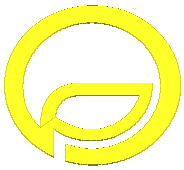

Pharmaceutical Pricing and Reimbursement Information

HUNGARY

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Pharmaceutical Pricing and Reimbursement Information project

HUNGARY

Final Version

Before the health care reforms
(according to the legislative environment of 2004-2006)

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Acknowledgments for contributions

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Executive summary

Background

The Hungarian health insurance system can be considered a Bismarckian-type social insurance system. The health care reforms in the 1990s transformed the Hungarian health care system into a split purchaser–provider contract model. The national health system is mostly based on Law No. LXXXIII of 1997. There are two main sources of funding, generating a mixture of tax and social insurance-based funds. In 2004 the total health expenditure (THE) was 8.47% of the gross domestic product (GDP), of which 71.79% was public and 28.21% private expenses.

Three main actors operate in the health care system. The Ministry of Health (Egészségügyi Minisztérium, EüM / MoH) has a dominant role (managing) and it is responsible for the overall pharmaceutical policy. The Ministry of Finance (Pénzügy Minisztérium, PM / MoF) manages the Health Insurance Fund (Egészségbiztosítási Alap, E. Alap), which is the main pharmaceutical sourcing channel, and the National Health Insurance Fund Administration (Országos Egészségbiztosítási Pénztár, OEP) finances the recurrent costs of health services and provides cash benefits such as sickness allowances. Further duties include the public procurement/tendering of pharmaceuticals, pricing procedures, and monitoring (e.g. of consumption). The low number of actors suggests that the Hungarian health system is centralised in structure.

The level of coverage is almost 100%, because most of the social groups that do not pay health insurance contributions (children, pensioners, unemployed people, etc.) are also covered by the State. There are no differences according to income level or age in the health care services provided.

Public out-patient care is remunerated by the National Health Insurance Fund Administration (OEP). The main financing method is similar to the German Point System.

In terms of hospital remuneration, two different types of care can be differentiated, with different financial approaches: acute and chronic care. Acute in-patient care is financed through the implementation of a system similar to the diagnosis-related groups (DRGs) (Hungarian “homogenous disease groups” (HBCS)). At chronic level, daily payments are applicable, weighted by different variables (e.g. hospice, rehabilitation).

Pharmaceutical system

The legal basis of the national pharmaceutical system is mostly based on Law No. XCV of 2005 on pharmaceuticals for human use and on the amendment of other regulations related to pharmaceuticals.

The reimbursement policy is regulated by Decree of the Ministry of Health 32/2004 on the criteria for inclusion of registered pharmaceuticals and foods satisfying particular dietary requirements into social insurance coverage, and on altering coverage or reimbursement status.

The most relevant actors include the Hungarian Ministry of Health (EüM / MoH), responsible for the regulatory framework in terms of pharmaceuticals; the National Health Insurance Fund Administration (OEP), advised by the Technology Appraisal Committee (TÉB), which is responsible for the reimbursement of pharmaceuticals; and the National Institute of Pharmacy (Országos Gyógyszerészeti Intézet, OGYI), acting as a medicines agency.

The pharmaceutical industry was an important branch of industry in previous decades. In the 1990s the Hungarian pharmaceutical industry was privatised and is nowadays mainly in the hands of foreign investors. The biggest national producer is Richter Gedeon, which also dominates the pharmaceutical market in terms of sales, followed by Egis. The pharmaceutical production in Hungary amounted to HUF 356,820 Mio. / € 1,407.46 Mio. in 2003. The local pharmaceutical industry covers approximately one third of the Hungarian market in value, and more than half of the pharmaceutical market in volume. The domestic share of pharmaceutical sales has constantly declined since 1990 [MAGYOSZ, 2005].

There are two main distribution channels. In the case of in-patient care the usual method is as follows: after the manufacturer level (production or import of the pharmaceutical) we find the wholesale level; hospitals buy the required pharmaceuticals directly from wholesalers and the patients are at the end of the distribution channel (cf. Figure 2.1).

In out-patient care, after the wholesale level there is retail trade. Patients can buy pharmaceuticals directly from the pharmacies.

The wholesale and pharmacy mark up is regulated by Decree of the Ministry of Health 19/2001 on the commercial price mark up of pharmaceuticals.

In 2004, expenditure on pharmaceuticals (HUF 458 billion) exceeded the amount that the social health insurance (SHI) had spent on in-patient care (HUF 364 billion). As a share of gross domestic product (GDP) the pharmaceutical spending totalled 2.1% (2002), ranking Hungary in third place compared within the European informant Organisation for Economic Co-operation and Development (OECD) countries. One third (32.8%, 2005) was financed by private households and two thirds through the social health insurance (SHI) and national government budget.

Pricing

In Hungary, there is a system of free pricing for all pharmaceuticals regardless of their prescription status (prescription-only medicine(s) (POM) or over-the-counter (OTC)) at manufacturer level (Law No. LXXXVII of 1990 on the establishment of prices implemented in the present system). Thus, pharmaceutical companies are free to set the prices of non-reimbursable pharmaceuticals at their will. There is no separate price-setting procedure. The legal framework for pricing is set out in Decree of the Ministry of Health 32/2004, together with the reimbursement-related regulation.

