta)
HTA	Health Technology Assessment
IIR	Institute for International Research
Inh.	Inhabitants
INN	International non-proprietary name
LEK-ZBOR	Lekarniška zbornica Slovenije (Slovenia)

LT	Lithuania
LV	Latvia
LZLA	Latvijas Zâïu lieltirgotâju asociâcija (Latvia)
M	Malta
MA	Market Authorisation
MAGYOSZ	Magyarországi Gyógyszergyártók Országos Szövetsége (Hungary)
MGYK	Magyar Gyógyszerész Kamara (Hungary)
Mill.	Millions
MS	Member States
NFZ	Narodowy Fundusz Zdrowia (Poland)
NHS	National Health Service
NMPAU	National Medicines Policy and Audit Unit (Malta)
n.a.	Not available
n.y.	No year quoted
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
OECD	Organisation for Economic Co-operation and Development
OEP	Országos Egészségbiztosítási Pénztár / National Health Insurance Fund (Hungary)
OGYI	Országos Gyógyszerészeti Intézet / National Institute of Pharmacy (Hungary)
OTC	Over-the-Counter
p.	Page
PB	Pharmaceutical Budget
Ph.	Pharmaceutical
PL	Poland
POM	Prescription-only medicines
PPI	Pharma Price Information (service on price information offered by ÖBIG)
PPP	Pharmacy Purchase Price
PPR	Pharma Pricing & Reimbursement (journal)
PPRI	Pharmaceutical Pricing and Reimbursement Information (EU Project coordinated by ÖBIG)
PRP	Pharmacy Retail Price
quo.	quoted in
RPS	Reference Price System
SAM	Ravimiamet / State Agency of Medicines (Estonia)
SAM	Sveikatos apsaugos ministerija (Lithuania)
SI	Social Insurance
SK	Slovakia
SLO	Slovenia
SPFFwP	Stowarzyszenie Przedstawicieli Firm Farmaceutycznych w Polisce (Poland)
SUKL	Státní Ústav pro Kontrolu Léčiv / State Institute for Drug Control (Czech Republic)
SUKL	Štátny Ùstav pre Kontrolu Liečiv / State Institute for Drug Control (Slovakia)
TÉB	Technológia Értékelő Bizottság / Technology Evaluation Committee (Hungary)
URPL	Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznychi Produktów Bio-bójczych / National Office for Registration of Medicinal Products, Medical Devices and Biocides (Poland)

VAT	Value added tax
VLK	Valstybinė ligonių kasa (Lithuania)
VM	Veselibas Ministrija (Latvia)
VOAVA	Veselibas obligatas apdrosinasanas valsts agentura (Latvia)
Vol.	volume
VVKT	Valstybinė vaistų kontrolės tarnyba (Lithuania)
VZA	Valsts zalu agentura (Latvia)
WHO	World Health Organisation
ZCA	Zalu Cenu Valsts Agentura (Latvia)
ZZZS	Zavod za zdravstveno zavarovanje Slovenjie / Health Insurance Institute of Slovenia (Slovenia)

Table of currencies

CYP	Cyprus pound
CZK	Czech koruna
EEK	Estonian kroon
HUF	Hungarian forint
LTL	Lithuanian litas
LVL	Latvian lats
MTL	Maltese lira
PLN	Polish zloty
SIT	Slovenian tolar
SKK	Slovak koruna

Table of conversion (2004)[1]

1 € =	0.58185 CYP
1 € =	31.891 CZK
1 € =	15.6466 EEK
1 € =	251.66 HUF
1 € =	3.4529 LTL
1 € =	0.6652 LVL
1 € =	0.428 MTL
1 € =	4.5268 PLN
1 € =	239.0874 SIT
1 € =	40.022 SKK

[1] Average annual rate ECB

1 Introduction

The Austrian Federal Ministry of Health and Women and the Federation of Austrian Social Insurance Institutions commissioned the Austrian Health Institute (ÖBIG/Österreichisches Bundesinstitut für Gesundheitswesen) to carry out a study on the pharmaceutical systems in the new EU Member States. The project started in April 2004, and the final report (in German) was submitted to the commissioning parties in July 2005. In September 2005 the German report (200 pages) “Arzneimittelsysteme in den neuen EU-Mitgliedstaaten” was published. The English version “Pharmaceutical Systems in the New EU Member States”, a briefer report (about 130 pages), but with the same structure as the German study, was also published in September 2005.

1.1 Background

The Health Economics department of the Austrian Health Institute (ÖBIG) has a long tradition of undertaking studies in the field of pharmaceuticals and health systems. The team members have acquired in-depth knowledge on the analysis of pharmaceutical systems. Due to this expertise, the Austrian Ministry of Health and Women and the Federation of Austrian Social Insurance Institutions commissioned the Austrian Health Institute (ÖBIG) in the year 2000 to establish the Pharma Price Information (PPI) service. PPI offers independent and up-to-date information on prices of pharmaceuticals at all price levels (ex-factory price, pharmacy purchase price, pharmacy retail price) in all EU Member States. Additionally, there has been available price information on Norway and Switzerland since summer 2004.

The PPI service enables ÖBIG to provide information on market availability of pharmaceuticals and to offer price comparisons at European level. In 2004, a new pricing procedure for pharmaceuticals (an average European price) was introduced in Austria, and Austrian law now provides that the Austrian Price Commission, when establishing the average European price, is advised by ÖBIG.

In May 2004, ten new Member States acceded to the European Union: Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, and Slovenia. Following the enlargement of the European Union, ÖBIG expanded its PPI service to the new Member States. On behalf of the Ministry of Health and Women and the Federation of Austrian Social Insurance Institutions ÖBIG undertook this study “Pharmaceutical Systems in the New EU Member States”, which provides background knowledge for the enlargement of the PPI service. Currently, the PPI service offered by ÖBIG covers all 25 Member States of the enlarged European Union, Norway and Switzerland.

1.2 Objectives

The study aims at the investigation and the analysis of the health care and pharmaceutical systems in the ten new Member States of the European Union. Thereby, the following issues are raised:

- How is the health care system organised?
- Who are the main actors in the pharmaceutical system, and how is the pharmaceutical system organised?
- Which instruments are used for the reimbursement of pharmaceuticals (positive list, reference price system, pharmaceutical budget, level of co-payment, etc)?
- How are prices set at the different price levels (ex-factory price, pharmacy purchase price, pharmacy retail price)?

1.3 Methodology

In order to obtain up-to-date, first-hand data and information, a range of data gathering techniques was applied:

- literature and internet research
- investigation of key data from national and international publications and databases such as OECD Health Data 2004, year books and statistical publications
- collection of information and data through written inquiries, telephone calls and personal interviews.

The project team contacted various institutions in the ten new Member States. Contact persons were primarily from Ministries of Health, State Agencies of Medicines and Social Insurance Funds, and sometimes also from interest groups.

1.4 Outline

As mentioned earlier, this publication follows the structure of the German report. The information and data on the pharmaceutical systems in the new Member States are provided in ten country profiles (listed in the order of the German alphabet). They are followed by a comprehensive benchmarking chapter, in which the results of the ten country profiles are summed up and analysed in a comparative way.

COUNTRY PROFILES

Estonia

Inhabitants	***1.4 million***
Life expectancy – women	***77.1 years***
Life expectancy – men	***65.3 years***
Gross domestic product per inhabitant	***€ 5,931.-***
Health expenditure per inhabitant	***€ 250.-***
Hospital beds per 1,000 inhabitants	***4.5***
Inhabitants per physician	***321***
Inhabitants per pharmacy	***4,274***
Conversion rate – 100 Estonian Kroon (EEK)	***€ 6.3912***

2 Estonia

2.1 Health Care System

After gaining independence in 1991, Estonia organised its health care as a decentralised social health insurance system. The responsibility for the overall organisation of health care and health policy lies with the Ministry of Social Affairs. 76 percent of health expenditure are financed through the state (taxation and social insurance contributions) and around 23 percent are privately financed.

Primary care is predominantly provided by general practitioners, who have contracts with the social insurance fund. GPs act as gatekeepers to secondary and tertiary care and refer patients to specialists or hospitals. They are remunerated on the basis of a combined system of monthly fixed budgets and capitation fees.

Since the early 1990-ties the organisation of specialist care has been modified. Specialist care is now provided by around 190 health centres and 50 out-patient clinics as well as 40 hospitals. In the last few years, small hospitals were closed. Since 2004 hospitals have been remunerated on the basis of a DRG system.

2.2 Pharmaceutical System

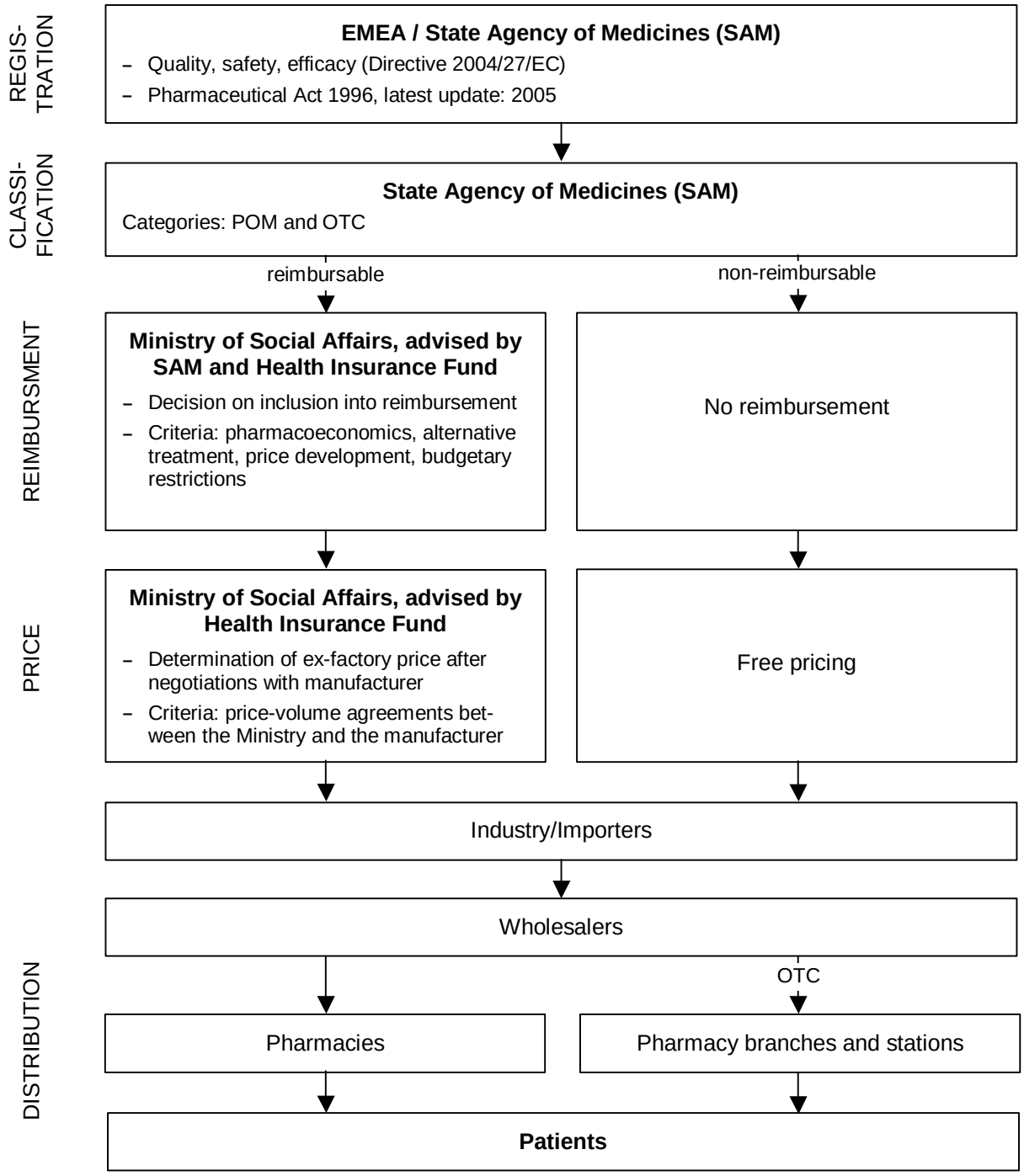
Since the 1990-ties the pharmaceutical system has undergone a lot of reforms, which resulted in the establishment of the State Agency of Medicines, the amendment of the Pharmaceutical Act, a new reimbursement system as well as the privatisation in the distribution market.

The main actors in the pharmaceutical system are the Ministry of Social Affairs, the State Agency of Medicines (SAM), and the Estonian Health Insurance Fund (Haigekassa).

2.2.1 Registration

The State Agency of Medicines (SAM) is responsible for registering pharmaceuticals. It is in charge of the classification of pharmaceuticals according to their prescription status as well as switches (change from prescription-only status to OTC). Registration is harmonised to EU legislation.

Figure 2.1: Estonia – Pharmaceutical system in 2005 (out-patient sector)



EC = European Community, EMEA = European Medicines Agency, OTC = Over-the-Counter, POM = Prescription-only medicines, SAM = State Agency of Medicines

Source: ÖBIG

2.2.2 Reimbursement

The Ministry of Social Affairs defines which diagnoses are considered reimbursable: pharmaceuticals which are used for the treatment of these diseases are thus reimbursed at defined rates. The positive list covers pharmaceuticals reimbursed by the Estonian Health Insurance Fund and is issued on the basis of these diagnoses. The positive list rarely includes OTC products.

Since 2003 Estonia has a reference price system, which is relevant for the decision on the reimbursement categories of 100 and of 75 percent. The reference price is the basis for reimbursement price which may be lower than the reference price.

In Estonia the reimbursement level of pharmaceuticals depends on the diagnosis. There are the following categories:

- 100 percent reimbursement (for 26 different diseases)
- 75 percent (for 40 diseases), plus a higher reimbursement level of 90 percent for certain people (children under the age of 10, disabled people and insured people over the age of 63 years)
- 50 percent

The reimbursement level varies with regard to the disease which the pharmaceutical is used for, for example diclofenac is 100 percent reimbursed in oncology, 75 percent in rheumatoid arthritis and 50 percent in all other treatments.

In Estonia manufacturers, who apply for reimbursement at the level of 100 or 75 percent, are obliged to submit pharmacoeconomic analyses which have to comply with the “Baltic Guideline for the Economic Evaluation of Pharmaceuticals”.

Patient for co-payment is both a flat prescription fee and a percentage charge, as well as any difference between the reference price and the actual price, as shown in Table 2.1.

Patients who pay more than EEK 6,000.- / € 383.- a year for pharmaceuticals are offered supplementary reimbursement by the Estonian Health Insurance Fund which is limited to EEK 9,500.- / € 607.- a year.

Table 2.1: Estonia – Reimbursement categories and co-payment in 2005

Reimbursement categories	Reimbursement by the Health Insurance	Co-payment
100%	Excess above EEK 20.- / € 1.28 (= flat fee[1])	EEK 20.- / € 1.28 (= flat fee)
90%[2]	plus 90% of excess above flat fee (EEK 20.- / € 1.28)	EEK 20.- / € 1.28 plus 10% of excess above flat fee
75%	plus 75% of excess above flat fee (EEK 20.- / € 1.28)	EEK 20.- / € 1.28 plus 25% of excess above flat fee
50%	plus 50% of excess above flat fee (EEK 50.- / € 3.20), but limited to EEK 200.- / € 12.80 per prescription	EEK 50.- / € 3.20 plus 50% of excess above flat fee

[1] Fixed co-payment = prescription fee

[2] For children under the age of 10, disabled people and patients over the age of 63 at the reimbursement category of 75 percent.

Source: Haigekassa 2005, data gathering by ÖBIG

Patients have to pay their co-payment to the pharmacy and, after receiving the prescription electronically, the health insurance fund pays the remainder to the pharmacy.

2.2.3 Pricing

In Estonia, there is statutory pricing (after negotiations) for reimbursable pharmaceuticals and free pricing for non-reimbursable products. The Ministry of Social Affairs sets the ex-factory price in line with price-volume agreements with the manufacturers.

The application for reimbursement by pharmaceutical companies needs to include information on the manufacturer prices in reference countries (Latvia, Lithuania, France, Portugal and Hungary) as well as a sales estimation.

The Ministry of Social Affairs is responsible for setting the maximum mark-ups for wholesalers and pharmacies. Those mark-ups apply to reimbursable as well as non-reimbursable pharmaceuticals.

As shown in Table 2.2, there is a regressive, maximum mark-up scheme for wholesalers with a maximum mark-up of € 6.40 per prescription.

Table 2.2: Estonia – Wholesale mark-ups in 2005

Ex-factory price from…to…in EEK / €	Wholesale mark-up in % of the ex-factory price
up to EEK 25.- / € 1.60	20%
from EEK 25.01 / € 1.6 to EEK 45.- / € 2.80	15%
from EEK 45.01 / € 2.8 to EEK 100.- / € 6.40	10%
from EEK 100.01 / € 6.4 to EEK 200.- / € 12.80	5%
from EEK 200.- / € 12.80 on	3% (max. EEK 100 / € 6.4 per prescription)

Source: Haigekasse 2005, data gathering by ÖBIG

For pharmacies, there is also a scheme with regressive maximum mark-ups, which is shown in Table 2.3.

Table 2.3: Estonia – Pharmacy mark-ups in 2005

PPP from…to…in EEK / €	Maximum pharmacy mark-up	
	Coefficient in % of PPP	Fixed mark-up in EEK / €
up to EEK 10.- / € 0.60	-	EEK 6.- / € 0.40
from EEK 10.01 / € 0.60 to EEK 20.- / € 1.30	40%	EEK 6.- / € 0.40
from EEK 20.01 / € 1.30 to EEK 30.- / € 1.90	35%	-
from EEK 30.01 / € 1.90 to EEK 40.- / € 2.50	30%	-
from EEK 40.01 / € 2.50 to EEK 50.- / € 3.20	25%	-
from EEK 50.01 / € 3.20 to EEK 100.- / € 6.40	20%	-
from EEK 100.01 / € 6.40 to EEK 700.- / € 44.70	15%	-
from EEK 700.01 / € 44.70 on	-	EEK 80.- / € 5.10

PPP = Pharmacy Purchase Price

Source: Haigekassa 2005, data gathering by ÖBIG

Since 2001 the VAT on pharmaceuticals is five percent.

2.2.4 Distribution

In Estonia, there are nine local pharmaceutical companies (mainly manufacturers of generics) as well as international research-based pharmaceutical companies. There are 32 companies with a wholesaler licence, with six of them dominating the market. In the pharmacy sector, there are 316 pharmacies and 158 pharmacy stations which are only allowed to sell OTC products.

Latvia

Inhabitants	***2.3 million***
Life expectancy – women	***76 years***
Life expectancy – men	***64.8 years***
Gross domestic product per inhabitant	***€ 4,233.-***
Health expenditure per inhabitant	***€ 203.-***
Hospital beds per 1,000 inhabitants	***5.7***
Inhabitants per physician	***338***
Inhabitants per pharmacy	***2,629***
Conversion rate – 100 Latvian Lats (LVL)	***€ 150.331***

3 Latvia

3.1 Health Care System

Health care in Latvia is organised on the basis of a social health insurance system. However, it is not funded through social insurance contributions but through central government's budget allocation. Due to inefficiencies of the decentralised health insurance a recentralisation process started in the mid 1990-ties. Since 2005 health insurance is provided by the Health Compulsory Insurance State Agency (VOAVA) and its five regional branches. The coverage of services by VOAVA is defined by the state; certain treatments such as dental care for adults are exempted from free health care.

Primary care is provided by physicians having contracts with the social insurance fund. They are remunerated on a capitation basis and act as gatekeepers to the specialist services. In the last few years the number of out-patient facilities has strongly increased, while in-patient capacities have been reduced.