There is no difference in pricing mechanism between the different types of pharmaceuticals: it rather depends on the type of reimbursement and the level of pharmaceutical pricing system (wholesale/retail price). Decisions on pricing are not made at any level; only the price margins (the retail and wholesale margins) are regulated by Decree of the Ministry of Health 19/2001. At

manufacturer level, prices (for pharmaceuticals applying for inclusion in the reimbursement lists) may be negotiated with the National Health Insurance Fund Administration (OEP), and this procedure is regulated statutorily.

Where innovative pharmaceuticals are concerned companies have to indicate external prices in their reimbursement application. The manufacturer price of a newly included preparation containing (an) active ingredient(s) that has not yet been granted reimbursement cannot be higher than the lowest existing manufacturer price in the countries listed in the application form. Internal price referencing is also available, mostly among the reimbursed generics.

In the Hungarian system both a percentage and the fixed amount are used. The wholesalers and the pharmacists are remunerated via regressive mark ups (cf. Table 3.4 and Table 3.5, respectively), and these regressive mark ups are regulated by Decree of the Ministry of Health 19/2001. The law regulates all pharmaceuticals. The average margin, assessed by the turnover data in 2005, was 19.46%.

In the last few years there have been several changes in the value-added tax (VAT) rates in Hungary, with the standard value-added tax (VAT) rate currently at 20%. For pharmaceuticals (human registered medicines) a 5% rate is applied, which is the minimum level allowed for reduced value-added tax (VAT) in the European Union (EU) according to the VAT Directive.

There are no rebates, margin cuts, or price reviews in Hungary, but both price-related and volume-related cost-containment measures have been set; these include price stops/freezes; price–volume agreements and manufacturer discounts/rebates, as well as agreements binding prices of imported pharmaceuticals to exchange rate fluctuations.

Reimbursement

The final decision on the inclusion of pharmaceuticals in the positive list is made by the Head of the Pharmaceuticals Department (in the case of hospital-only medicine(s) (HOM)), by the Head of Department of Curative-Preventive Provisions of the National Health Insurance Fund Administration (OEP) based on the pre-expertise of the Transparency Secretariat, and by the Health Technology Assessment Institute and the Technology Appraisal Committee (TÉB). At the end of the appeal procedure (cf. 4.2.1) a Superior Committee (made up of delegates of the Ministry of Health (EüM / MoH), the National Health Insurance Fund Administration (OEP), the National Institute of Pharmacy (OGYI), etc.) has the right to make the final decision. During these procedures the pricing and reimbursement policies are always interlinked. Decree of the Ministry of Health 32/2004 contains the exact terms of the reimbursement and pricing criteria.

There is a positive as well as a negative list, both of which are registered by the National Health Insurance Fund Administration (OEP). If the market authorisation holder of the reference preparation cannot show that it can meet its supply obligation for three consecutive months, the National Health Insurance Fund Administration (OEP) will delist the preparation from reimbursement and that preparation cannot be included in reimbursement procedures for two years effective from the next setting of the reference price. The main determinants of inclusion are the following: product-specific criteria, economic criteria and all of the patient-specific and disease criteria.

Decree of the Ministry of Health 32/2004 defines the different categories. Pharmaceuticals on the positive list are generally reimbursed in kind, at rates of 90%, 70% and 50% (so-called normative reimbursement), as a percentage of the pharmacy retail price (PRP). Normative reimbursement accounts for approximately one quarter of the National Health Insurance Fund Administration's (OEP) pharmaceutical expenditure (PE). Furthermore, expensive pharmaceuticals with approved special indications are reimbursed at 100%, or 90% if prescribed by a specialist or on behalf of the written recommendation of a specialist, otherwise they fall under the lower reimbursement levels of normative reimbursement (preferential reimbursement category). The list of disease conditions is defined by the Ministry of Health (EüM / MoH), along with the Ministry of Finance (PM / MoF). In addition, there is special reimbursement for people with low income, and pharmaceuticals can be also reimbursed on behalf of individual applications. In addition, the National Health Insurance Fund Administration (OEP) provides very expensive pharmaceuticals through a special budget; these pharmaceuticals are purchased centrally by the National Health Insurance Fund Administration (OEP) via tenders (e.g. for haemophilia).

In Hungary two types of reference price system are in operation (based on active ingredient(s) and on therapeutic group(s)) under the supervision of the Pharmaceutical Department of National Health Insurance Fund Administration (OEP). The legal basis is the same as that which regulates the whole reimbursement system, namely Decree of the Ministry of Health 32/2004.

Fixed co-payments are not relevant in Hungary. However, percentage co-payments are applicable for all categories of reimbursed pharmaceutical (cf. 4.2.2). The basic principle is that the patient has to pay the remaining percentage of the price. In the case of the 100% reimbursement category (EÜ100), the patient does not have to pay (all costs are paid by the National Health Insurance Fund Administration (OEP)). At the time of writing, neither minimum co-payment, nor annual or monthly out-of-pocket maximum payments, nor deductibles, are used.

There is a difference between reimbursement in the in-patient and out-patient sectors. The main difference is the financing source. In hospitals, the pharmaceuticals are financed through diagnosis-related groups (DRGs).

The reference price system has been operating since 2004 (Decree of the Ministry of Health 32/2004). Hungary started this programme at Anatomic Therapeutic Chemical classification ATC-5 level. Looking at the starting date, it seems that the number of these pharmaceuticals has been growing significantly. There were three main periods when claw-backs were in use: (1) Global Reimbursement Volume Contract, Sept-Dec 2003; Price cuts, Apr-July 2004; and a 2.5-year agreement, from July 2004 to December 2006.

Rational use of pharmaceuticals

Doctors have access to updated treatment guidelines and the national formulary. These are published on the official home page of the National Health Insurance Fund Administration (OEP) and in the Health Bulletin.

Marketing directives, as stated in Directive 2001/83/EC, were implemented in Hungary through acts and regulations. Under certain conditions (e.g. for over-the-counter (OTC) or curative products with name and international name, examples of proper use, giving a brief, etc.) Hungarian

law allows the advertising of over-the-counter (OTC) products in all media except children's channels (Decree of the Ministry of Health 64/2003). Requirements for the labelling of pharmaceuticals and handouts for patients in packs are also regulated (Decree of the Ministry of Health 30/2005).

There have not yet been any measures implemented to control the prescribing and use of pharmaceuticals.

In 2004, the National Institute for Strategic Health Research (Egészségügyi Stratégiai Kutatóintézet, ESKI) was established, which assists in decision-making in four major areas of health policy and financing: medical informatics and information policy, health economics, health services research and health technology assessment.

Generic substitution is allowed (but it is not obligatory) in cases in which the doctor does not forbid it. Individual consumption data is not monitored.

Current challenges

From the beginning of 2007 a new legislative regulation is to be in operation, so in the near future it will be necessary to evaluate the new environment.

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Abbreviations

ADCT / NTKÁ	Average Daily Cost of Therapy / Napi Terápiás Költség Átlaga
AIPM	Innovatív Gyógyszergyártók Egyesülete / Association of Innovative Pharmaceutical Manufacturers (Hungary)
ÁNTSZ	Állami Népegészségügyi és Tisztiorvosi Szolgálat / National Public Health and Medical Officer Service (Hungary)
APEH	Adó-és Pénzügyi Ellenőrzési[Hivatal / Hungarian Tax and Financial Control Administration (Hungary)
ASGP	Association of Generic Producers
ATC	Anatomic Therapeutic Chemical classification
CEE	Central and Eastern Europe(an) (countries)
DCT / NTK	Daily Cost of Therapy / Napi Terápiás Költség
DOT	Days of therapy / Terápiás Napok Száma
DRGs / HBCS	Diagnosis-Related Groups / Homogeneous Disease Groups (Homogén betegségcsoportok)
DDD	Defined Daily Dose
E. Alap / HIF	Egészségbiztosítási Alap / Health Insurance Fund (Hungary)
EC	European Commission
EU10	Member Stats joining the EU in May 2004
EU25	All EU Member States before the expansion of 2007
EÜ100	Reimbursement category bound to indication. Reimbursed by 100%
EÜ90	Reimbursement category bound to indication. Reimbursed by 90%
ESKI	Egészségügyi Stratégiai Kutatóintézet / National Institute for Strategic Health Research (Hungary)
ESKI-TÉI	Office of Health Technology Assessment (TÉI) of the National Institute for Strategic Health Research (ESKI) (Hungary)
EüM / MoH	Egészségügyi Minisztérium / Ministry of Health (1986-1990: Ministry of Health and Social Affairs; 1990-1998: Ministry of Welfare; 2004-2004: Ministry of Health Social and Family Affairs) (Hungary)
EMEA	European Medicines Agency
FB	Fellebbviteli Bizottság / Appeal Committee (Hungary)
GDP	Gross Domestic Product
GKM	Gazdasági és Közlekedési Minisztérium / Ministry of Economy and Transport (Hungary)
GP	General Practitioner
GVH	Gazdasági Versenyhivatal / Office of Economic Competition (Hungary)
GGE	General Government Expenditure

G10 Medicines	(European Commission) High Level Group on Innovation and the Provision of Medicines
HAPW	Gyógyszer-Nagykereskedők Szövetsége / Hungarian Association of Pharmaceutical Wholesalers (Hungary)
HE	Health Expenditure
HOM	Hospital-Only Medicine(s)
HUF	Magyar Forint / Hungarian Forint (National currency of Hungary)
ICD	International Classification of Diseases (WHO coding system)
ICPM	International Classification of Procedures in Medicine (WHO coding system)
IMS	IMS Health (Company)
INN	International Nonproprietary Name
KSH	Központi Statisztikai Hivatal / Hungarian Central Statistical Office (Hungary)
MAGYOSZ	Magyar Gyógyszergyártók Országos Szövetsége / Hungarian Pharmaceutical Manufacturers Association (Hungary)
META	Magyar Egészség-gazdaságtani Társaság / Hungarian Health Economics Association (Hungary)
MGYK	Magyar Gyógyszerész Kamara / Hungarian Chamber of Pharmacists (Hungary)
MGYT	Magyar Gyógyszerésztudományi Társaság / Hungarian Society for Pharmaceutical Sciences (Hungary)
Mio.	Million (Thousand Mio. = Billion)
MKEH	Magyar Kereskedelmi Engedélyezési Hivatal / Hungarian Trade Licensing Office (Hungary)
MOK	Magyar Orvosi Kamara / Hungarian Chamber of Physicians (Hungary)
MOSZ	Magángyógyszerészek Országos Szövetsége / Association of Private Pharmacists (Hungary)
NCU	National Currency Unit
NHS	National Health Service
NTKÁT	Napi terápiás költség átlagához rendelet támogatási érték forintban / The reimbursement amount (in HUF) assigned to the Average Daily Cost of Therapy
OEP	Országos Egészségbiztosítási Pénztár / National Health Insurance Fund Administration (Hungary)
OECD	Organisation for Economic Co-operation and Development
OGYI	Országos Gyógyszerészeti Intézet / National Institute of Pharmacy (Hungary)
OPP(s)	Out-of-Pocket Payment(s)
OSAP	Országos Statisztikai Adatgyűjtési Program / National Programme of Statistical Data Acquisition (Hungary)