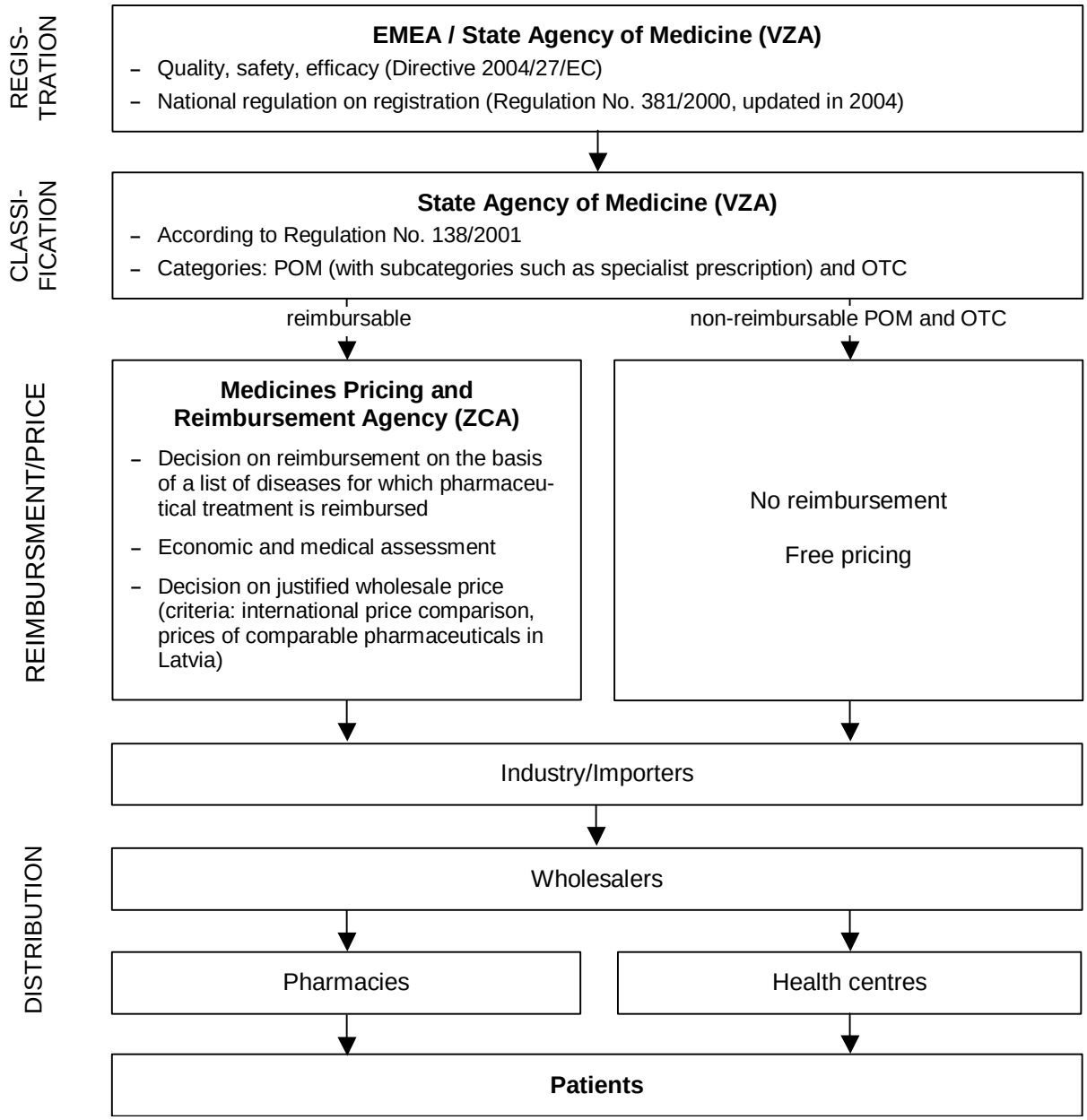
3.2 Pharmaceutical System

In Latvia, the Ministry of Health (VM), which is responsible for the overall pharmaceutical legislation, the State Agency of Medicines (VZA), which is responsible for registration, and the Medicines Pricing and Reimbursement Agency (ZCA), in charge of reimbursement and pricing, are the main actors in the pharmaceutical system.

3.2.1 Registration

The State Agency of Medicines is responsible for the registration of pharmaceuticals. It is also in charge of classifying pharmaceuticals into prescription-only medicines (POM), including sub-categories (like prescription only by certain specialists), and Over-the-Counter medicines (OTC). Registration is harmonised to EU legislation.

Figure 3.1: Latvia – Pharmaceutical system in 2005 (out-patient sector)



EC = European Community, EMEA = European Medicines Agency, OTC = Over-the-Counter, POM = Prescription-only medicines, VZA = Valsts zalu agentura, ZCA = Zalu Cenu Valsts Agentura

Source: ÖBIG

3.2.2 Reimbursement

The Medicines Pricing and Reimbursement Agency (Zalu Cenu Valsts Agentura, ZCA) is in charge of issuing the positive list and of deciding on the reimbursement prices of pharmaceuticals.

In Latvia reimbursement of pharmaceuticals is provided according to the diagnosis and the severity of the disease. Pharmaceuticals used in the treatment of listed diseases (Regulation No. 418/2005) are reimbursed at categories of 100 percent, 90 percent, 75 percent or 50 percent according to the diagnosis character and severity of the disease. The list of diseases covers severe and chronic illnesses. Criteria for the inclusion of a pharmaceutical into the positive list, are besides the indication the therapeutic value of the product, its cost-effectiveness and its impact on health care budget. OTC and homeopathic products are excluded from the positive list.

Pharmaceuticals eligible for reimbursement are classified into one of the four main categories:

- Category 1: 100 percent reimbursement for the treatment of severe chronic diseases with life threatening character such as cancer and HIV/AIDS
- Category 2: 90 percent reimbursement for the treatment of severe chronic diseases, which affect vital life functions such as endocrine diseases
- Category 3: 75 percent reimbursement for the treatment of chronic diseases such as asthma and hypertension
- Category 4: 50 percent reimbursement for the treatment of acute or chronic diseases such as rheumatic diseases

There are some diseases where additional regulations with regard to reimbursement apply, such as age (children under three years) or time limits for a therapy. A pharmaceutical used for different indications can be reimbursed at different rates – according to the reimbursement rate assigned to the underlying condition (like in Estonia and Lithuania, cf. Chapter 2.2.2 and 4.2.2).

Patients must cover the difference between the pharmacy retail price of the product and the reimbursement price. For all medicines not eligible for reimbursement, patients have to pay the full retail price.

In July 2005 the positive list was split into list A with groups of interchangeable pharmaceuticals, each group having its own reference price; and list B with products without comparable pharmaceuticals. Thus, a reference price system was introduced. The reference price is set according to the cheapest product of each cluster.

For innovative pharmaceuticals companies have to provide cost-effectiveness data according to the Baltic Guideline for Economic Evaluation of Pharmaceuticals.

There are pharmaceutical budgets for doctors. With penalties for overspending these budgets, doctors have a strong financial interest in prescribing rationally. Pharmacies are obliged to generic substitution unless ruled out by the prescribing physician.

3.2.3 Pricing

In Latvia, there is statutory pricing for reimbursable medicines, and free pricing for non-reimbursable pharmaceuticals.

The pharmaceutical companies have to apply to the ZCA for reimbursement status and approval of the wholesale price. The application to the ZCA has to include, amongst others, the proposed wholesale price, the price of similar products in Latvia as well as an international price comparison. Budget impact analysis on the basis of estimated sales volume and pharmacoeconomic evaluation for new active substances must be submitted with the application as well.

The mark-up schemes for reimbursable pharmaceuticals are set by the state both for wholesalers and pharmacies. For non-reimbursable pharmaceuticals the maximum wholesale mark-up is set at 15 percent of the ex-factory price, the pharmacy mark-up is also regulated in a regressive scheme.

Table 3.1: Latvia – Wholesale mark-ups for reimbursable pharmaceuticals in 2005

Ex-factory price/CIP from…to…in LVL / €	**Wholesale mark-up in % of the ex-factory price / CIP**
LVL 0.01 / € 0.01 – LVL 1.99 / € 2.99	10
LVL 2.00 / € 3.01 – LVL 3.99 / € 6.00	9
LVL 4.00 / € 6.01 – LVL 7.99 / € 12.02	7
LVL 8.00 / € 12.03 – LVL 14.99 / € 22.54	6
LVL 15.00 / € 22.55 – LVL 19.99 / € 30.05	5
from LVL 20.00 / € 30.06 on	4

CIP = Cost, Insurance and Packaging

Source: Regulation No. 428/1998 (amended in 2002), data gathering by ÖBIG

As it is shown in Table 3.2 and Table 3.3 there are different pharmacy mark-up schemes for reimbursable and non-reimbursable pharmaceuticals. The pharmacy retail price is calculated on the basis of the wholesale price, the mark-up coefficient and the correction sum.

Table 3.2: Latvia - Pharmacy mark-ups for reimbursable pharmaceuticals in 2005

PPP from...to...in LVL / €	Maximum pharmacy mark-up	
	Coefficient	Correction sum in LVL / €
from LVL 0.01 / € 0.02 to LVL 0.99 / € 1.49	1.30	LVL 0.00 / € 0.00
from LVL 1.00 / € 1.50 to LVL 1.99 / € 2.99	1.25	LVL 0.05 / € 0.08
from LVL 2.00 / € 3.00 to LVL 2.99 / € 4.49	1.20	LVL 0.15 / € 0.23
from LVL 3.00 / € 4.50 to LVL 4.99 / € 7.50	1.17	LVL 0.30 / € 0.45
from LVL 5.00 / € 7.51 to LVL 9.99 / € 15.02	1.15	LVL 0.40 / € 0.60
from LVL 10.00 / € 15.03 to LVL 14.99 / € 22.53	1.10	LVL 0.90 / € 1.35
from LVL 15.00 / € 22.54 to LVL 19.99 / € 30.05	1.07	LVL 1.35 / € 2.03
from LVL 20.00 / € 30.06 on	1.05	LVL 1.75 / € 2.63

PPP = Pharmacy Purchase Price

Source: Regulation No. 428/1998 (amended in 2002), data gathering by ÖBIG

The pharmacy mark-up scheme for reimbursable pharmaceuticals will be modified in January 2006.

Table 3.3: Latvia – Pharmacy mark-ups for non-reimbursable pharmaceuticals in 2005

PPP from...to...in LVL / €	Maximum pharmacy mark-up	
	Coefficient	Correction sum in LVL / €
from LVL 0.01 / € 0.02 to LVL 0.99 / € 1.49	1.40	LVL 0.01 / € 0.02
from LVL 1.00 / € 1.50 to LVL 1.99 / € 2.99	1.35	LVL 0.06 / € 0.09
from LVL 2.00 / € 3.01 to LVL 2.99 / € 4.49	1.30	LVL 0.16 / € 0.24
from LVL 3.00 / € 4.50 to LVL 4.99 / € 7.50	1.25	LVL 0.31 / € 0.47
from LVL 5.00 / € 7.51 to LVL 9.99 / € 15.02	1.20	LVL 0.56 / € 0.84
from LVL 10.00 / € 15.03 to LVL 19.99 / € 30.05	1.15	LVL 1.06 / € 1.59
from LVL 20.00 / € 30.06 on	1.10	LVL 2.06 / € 3.10

PPP = Pharmacy Purchase Price

Source: ZCA 2005, data gathering by ÖBIG

For non-reimbursable pharmaceuticals, distribution actors usually do not make total use of the maximum mark-ups allowed. Thus, the retail prices vary between pharmacies.

VAT on pharmaceuticals is 5 percent, and the standard VAT rate is 18 percent.

3.2.4 Distribution

In Latvia, the 12 local pharmaceutical manufacturers cover only 5 percent of the total pharmaceutical sales. In 2004, there were 40 wholesalers registered in Latvia, with the biggest

five holding about 80 percent of the market. The market leader Tamro holds 30 percent of the market, followed by Recipe Plus, Magnum Medical, oriola riga and Briz.

After the liberalisation of the ownership of pharmacies in 1999 the number of pharmacies has increased. Five pharmacy chains with each 20 pharmacies have been built up. In 2002, geographic and demographic criteria for setting up pharmacies were introduced. In 2004, there were 882 pharmacies; besides pharmacies, health centres are entitled to dispense pharmaceuticals under certain conditions.

Lithuania

Inhabitants	***3.5 million***
Life expectancy – women	***77.5 years***
Life expectancy – men	***63.3 years***
Gross domestic product per inhabitant	***€ 4,699.-***
Health expenditure per inhabitant	***€ 247.-***
Hospital beds per 1,000 inhabitants	***6***
Inhabitants per physician	***251***
Inhabitants per pharmacy	***2,445***
Conversion rate – 10 Lithuanian Litas (LTL)	***€ 2.8961***

4 Lithuania

4.1 Health Care System

In 1996, the State Sickness Fund (VLK) and its ten territorial branches were founded. In 2003 changes took place, with the reduction from ten territorial branches to five, and the State Sickness Fund being brought under control of the Ministry of Health. The State Sickness Fund is funded through social insurance contributions of the insured, tax and state budget allocations.

The Ministry of Health sets the fees for medical services, all primary care facilities have to offer services at these fees. Primary care is mainly provided in municipality health centres and polyclinics. Besides these institutions, health points in rural areas, employing feldshers and midwives, provide basic health services. Primary care physicians are remunerated on a capitation basis and act as gatekeepers to the specialist services. Almost all hospitals and polyclinics are public.

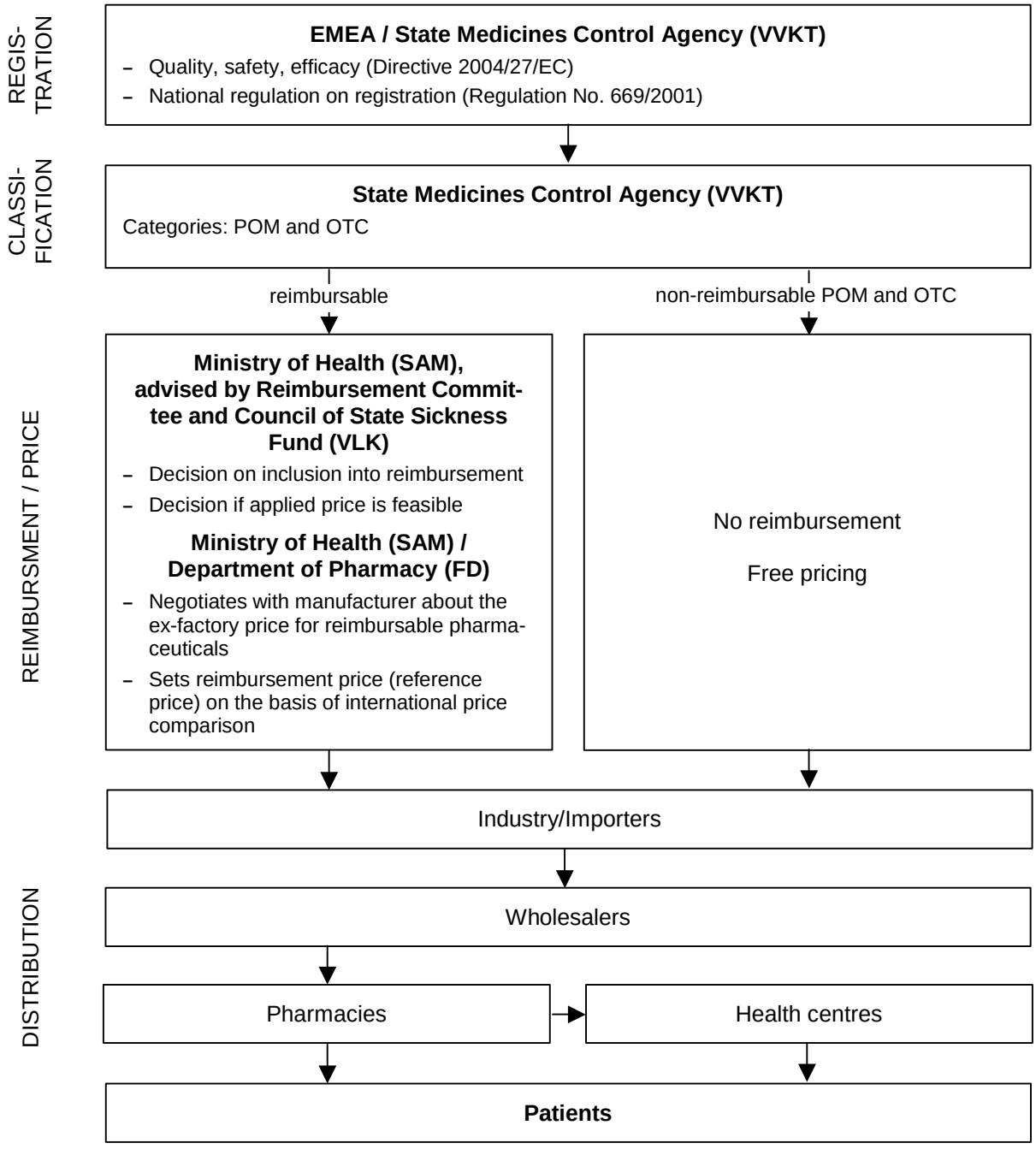
4.2 Pharmaceutical System

The Ministry of Health (SAM) is responsible for the overall pharmaceutical policy and legislation. Further key actors in the pharmaceutical system are the Department of Pharmacy (FD) under the Ministry of Health, responsible for the implementation of the pharmaceutical policy and for ensuring the provision of efficient and safe pharmaceuticals at socially acceptable prices; and the State Medicines Control Agency (VVKT).

4.2.1 Registration

The responsibility of registering, classifying (with regard to prescription status), and controlling the quality of pharmaceuticals lies with the State Medicines Control Agency (VVKT). The registration procedure has, in general, been harmonised to EU legislation, but still pharmaceuticals with non EU-conform marketing authorisation may be distributed within Lithuania until the end of 2006.

Figure 4.1: Lithuania – Pharmaceutical system in 2005 (out-patient sector)



EC = European Community, EMEA = European Medicines Agency, OTC = Over-the-Counter, POM = Prescription-only medicines, SAM = Sveikatos apsaugos ministerija, VVKT = Valstybinė vaistų kontrolės tarnyba

Source: ÖBIG

4.2.2 Reimbursement

The Ministry of Health (SAM) is the institution deciding on the inclusion of pharmaceuticals to the positive list. SAM is advised by the Medicines Reimbursement Committee, which is an interdisciplinary committee with representatives of SAM, the Department of Pharmacy (FD), the State Medicines Control Agency (VVKT) and the State Sickness Fund (VLK); as well as by the Council of the VLK. OTC products are excluded from the positive list. The positive list has two categories:

- List A covers pharmaceuticals, which are reimbursed with regard to the severity of the disease at: 100 percent (e.g. cancer, asthma, schizophrenia); 90 percent (a category introduced in 2002); 80 percent (e.g. hepatitis B and C) or 50 percent (e.g. osteoporoses). Reimbursement from the disease based list amounts to approximately 85 percent of the total drug reimbursement.
- List B covers all pharmaceuticals, which are reimbursed because of social reasons at: 100 percent (treatment of children under the age of 18 and disabled people) or 50 percent (retired people and other social groups). The reimbursement list on the basis of social groups has been progressively reduced.

The Ministry of Health sets - on proposal of the Department of Pharmacy - the so-called basic price (reimbursement price, reference price) for reimbursable pharmaceuticals as the basis for reimbursement. In September 2005, a new law was passed regulating that the reference price would be set based on a price comparison with six EU Member States having a similar per capita income to Lithuania.

Furthermore, a reference price system, clustering pharmaceuticals with the same active ingredients in reference price groups, is applied. The reference price for such clusters is set at the price of the cheapest drug of each group.

Patients are obliged to pay the difference between the reimbursement sum, calculated from the reference price and the reimbursement category, and the pharmacy retail price, with the reference price always being lower than the maximum pharmacy retail price.

Companies are required to submit pharmacoeconomic analyses, in accordance with the Ministry of Health’s regulations and based on the Baltic Guideline for Economic Evaluation of Pharmaceuticals.

Prescribing budgets for health centres are in place, but no sanctions for overspending have been taken. Rational prescribing is promoted by a prescribing passport for all patients, listing all prescriptions. Since 2002, pharmaceuticals can also be prescribed by trade name, and pharmacies are obliged to offer generic substitution.

4.2.3 Pricing

In Lithuania, there are negotiations on prices for reimbursable pharmaceuticals and free pricing for non-reimbursable pharmaceuticals. Companies have to submit an application for price approval to the Ministry of Health. The following information needs to be included in the application: requested CIP price (ex-factory price plus import costs), the ex-factory price of the pharmaceutical in all EU Member States, estimated sales volumes for the first three years, and effects of sales of competing pharmaceuticals. CIP prices are negotiated between the Ministry of Health and the companies.

In the hospital sector there is free pricing, hospital products are usually purchased through tendering by hospitals. Some very expensive pharmaceuticals are purchased centrally by the State Sickness Fund.

Maximum wholesale and pharmacy mark-ups for reimbursable pharmaceuticals are regulated as regressive schemes. In the non-reimbursable segment, there are no regulations on wholesale or pharmacy mark-ups.

Table 4.1: Lithuania – Wholesale mark-ups for reimbursable pharmaceuticals in 2005

Ex-factory price/CIP from...to...in LTL / €	Wholesale mark-up in % of the ex-factory price/CIP in LTL / €
up to LTL 6.43 / € 1.86	14%
from LTL 6.44 / € 1.87 to LTL 10.00 / € 2.89	LTL 0.90 / € 0.26
from LTL 10.01 / € 2.90 to LTL 19.44 / € 5.63	9%
from LTL 19.45 / € 5.64 to LTL 25.00 / € 7.24	LTL 1.75 / € 0.51
from LTL 25.01 / € 7.25 to LTL 53.57 / € 15.51	7%
from LTL 53.58 / € 15.52 to LTL 68.18 / € 19.74	LTL 3.75 / € 1.09
from LTL 68.19 / € 19.75 to LTL 909.09 / € 263.28	5.5%
from LTL 909.10 / € 263.29 on	LTL 50.00 / € 14.48

CIP = Cost, Insurance and Packaging

Source: Order of the Ministry of Health Nr. V-170 per 30 March 2004, data gathering by ÖBIG

Table 4.2: Lithuania – Pharmacy mark-ups for reimbursable pharmaceuticals in 2005

PPP from...to...in LTL / €	Pharmacy mark-up in % of the PPP in LTL / €
up to LTL 8.19 / € 2.37	22%
from LTL 8.20 / € 2.38 to LTL 10.00 / € 2.89	LTL 1.80 / € 0.52
from LTL 10.01 / € 2.90 to LTL 15.28 / € 4.42	18%
from LTL 15.29 / € 4.43 to LTL 25.00 / € 7.24	LTL 2.75 / € 0.80
from LTL 25.01 / € 7.25 to LTL 27.28 / € 7.90	11%
from LTL 27.29 / € 7.91 to LTL 75.00 / € 21.72	LTL 3.00 / € 0.87
from LTL 75.01 / € 21.73 to LTL 500.00 / € 144.81	4%
from LTL 500.00 / € 144.81 on	LTL 20.00 / € 5.79

PPP = Pharmacy Purchase Price

Source: Order of the Ministry of Health Nr. V- 171 per 11 April 2002, data gathering by ÖBIG

The standard VAT rate is 18 percent, the VAT on pharmaceuticals is 5 percent.