OSZMK	Országos Szakfelügyeleti Módszertani Központ / National Methodological and Professional Supervisory Centre (Hungary)
OTC	Over-The-Counter (pharmaceuticals)
PE	Pharmaceutical Expenditure
PET	Positron Emission Tomography
PM / MoF	Pénzügy Minisztérium / Ministry of Finance (Hungary)
POM	Prescription-Only Medicine(s)
PPP	Pharmacy Purchasing Price
PPPa	Purchasing Power Parity
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy Retail Price
QALY	Quality-Adjusted Life Year
SD	Self-Dispensing (Doctor(s))
SHI	Social Health Insurance
TÉB	Technológia Értékelő Bizottság / (Health) Technology Appraisal Committee (Hungary)
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
VAT	Value-Added Tax
VHI	Voluntary Health Insurance
WHO	World Health Organisation

Introduction

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

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

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

disseminating the outcomes of the project.

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

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

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

1 Background

1.1 Demography

The Hungarian population is approximately 10 Mio. This is similar in size to Belgium, Greece, the Czech Republic, Portugal and the Netherlands. From this point of view, Hungary is a medium-sized country in Europe.

The surface area of Hungary is 93,000 km². The population density is varied and uneven, with the average at 110 inhabitants per km². In the capital, Budapest, the population density is much higher than in other parts of Hungary. Budapest itself has approximately 1.7 Mio. inhabitants (2005). It is peculiar that 66% (in 2005) of the total population lives in towns (including Budapest). On the other hand, in the Great Plain (south to south-east Hungary) population density is low. The main types of settlements in this region are small towns, villages and farms, meaning that relatively fewer people live in a relatively much larger area.

The average life expectancy at birth was approximately 73 years in 2004, but there is a big gap between men and women. The life expectancy at birth shows a very moderate increase, but life expectancy for the most endangered age groups shows an even less steady increase. In light of the average life expectancy, Hungary lags significantly behind the similarly developed countries and those systems that are operating with a similar health care budget. The often-mentioned explanatory factors are the unhealthy lifestyle of the population and the unsuitable state of the health care system.

The main causes of mortality and morbidity are acute myocardial infarction (International Classification of Diseases (ICD) I21-I23), other ischaemic heart diseases (ICD I20, I24, I25) and cerebrovascular diseases (ICD I60-I69). In 2004, 37.35% of all causes of death were from these International Classification of Diseases (ICD) groups. The second main mortality cause is malignant neoplasms of the trachea, bronchus and lung (ICD C33-C34) and the third is the group of diseases of the liver (ICD K70-K76) [Statistical Yearbook of Hungary, 2004].

The above-mentioned factors have caused several serious problems. First, the population is decreasing thanks to the low birth rate, which has been below the mortality rate since 1981. Population projections show that in 2025 there will be 9.6 Mio. inhabitants and in 2050 only 8.9 Mio. inhabitants in Hungary [Eurostat, 2006]. There will therefore be fewer and fewer employees to support the ageing society, so the pressure on the social welfare system will be intensified.

As a result of the low birth rate and the growing life expectancy, the Hungarian population is ageing progressively (cf. Table 1.1), thus ageing is the relevant population trend. The ageing index was 99.9 in 2005, so the number of inhabitants in the age groups 0-14 and over 64 are just about equal. In 2005 the old-age dependency ratio was 22.7. The percentage of elderly people has been increasing year on year. According to the forecasts, in 2021 every fifth inhabitant would be in the over-64 age group. However, in the last 20-30 years of their lives people's level of dependency increases. Hungary has become aware of the need for a complex and integrated system for the care of elderly people. The Government plans to establish a self-sufficient system of care and security, including the integration of the social support system.

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

Variable	1995	2000	2003	2004/2005
Total population	10,246,300	10,222,000	10,142,000	10,098,0001
Population density per km^2	110.14	109.88	109.02	108.551
Population aged 0-14 (as a % of total)	18.25	16.92	16.11	15.651
Population aged 15-64 (as a % of total)	67.52	68.10	68.15	68.731
Population aged > 64 (as a % of total)	14.23	14.98	15.74	15.631
Life expectancy at birth, total	70.07	71.55	72.62	72.962
Life expectancy at birth, females	74.50	75.59	76.53	76.902
Life expectancy at birth, males	65.25	67.11	68.29	68.592

[1] data available in 2005; [2] data only available in 2004

Sources: : Statistical Yearbook of Hungary - 1995, 2004; Hungarian Statistical Pocketbook – 2005

1.2 Economic background

The Hungarian national currency unit (NCU) is the Hungarian Forint (HUF). The gross domestic product (GDP) was HUF 5,614 billion in 1995. In that same year the volume indices was only 88.7 (1990 = 100). This is important because Hungary completed its political transformation in 1990, but reached the 1990's gross domestic product (GDP) value only in 1999. However, in 2005 this index reached the value of 133.6% [Statistical Yearbook of Hungary, 2004]. In 2005 the gross domestic product (GDP) at purchasers' price was HUF 22,026.8 billion.