4.2.4 Distribution

In Lithuania, there are about 30 local pharmaceutical companies. The main markets of the local pharmaceutical industry are, besides Lithuania, Russia and the CIS countries. In 2004, there were 73 wholesalers registered in Lithuania. The wholesale market is in private hands. The five leading wholesalers have a total market share of about 70 percent. Tamro and Limedika both cover approximately 20 percent of the market, followed by Medikona, Armila and LRG Farmacija.

The dispensing of all pharmaceuticals, homeopathic products as well as food complementary products is only allowed in pharmacies. There are no geographic or demographic criteria for the establishment of a new pharmacy. Furthermore, pharmacy chains are permitted in Lithuania, of which one of the biggest is Eurovaistine. Tamro, a leading wholesaler, holds the pharmacy chain Farmacijos and took over further pharmacy outlets of the Vogne chain in 2005. In 2003, there was a total of 1,416 pharmacy outlets in Lithuania, of which 662 were registered pharmacies and 794 subsidiaries. Doctors are not allowed to dispense pharmaceuticals.

Malta

Inhabitants	***0.4 million***
Life expectancy – women	***81 years***
Life expectancy – men	***75.9 years***
Gross domestic product per inhabitant	***€ 10,772.-***
Health expenditure per inhabitant	***€ 557.-***
Hospital beds per 1,000 inhabitants	***3.4***
Inhabitants per physician	***321***
Inhabitants per pharmacy	***1,904***
Conversion rate – 10 Maltese Lira (MTL)	***€ 23.3645***

5 Malta

5.1 Health Care System

The health care system in Malta is organised on the basis of a National Health Service. The key actor in the NHS is the Ministry of Health, the Elderly and Community Care, which provides services free at the point of delivery for the entire resident population. Primary care is mainly delivered through eight health centres, which offer a range of preventive, remedial, and rehabilitation services. Secondary care is provided by public hospitals with in-patient and out-patient departments.

Besides that, there is also a significant private sector, in which general practitioners and specialists as well as three private hospitals operate. There is a comparatively high demand for private health services.

The public health system is funded through taxation. In Malta, there is a National Social Insurance, but their funds are used for other social services, such as pension funds. The Ministry of Finance is responsible for allocating resources to the health care system; while the Ministry of Health, the Elderly and Community Care is in charge of administering the funds. Private health insurance can be purchased on a voluntary basis and is becoming increasingly popular. Patients have to pay out-of-pocket for the services of general practitioners and specialists in the private sector.

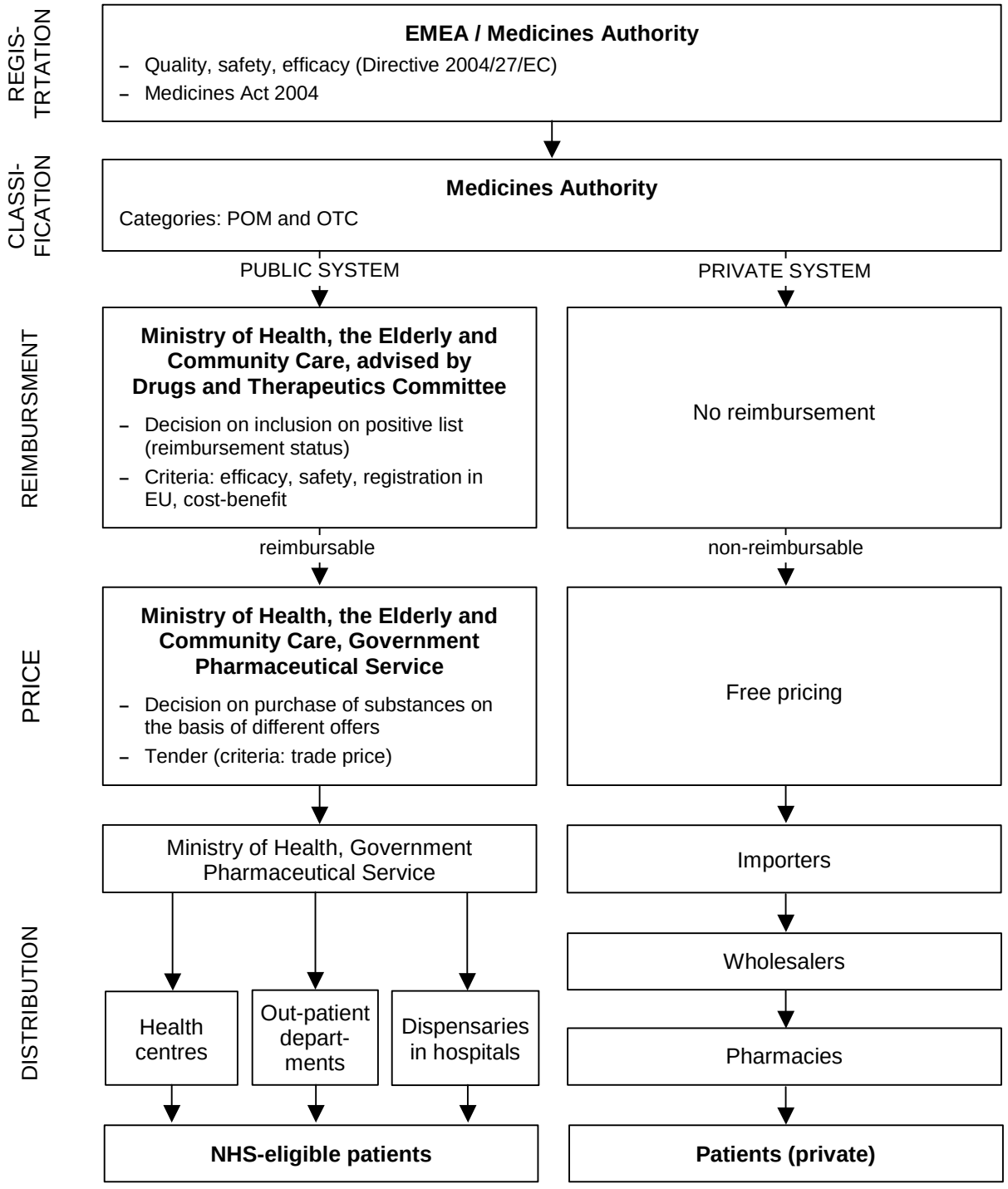
5.2 Pharmaceutical System

In Malta, two different pharmaceutical systems exist next to each other: a public and a private system. Depending under which system a pharmaceutical falls, there are different regulations for reimbursement, pricing and distribution.

5.2.1 Registration

The key authority for registering pharmaceuticals is the Medicines Authority, which is responsible for controlling and assuring quality, safety and efficacy of all pharmaceuticals (either imported, or locally produced) in Malta. The registration procedure was harmonised to EU legislation in 2002, but there is still a transitional period (until the end of 2006) for pharmaceuticals which had been registered before 2002. Since 2004, the Medicines Act has been in force, which includes regulations for the registration, the production and the distribution of pharmaceuticals.

Figure 5.1: Malta – Pharmaceutical system in 2005 (out-patient sector)



EC = European Community, EMEA = European Medicines Agency, NHS = National Health Service, OTC = Over-the-Counter, POM = Prescription-only medicines

Source: ÖBIG

5.2.2 Reimbursement

In the private system there is no reimbursement. Only NHS pharmaceuticals are reimbursable and included in the positive list.

Malta runs a positive list under the name “Essential Drugs List“. This list was set up on the basis of the “Essential Drugs List“ of the WHO, but is much larger. Pharmaceuticals are listed under their generic name. The list of pharmaceuticals is regularly updated at meetings held by the Drugs and Therapeutics Committee (DTC) under the Ministry of Health. The following criteria are crucial for including pharmaceuticals on the “Essential Drugs List“: clinical efficacy, safety of the product, whether the product is licensed in the EU, a comparison of the product with alternative treatments on the list, protocol for use of the product, cost and cost-effectiveness, prioritisation in the allocation of resources.

There are no reimbursement categories as such. Instead, patients are either eligible for free medicines or must pay the full cost of their medication out-of-pocket. The following population groups qualify for free medicines:

- Citizens under a certain income level (pink card holders)
- Citizens with certain sicknesses (yellow card holders)
- Further population groups (e.g. members of religious orders, patients in charitable facilities, members of the police and the armed forces)

Patients who are eligible for free medicines need to have a doctor’s prescription for having access to NHS pharmaceuticals. There is no prescription fee.

There is no reference price system in Malta. Formal pharmacoeconomic submissions are not required, although cost-effectiveness data is taken into consideration when the Essential Drugs List is complied.

5.2.3 Pricing

Malta has no official pricing system. In the public system, the NHS pharmaceuticals are purchased through tendering (most of the medicines are imported). The key authority for purchasing pharmaceuticals is the Healthcare Procurement and Supplies Service (HPSS) under the Government Pharmaceutical Service within the Ministry of Health. The tender price is the main criterion in the tendering process.

In the private system, there is free pricing for manufacturers and importers.

NHS pharmaceuticals are dispensed by hospitals, out-patient departments and health centre dispensaries without any mark-ups. In the private system, there is a linear mark-up of 15 percent on the ex-factory price or the CIF price for wholesalers; the mark-up for pharmacies is 20 percent on the wholesale price. Both mark-ups are for prescription-only medicines as well as for OTC products.

There is no value added tax (VAT), but it is planned to introduce a five percent VAT on pharmaceuticals by 2010.

5.2.4 Distribution

There is one local manufacturer in Malta; most pharmaceuticals are imported.

In the public system, pharmaceuticals are dispensed through NHS dispensaries, such as health centres, out-patient departments and some public hospitals. The health centres run dispensaries for pharmaceuticals, which are exclusively for patients from that specific catchment area. Besides that, there are 210 private pharmacies, where patients have to pay out-of-pocket the full price for pharmaceuticals.

Poland

Inhabitants	***38.4 million***
Life expectancy – women	***78.7 years***
Life expectancy – men	***70.4 years***
Gross domestic product per inhabitant	***€ 5,265.-***
Health expenditure per inhabitant	***€ 319.-***
Hospital beds per 1,000 inhabitants	***4.6***
Inhabitants per physician	***436***
Inhabitants per pharmacy	***3,493***
Conversion rate – 100 Polish Zloty (PLN)	***€ 22.091***

6 Poland

6.1 Health Care System

In 1999 a mandatory social health insurance scheme was established. In each of the 16 provinces self-administering, regional sickness funds were set up; furthermore sickness funds for certain professions were installed. This system proved to be inefficient and therefore the National Health Fund (NFZ) was established in 2003 under the control of the Ministry of Health. The NFZ is organised in 16 regional branches. The system is funded through contributions by employees (8.5 percent), whereas employers pay no contributions. The health insurance covers all working, unemployed and retired people and their families.

The regional branches of the NFZ have contracts with health care providers. Local administration ("Gmina") is in charge of the organisation of primary care which is provided in public health centres and general practitioners' practices. GPs act as gatekeepers to the specialist services (with some exceptions such as dentists, gynaecologists, and dermatologists). They are remunerated on a capitation basis. In the out-patient sector, specialists mainly work in out-patient clinics (former polyclinics) or in health centres, and they are paid on a fee-for service basis.

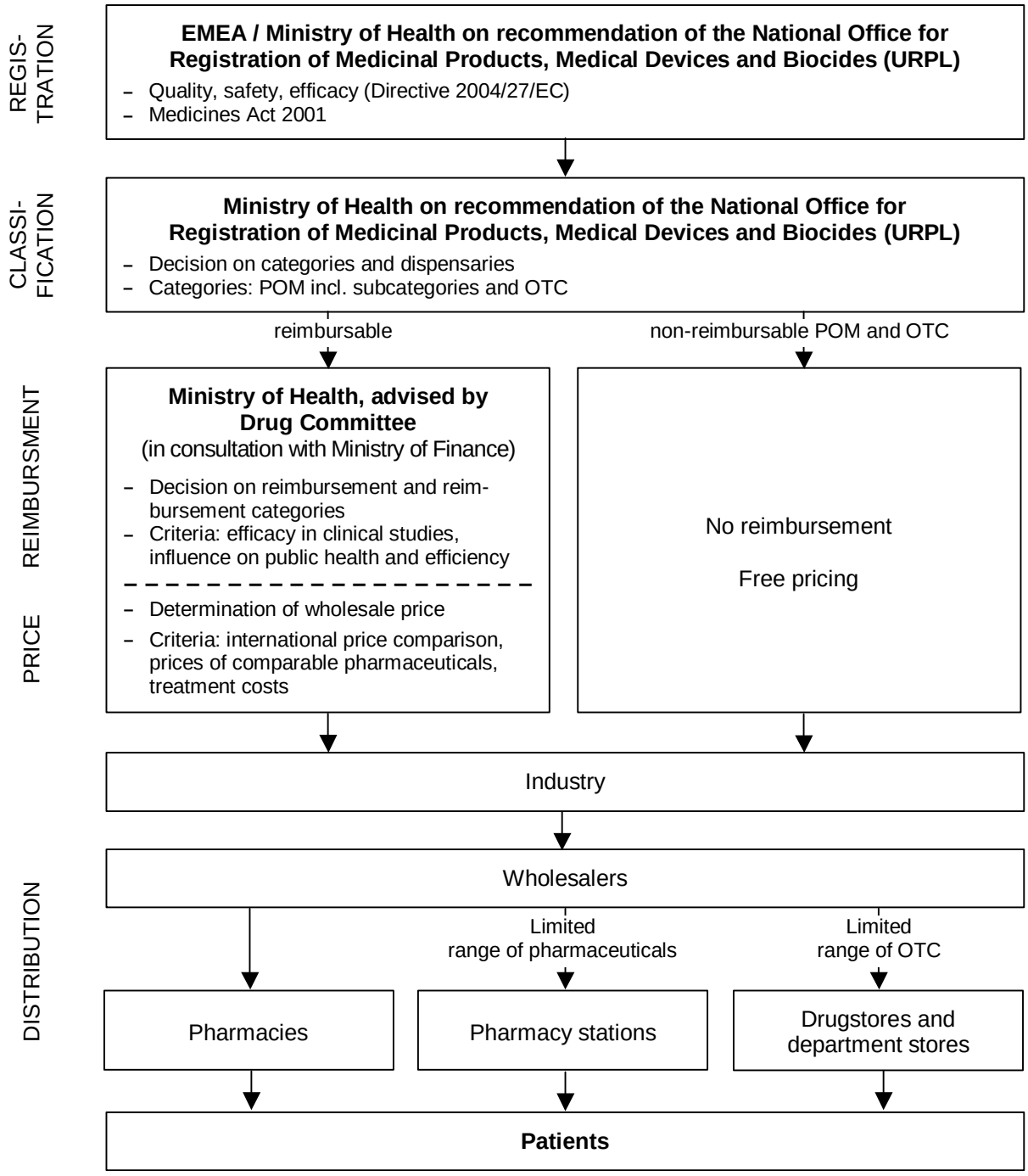
6.2 Pharmaceutical System

In Poland the main actors in the pharmaceutical system are the Ministry of Health, responsible for the legal framework of the pharmaceutical market and for pricing and reimbursement decisions, the advisory Drug Committee (Drug Management Team), and the National Office for Registration of Medicinal Products, Medical Devices and Biocides (URPL) under the control of the Ministry of Health.

6.2.1 Registration

The responsibility of registering pharmaceuticals lies with the National Office for Registration of Medicinal Products, Medical Devices and Biocides (URPL). Furthermore, the URPL is in charge of classifying pharmaceuticals into prescription-only medicines (POM) and Over-the-Counter (OTC) drugs. The formal decision is taken by the Ministry of Health on proposal of the URPL. Marketing authorisations granted before the accession are still valid within a transitional period until the end of 2008. For brands the transitional period already ends in December 2005. The list of products under this regulation is quite extensive.

Figure 6.1: Poland – Pharmaceutical system in 2005 (out-patient sector)



EC = European Community, EMEA = European Medicines Agency, OTC = Over-the-Counter, POM = Prescription-only medicines, SAM = State Agency of Medicines, URPL = Urząd Rejestracji Produktów Leczniczych

Source: ÖBIG

6.2.2 Reimbursement

The Ministry of Health is responsible for issuing the positive list. In order to have a pharmaceutical included in the positive list, the manufacturer needs to submit an application for reimbursement and one for setting the price. An advisory drug committee, the Drug Management Team, considers the application for the reimbursement status, and on its advice the Ministry of Health takes the formal decision. The positive list includes prescription-only medicines, OTC products are excluded.

Pharmaceuticals are classified into one of the three categories:

- Basic list: pharmaceuticals as well as magistral preparations are reimbursed at 100 percent (up to the reference price)
- Supplementary list: pharmaceuticals are reimbursed at 70 or 50 percent. The amount of reimbursement is calculated from the reference price of the pharmaceutical.
- Special reimbursement list: reimbursement for pharmaceuticals for severe or chronic diseases such as cancer or osteoporoses at 100, 70, or 50 percent.

For pharmaceuticals on the basic list, patients have to pay a flat rate of € 0.76 for pharmaceutical specialities and € 1.20 for magistral preparations. For pharmaceuticals on the supplementary list, patient co-payment is 30 or 50 percent, depending on the reimbursement category. Furthermore, patients are obliged to pay the difference between the reference price and the pharmacy retail price of pharmaceuticals included in reference price clusters.

Poland has a reference price system, in which the reference price is calculated on the basis of the cheapest generic pharmaceutical in a cluster: Clusters are either formed for products with the same active ingredient (INN), pharmaceutical dosage and way of administration or for therapeutic groups (products must have the same indication, proof of clinical efficacy, the same portfolio of side-effects and the same way of administration, but since 2005 no longer the same mechanism of action).

Pharmacies are obliged to offer generic substitution to the patients. For doctors guidelines for rational prescribing are in place.

In Poland, there are guidelines for pharmacoeconomic studies, there is demand for more pharmacoeconomic analyses.

There are plans to refine the reimbursement system in future.

6.2.3 Pricing

In Poland, there is statutory pricing at the wholesale level for reimbursable pharmaceuticals and free pricing for non-reimbursable pharmaceuticals (including all OTC products). The pricing procedure in the reimbursable segment is the same for locally produced and imported pharmaceuticals, as well as for original products and generics. The competent authority for

setting the price is the Ministry of Health, supported by an advisory drug committee (Drug Management Team).

Pharmaceutical companies have to submit an application for the pharmacy purchase price of reimbursable pharmaceuticals. This application needs to include an international price comparison, and the price of the pharmaceuticals of the same indication group in Poland as well as production cost.

The ex-factory price of reimbursable pharmaceuticals is indirectly regulated by a maximum mark-up for wholesalers of 9.78 percent on the ex-factory price. The maximum pharmacy mark-ups are regulated in a regressive scheme (cf. Table 6.1).

Table 6.1: Poland – Pharmacy mark-ups for reimbursable pharmaceuticals in 2005

PPP from…to…in PLN / €	**Pharmacy mark-up in % of the PPP in PLN / €**
up to PLN 3.60 / € 0.79	40%
from PLN 3.61 / € 0.80 to PLN 4.80 / € 1.06	PLN 1.44 / € 0.32
from PLN 4.81 / € 1.06 to PLN 6.50 / € 1.43	30%
from PLN 6.51 / € 1.44 to PLN 9.75 / € 2.15	PLN 1.95 / € 0.43
from PLN 9.76 / € 2.16 to PLN 14.00 / € 3.09	20%
from PLN 14.01 / € 3.10 to PLN 15.55 / € 3.43	PLN 2.80 / € 0.62
from PLN 15.56 / € 3.44 to PLN 30.00 / € 6.62	18%
from PLN 30.01 / € 6.63 to PLN 33.75 / € 7.45	PLN 5.40 / € 1.19
from PLN 33.76 / € 7.46 to PLN 50.00 / € 11.04	16%
from PLN 50.01 / € 11.05 to PLN 66.67 / € 14.72	PLN 8.00 / € 1.77
from PLN 66.68 / € 14.73 to PLN 100.00 / € 22.09	12%
from PLN 100.00 / € 22.09 on	PLN 12.00 / € 2.65

PPP = Pharmacy Purchase Price

Source: Polish Pricing Act of 5th July 2001 (Dz. U. No. 97 z 11.09.2001), data gathering by ÖBIG

Margins of non-reimbursable pharmaceuticals are not regulated, neither for wholesale nor for pharmacies. The average wholesale margin amounts to 14.5 percent of the pharmacy purchase price, and the average pharmacy margin amounts to 23 percent of the pharmacy retail price.