Hungary is in the group of the least developed countries in the European Union (EU). The gross domestic product (GDP) per capita in Purchasing Power Standards (PPS), compared with all 25 European Union (EU) Member States (EU25) (EU25 = 100 %), was only 62.5 % in 2005 [Eurostat, 2006]. In 2005 the gross domestic product (GDP) per capita in current prices was approximately HUF 2.1 Mio. (€ 8,803). In a worldwide comparison Hungary is a medium-developed country.

At the same time the scale of the economic growth is emerging. The average of this indicator was 4.07 % between 1995 and 2005. Even during the recession of the early 2000s, Hungary showed a growth rate of 3.4-3.8 %. The key driver of growth is foreign investment, mainly via the Foreign Direct Investment.

Hungarian economic development mainly depends on the world market. Because of the membership of the European Union (EU), it is obligatory for Hungary to achieve the Convergence Criteria. This is an essential determinant of any further developments in Hungarian economic policy. The rationalisation of the social security system is also crucial. Recently, privatisation in health care has been the principal focus.

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

Variable (in national currency unit (NCU) or %)	1995	2000	2001	2002	2003	2004	2005
GDP in NCU (billion, HUF)	5,614	13,272.2	14,989.8	16,915.3	18,650.7	20,429.5	22,026.8
GDP per capita (in HUF)	549,208	1,301,196	1,473,199	1,667,847	1,843,501	2,023,123	2,181,303
GDP per capita in PPPa (in €)	n.a.	10,636	11,644	12,523	12,897	13,643	n.a.
Annual economic growth rate in %	3.62[1]		4.3	3.8	3.4	5.2	4.1
GGE[2] (billion, HUF)	n.a.	6,171.57	7,105.17	8,660.63	9,157.49	9,969.60	1,0870.8
GGE as a % of GDP	n.a.	46.5	47.4	51.2	49.1	48.8	49.9
Exchange rate (NCU per €, annual rate)	178.80	264.94	246.33	235.90	262.23	245.93	252.73

[1] Average value of 1995-2000

[2] Source = Eurostat 2006

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

Sources: Statistical Yearbook of Hungary - 1995, 2004; Hungarian Statistical Pocketbook – 2005; Web site of Hungarian National Bank, Eurostat database 2006;

1.3 Political context

The Republic of Hungary is an independent, democratic and constitutional State. The country‘s political framework is a parliamentary representative democratic republic, whereby the Prime Minister is the Head of the Government and the Parliament is a multi-party assembly.

The effective constitution of Hungary is the Constitution of 1949, together with its amendments. Since the political reform of 1989, encompassing the amendment of the Constitution proclaimed on 23 October 1989, the Hungarian State has been a parliamentary republic. The first two-round democratic elections were held in the spring of 1990.

In autumn 2006 the majority of the National Assembly was made up of the Hungarian Socialist Party (Magyar Szocialista Párt - MSZP), which is the governing party, in coalition with the liberal Alliance of Free Democrats (Szabad Demokraták Szövetsége - SZDSZ). Both are centre-left parties, together holding 210 of the 386 seats (54.4 %). In the opposition position is the former government party the Hungarian Civic Party (Fiatal Demokraták Szövetsége - FIDESZ), along with the Christian Democratic Party (Keresztény Demokrata Néppárt – KDNP) and the centre-right Forum of Hungarian Democrats (Magyar Demokrata Fórum - MDF).

The Government exercises executive power, while the legislative power is vested in both the Government and the Parliament. The Judiciary is independent of the executive and the legisla-

tive powers. In principle, power within the Government is controlled by the National Assembly, and the Prime Minister and the Council of Ministers form the Government as the Chief Executive Board of the State.

As described, the unicameral National Assembly (with 386 members) exercises legislative power. Members of the National Assembly are elected for four years. The basic legal provisions pertaining to the Government are set out in the Constitution, and detailed procedures are specified in the Government's procedural rules. The law provides for a listing of the ministries and the scope of the competencies of the ministers are regulated by government resolutions.

Owing to the Hungarian Constitution, which has been based on the post-Second World War Basic Law of the Federal Republic of Germany, the Prime Minister has a leading role in the Executive Board since (s/)he selects Cabinet Ministers and has the exclusive right to dismiss them (similarly to the competences of the German Federal Chancellor). Each cabinet nominee appears before one or more parliamentary committees in consultative open hearings, has to be elected by the Parliament and must be formally approved by the President.

The President of the Republic, elected by the National Assembly every five years, has a largely ceremonial role, but (s/)he is nominally the Commander-in-Chief of the armed forces and (her/)his powers include the nomination of the Prime Minister, who is to be elected by a majority of the votes of the Members of Parliament, based on a recommendation made by the President.

Hungary is subdivided administratively into 19 counties**.** Since the admission to the European Union (EU), Hungary has been subdivided into seven euro-regions. The capital of Hungary is Budapest.

In Hungary, the local government has been developed according to a three-tiered organisation. Besides the 19 county self-governments and 3,300 settlement and municipal self-governments established by election, seven territorial-statistical regions carry out regional development and programming duties, although they have no administrative or state-related realm of authority.

The state administration organisations perform primarily executive law-enforcement duties as relevant authorities, while local governments primarily have duties and powers in the field of provision of local public services, but they also exercise certain legislative rights. Furthermore, to ensure expedient task performance, local governments also perform some state administration duties conferred to them by the Government. In this way, the local power is represented by the county self-governments, albeit without tax-raising powers, and the local self-governments have equal legal status, equal rights, and specific independent powers, including tax-raising power.

1.4 Health care system

1.4.1 Organisation

It is difficult to define exactly what type of health care system is in operation in Hungary. Although it is a kind of mix of the “Beveridge” and “Bismarck” systems, the Hungarian health insurance system could be considered predominantly as a Bismarckian-like social insurance system. The health care reforms in the 1990s transformed the Hungarian health care system into a split purchaser–provider contract model.

The National Health Insurance Fund Administration (Országos Egészségbiztosítási Pénztár, OEP) is the only health insurance fund in Hungary, with the responsibility of financing benefits in kind (health services, cost allowances) and benefits in cash from the Health Insurance Fund (Egészségbiztosítási Alap, E. Alap / HIF). Due to the fact that it is a system with only one insurance fund, there is no possibility for patients to choose sickness funds. Participation in the social insurance system is statutory for all Hungarian citizens and there is no possibility of stepping out of the system.

Act No. LXXX and Act No. LXXXIII of 1997 define the scope of citizens eligible for social insurance services and thus the benefits of mandatory health insurance.

The level of coverage is almost 100% because most of the social groups who do not pay health insurance contributions (children, pensioners, unemployed people, etc.) are also covered. There are no differences due to income in the health care services provided. All health services are fully covered and exclusions are stipulated in Act No. LXXXIII of 1997 and related acts. This Act also regulates the health insurance system, and it contains the exact entitlements and rights. There are several health services which are free of charge, but at some point in the process patients have to pay a certain level of co-payment. The Act defines the negative list, too (non-reimbursed services, e.g. services without healing aims, plastic surgery).

The Hungarian health care system is regulated by several acts and decrees. The main acts are listed here (cf. 7.1 for the entire list of laws and decrees).

- Law No. XCV of 2005 on pharmaceuticals for human use and on the amendment of other regulations related to pharmaceuticals.
- Law No. LXXXIII of 1997 on compulsory health services in the framework of social security and Decree of the Government 217/1997 on compulsory health service provision.
- Law No. LIV of 1994 on establishment and operation of pharmacies.
- Law No. LVIII of 1997 on economic sales promotion activity.
- Law No. CLIV of 1997 on health.
- Law No. XXXIV of 2001 on specialised care obligation.
- Decree of the Ministry of Health 44/2004 on the order and handing over of medical products.
- Decree of the Ministry of Health 52/2005 on the market authorisation of pharmaceuticals for human use in accordance with Directive 2001/83/EC.

- Decree of the Ministry of Health 1/2003 on the pharmaceuticals co-financed by social insurance and its amount.
- Decree of the Ministry of Health 32/2004 on the criteria of inclusion of registered pharmaceuticals and foods satisfying particular dietary requirements into social insurance coverage, and on altering coverage or reimbursement status.
- Decree of the Ministry of Health 64/2003 on the advertising and promotion of pharmaceuticals for human use and of therapeutic substances and preparations.
- Decree of the Government 43/1999 on detailed regulations on financing health supply.

The current structure has been transforming since 1989. After the political changes the health care system returned from being a Semashko-like system to Bismarckian solidarity-based traditions. The responsibility of providing health care services was transferred to local governments.

The former socialist model has been replaced by a more pluralist system, based on contractual relationships and quasi-public arrangements. The main authorities and relevant bodies at central local level are listed here.

- **National Assembly**: is the key actor in all national legislation areas, including health.
- **National Government**: (central Government) formulates health policy and regulates the health sector.
- **Prime Minister's Office**: coordinates government legislation.
- **Ministry of Health (EüM / MoH)**: has the dominant role in health management and overall control over pharmaceutical policy.
- **Ministry of Finance (Pénzügy Minisztérium, PM / MoF**): is responsible for fiscal policy and the state budget, including the national government budget, the local government budget and the Health Insurance Fund (E. Alap / HIF).
- **Tax Office**: has been collecting social insurance contributions since January 1999.
- **Ministry of Education and Culture**: supervises higher education institutions in health.
- **National Health Insurance Fund Administration (OEP)**: finances the recurrent costs of health services; provides cash benefits such as sickness allowances; deals with public procurement/tendering of pharmaceuticals, pricing procedures and monitoring (e.g. of consumption).
- **Local governments**: are the main owners of health care providers in the Hungarian health care system.
- **National Institute of Pharmacy (Országos Gyógyszerészeti Intézet, OGYI)**: deals with market authorisation/licensing of pharmaceuticals; possible classifications (e.g. concerning prescription status, whether hospital-only or not, etc.)
- **Hungarian Chamber of Pharmacists (Magyar Gyógyszerész Kamara, MGYK)**: deals with professional representation of interest, and pricing procedures of non-reimbursed pharmaceuticals.
- **Manufacturers**: deal with pricing procedures and negotiations.

- **National Institute for Strategic Health Research (Egészségügyi Stratégiai Kutatóintézet, ESKI)**: is responsible for the assessment and evaluation of pharmaceuticals.
- **National Public Health and Medical Officer Service (Állami Népegészségügyi és Tisztiorvosi Szolgálat, ÁNTSZ)**: deals with distribution, which is regulated by Act No. XI of 1991 and pharmacy allowances.