Due to the fact that mark-ups are of maximum nature and not fully utilized, pharmacy retail prices vary between pharmacies – for non-reimbursable as well as for reimbursable pharmaceuticals.

Maximum prices for pharmaceuticals used in NFZ contracting hospitals may be regulated by the Ministry of Health. A list of products, which would fall under this regulation, has not been published by now. Hospitals usually purchase pharmaceuticals on the basis of tenders.

The standard value-added tax (VAT) is 22 percent, and the VAT on pharmaceuticals is 7 percent.

6.2.4 Distribution

In 2005, there are about 300 pharmaceutical companies registered in Poland. The biggest local producer is Polpharma with a market share of about 5 percent (in value) followed by Glaxo Smith Kline. The local pharmaceutical industry is characterised by a large share of products with non-EU-conform market authorisation.

In 2005, 663 pharmaceutical wholesalers are registered in Poland, market leaders are PGF, Farmacol and Prosper holding a total market share of approximately 45 percent of the wholesale market.

No geographic or demographic criteria exist for setting up a pharmacy. In 2005, there are approximately 11,000 community pharmacies in Poland. Certain OTC products can also be sold in pharmacy stations and drugstores. For this purpose, the Ministry of Health issues a list of pharmaceuticals, which are allowed to be sold outside pharmacies.

Slovakia

Inhabitants	***5.4 million***
Life expectancy – women	***77.8 years***
Life expectancy – men	***69.9 years***
Gross domestic product per inhabitant	***€ 4,774.-***
Health expenditure per inhabitant	***€ 272.-***
Hospital beds per 1,000 inhabitants	***5.5***
Inhabitants per physician	***280***
Inhabitants per pharmacy	***4,620***
Conversion rate – 100 Slovak Koruna (SKK)	***€ 2.4986***

7 Slovakia

7.1 Health Care System

In 1994, a compulsory health insurance system was established in Slovakia. In 2005, there are five health insurance funds, thus representing a major decrease (12 health insurance institutions in 1995). The system is funded through contributions by the employers (10 percent), the employees (4 percent) and the state paying the contributions for children, retired and unemployed.

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

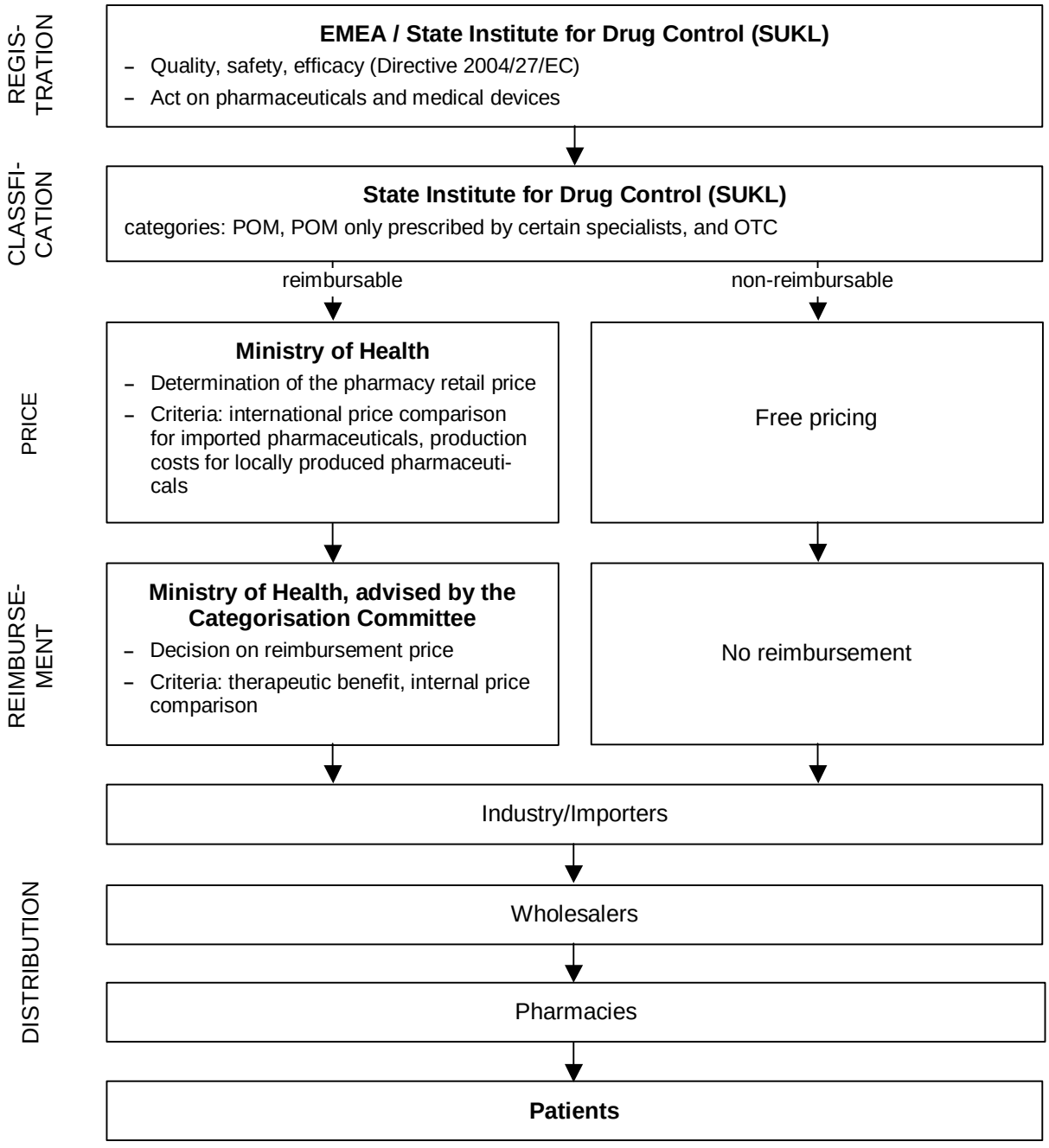
7.2 Pharmaceutical System

In Slovakia the main actors in the pharmaceutical system are the Ministry of Health, the advising Categorisation Committee and the State Institute for Drug Control (SUKL) under the Ministry of Health.

7.2.1 Registration

The responsibility of registering pharmaceuticals bears with the State Institute for Drug Control (SUKL). It acts as authorisation authority and is in charge of the classification of pharmaceuticals according to their prescription status (prescription-only medicines with sub-categories limiting the prescription to certain specialists, and OTC products) as well as of switches (change from prescription-only status to OTC). Registration is harmonised to EU legislation.

Figure 7.1: Slovakia – Pharmaceutical system in 2005 (out-patient sector)



EC = European Community, EMEA = European Medicines Agency, OTC = Over-the-Counter, POM = Prescription-only medicines, SUKL = State Institute for Drug Control

Source: ÖBIG

7.2.2 Reimbursement

Pharmaceuticals are classified into one of the three main categories: I – full reimbursement, S – partial reimbursement (however, there are no fixed percentage rates for reimbursement), and N – no reimbursement. Furthermore the positive list specifies certain sub-categories such as vaccination products, very expensive pharmaceuticals. Additionally, there are hospital pharmaceuticals which are financed out of the hospitals' budget.

The Categorisation Committee, which is an advisory body to the Ministry of Health, decides on the reimbursement level and any prescribing or indication limitations. The reimbursement level is based on the following criteria: therapeutic benefit of the drug, cost of the drug, reimbursement price for all comparable drugs of the respective reference price group.

In 1995, a reference price system was introduced. In order to set maximum reimbursement prices, pharmaceuticals are clustered into therapeutic groups based on ATC-5 (same active ingredient) or ATC-4 (therapeutically similar products) level. For calculating the reference price of a group, usually the price of the cheapest available product is taken. At least one pharmaceutical per group is fully reimbursed. In 2003, the number of therapeutic groups was drastically reduced, thus having more pharmaceuticals in a group.

In 2003 the Ministry of Health introduced further cost-containment reforms:

- a so-called agreed price – a fixed price at which the manufacturer has agreed to sell the pharmaceuticals – followed by the re-calculation of the reimbursement price;
- co-payments for patients for certain services as well as a prescription fee;
- prescribing budgets for physicians, combined with monitoring of the prescription pattern of physicians.

7.2.3 Pricing

Since autumn 2004, the pharmacy retail prices for reimbursable pharmaceuticals (original products as well as generics) have been set by the Ministry of Health. Before, the ex-factory price was regulated. There is free pricing for non-reimbursable products.

The determination of the price for imported pharmaceuticals is based on a price comparison of nine European countries (with special focus on Poland, Czech Republic and Hungary). The price corresponds to the average of the prices of the three cheapest pharmaceuticals plus a mark-up of 10 percent. If the product is locally produced, the pharmaceutical companies are granted a price taking into account production costs. A company may only apply for reimbursement after the maximum price has been fixed.

Maximum mark-ups for wholesale and pharmacies are regulated for all pharmaceuticals (independent from the prescription and reimbursement status). In July 2005, the mark-up schemes changed and are now as follows: In general, for reimbursable pharmaceuticals the maximum wholesale mark-up is 13 percent on the ex-factory price; the maximum pharmacy

mark-up is 21 percent on the ex-factory price. There are extra categories for special reimbursable pharmaceuticals, such as very expensive products (wholesale: 4 percent and pharmacy: 6 percent) and vaccination products (wholesale: 5 percent and pharmacy: 7 percent); and for non-reimbursable pharmaceuticals. The mark-ups for non-reimbursable pharmaceuticals, which are mainly OTC products, are 5 percent for wholesalers and 15 percent for pharmacies. Hospital products have a common mark-up for pharmacies and wholesalers of 10 percent.

The value-added tax (VAT) on pharmaceuticals is 19 percent, which is the standard VAT rate.

7.2.4 Distribution

In Slovakia, the production and the distribution sector had been in the hands of the state until 1989, and from the 1990-ties on, these sectors were privatised, which led to an increase in the number of (foreign) research-based manufacturers. The number of wholesalers and pharmacies also increased but due to financial difficulties some wholesale companies went bankrupt. There are 80 hospital pharmacies serving only in-patients. Self-dispensing doctors are not allowed.

Currently, there are about 1,160 pharmacies in Slovakia. In autumn 2004, ownership rules for pharmacies were changed, allowing ownership of pharmacies by other persons than a pharmacist.

Slovenia

Inhabitants	***2 million***
Life expectancy – women	***80.5 years***
Life expectancy – men	***72.7 years***
Gross domestic product per inhabitant	***€ 12,319.-***
Health expenditure per inhabitant	***€ 812.-***
Hospital beds per 1,000 inhabitants	***4.1***
Inhabitants per physician	***449***
Inhabitants per pharmacy	***7,340***
Conversion rate – 1,000 Slovenian Tolar (SIT)	***€ 4.1826***

8 Slovenia

8.1 Health Care System

In Slovenia health care is based on a health insurance system. The Health Insurance Institute of Slovenia (Zavod za zdravstveno zavarovanje Slovenjie, ZZZS) provides universal coverage for the entire population. Health insurance is financed though payroll-based contributions of employers and employees as well as contributions of self-employed, farmers and pensioners. In addition, there is voluntary private insurance, which mainly covers co-payments. In Slovenia, private insurance plays an important role, and approximately 90 percent of the insured who are subject to co-payments have contracts with private insurance schemes.

Primary care is mainly provided in municipality health centres or small health care stations, in which doctors with contracts with the health insurance work. General practitioners act as gatekeepers to the specialist services. They are remunerated on the basis of a combination of capitation fees and fee-for-service payments. Specialists are mainly employed in public hospitals and polyclinics, to a smaller extent they also work in health centres. The hospital sector is predominantly in public ownership.

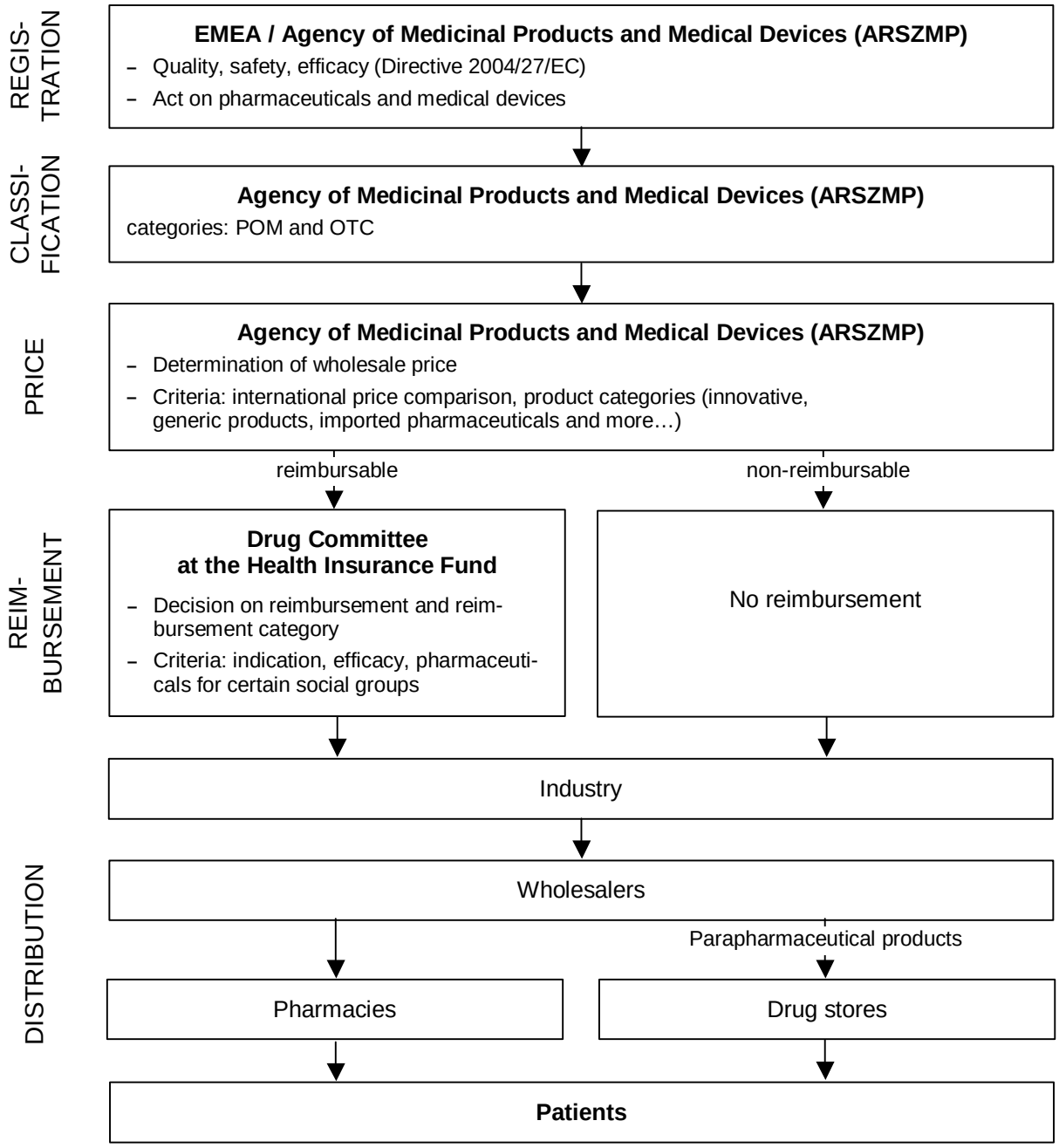
8.2 Pharmaceutical System

In Slovenia, the main actors in the pharmaceutical system are the Agency of Medicinal Products and Medical Devices (ARSZMP) and the Health Insurance Institute (ZZZS). The Ministry of Health is responsible for the overall legislation in the pharmaceutical sector.

8.2.1 Registration

The Agency of Medicinal Products and Medical Devices (ARSZMP) is responsible for the registration of pharmaceuticals. The ARSZMP is also in charge of the classification of pharmaceuticals according to their prescription status. Slovenian market authorisations will fully comply with EU legislation after a transitional period ending in December 2007.

Figure 8.1: Slovenia – Pharmaceutical system in 2005 (out-patient sector)



ARSZMP = Agencija Republike Slovenije za zdravila in medicinske pripomočke, EC = European Community, EMEA = European Medicines Agency, OTC = Over-the-Counter, POM = Prescription-only medicines

Source: ÖBIG

8.2.2 Reimbursement

The Health Insurance Institute (ZZZS) is responsible for, at least partial, reimbursement of pharmaceuticals; besides, co-payments are refunded by voluntary health insurance.

A drug committee, consisting of 15 representatives of different medical and public institutions such as the ZZZS and Ministry of Health, decides if pharmaceuticals are included into reimbursement. There are two reimbursement lists: a positive list and a so-called intermediate list.

Criteria for categorisation either in the positive list or the intermediate list are legally defined:

- The positive list includes pharmaceuticals for prevention, therapy of certain social groups (such as children under 18 years) or for the treatment of certain diseases defined in law (such as HIV/AIDS, diabetes) at a 100 percent reimbursement rate.

  Further pharmaceuticals are included in the positive list due to their effectiveness and treatment alternatives at a reimbursement rate of 75 percent.

- The intermediate list covers all other reimbursable pharmaceuticals. They are reimbursed at a rate of 25 percent.

Most of the non-reimbursable pharmaceuticals are OTC products.

In 2003, a reference price system was introduced. Mutually interchangeable pharmaceuticals are clustered by the ARSZMP. The ZZZS is responsible for attributing a maximum price to each group, usually at the level of the cheapest pharmaceutical of that group. The difference between the reimbursement sum, which is calculated on the basis of the reimbursement level and the reference price, and the pharmacy retail price has to be covered by the patient. Private insurances only cover the co-payment up to the reference price.

Generic substitution was allowed to pharmacies with the introduction of the reference price system.

The ZZZS analyses the pharmaceutical consumption on national and individual level. Rational prescribing is encouraged by the ZZZS (e.g. by public presentations and mailings). In Slovenia, there are no pharmacoeconomic guidelines, economic evaluations may be presented when applying for higher prices.

8.2.3 Pricing

In Slovenia, there is statutory pricing for all pharmaceuticals at the wholesale level. The relevant authority is the State Agency of Medicinal Products and Medical Devices (ARSZMP). The wholesale prices are determined on the basis of an international price comparison (Italy, France and Germany). The pharmacy purchase price may not exceed 85 percent of the average wholesale price of the three reference countries, for imported pro-

ducts an extra 0.5 percent may be added. There are additional regulations for innovative products and generics.

There are no regulated mark-ups for pharmaceutical wholesale. Wholesalers freely negotiate the prices and thus their margins with the pharmaceutical industry. According to the European self-medication association AESGP, the average wholesale margin was 9 percent for prescription-only medicines and 12 percent for OTC products in 2002.

Pharmacies are remunerated on a fee-for-service system, which corresponds to an average pharmacy margin of 11.7 percent for POM and 30 percent for OTC products in 2002 according to AESGP.

In Slovenia, the standard value added tax (VAT) is 20 percent, the VAT rate on pharmaceuticals is 8.5 percent.

8.2.4 Distribution

There are five local manufacturers in Slovenia, with two of them dominating: Lek d.d. and Krka d.d. serve about one third of the Slovenian pharmaceutical market. Eleven companies are involved in pharmaceutical wholesale; the two market leaders, Kemofarmacija and Salus, cover nearly three quarters of the wholesale market.

In Slovenia, geographic and demographic criteria are in place for opening a pharmacy. In 2005, there are 272 community pharmacies in the out-patient sector. 188 of them are in public ownership. Only publicly-owned pharmacies are permitted to run chain pharmacies. Two of the 27 hospital pharmacies act as a community pharmacy accessible to the public.

Czech Republic

Inhabitants	***10.2 million***
Life expectancy – women	***78.7 years***
Life expectancy – men	***72.1 years***
Gross domestic product per inhabitant	***€ 7,239.-***
Health expenditure per inhabitant	***€ 536.-***
Hospital beds per 1,000 inhabitants	***6.5***
Inhabitants per physician	***286***
Inhabitants per pharmacy	***4,639***
Conversion rate – 100 Czech Koruna (CZK)	***€ 3.1357***

9 Czech Republic

9.1 Health Care System

Since 1993, the health care system in the Czech Republic has been based on a mandatory social health insurance. Today, there are nine health insurance funds (with regard to 27 health insurances in 1994). The system is funded through social insurance contributions which for children, elderly and unemployed people are covered by the state.

Primary care is provided by general practitioners (GP) within a family physician system. Patients register with GPs who have a contract to their health insurance and receive treatment free of charge. In general, GPs act as gatekeepers to specialist services. Secondary care is provided by specialists in out-patient practices, the still existing polyclinics and out-patient departments, while community, regionally and centrally run hospitals offer tertiary care. The main problem of public hospitals is funding due to limited resources, which is expected to have improved through the introduction of the remuneration on the basis of DRGs.