1.4.2 Funding

The health care system is financed by the National Health Insurance Fund Administration (OEP) from the national Health Insurance Fund (E. Alap / HIF), which is primarily responsible for recurrent health care costs. The Health Insurance Fund (E.Alap / HIF) was established in 1993. Among the National Health Insurance Fund Administration's (OEP) funding sources there are health insurance contributions and proportional payroll taxes. These revenues are paid by the employers and partly by the employees. The other financing channel of the National Health Insurance Fund Administration (OEP) is the so-called "hypothecated health care tax", containing the lump sum tax and the proportional tax [Peter Gaál, 2004]. However, the National Health Insurance Fund Administration (OEP) is underfinanced and the Government is therefore obliged to cover its deficit through the revenue from local and general taxation. In summary, the Hungarian health care system is financed via two main channels, which generates a mixture of tax and social insurance-based funds.

In 2004, the total income of the Health Insurance Fund (E. Alap / HIF) was HUF 1,100,140.2 Mio. This amount mainly flows from the health insurance contributions and proportional payroll taxes, while on the other side the expenditure was HUF 1,443,792.9 Mio., so the deficit was HUF 343,652.7 Mio., which has to be financed by the State [Boncz I - Sebestyén A, 2006].

In 2004, the total health expenditure (THE) was 8.4% of the total gross domestic product (GDP). The general government expenditure (GGE) on health was 71.8% of the total health expenditure (THE); the other 28.2% was private health expenditure (HE), of which the share of out-of-pocket payments (OPPs) was 89.1% [WHO, 2006].

Act No. XCVI of 1993 on Voluntary Mutual Insurance Funds created the legal framework for complementary insurance schemes on a non-profit-making basis, similar to the model of the French mutualité system. The Government subsidises the purchase of health insurance from voluntary mutual funds with a 30% tax rebate/discount up to a certain limit. But only a few voluntary funds have been established so far. In exchange for a membership fee, the existing plans are allowed to offer benefits not covered or not fully covered by the Health Insurance Fund (E. Alap / HIF). Approximately 5-6% of the Hungarian population belongs to voluntary funds.

Table 1.3 contains the details of the contribution levels and tax paid by the employer and employee from 1994.

Table 1.3: Hungary – Employer and employee contributions 1994-2006

Years	Employer contribution rate (%)	Employee contribution rate (%)	Lump sum health tax paid by the employers (HUF per month per person)	Proportional health care tax (%)
1994	19,5	4.0	n. app.	n. app.
1995	19,5	4.0	n. app.	n. app.
1996	18,0	4.0	n. app.	n. app.
1997	15,0	4.0	1,800	11.0
1998	15,0	3.0	2,100	11.0
1999	11.0	3.0	3,600	11.0
2000	11.0	3.0	3,900	11.0
2001	11.0	3.0	4,200	11.0
2002	11.0	3.0	4,500	11.0
2003	11.0	3.0	3,450	11.0
2004	11.0	4.0	3,450	11.0
2005	11.0	4.0	3,450	11.0
01.2006 - 09.2006	11.0	4.0	1,950	11.0
09.2006 – 12.2006	11.0	6.0	1,950	11.0

Source: OEP, 2006

The Hungarian health care system is based on a Bismarckian type of social health insurance (SHI) system. Therefore public finance dominates as the main source of funding. The structure of the health care financing is organised as shown here.

- The Health Insurance Fund (E. Alap / HIF) is responsible for recurrent expenditure.
- National and local governments have duty to cover all investments.
- The National Government and the Parliament are responsible for covering any deficit incurred at the Health Insurance Fund (E. Alap / HIF).
- The National Government also has to pay for recurrent expenditure for special and high-cost services (blood supply, public health system, co-payment for residents with low income, state hospitals).

The revenue sources of the health care system consist of the following elements:

- employer contribution rate, which is a proportional pay-roll contribution;
- employee contribution rate, which is a proportional pay-roll contribution;
- lump-sum health care tax (levied to cover the cost of the non-paying groups);
- proportional health care tax (levied only on incomes that are not subject to social contribution payments);
- general taxation;

- out-of-pocket payments (OPPs);
- voluntary health insurance (VHI);
- other private sources.

Three acts regulate the National System, namely Act No. LXXX of 1997. on those Entitled to the Services of Social Insurance and Private Pensions and the Funding of these Services; Act No. LXXXVIII of 1996; and Act No. LXVI of 1998 on Health Care Tax.

Table 1.4: Hungary - Health expenditure (HE), 1995, 2000-2005

Health expenditure (HE)	1995	2000	2001	2002	2003	2004	2005
THE (in HUF)	419.6	939.4	1,093.7	1,299.7	1,553.9	1,714.5	n.a.
THE as a % of GDP	7.5	7.10	7.30	7.70	8.37	8.43	n.a.
THE per capita (in HUF)	40,623	92,097	107,490	128,154	153,593	169,782	n.a.
Public HE (as a % of THE)	84.00	70.74	68.98	70.21	72.38	71.79	n.a.
Private HE (as a % of THE)	16.00	29.26	31.02	29.79	27.62	28.21	n.a.

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

Source: OECD Health Data 2004,2006; WHO HFA 2006

1.4.3 Access to health care

1.4.3.1 Out-patient care

In Hungary the general practitioners (GPs) belong in the primary care setting (together with mother, child and youth protection services, dental care, etc.). From a financial point of view, out-patient and in-patient care are special forms of provision (together with such services as computerised tomography (CT)/magnetic resonance (MR) imaging, laboratory services, etc.).

There is a strong distinction in the Hungarian health care system between general practitioners (GPs) and out-patient specialists. The general practitioners (GPs) run their own practises in their own offices and the out-patient specialists work in out-patient departments of polyclinics or hospitals.