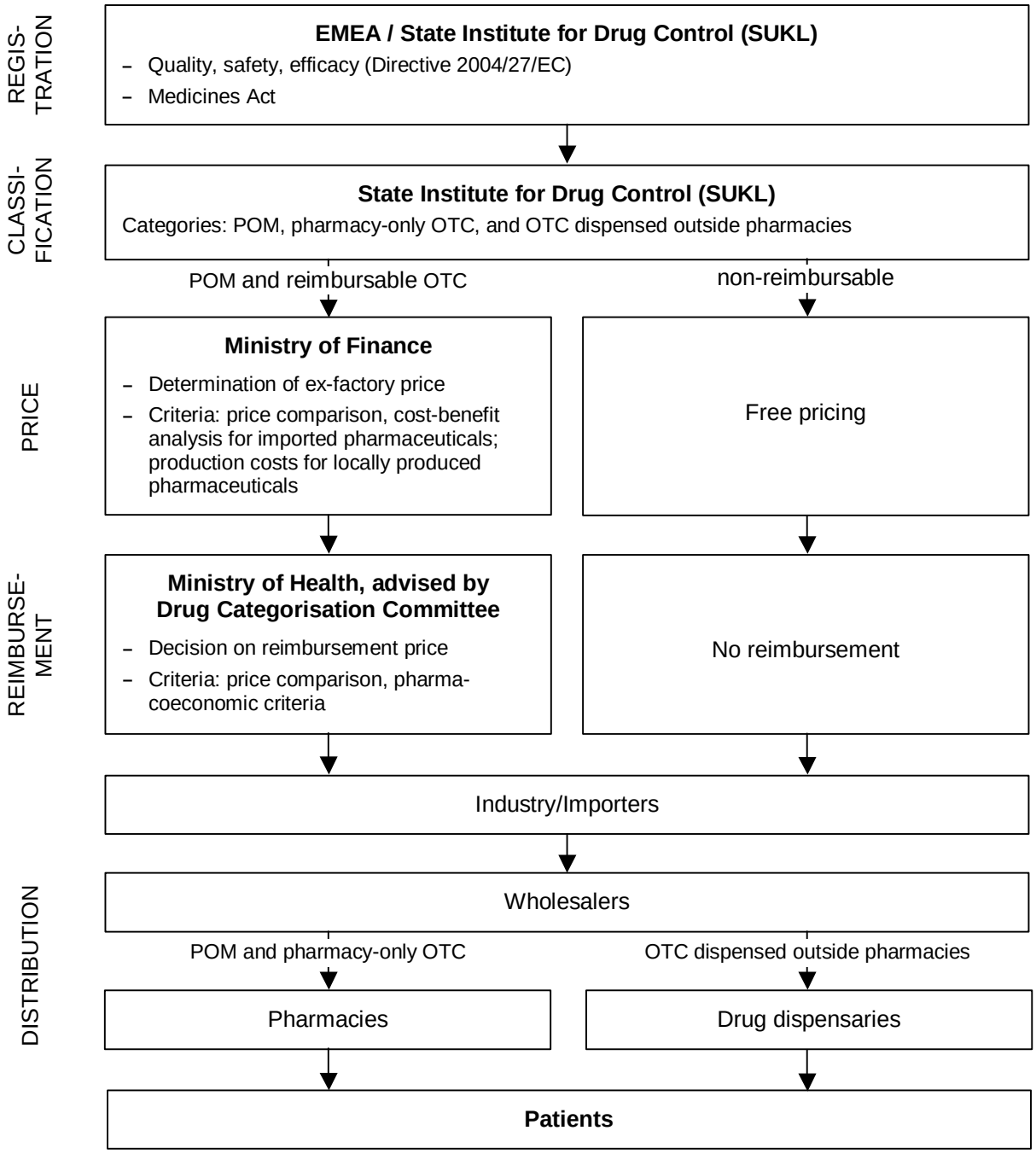
9.2 Pharmaceutical System

In the Czech Republic the main actors in the pharmaceutical system are the Ministry of Health, supported by the Categorisation Committee and the State Institute for Drug Control (SUKL), and the Ministry of Finance which is in charge of pricing.

9.2.1 Registration

The State Institute for Drug Control (SUKL) is responsible for registering pharmaceuticals. It is also in charge of the classification of pharmaceuticals according to their prescription (and distribution) status as well as switches (change from prescription status to OTC). There are prescription-only pharmaceuticals, pharmacy-only OTC products, and OTC products dispensable outside of pharmacies. Registration is harmonised to EU legislation.

Figure 9.1: Czech Republic – Pharmaceutical system in 2005 (out-patient sector)



EC = European Community, EMEA = European Medicines Agency, OTC = Over-the-Counter, POM = Prescription-only medicines, SUKL = State Institute for Drug Control

Source: ÖBIG

9.2.2 Reimbursement

The Ministry of Health, advised by the Categorisation Committee, decides to which extent a pharmaceutical is reimbursed by the health insurance. There are four reimbursement categories: H – reimbursement only in hospital setting; L – reimbursement only through a prescription of a specialist; P – reimbursement only for certain therapeutic indications; I – full reimbursement. Apart from one exception (anti-allergics), there are no fixed reimbursement rates for pharmaceuticals or patient groups; reimbursement is closely linked to the reference price system.

In the mid-1990-ties a reference price system was introduced. In order to set maximum reimbursement prices, products were clustered into 521 pharmaco-therapeutic groups based on ATC-5 (same active ingredient) or ATC-4 (therapeutically similar pharmaceuticals) level. In each of these groups at least one pharmaceutical has to be fully reimbursed. For the other pharmaceuticals, patients are obliged to pay the difference between the reference price and the pharmacy retail price.

Pharmacoeconomic studies are desired as part of the application for reimbursement, but not compulsory; it has been criticized that there are no clear rules concerning the decision on reimbursement.

9.2.3 Pricing

In the Czech Republic, the Ministry of Finance sets the maximum ex-factory prices as well as the mark-ups for wholesalers and pharmacies. There are different criteria for pricing locally manufactured (production costs) or imported pharmaceuticals (international price comparison). These criteria are valid for all pharmaceuticals except for non-reimbursable OTC products.

There is a common maximum mark-up for wholesalers and pharmacies which amounts to 32 percent on the ex-factory price. This mark-up applies to all pharmaceuticals (also non-reimbursable pharmaceuticals and OTC products). Usually, the actors in pharmaceutical distribution do not make use of the maximum mark-ups granted, therefore the prices of pharmaceuticals, especially OTC products, vary between pharmacies.

The standard value-added tax (VAT) rate is 19 percent, and the VAT on pharmaceuticals is 5 percent.

9.2.4 Distribution

In the Czech Republic the production and distribution of pharmaceuticals had formerly been in the hands of the state. After transition these markets were privatised, which led to an increase in the number of (foreign) research-based manufacturers and wholesalers. There are around 220 pharmaceutical companies. In pharmaceutical wholesale, there are still, after

a strong consolidation, 160 companies with a wholesale licence, but in fact five of them control the market. Around 2,200 pharmacies dispense pharmaceuticals to the patients. A limited range of OTC products is allowed to be sold outside pharmacies, in drug dispensaries. Self-dispensing doctors are not allowed.

Hungary

Inhabitants	***10.2 million***
Life expectancy – women	***76.7 years***
Life expectancy – men	***68.4 years***
Gross domestic product per inhabitant	***€ 6,782.-***
Health expenditure per inhabitant	***€ 527.-***
Hospital beds per 1,000 inhabitants	***5.9***
Inhabitants per physician	***313***
Inhabitants per pharmacy	***5,004***
Conversion rate – 1,000 Hungarian Forint (HUF)	***€ 3.9736***

10 Hungary

10.1 Health Care System

Health care is organised on the basis of a social insurance system (Bismarckian model). Besides the National Health Insurance Fund (Országos Egészségbiztosítási Pénztár, OEP) who covers mainly recurrent costs of health care, the state plays an important role in the organisation and financing of the health care system.

The OEP is financed by contributions from the employees (4 percent) and the employers (11 percent), contributions of the self-employed and other groups (e.g. farmers). Provisions for the non-contributing insured are partly borne by the state. In addition to the proportional contributions for obligatory health insurance, the employers and self-employed have to pay a flat-rate health contribution.

The state mainly finances the capital costs of the health care system, the maintenance costs are covered by local and central government taxes. Local governments are often the owner of health care institutions, and fund them together with central government subsidies.

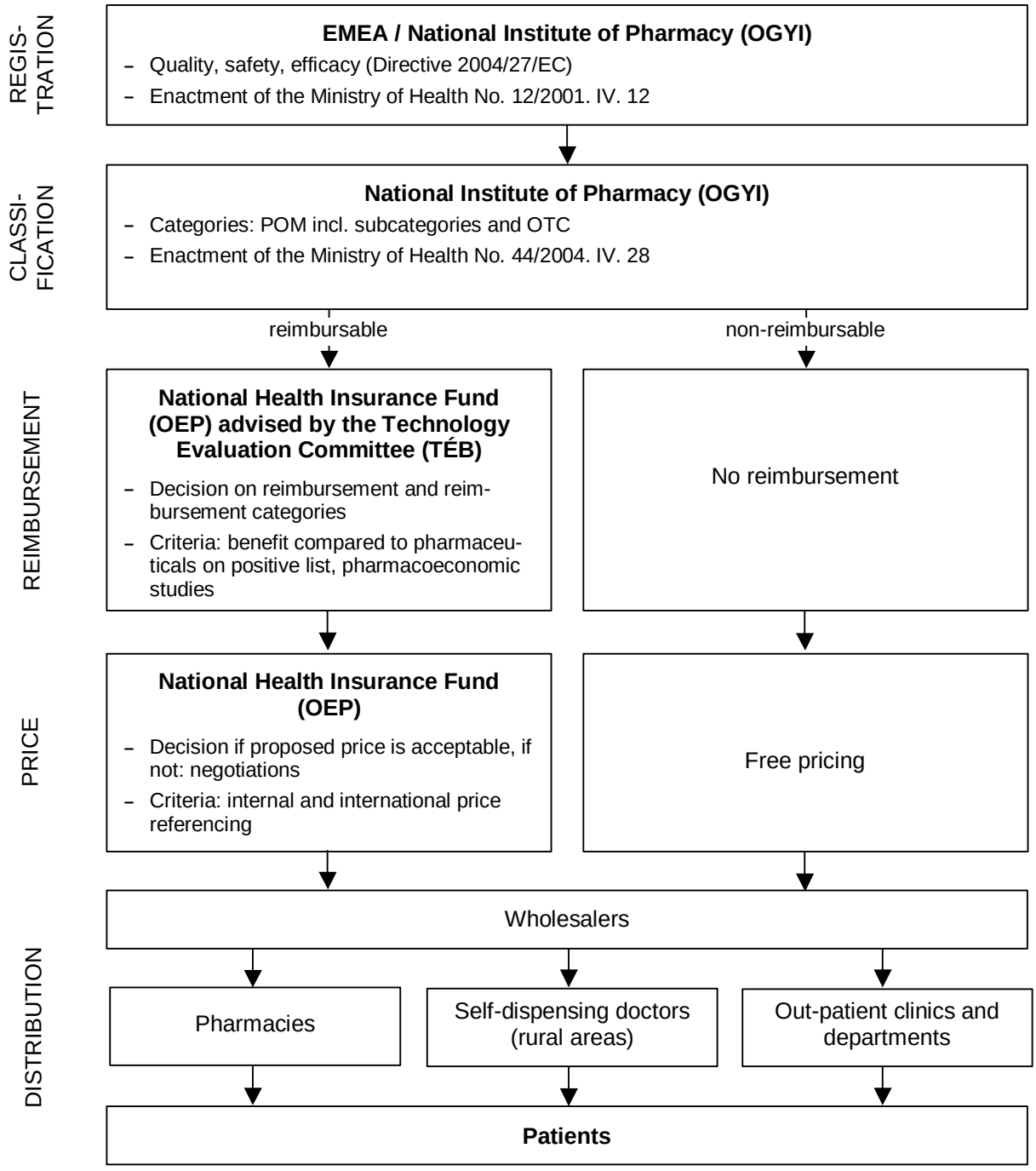
In the family doctor system primary care physicians have contracts with the regional branches of the OEP and usually work in publicly owned practices. The scope of medical coverage is regulated by the state. GPs act as gatekeepers to specialised services and are remunerated primarily on a capitation basis. Specialist services are provided in publicly owned polyclinics and out-patient departments. The in-patient sector is mainly in public hands, with only a few hospitals being operated by churches and private institutions. Services of the in-patients sector are financed on the basis of a DRG system.

The Hungarian health care system remains financially under-covered, which explains high out-of pocket payments of patients.

10.2 Pharmaceutical System

In Hungary, the main actors in the pharmaceutical system are the Ministry of Health, the National Health Insurance Fund (OEP), advised by the Technology Evaluation Committee, and the National Institute of Pharmacy (OGYI).

Figure 10.1: Hungary – Pharmaceutical system in 2005 (out-patient sector)



EC = European Community, EMEA = European Medicines Agency, OEP = Országos Egészségbiztosítási Pénztár, OGYI = Országos Gyógyszerészeti Intézet, OTC = Over-the-Counter, POM = Prescription-only medicines, TÉB = Technológia Értékelő Bizottság

Source: ÖBIG

10.2.1 Registration

The responsibility of registering pharmaceuticals bears with the National Institute of Pharmacy (OGYI). It is also in charge of the classification of pharmaceuticals according to their prescription status into non-prescription medicines (OTC) and prescription-only medicines (POM) with sub-categories (e.g. prescription on specialists advise). Registration is harmonised to EU legislation.

10.2.2 Reimbursement

The National Health Insurance Fund is responsible for the reimbursement of pharmaceuticals in the out-patient sector, while in the in-patient sector pharmaceutical expenditure is covered through the DRG system.

The OEP operates a positive list for reimbursable pharmaceuticals, there is no negative list.

The manufacturer has to submit an application for inclusion into reimbursement to the OEP, which has to include, among others, the proposed ex-factory price, the reimbursement category, benefits compared to already reimbursed pharmaceuticals and prices in other countries (international price referencing). The application is considered by the Technology Evaluation Committee (TÉB), who consists of representatives of the OEP, the Hungarian Chamber of Doctors, Special Boards of Doctors and the Hungarian Chamber of Pharmacists. Among the criteria taken into consideration by the TÈB are the submitted price proposal and an analysis made by the National Institute for Strategic Health Research (ESKI). The reimbursement decision is taken by the head of the Pharmaceutical Department on basis of the recommendation of the TÉB.

Pharmaceuticals on the positive list are generally reimbursed at 90, 70 and 50 percent (so-called normative reimbursement). Furthermore, high cost pharmaceuticals with approved special indications are reimbursed at 100 or 90 percent if prescribed by a specialist or on behalf of the recommendation of a specialist.

In addition, there is special reimbursement for people with low income and high medical consumption; furthermore pharmaceuticals can be reimbursed on behalf of individual applications.

In 1997, a reference price system on the basis of the same active ingredient (INN) was introduced. There are about 95 reference price clusters in the normative reimbursement category and further 40 reference price groups reimbursed on the basis of special indications. The reimbursement price for each cluster is set on the basis of the cheapest product available on the market. In 2003, the first therapeutic reference price group (covering therapeutically similar products) was introduced, in 2005, there were about 20 therapeutic reference price clusters either in normative or preferential reimbursement category.

The patient has to pay the difference between the reimbursement sum, calculated from the reimbursement category and the reimbursement price (either reference price or retail price), and the retail price in the pharmacy.

In Hungary, there are guidelines for pharmacoeconomic evaluation studies. In the course of the reimbursement procedure, the National Institute for Strategic Health Research (ESKI) issues HTA and pharmacoeconomic studies.

Physicians in hospitals are obliged to prescribe generically (by INN) on discharge of patients, there is no such obligation for doctors in the out-patient sector. Pharmacies are obliged to inform patients on the possibility of generic substitution.

10.2.3 Pricing

According to the Price Act of 1990 and the Enactment of the Ministry of Health of 1997 ex-factory prices can be set freely.

If a product shall be included in the positive list, the manufacturer has to apply for reimbursement to the OEP – the application has to include the proposed manufacturer price.

For innovative products companies have to indicate prices in other EU Member States. Usually, the prices in France, Ireland, Germany, Spain, Portugal, Italy, Greece, Poland, the Czech Republic, Slovenia, Slovakia, Belgium and Austria are taken into account. As a general rule, the reimbursement price in Hungary must be lower than the price of the product in all reference countries. The price of generic products needs to be at least 20 percent lower than the price of the original product.

The proposed price is either approved by the OEP or negotiations take place. The Ministry of Health and the Chamber of Pharmacists are notified by the company on the prices of reimbursable pharmaceuticals.

Since 1993, wholesale mark ups and pharmacy mark-ups have been regulated as regressive mark-up schemes, valid for all registered pharmaceuticals. The wholesale mark-up scheme was last modified in 2001, the pharmacy mark-up scheme in the year 2004.

Table 10.1: Hungary – Wholesale mark-ups in 2005

Ex-factory price / CIP from...to...in HUF / €	Wholesale mark-up in % of the ex-factory price/CIP in HUF / €
up to HUF 150.- / € 0.59	12%
from HUF 150.01 / € 0.60 to HUF 180.- / € 0.71	HUF 18.- / € 0.07
from HUF 180.01 / € 0.72 to HUF 300.- / € 1.19	10%
from HUF 300.01 / € 1.20 to HUF 333.- / € 1.32	HUF 30.- / € 0.12
from HUF 333.01 / € 1.33 to HUF 500.- / € 1.98	9%
from HUF 500.01 / € 1.99 to HUF 600.- / € 2.38	HUF 45.- / € 0.18
from HUF 600.01 / € 2.39 to HUF 1,000.- / € 3.97	7.5%
from HUF 1,000.01 / € 3.98 to HUF 1,154.- / € 4.58	HUF 75.- / € 0.30
from HUF 1,155.01 / € 4.59 to HUF 2,000.- / € 7.94	6.5%
from HUF 2,000.01 / € 7.95 to HUF 2,600.- / € 10.33	HUF 130.- / € 0.52
from HUF 2,600.01 / € 10.33 on	5%

CIP = Cost, Insurance and Packaging

Source: Enactment of the Ministry of Health 19/2001, data gathering by ÖBIG

Table 10.2: Hungary – Pharmacy mark-ups in 2005

PPP from...to...in HUF / €	Pharmacy mark-up in % of the PPP in HUF / €
up to HUF 500.- / € 1.98	26%
from HUF 501,- / € 1.99 to 590.- / € 2.34	HUF 130.- / € 0.52
from HUF 591,- / € 2.35 to 1,500.- / € 5.96	22%
from HUF 1,501,- / € 5.97 to 1,737.- / € 6.90	HUF 330.- / € 1.31
from HUF 1,738,- / € 6.91 to 3,500.- / € 13.90	19%
from HUF 3,501,- / € 13.91 to 3,911.- / € 15.54	HUF 665.- / € 2.64
from HUF 3,912,- / € 15.55 to 5,000.- / € 19.86	17%
from HUF 5,001.- / € 19.87 on	HUF 850.- / € 3.38

PPP = Pharmacy Purchase Price

Source: Enactment of the Ministry of Health 70/2003, data gathering by ÖBIG

The standard VAT is 25 percent, the reduced VAT on pharmaceuticals is 5 percent. Furthermore, there is a VAT rate of 15 percent for parapharmaceutical products.

10.2.4 Distribution

The Hungarian pharmaceutical industry is mainly in the hands of foreign investors. The biggest local producer is Richter Gedeon, followed by Chinoin Rt., Egis Gyógyszergyár and Biogal Gyógyszergyár. The local pharmaceutical industry covers approximately one third of the Hungarian market in value, and more than half of the pharmaceutical market in volume. In 2005, there are 80 companies holding a wholesale license, but in fact only four of them

(Phoenix Pharma, Hungaropharma, Medimpex and Pannonmedicina) dominate the market with an estimated total 85 percent market share. There are 2,030 community pharmacies in Hungary. Geographic and demographic criteria for setting up a pharmacy are in place, furthermore the ownership of a pharmacy is only allowed for trained pharmacists. Though multiple ownership of pharmacies is not permitted, approximately 250 pharmacies are organised in form of chains. Self-dispensing doctors are allowed and do exist in rural areas, besides hospitals are entitled to dispense pharmaceuticals to out-patient patients. Distance selling of pharmaceuticals, e.g. via internet, is not legitimized.

Cyprus

Inhabitants	***0.7 million***
Life expectancy – women	***81 years***
Life expectancy – men	***76.1 years***
Gross domestic product per inhabitant	***€ 16,284.-***
Health expenditure per inhabitant	***€ 887.-***
Hospital beds per 1,000 inhabitants	***4***
Inhabitants per physician	***379***
Inhabitants per pharmacy	***1,660***
Conversion rate – 10 Cyprus Pound (CYP)	***€ 17.1866***

11 Cyprus

11.1 Health Care System

The Republic of Cyprus operates a de facto National Health Service, even though it has never been officially called NHS. The government provides a comprehensive range of health care services free or at reduced rates to eligible population. Beside the public system, there is an important private sector. Around 85 to 90 percent of the population are eligible for free services or at reduced rates, although a lot of people rather opt for private health services which they expect to provide quicker access to diagnosis and treatment.

Public health care is provided in about 300 health centres, 11 out-patient departments and 4 district hospitals. At present patients can freely choose their doctors; there is no gatekeeping system.

In the course of health reforms, Cyprus plans to change to a social insurance system which also foresees a gatekeeping function for general practitioners. The social insurance system is expected not to be fully implemented before 2007. The in-patient sector has already undergone many reforms.

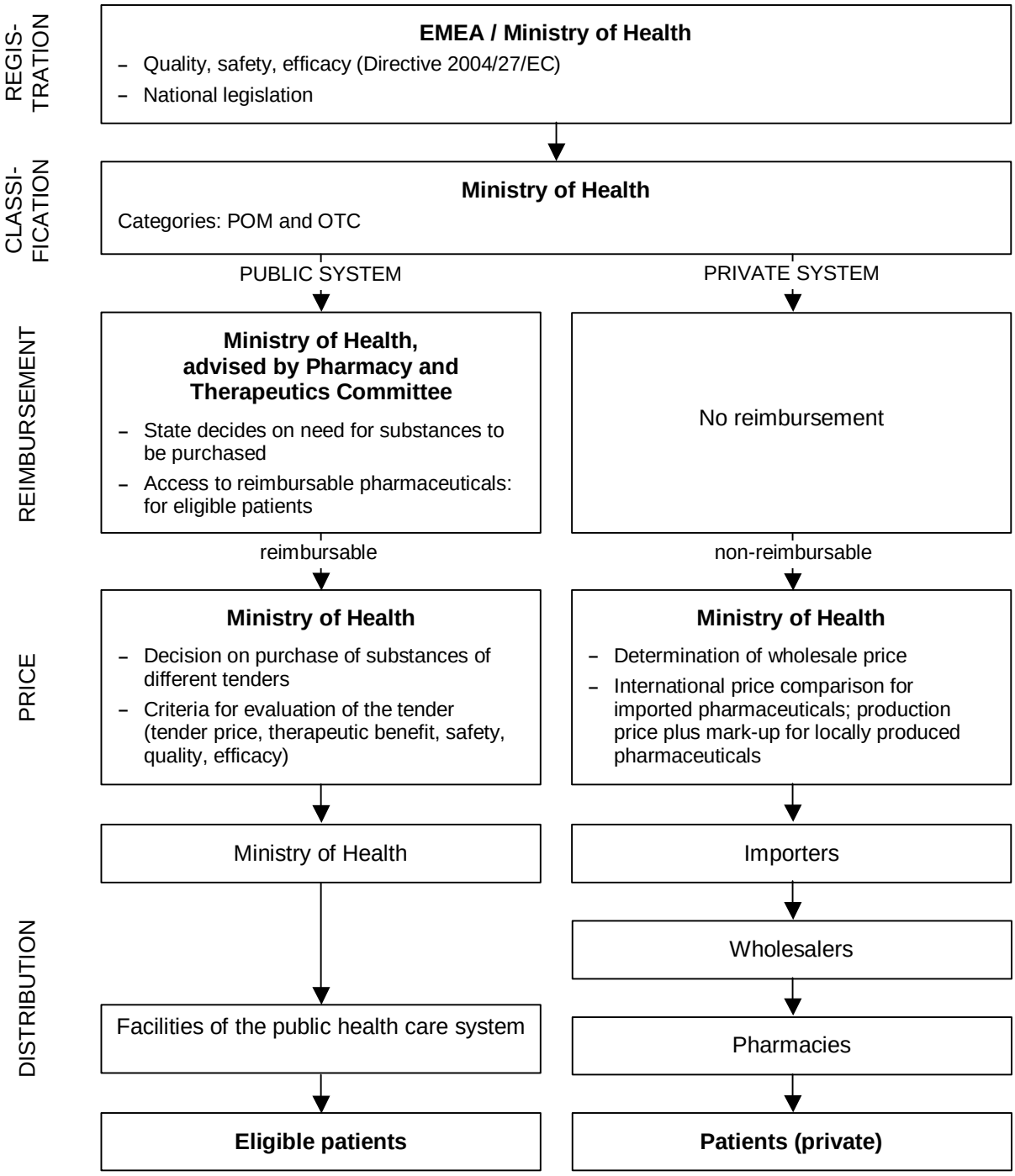
11.2 Pharmaceutical System

As for health care in general, there are two distinct systems: a public and a private system. Those two sectors exist next to each other, but are not complementary.

- In the private system, pharmaceuticals are either locally produced or imported, with imported pharmaceuticals being the majority. Pharmaceuticals have to be registered and are dispensed to patients in (private) retail pharmacies. Patients have to pay the full price for pharmaceuticals.
- Under the public system, pharmaceuticals are dispensed free of charge or at reduced rates to eligible patients. The government purchases pharmaceuticals via tendering, in the tender decision the cost of the therapy, the safety, quality, efficacy and especially the price are considered. The public sector also offers non-registered pharmaceuticals. There are no margins for wholesalers or pharmacies in the public sector.

The Ministry of Health is the key authority for purchasing pharmaceuticals (only public sector), setting prices and registering pharmaceuticals in the public and the private sector.

Figure 11.1: Cyprus – Pharmaceutical system in 2005 (out-patient sector)



EC = European Community, EMEA = European Medicines Agency, OTC = Over-the-Counter, POM = Prescription-only medicines

Source: ÖBIG

11.2.1 Registration

The Department of Pharmaceutical Services of the Ministry of Health is responsible for registering pharmaceuticals. The registration procedure was harmonised to EU legislation in 2001, but there is still a transitional period (until the end of 2005) for pharmaceuticals registered before 2001.

11.2.2 Reimbursement

There is no reimbursement in the private sector.

Under the public system, the national formulary of approved medicines lists pharmaceuticals which are reimbursed at 100 percent or 50 percent of the tendered price for eligible patients. Eligibility and the level of reimbursement depend on the income level of the patient. The Ministry of Health, advised by Pharmacy and Therapeutic Committee, decides whether a pharmaceutical should be listed and whether any restrictions should be placed on the specialisation of the prescribing doctor. New products are added to the list on request of a physician working in the public health care sector. The national formulary of approved medicines mainly includes generics.

11.2.3 Pricing

A new pricing procedure came into force in March 2005. This procedure is relevant for the private sector, since the public sector purchases pharmaceuticals through tendering.

In the private system, the Ministry of Health sets the prices advised by a Price Committee. The wholesale price for imported pharmaceuticals is fixed on the basis of an international price comparison with four countries. The ex-factory price for imported pharmaceuticals is freely negotiated between the importer and the wholesaler.

For locally produced pharmaceuticals, the ex-factory price is set on the basis of the production cost plus a mark-up of 20 percent.

The maximum mark-up for pharmacies is 33 percent, corresponding to a maximum margin of 25 percent of the pharmacy retail price.

There is no VAT on pharmaceuticals.

11.2.4 Distribution

In Cyprus, there are 5 local manufacturers, which mainly produce generics, and about 60 importers. Most of the importers also act as wholesalers.

There are 440 private retail pharmacies. In general, pharmacies have the monopoly for dispensing pharmaceuticals. There are two exceptions: Aspirin is also allowed to be sold in shops, and there are very few self-dispensing doctors. Besides, there are 40 hospital pharmacies, acting as community pharmacies for eligible patients under the public system.

BENCHMARKING

12 Benchmarking

In this chapter, the findings on the pharmaceutical systems in the ten new Member States are summarised and analysed, taking into consideration the overall framework such as Community law. An introduction on economic and demographic data is followed by information on the organisation and financing of the health care systems of the new Member States. The main focus of this chapter lies on the pharmaceutical system (registration, reimbursement, pricing, distribution) with an outlook on developments and trends.

12.1 Overview

12.1.1 Demography

The ten new Member States of the European Union differ considerably in their size and population number (cf. Table 12.1), as well as in their political and economic development.

Concerning the geographical position and the historical development of the new Member States, two groups of countries may be distinguished:

- the two Mediterranean islands Malta and Cyprus and
- the Central and Eastern European countries (CEECs).

The Central and Eastern European countries share a similar history. Among them, there are some states that were newly founded in 1990-ties, such as the three Baltic States, Slovenia, and the Czech Republic and Slovakia.

Malta and Cyprus are not only both small islands in the Mediterranean sea, but show also similarities in the organisation of their health care and pharmaceutical system.

12.1.2 Economic situation

Economic prosperity in the new Member States is lower than in the “old” ones: The gross domestic product (GDP) amounts, on average, to € 10,700. - (year 2003), while in the enlarged Union (EU-25) it is about € 19,000.- on the average.

There are, however, major differences in the economic wealth of the ten new Member States, with the per capita GDP of Malta, Slovenia and Cyprus being above the EU-10-average, while Estonia, Lithuania and Latvia are ranking last (cf. Table 12.1). In the Baltic states, there have been important growth rates though.

Table 12.1: Benchmarking – Key data of the new Member States

Member States[1]	General data			Economic data	
	Inh. (in mill.)	Size (in km²)	State founded in year	GDP/inh. 2003 (in €)	Growth rate 1995-2002
Estonia (EST)	1.4	45,227	1991	5,931	176%
Latvia (LV)	2.3	64,589	1991	4,233	179%
Lithuania (LT)	3.5	65,301	1991	4,699	220%
Malta (M)	0.4	316	1964	10,722	13%[3]
Poland (PL)	38.4	312,685	1918	5,265[2]	96%
Slovakia (SK)	5.4	49,034	1993	4,774[2]	73%
Slovenia (SLO)	2.0	20,353	1991	12,319	53%
Czech Republic (CZ)	10.2	78,866	1993	7,239[2]	88%
Hungary (H)	10.2	93,030	1918	6,782[2]	105%
Cyprus (CY)	0.7	9,251	1960	16,284	45%

GDP = Gross Domestic Product, Inh. = inhabitants, mill. = millions

[1] In the following tables and charts of this chapter, the new Member States are mentioned with these abbreviations.

[2] year 2002

[3] from 1999-2002

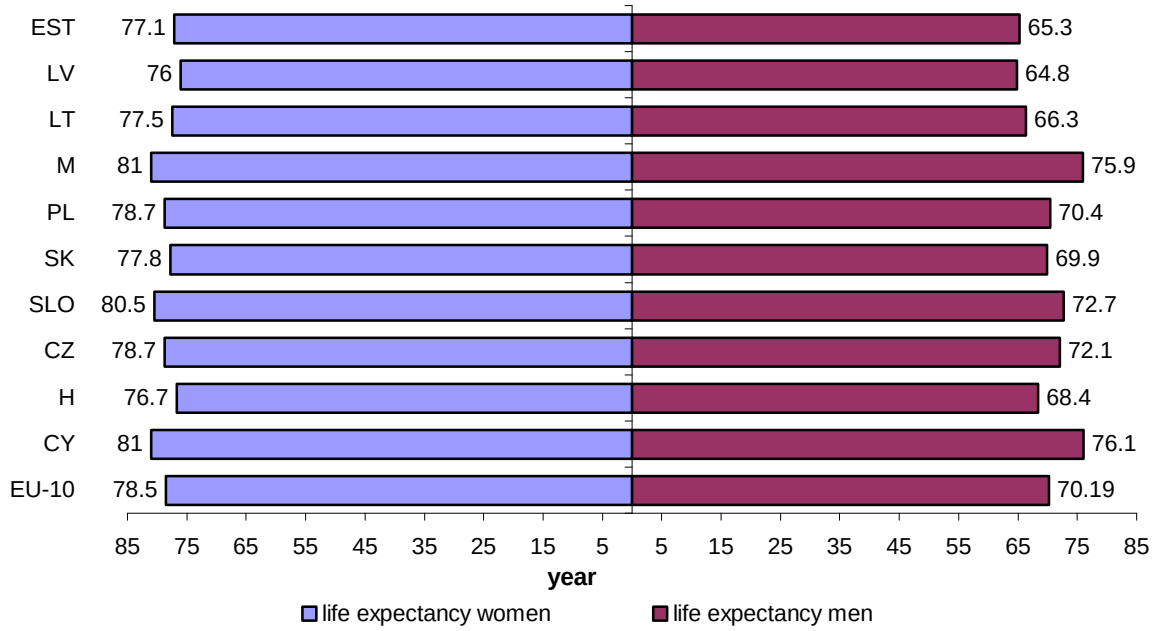
Source: OECD Health Data 2004, EUROSTAT 2005; data gathering by ÖBIG

12.1.3 Health status

Health status in the new Member States has improved in the course of the last 10 to 15 years. However, in most of these countries, except for Malta, Cyprus and Slovenia, health indicators still show worse results compared to the “old“ EU-15-countries. This is, for example, demonstrated with the indicator of “life expectancy” (cf. Figure 12.1). While the average life expectancy in Malta and Cyprus is 81 years for women and around 76 years for men, thus clearly above the EU-10-average, it is approximately 76 to 77 years for women and 65 years for men in Latvia and Estonia.

Morbidity and mortality in Central and Eastern Europe concerns the same diseases (especially cardiovascular diseases, cancer, etc.) as in the old Member States. A high health risk in the new Member States are infectious diseases (e.g. high incidence rate of TBC in Latvia and Estonia), which have been reduced in the old Member States. Like in the old Member States, life-style problems (nutrition, tobacco, little physical exercise) are getting acute in the new Member States as well.

Figure 12.1. Benchmarking – Life expectancy in the new Member States in 2002[1]



[1] CY – year 2001

Source: OECD Health Data 2004, EUROSTAT 2005

12.2 Health care systems

12.2.1 Organisation

In general, there are two different types of health care systems in the new EU Member States (cf. Table 12.2):

National Health Service in Malta and Cyprus

Health care is publicly provided and financed by the state through taxation (Beverage system). Thus, patients have access to health care free of charge or at limited co-payments. Public health services are offered in health care centres, out-patient departments and hospitals.

Besides public health care, there is also an important private sector which is, in spite of considerable out-of pocket payments, increasingly used by patients.

Within the next few years, Cyprus plans to implement a social insurance system, with general practitioners acting as gatekeepers (i.e., for secondary and tertiary care, provided at the expense of the social insurance, a referral of a general practitioner is required).

Social Insurance systems in Central and Eastern Europe

Since the transition in Central and Eastern European countries, health care provision has changed from Soviet-style centrally planned systems (Semaskho model) to more decentralised social insurance systems (Bismarck model). Latvia, though having introduced a social insurance fund, is an exception as the social health insurance is not financed through contributions of the insured but via general taxation.

Table 12.2: Benchmarking – Organisation of the health care systems in the new Member States in 2005

Member States	Organisation of health care			Family physician/ gatekeeping
	SI	NHS	since	
EST	✓	-	1991	✓
LV	(✓)[1]	-	1993	✓
LT	✓	-	1991	✓
M	-	✓	-[2]	-
PL	✓	-	1999	✓
SK	✓	-	1994	✓
SLO	✓	-	1992	✓
CZ	✓	-	1993	✓
H	✓	-	1993	✓
CY	-	✓	-[2]	-

NHS = National Health Service, SI = Social Insurance

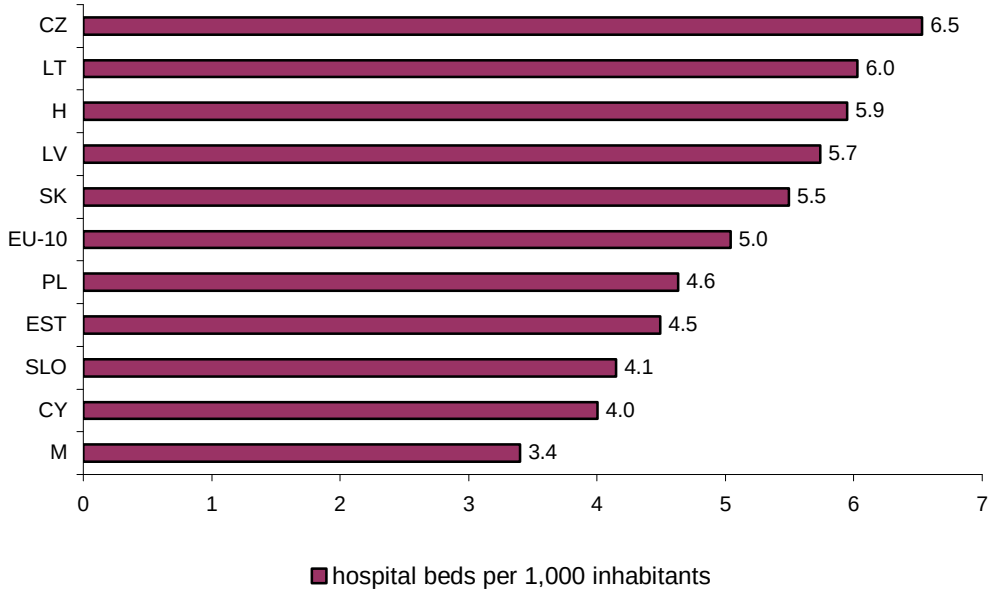
[1] limited social insurance system; funding of the health care system mainly through taxation
[2] dating back to the times as British colony

Source: data gathering by ÖBIG

Before the 1990-ties, the focus of the health systems in Central and Eastern Europe was on the in-patient sector. Nowadays, in line with privatisation and decentralisation in the organisation of health care, more emphasis is put on out-patient primary and secondary care. Physicians make contracts with the social insurance funds; general practitioners act, more or less, as gatekeepers, thus representing the first contact for the patients.

In in-patient care, the Central and Eastern European countries have been reducing the number of acute care beds and the length of stay in hospitals. Nevertheless, the number of acute care beds per 1,000 inhabitants of the new Member States (on average: 5.0) is still higher compared to the “old” Member States (4.3 beds per 1,000 inhabitants, cf. Figure 12.2).

Figure 12.2: Benchmarking – Hospital beds in the new Member States in 2002[1]



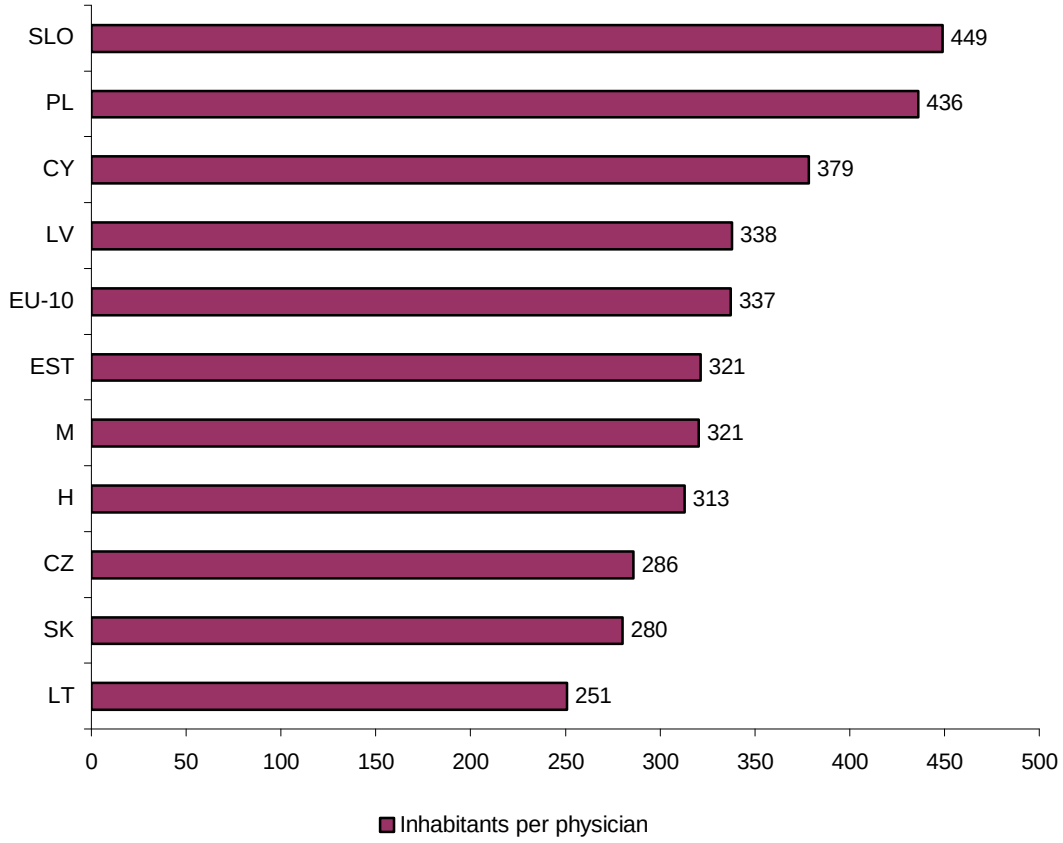
[1] LV – year 2001

Note: data refer to acute care beds

Source: OECD Health Data 2004, EUROSTAT 2005, data gathering by ÖBIG

Looking at the provision with physicians (cf. Figure 12.3), the EU-10-average (337 inhabitants per physician) is very close to the EU-25-average (328 inhabitants per physician). However, there are considerable variations between the new Member States: there are fewer than 300 inhabitants per physician in Latvia, Slovakia and the Czech Republic, whereas in Poland and Slovenia the number of inhabitants per physician is more than 400.

Figure 12.3: Benchmarking – Number of physicians in the new Member States in 2002[1]



[1] LV and M – year 2001

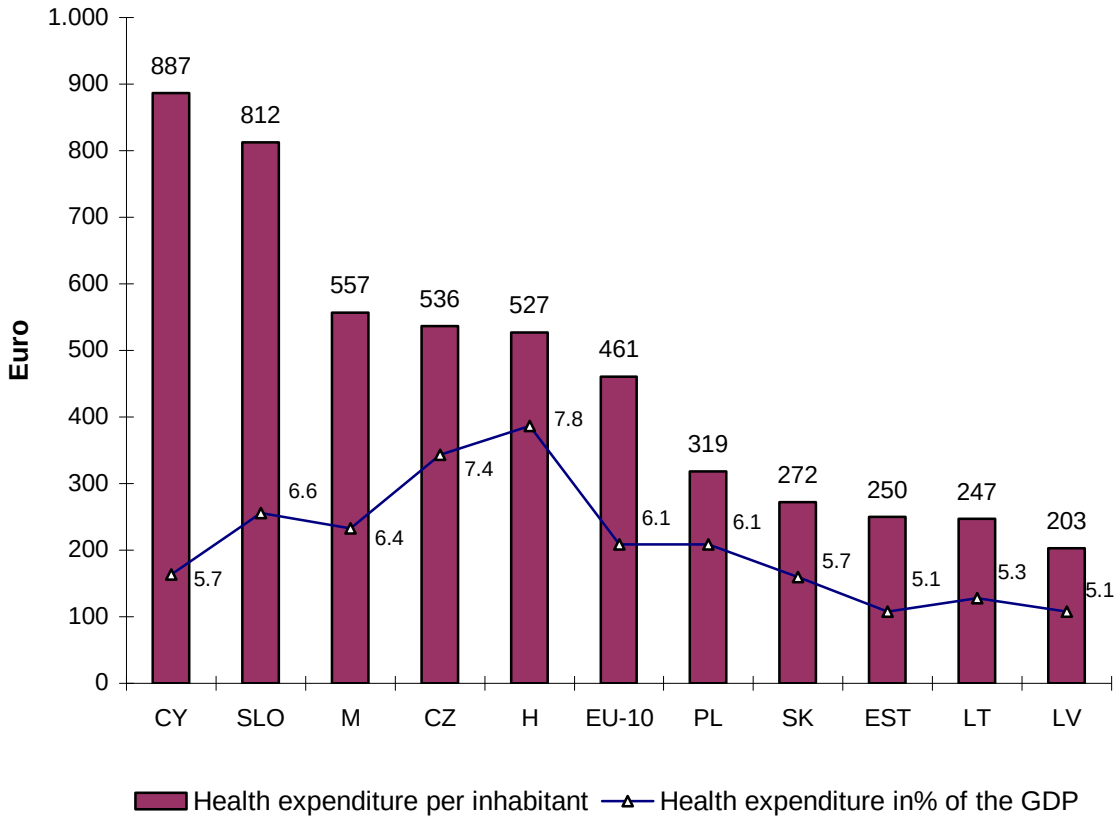
Source: OECD Health Data 2004, EUROSTAT 2005, data gathering by ÖBIG

12.2.2 Financing

As described in chapter 12.2.1, health care in Malta and Cyprus as well as in Latvia is mainly financed through taxation. The other new EU Member States fund health care primarily through health insurance contributions.

Investment in health is lower in the new EU Member States than in the “old” EU countries. The new Member States spend, on average, 6.1 percent of the gross domestic product (GDP) on health, whereas on average in all 25 Member States health expenditure accounts for 7.6 percent of the GDP. Figure 12.4 displays major differences between the ten new Member States. In 2002, Cyprus and Slovenia spent twice as much on health as the new Member States on average (€ 461.-), while in the Baltic States, ranking last, health expenditure amounts to around € 200.- to € 250.-.

Figure 12.4: Benchmarking – Health expenditure in the new Member States in 2002[1]



GDP = Gross Domestic Product

[1] EST – year 2001, M – year 1997

Source: OECD Health Data 2004, EUROSTAT 2005, data gathering by ÖBIG

The new Member States are continuously struggling with the financing of health care. Therefore, cost-containment strategies are on top of the agenda in health reforms.

12.3 Pharmaceutical systems

12.3.1 Market

In the new Member States, market data show a lower performance (average pharmaceutical sales per inhabitant: € 122.- in 2003) compared to the old Member States (EU-25 average: € 233.-), which also reflects disparities in economic prosperity.

Pharmaceutical sales of Cyprus, Slovenia and Hungary are clearly above the average of the new Member States, whereas the Baltic States and Poland rank at the lower end of the scale (cf. Table 12.3). With regard to market expansion, the Czech Republic and Hungary have shown comparably high growth rates in the last few years.

Table 12.3: Benchmarking – Pharmaceutical market of the new Member States in 2003[1]

Member State	Ph. sales / inh. in €	Growth since 2000 (total market)	OTC-sales in % of total market
EST	90.-	38.6%	21.7%
LV	69.-	n.a.	n.a.
LT	100.-	n.a.	n.a.
PL	77.-	14.5%	22.7%
SK	124.-	27.7%	14.5%
SLO	182.-	18.7%[2]	n.a.
CZ	117.-	50.6%	24.4%
H	149.-	64.7%	15.7%
CY	190.-	n.a.	n.a.

inh. = Inhabitants, n.a. = not available, OTC = Over-the-Counter, ph. = pharmaceutical

[1] Data for EST, LV and LT – year 2004; data for CY – year 2002; no data for M available; based on pharmacy retail price, unless Poland – based on ex-factory price

[2] Growth rate from 2000 to 2002

Source: SAM 2005 (EST), LZLA (LV) and ALP (LIT) – data gathering by ÖBIG; AESGP 2004 (other new Member States); calculations by ÖBIG

In value, the OTC market accounts for 15 to 25 percent of the total pharmaceutical market in the new Member States. In the last years, there has been a strong increase in OTC turnover in Slovakia, the Czech Republic and Hungary.

12.3.2 Registration

For pharmaceuticals, Community law primarily focuses on registration and distribution. Reimbursement and pricing is mainly in the hands of the Member States, though provisions of the European Union, such as the Transparency Directive, have had impact on national legislation.

In the 1990-ties, the legal framework for the registration of pharmaceuticals in the EU was modified, basically with the Directive 93/39/EEC, introducing the centralised and decentralised registration procedure. In 2004, further key amendments were made following the so-called Pharmaceutical Review. A comparative overview of the new EU provisions on pharmaceuticals is given in Table 12.4.

Table 12.4: Benchmarking – Legal framework on the registration of pharmaceuticals in the European Union

Subject	Directives before March 2004	New directives
Legal basis	- Directive 93/39/EEC of the Council of 14 June 1993 for the revision of the Directive 65/65/EEC, 75/318/EEC, 75/319/EEC concerning pharmaceuticals - Council Regulation 2309/93/EEC laying down community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products	- Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use[1] - Regulation 726/2004/EC of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2]
EMEA	- Name: European Agency for the Evaluation of Medicinal Products - Registration authority	- Renaming: European Medicines Agency - Strengthening of the position of EMEA (e.g. inclusion of patients' organisations and doctors' organisations in the EMEA Management Board) - Additional tasks: pharmacovigilance, product database, consolidated information to the public
Procedures	- Centralised registration - Decentralised registration (mutual recognition) - National registration	- Centralised registration - Decentralised registration (incl. special mutual recognition procedure for pharmaceuticals already registered in one or more Member States) - National registration plus „compassionate use" for non-authorised pharmaceuticals
Coverage of centralised registration	<u>Centralised registration – obligatory:</u> - bio-technologically produced pharmaceuticals <u>Centralised registration – facultative:</u> - innovative pharmaceuticals	<u>Centralised registration – obligatory:</u> - bio-technologically produced pharmaceuticals - new substances for HIV/AIDS, cancer, neurodegenerative diseases, diabetes - from 2008 on: autoimmune diseases, other virus diseases - pharmaceuticals for rare diseases (orphan drugs) <u>Centralised registration – facultative:</u> - significant innovation or of interest for the Community - other new substances

[1] Directive 2001/83/EC has been replaced by Directive 93/39/EEC

[2] It replaces the Council Regulation 2309/93/EEC

Source: ÖBIG

The Member States are obliged to ratify the 2004 EU provisions within a transitional period of 18 months, so that from 30 October 2005 on, the new regulation will be in act.

Before acceding to the European Union, the candidate countries had to adjust their legislation to EU law. Five of the ten candidates requested a transitional period:

- Cyprus: 31 December 2005
- Lithuania: 31 December 2006
- Malta: 31 December 2006
- Slovenia: 31 December 2007
- Poland: 31 December 2008 (for original products: 31 December 2005)

These transitional periods apply to pharmaceuticals already registered a few years ago.

In the new Member States responsible authorities for registering pharmaceuticals are either Ministries of Health or Medicines Agencies acting as advisory bodies to the Ministries of Health (cf. Table 12.5).

Table 12.5: Benchmarking – Registration of pharmaceuticals in the new Member States in 2005

Member State	Authority	Registered pharmaceuticals in 2005		POM
		Number	Counting	in %
EST	State Agency of Medicines	2,770	incl. different pharmaceutical forms and dosages	n.a.
LV	State Agency of Medicines	4,500	n.a.	71%
LT	State Medicines Control Agency	5,100	n.a.	73%
M	Medicines Authority	2,300[1]	incl. different pharmaceutical forms, excl. pack sizes and dosages	n.a.
PL	Ministry of Health, Office for Registration of Medicinal Products, Medical Devices and Biocides	8,090	incl. different pharmaceutical forms and dosages	73%
SK	State Institute for Drug Control	14,340	incl. different pharmaceutical forms, pack sizes and dosages	88%
SLO	Agency for Medicinal Products and Medical Devices	3,000[3]	excl. different dosages and pack sizes	65%
CZ	State Institute for Drug Control	14,000[2]	incl. different pharmaceutical forms, pack sizes and dosages	57%
H	National Institute of Pharmacy	5,100[3]	n.a.	~ 85%
CY	Ministry of Health	2,210[1]	incl. different pharmaceutical forms and dosages	n.a.

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

[1] in the private sector

[2] year 2003

[3] excluding centralised registered pharmaceuticals

Source: data gathering by ÖBIG

The amount of registered pharmaceuticals varies between 14,000 in the Czech Republic and Slovakia and around 2,000 in Malta and Cyprus. The difference in the number of registered

pharmaceuticals not only depends on the market size, but is also due to different counting methods in each country (cf. Table 12.5).

The authorisation authorities, listed in Table 12.5, are also in charge of the classification of pharmaceuticals according to their prescription status as well as of switches (change from prescription status to OTC). The share of prescription-only medicines is comparably high in the new Member States, and amounts to 70-80 percent of the registered pharmaceuticals (cf. Table 12.5). However, the share of reimbursable pharmaceuticals is much lower: In several new Member States (e.g. Poland, Slovakia, Slovenia and Cyprus), only 30 to 50 percent of the pharmaceuticals are reimbursable.

12.3.3 Reimbursement

With the EU providing overall provisions for reimbursement and pricing of pharmaceuticals, each Member State can freely develop its own legislation within this framework, which results in 25 different pharmaceutical systems in the European Union.

The principal EU framework is represented in the Transparency Directive (Council Directive 89/105/EEC of 21 December 1988, relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems). The aim of this Directive is to guarantee transparent, objective and verifiable criteria for the decision on reimbursement as well as for price setting of pharmaceuticals.

One key requirement of the Transparency Directive regards time limits. Within 90 days, starting on the day the application has been submitted, the national authorities need to decide on:

- the approval of prices,
- the approval of price increases,
- the admission of reimbursable pharmaceuticals to the positive list.

All in all there is a maximum time limit of 180 days for the whole pricing and reimbursement procedure. Any decision shall contain a statement of reasons based upon objective and verifiable criteria.

A positive list includes pharmaceuticals that are reimbursed by public funds (social health insurance or National Health Service). All ten new Member States have positive lists (cf. Table 12.6). However, the size of those lists varies, which is a consequence of budgetary restrictions. Some new Member States include only half or one third of all registered pharmaceuticals in the positive list.

Table 12.6: Benchmarking – Reimbursement of pharmaceuticals in the new Member States in 2005

MS	Authority	Criteria	PI	RPS	PB	Other
EST	Ministry of Social Affairs, State Agency of Medicines, and Health Insurance Fund	reimbursable diseases[1], pharmacoeconomic evaluation (alternative treatment, price development, budgetary restrictions,…)	✓	✓	-	Guideline[2], monitoring of the prescription pattern and feedback, generic substitution
LV	Medicines Pricing and Reimbursement Agency	reimbursable diseases[1], pharmacoeconomic evaluation	✓	✓[3]	✓	Guideline[2], generic substitution
LT	Ministry of Health, Medicines Reimbursement Committee	reimbursable diseases[1], pharmacoeconomic evaluation (incl. international price comparison)	✓	✓	-	Guideline[2], generic substitution
M	Ministry of Health, the Elderly and Community Care	pharmacoeconomic criteria (efficacy, safety, cost-benefit)	✓	-	-	generic substitution[4]
PL	Ministry of Health, Drug Management Team	pharmacoeconomic criteria (efficacy in clinical studies, importance for health care, cost-effectiveness)	✓	✓	-	generic substitution
SK	Ministry of Health, Categorisation Committee	pharmacoeconomic criteria (therapeutic benefit, internal price referencing)	✓	✓	✓	monitoring of the prescription pattern and feedback
SLO	Health Insurance Institute, Drug Committee	pharmacoeconomic criteria (diagnosis, effectiveness)	✓	✓	-	monitoring of the prescription pattern, generic substitution
CZ	Ministry of Health, Drug Categorisation Committee	pharmacoeconomic criteria (incl. international price comparison)	✓	✓	✓	generic substitution
H	National Health Insurance Fund, Technology Evaluation Committee	pharmacoeconomic criteria (incl. international price comparison)	✓	✓	-	generic substitution
CY	Ministry of Health, Pharmacy and Therapeutics Committee	pharmacoeconomic criteria (need of pharmaceuticals, cost-effectiveness)	✓	-	-	-

MS = Member State, PB = Pharmaceutical budget for physicians, PI = positive list, Other = other control instruments for reimbursement, RPS = reference price system

1 list of diagnoses for which pharmaceuticals used in treatment are reimbursed
2 Baltic Guideline for Economic Evaluation of Pharmaceuticals
3 introduced in July 2005
4 allowed in limited scope

Source: data gathering by ÖBIG

In most new Member States, the competent authority for reimbursement is the Ministry of Health or the Ministry of Social Affairs (e.g. Estonia, Lithuania, Slovakia, Czech Republic), or

the health insurance fund (in Slovenia or Hungary). These authorities are often advised by special reimbursement committees, consisting of representatives from ministries and social insurance and in addition members from the pharmaceutical industry, patients' and doctors' organisations and sometimes also distribution actors.

In some Member States (such as Slovakia, Slovenia and the Czech Republic), the pharmaceutical companies may only apply for reimbursement after completion of the pricing procedure. In other countries (such as Estonia and Cyprus), the decision on reimbursement is taken before price setting of reimbursable pharmaceuticals. Reimbursement and pricing may also be interlinked, as is the case in Poland and Latvia, where the decision on reimbursement and on prices for reimbursable pharmaceuticals is taken by the same authority.

The main criteria for reimbursement are pharmacoeconomic ones, such as medical evaluations (therapeutic benefit or improvement, alternative treatments) and economic considerations. Thus, the prices of similar products in the same country (so-called "internal price referencing") or the price of the same pharmaceuticals in reference countries (international price comparison/"external price referencing", e.g. in Lithuania and the Czech Republic) are taken into consideration. In this context, it should be mentioned that in 2002 the Baltic States have adopted the Baltic Guideline for Economic Evaluation of Pharmaceuticals. This guideline specifies the criteria which pharmaceutical companies have to fulfil for the application of reimbursement. For instance, pharmacoeconomic studies should focus on the direct costs and benefits of the pharmaceutical for the health care system. Furthermore, some other countries (e.g. Poland, Hungary) have developed national guidelines on pharmacoeconomic evaluations.

All new Member States in Central and Eastern Europe have introduced a reference price system. Reference price systems cover reimbursable pharmaceuticals, which are clustered on ATC-5-level (products with same active ingredient) or on ATC-4-level (therapeutically similar products). For each group a reference price is set as the basis for reimbursement; patients have to pay the difference between the reference price and the actual retail price of a product.

A prerequisite for reference price systems is a more or less high number of interchangeable pharmaceuticals on the market in order to cluster identical or similar products. Thus, reference price systems have usually developed in countries with a higher number of generics (or non-bioequivalent copy-products) which is the case in the new Member States. In most of the new Member States generic substitution is permitted (cf. Table 12.6).

Furthermore, in some new Member States, such as Latvia, Slovakia and the Czech Republic, pharmaceutical budgets for physicians were introduced. In other countries (e.g. Estonia and Slovenia), the prescription pattern of physicians is monitored.

Table 12.7: Benchmarking – Co-payments in the new Member States in 2005

Member State	Prescrip-tion fee	Patient co-payment for reimbursable pharmaceuticals[1]	
		Criteria	Co-payment rates[2]
EST	€ 1.28	diagnosis; social criteria	0%, 25% (or 10%[3]), 50%
LV	-	diagnosis	0%, 10%, 25%, 50%
LT	-	diagnosis ("list A"), social criteria ("list B")	"list A": 0%, 10%, 20%, and 50% "list B": 0% and 50%
M	-	selected population groups[4]	0%
PL	€ 0.76 / € 1.20[5]	social criteria, severity of the disease	0%, 30%, 50%
SK	€ 0.48	availability of similar pharmaceuticals (reference price system)	no fixed rates[6]
SLO	-	social criteria, severity of the disease	0%, 25% and 75%
CZ	-	availability of similar pharmaceuticals (reference price system)	no fixed rates[6]
H	-	social criteria, severity of the disease	0%, 10%, 30%, 50%
CY	-	social criteria	0% and 50%

[1] around 30 to 50 percent of all pharmaceuticals are reimbursable

[2] with regard to the reimbursement / reference price

[3] for children under 10 years, disabled people, people over the age of 63

[4] selected population groups (income threshold, certain diseases or handicaps; certain professions) have access to reimbursable pharmaceuticals

[5] € 0.76 for pharmaceutical specialities, € 1.20 for magistral preparations – pharmaceuticals on the basic list

[6] co-payment results from the difference between the retail price of the pharmaceutical and the reimbursement price of a similar product in the same group (so-called reference price)

Source: data gathering by ÖBIG

In the new Member States only some pharmaceuticals on the positive list are fully reimbursed. For the other pharmaceuticals on the list lower reimbursement rates apply. The reimbursement rates are the counter-part of the co-payment rates shown in Table 12.7. The rates usually depend on the diseases or on social criteria. In the three Baltic States, the reimbursement level is linked to the diagnosis ("list of reimbursable diseases"), which means that one pharmaceutical used in the treatment of different diagnoses may have different reimbursement rates (e.g. in Estonia, diclofenac is reimbursed at 100 percent in oncology, at 75 percent in rheumatoid arthritis and at 50 percent in all other cases).

Specific population groups, such as children, elderly people, families with low income and/or patients with certain diseases or disabilities, are exempted from co-payment or granted lower co-payment rates.

In general, co-payment is a very sensitive issue in the new Member States. In former times, all pharmaceuticals were freely dispensed in Central and Eastern Europe. By now, only a few countries (i.e. Estonia, Poland – only for some pharmaceuticals, Slovakia) have introduced prescription fees, thus explicitly asking patients to share cost. However, co-payments and

private expenditure on pharmaceuticals have increased to a major extent, as even reimbursable pharmaceuticals (30-50 percent of the registered pharmaceuticals) are only reimbursed up to the reimbursement / reference price. For non-reimbursable pharmaceuticals patients have to pay the full price. All these developments pose concerns with regard to the affordability and accessibility of medicines in the new Member States.

12.3.4 Pricing

In general, there are three options to set prices:

- statutory pricing (including price control)
- negotiations between pharmaceutical companies and the state, and
- free pricing for pharmaceutical companies.

This usually regards prices at manufacturer level (ex-factory price) as well as at wholesale level (pharmacy purchase price). Wholesale and pharmacy mark-ups can also be regulated by the state or may be freely negotiated between the actors in the pharmaceutical market.

As shown in Table 12.8, in the new EU Member States statutory pricing for reimbursable pharmaceuticals is the common pricing procedure; with Slovenia applying statutory pricing at wholesale level for all pharmaceuticals. For non-reimbursable pharmaceuticals, there is free pricing in most new Member States.

In Malta and Cyprus, the public and the private system are to be distinguished. In the public system reimbursable pharmaceuticals are dispensed to eligible patients in facilities of public health care, whereas in the private sector only non-reimbursable pharmaceuticals are sold in pharmacies. In the public system pharmaceuticals are purchased by the state via tendering, while in the private sector the manufacturers can freely determine the prices. However, there is statutory pricing for pharmaceuticals at the wholesale level in Cyprus.

The competent authority for pricing is, in some countries, the same authority as for reimbursement. This authority is either the Ministry of Health or the Ministry of Social Affairs, the Social Insurance, or the State Agency of Medicines (as shown in Table 12.8). As mentioned earlier, due to the Transparency Directive a basic framework (such as application of objective, verifiable criteria, time limits) needs to be respected in the pricing procedure.

Table 12.8: Benchmarking – Regulations on pharmaceutical prices in the new Member States in 2005

MS	Reg.	Authority	Pricing procedure	Criteria[1]	Level	Scope
EST	✓	Ministry of Social Affairs, Health Insurance Fund	statutory pricing after negotiations	price-volume agreements	ex-factory price	reim. ph.
LV	✓	Medicines Pricing and Reimbursement Agency	statutory pricing after negotiations	internal and international price comparison	PPP	reim. ph.
LT	✓	Ministry of Health, Medicines Reimbursement Committee, Department of Pharmacy	statutory pricing after negotiations	internal and international price comparison	CIP	reim. ph.
M	-	-	free pricing	-	ex-factory price	private system[2]
PL	✓	Ministry of Health, Drug Management Team	statutory pricing after negotiations	internal and international price comparison	PPP	reim. ph.
SK	✓	Ministry of Health	statutory pricing	international price comparison	PRP	reim. ph.
SLO	✓	Agency for Medicinal Products and Medical Devices	statutory pricing (price control)	international price comparison	PPP	all ph.
CZ	✓	Ministry of Finance	statutory pricing	international price comparison	ex-factory price	reim. ph.
H	✓	National Health Insurance Fund	price notification (negotiations)	international price comparison	ex-factory price	reim. ph.
CY	✓	Ministry of Health	statutory pricing	international price comparison (private system); best tender (public)	PPP[3]	private and public system[2]

CIP = Cost, Insurance and Packaging, MS = Member State, ph. = pharmaceutical, PPP = Pharmacy Purchase Price, PRP = Pharmacy Retail Price, Reg. = regulation existing, reim. = reimbursable

[1] relating to imported pharmaceuticals; for locally produced pharmaceuticals usually production cost are taken into consideration, on which a profit mark-up is granted.

[2] private system: dispensing of pharmaceuticals through pharmacies; public system: purchase via tendering on behalf of the Ministry of Health, dispensing of pharmaceuticals in facilities of the public health care system

[3] for imported pharmaceuticals; for locally produced pharmaceuticals the ex-factory price continues to be fixed

Source: data gathering by ÖBIG

Table 12.9: Benchmarking – Regulation of wholesale and pharmacy mark-ups and VAT in the new Member States in 2005

Member State	Wholesale mark-up			Pharmacy mark-up			VAT	
	Reg.	Content	Scope	Reg.	Content	Scope	Ph.	Standard
EST	✓	regress. mark-ups	all ph.	✓	regress. mark-ups	all ph.	5%	18%
LV	✓	linear mark-up and regress. mark-ups	all ph.[1]	✓	regress. mark-ups	all ph.[1]	5%	18%
LT	✓	regress. mark-ups	reim. ph.	✓	regress. mark-ups	reim. ph.	5%	18%
M	✓	linear mark-up	in the private system[2]	✓	linear mark-up	in the private system[2]	0%	0%
PL	✓	linear mark-up	reim. ph.	✓	regress. mark-ups	reim. ph.	7%	22%
SK	✓	linear mark-up	all ph.[1]	✓	linear mark-up	all ph.[1]	19%	19%
SLO	-	-	-	✓	fee-for-service	all ph.	8.5%	20%
CZ	✓	linear mark-up[3]	all ph.	✓	linear mark-up[3]	all ph.	5%	19%
H	✓	regress. mark-ups	all ph.	✓	regress. mark-ups	all ph.	5%	25%
CY	-	-	-	✓	linear mark-up	in the private system[2]	0%	0%

ph. = pharmaceuticals, regress. = regressive, reg. = regulation existing, reim. = reimbursable

[1] different regulations for reimbursable and non-reimbursable pharmaceuticals; in Slovakia since July 2005 further linear wholesale and pharmacy mark-ups for additional product groups (hospital-only pharmaceuticals, vaccinations, etc.)

[2] private system: distribution of pharmaceuticals through wholesale and pharmacies; public system: dispensing of pharmaceuticals in facilities of the public health care system, with no mark-ups granted

[3] common linear mark-up for wholesale and pharmacy

Source: data gathering by ÖBIG

Most new Member States determine the prices at manufacturer level. However, Cyprus (for imported pharmaceuticals), Latvia, Poland and Slovenia set the pharmacy purchase prices. As the wholesale mark-ups are not regulated in Slovenia and Cyprus, the pharmaceutical companies can freely determine the ex-factory prices for all pharmaceuticals (reimbursable and non-reimbursable). In Latvia and Poland, however, the wholesale mark-ups are set by the state and the ex-factory prices are thus indirectly regulated. A similar situation can be found in Slovakia, where in 2004 “the ex-factory prices were deregulated” and now the pharmacy retail prices are determined. Through fixed wholesale and pharmacy mark-ups there is also an indirect regulation of the ex-factory prices (so-called “virtual ex-factory price”).

As it is shown in Table 12.9, which gives an overview on the current regulations of the wholesale and pharmacy mark-ups, Slovenia and Cyprus are the only new Member States where the wholesale mark-up is the outcome of negotiations between manufacturers / importers and wholesalers. The rest of the new Member States have regulations on maximum wholesale mark-ups – either linear or regressive schemes.

In all new EU Member States pharmacy mark-ups are regulated, with the Czech Republic having a common mark-up for pharmacies and wholesalers and Slovenia a fee-for-service remuneration for pharmacies. In most Central and Eastern European Member States retail prices, especially in the OTC market, differ between pharmacies, as the wholesale and pharmacy mark-ups are not fully utilised. As a consequence patients may shop around for the cheapest product.

Table 12.9 also displays the value-added tax (VAT) for pharmaceuticals in comparison to the standard rate. In most new Member States the VAT on pharmaceuticals is five percent, which is the required minimum VAT on pharmaceuticals in the EU. Only Malta and Cyprus have no VAT on pharmaceuticals by now: Malta will introduce a five percent VAT on pharmaceuticals after a transitional period until 2010, while Cyprus has so far no plans to charge a VAT.

12.3.5 Distribution

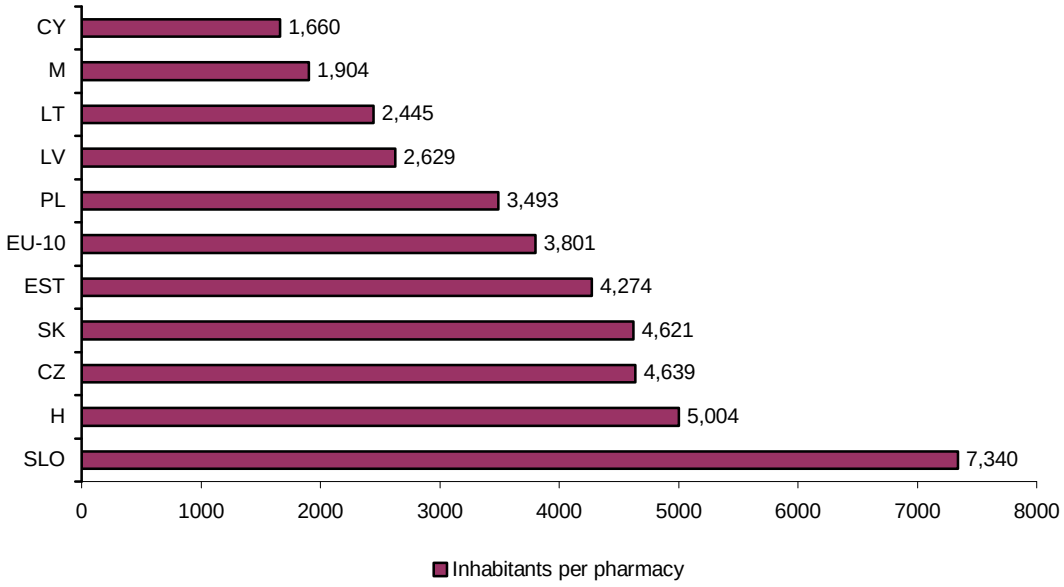
Usually, pharmaceuticals, being either locally produced or imported, are delivered by wholesalers to the pharmacies, which dispense them to the patients. Hospital-only pharmaceuticals are provided by pharmaceutical companies, importers, and wholesalers to hospitals mainly for internal use.

In Malta and Cyprus, the state purchases pharmaceuticals via tendering and dispenses them in publicly owned health centres, out-patient departments and dispensaries of hospitals. The common distribution channel (as explained above) only exists in the private sector in these countries. Also in other new Member States (e.g. in the Baltic countries), expensive pharmaceuticals used in hospitals are centrally purchased on the basis of tendering.

Before the political change at the end of the 1980-ties, the pharmaceutical industry in Central and Eastern Europe had been dominated by locally producing generic companies. In the years after the transition many multinational pharmaceutical companies entered these markets.

Importers and wholesalers (often being the same companies) play an important role in distribution. Their number varies with the size of the market: For instance, in the Czech Republic, there are around 160 wholesalers, whereas in Latvia and Slovenia there are about 10. However, several wholesalers have gone bankrupt. Meanwhile the pharmaceutical wholesale has consolidated. Now a few wholesale companies dominate the market, as it is the case for the leading wholesaler Tamro in the three Baltic States.

Figure 12.5: Benchmarking – Provision with pharmacies in the new Member States in 2005[1]



[1] LV and LT – year 2004, SK – year 2002

Source: data gathering by ÖBIG

The main dispensaries of pharmaceuticals are pharmacies. In the new Member States, there is, on average, one pharmacy per 3,800 inhabitants (cf. Figure 12.5). Thus, the provision with pharmacies in the new EU Member States is more dense than in the EU-25 (around one pharmacy per 5,400 inhabitants).

Additionally, Estonia, Poland, Slovenia and the Czech Republic have other dispensaries such as drugstores, outlets and pharmacy stations which usually are only allowed to sell a limited range of products (mostly OTC products). Malta and Cyprus run dispensaries in public health centres and out-patient departments. In the new Member States, self-dispensing doctors are not very common (e.g. they can be found in rural areas in Hungary).

In general, a trend towards liberalisation in the pharmacy sector has been observed (in particular in Estonia), which is reflected in the authorisation of multiple ownership and the establishment of pharmacy chains.

12.3.6 Development

Central and Eastern European Member States have seen major changes in their health care systems; to name a few: change to social insurance systems, a stronger focus on primary care, introduction of family doctors.

In pharmaceutical systems, the following developments have been observed:

- New players

  In the early 1990-ties a trend of liberalisation and privatisation in the pharmaceutical market in the Central and Eastern European new Member States could be noticed. This especially affected the distribution sector, which had previously been in the hands of the state. The local producers (generic companies) had to face competition of international research-oriented pharmaceutical companies. Several new wholesalers emerged, however, some companies had to close after some years.

  At the level of competent authorities, several new EU Member States established new structures and institutions, for instance Medicines Agencies (e.g. Latvia, Slovenia).

- Accession to the European Union

  In preparation for the accession to the EU, candidate countries have been harmonising their national legislation with the „Acquis Communitaire“ (Community law). In the pharmaceutical sector it especially concerns registration and distribution of pharmaceuticals. Furthermore, reimbursement and pricing, mainly in the hands of the Member States themselves, has to take into account the EU framework (e.g. Transparency Directive).

- Cost-containment measures

  All new EU Member States face the problem of financing the provision of safe and effective pharmaceuticals to the population. Therefore the governments of the new Member States decided to implement cost-containment measures, such as co-payments on pharmaceuticals (e.g. prescription fees) or exclusion from reimbursement. This caused vivid discussion in the new Member States in Central and Eastern Europe, as in former times patients were receiving all health services for free.

The new Member States are facing a dilemma: on the one hand they have to live up to the expectations of the population to offer them effective and innovative pharmaceuticals; on the other hand there are financial restraints. Therefore the new Member States feel obliged to constantly set reform measures. For instance, Slovakia has been continuously renewing its legislation of the pharmaceutical sector since 2003.

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ANNEX

Key indicators

Indicators[1]	Estonia	Latvia	Lithuania	Malta	Poland	Ø EU-10[2]	Ø EU-25[3]
Inhabitants	1.4 mill. (2004)	2.3 mill. (2004)	3.5 mill. (2003)	0.4 mill. (2004)	38.4 mill. (2002)	-	-
Life expectancy women	77.1 years (2002)	76 years (2002)	77.5 years (2002)	81.0 years (2002)	78.7 years (2002)	78.5 years	80.2 years
Life expectancy men	65.3 years (2002)	64.8 years (2002)	66.3 years (2002)	75.9 years (2002)	70.4 years (2002)	70.2 years	73.4 years
GDP / inhabitant in €	5,931 € (2003)	4,233 € (2003)	4,699 € (2003)	10,722 € (2003)	5,265 € (2002)	7,825 €	18,987 €
Health expenditure / inhabitant in €	250 € (2001) [4]	203 € (2002) [5]	247 € (2003) [6]	557 € (1997) [7]	319 € (2002)	461 €	1,505 €
Hospital beds / 1,000 inhabitants	4.5 beds (2002)	5.7 beds (2001)	6.0 beds (2002)	3.4 beds (2003)	4.6 beds (2002)	5.0 beds	4.3 beds
Inhabitants / physician	321 inh. (2002)	338 inh. (2001)	251 inh. (2002)	321 inh. (2001)	436 inh. (2002)	337 inh.	328 inh.
Inhabitants / pharmacy[8]	4,274 inh. (2005)[9]	2,629 inh. (2004)[10]	2,445 inh. (2004)[11]	1.904 inh. (2005)[12]	3,493 inh. (2005)[13]	3,801 inh.	5,415 inh.
Conversion rate Country currency equals € [14]	100 EEK 6.3912 €	10 LVL 15.0331 €	10 LTL 2.8961 €	10 MTL 23.3645 €	100 PLN 22.091 €	-	-

GDP = gross domestic product, inh. = inhabitants, mill. = million

Sources: [1] OECD Health Data 2004; Eurostat 2005, unless stated otherwise

[2] the EU-10 average was calculated on the basis of the available data

[3] the EU-25 average was calculated on the basis of the available data

[4] Haigekassa 2005

[5] WHO Collaborating Centre; data gathering by ÖBIG

[6] Health Information Centre WHO Collaborating Centre; data gathering by ÖBIG

[7] European Observatory on Health Care Systems 1999a

[8] community pharmacies (i.e. open to the public), excl. other dispensaries

[9] SAM 2005

[10] VM; data gathering by ÖBIG

[11] VVKT 2004

[12] Ministry of Health (Malta); data gathering by ÖBIG

[13] GIF; data gathering by ÖBIG

[14] Average annual rate of the year 2004 by the ECB

Key indicators - continuation

Indicators[1]	Slovakia	Slovenia	Czech Rep.	Hungary	Cyprus	Ø EU-10[2]	Ø EU-25[3]
Inhabitants	5.4 mill. (2002)	2.0 mill. (2004)	10.2 mill. (2002)	10.2 mill. (2002)	0.7 mill. (2003)	-	-
Life expectancy women	77.8 years (2002)	80.5 years (2002)	78.7 years (2002)	76.7 years (2002)	81.0 years (2001)	78.5 years	80.2 years
Life expectancy men	69.9 years (2002)	72.7 years (2002)	72.1 years (2002)	68.4 years (2002)	76.1 years (2001)	70.2 years	73.4 years
GDP / inhabitant in €	4,774 € (2002)	12,319 € (2003)	7,239 € (2002)	6,782 € (2002)	16,284 € (2003)	7,825 €	18,987 €
Health expenditure / inhabitant in €	272 € (2002)	812 € (2003)[15]	536 € (2002)	527 € (2002)	887 € (2002)[16]	461 €	1,505 €
Hospital beds / 1,000 inhabitants	5.5 beds (2002)	4.1 beds (2002)	6.5 beds (2002)	5.9 beds (2002)	4.0 beds (2002)	5.0 beds	4.3 beds
Inhabitants / physician	280 inh. (2002)	449 inh. (2002)	286 inh. (2002)	313 inh. (2002)	379 inh. (2002)	337 inh.	328 inh.
Inhabitants / pharmacy[8]	4,621 inh. (2002)[17]	7,340 inh. (2005)[18]	4,639 inh. (2005)[19]	5,004 inh. (2005)[20]	1,660 inh. (2005)[21]	3,801 inh.	5,415 inh.
Conversion rate Country currency equals € [14]	100 SKK 2.4986 €	1,000 SIT 4.1826 €	100 CZK 3.1357 €	1,000 HUF 3.9736 €	10 CYP 17.1866 €	-	-

Czech Rep. = Czech Republic, GDP = gross domestic product, inh. = inhabitants, mill. = million

Sources - continuation:

[15] Republic of Slovenia, Ministry of Finance 2005

[16] European Observatory on Health Systems and Policies 2004a

[17] European Observatory on Health Systems and Policies 2004d

[18] LEK-ZBOR; data gathering by ÖBIG

[19] Ceská Lékárnická Komora; data gathering by ÖBIG

[20] MGYK; data gathering by ÖBIG

[21] Ministry of Health of the Republic of Cyprus; data gathering by ÖBIG

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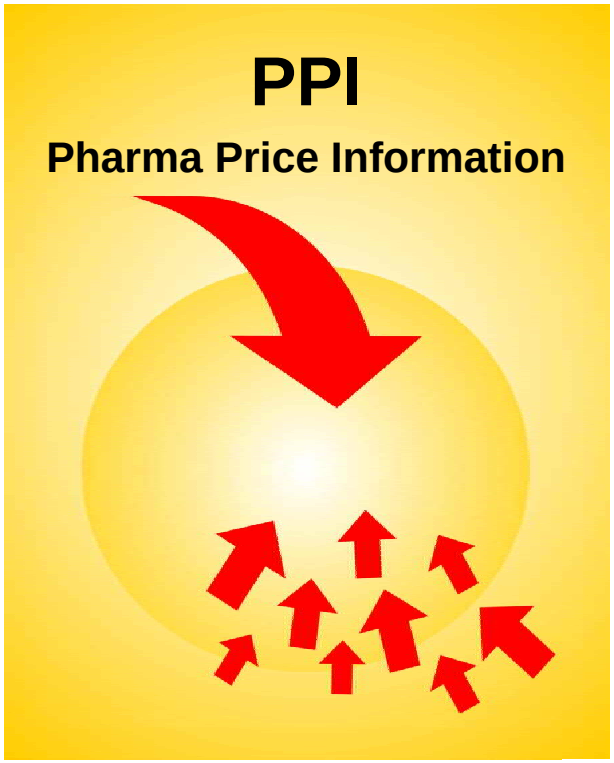

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Pharmaceutical Pricing and Reimbursement Information

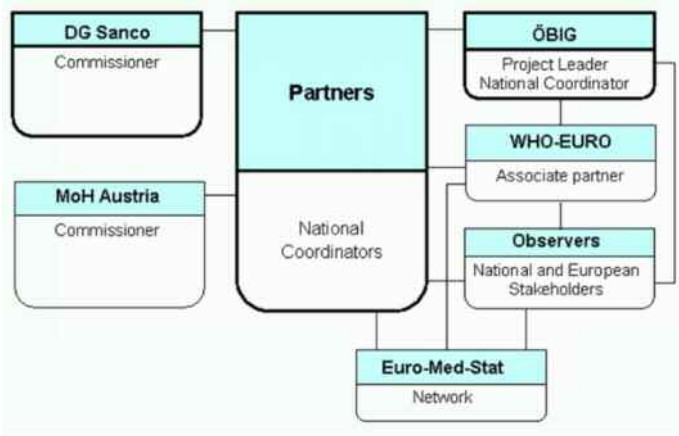
PPRI project

The pricing and reimbursement of pharmaceuticals is a national issue. Consequently there are 25 pharmaceutical pricing and reimbursement systems in the enlarged European Union which often differ greatly. Therefore, the objective of the PPRI project is to develop a network of authorities and institutions in order to improve information and knowledge about the pharmaceutical systems in the enlarged Europe, by providing a comprehensive report with 25 country reports on the Member States and a comparative analysis.

Project organisation

The PPRI project is commissioned and funded by the European Commission, Health and Consumer Protection Directorate-General and co-funded by the Federal Ministry for Health and Women's Issues, Austria. The project team consists of the main partner (ÖBIG / Austrian Health Institute), an associate partner (WHO-EURO) and a network of other partners from a large range of Member States of the enlarged Europe, and Bulgaria.

The PPRI project is designed to run from April 2005 to spring 2007. The results will be disseminated during a **Spring 2007 conference in Vienna**.



Project description

The PPRI project is subdivided into 6 work packages, which are linked to the specific objectives of the study.

Specific objective of the PPRI project:	Work package(s):	Deliverables of the PPRI project:
Strenghtening the networking of institutions in the field of pharmaceuticals in Member States	WP 1 'Coordination'	Good communication and cooperation within the project, for delivering a project of high quality on time
	WP 2 'Dissemination'	A website (http://ppri.oebig.at) and a conference at the end of the project (Spring 2007, Vienna)
Assessing the information needs concerning pharmaceutical pricing and reimbursement	WP 3 'Assessment'	A questionnaire to be used in the interviews, with a list of key information and data to be collected
Collection, reporting and analysis of information on pricing and reimbursement in Members States	WP 4 'Survey'	Pharma Profiles (=country reports on the pharmaceutical pricing and reimbursement systems) of the EU Member States
Deleveloping indicators for comparative analysis	WP 5 'Development of comparable indicators'	A list of indicators for analysing pricing and reimbursement in a comparative way
Benchmarking pharmaceutical pricing and reimbursement in the enlarged Europe	WP 6 'Comparative analysis'	Benchmarking of pricing and reimbursement in the Member States in a draft report
Dissemination of project results	WP 2 'Dissemination'	International publications and organisation of the Spring 2007 conference

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ISBN 3-85159-081-3