The role of private providers is dominant in the case of general practitioners (GPs), whereas in out-patient and in-patient care the market share of private providers is negligible. Most general practitioners (GPs) are responsible for a certain catchment area, with a territorial supply obligation to that area. Publicly funded providers have to contract with the National Health Insurance Fund Administration (OEP).

The patients have a right to choose their general practitioner (GP) freely, and they can change for any reason at any time. Ideally, the general practitioner (GPs) should be a gatekeeper, and

the national health policy supports this system. In practice, however, general practitioners (GPs) do not fulfil the role of gatekeeper to the extent that is desired.

Table 1.5: Hungary – Out-patient care 1995, 2000, 2002, 2004 and 2005

Variable	1995	2000	2002	2004	2005
Total no. of doctors[1]	n.a.	27,854	27,524	28,214	28,285
No. of doctors per 1,000 inhabitants	n.a.	2.225	2.304	2.409	2.417
Total no. of out-patient doctors	n.a.	22,745	23,446	24,376	24,410
of which GPs	n.a.	6,732	6,743	6,678	6,652
of which dentists	n.a.	3,209	3,204	3,292	3,233
No. of out-patient doctors per 1,000 inhabitants	n.a.	2.225	2.304	2.409	2.417
No. of out-patient clinic departments in secondary care	136	371	368	339	346
No. of out-patient clinic departments in primary care	n.a.	n.a.	6,206	6,241	6,240
No. of doctors who work both in in-patient and out-patient care	n.a.	6,824	7,816	8,311	8,561

[1] No data available about numbers of retired and non-practising doctors

GP = general practitioner, n.a. = not available, values are estimates only

Source: OEP, 2006

General practitioners (GPs) are remunerated through capitation (head-count quota) and they receive fixed fees (for operational costs) and supplementary fees (for equalling differences of practice locations). Furthermore, they receive reimbursement for being on duty and a case fee for treatment of the cases that they are not registered to deal with.

Out-patient care is carried out by specialists only in hospitals and in out-patient clinics (polyclinics). General practitioners (GPs) have the right to hospitalise patients into ambulatories, but there are also out-patient services which can be visited without any referral. (e.g. ophthalmological and gynaecological out-patient care).

Public out-patient care is remunerated by the National Health Insurance Fund Administration (OEP). The main financing method is the German Point System. Medical procedures are listed according to the International Classification of Procedures in Medicine (ICPM) code system of the World Health Organisation (WHO). This means that every treatment has a point value and this value is also assigned a statutory monetary value. These rates are adjusted according to the Health Budget. General practitioners (GPs) have different financial sources, such as capitation fees (weighted by different variables) and allowances. In the past few years a voluntary threshold has been determined.

The public institutes are free for all insured citizens, but co-payment is applicable in certain circumstances (e.g. for orthodontic treatment under the age of 18; dental care and tooth replacement over the age of 18).

1.4.3.2 In-patient care

In the Hungarian health care system public hospitals dominate. Mostly the local or regional governments maintain these institutes. In addition, there are some hospitals that are the property of the State (e.g. the Hospital of National Defence, the Hospital of the Hungarian Railway), churches, foundations, and university clinics, private hospitals and hospitals owned by public companies. Among these institutes there is a hierarchy, defined according to progressivism (urban hospitals, county hospitals and capital hospitals, and at the highest level: national medical institutes (e.g. oncology, neurology) and university clinics, as well as children's hospitals, special hospitals (e.g. pulmonology) and sanatoria).

The doctors are public servants, so they are employed by the hospital.

As a general rule the National Health Insurance Fund Administration (OEP) finances the running costs from the Health Insurance Fund (E. Alap / HIF), whereas covering capital costs is the duty of the owner of the individual health care institute [Boncz et. al, 2004]. In terms of hospital remuneration, two different types of care can be differentiated – acute and chronic – with different financial techniques, as shown here.

- Acute in-patient care is financed through the implementation of a system similar to the diagnosis-related groups (DRGs) (Hungarian "homogeneous disease groups" – DRGs [Boncz et al, 2004]). It covers all costs occurring during hospital care, except investment costs, including costs related to: diagnosis and therapy; pharmaceuticals; staff salaries (doctors, nurses, etc.); accommodation (heating, cleaning, meals, etc.); and hospital management.
- Howevere, there are also fixed payments, such as fees based on progressivism for the higher levels of care, fixed fees for availability of care at the emergency care unit, for traumatology services, intensive care unit, septic unit, etc. Hospitals can apply for special reimbursement in the event of extraordinary cases and the special, high-tech, very expensive devices and procedures are financed according to a detailed list.
- At chronic level, daily payments are applicable which are weighted by different variables (e.g. hospice, rehabilitation). In addition there is a volume threshold, which was frozen at 95% of the value in 2005.

There is ex-post financing but the fixed payments and the different diagnosis-related group (DRG) values are declared ex-ante.

Out-of-pocket payments (OPP) occur in hospitals in the case of those provisions for which only partial payment can be charged, e.g. for extra meals and accommodation, when these are available in the hospital. These include the provisions listed here.

- sanitaria provisions;
- requisition of services, which are liable for referral, without referral;
- requisition of services by a different health care provider from the location at which the physician initiated the treatment;
- requisition of services for self-initiation, differing from standard protocols and/or incurring extra costs;

- accommodation with the aim of nursing by the relevant provider (for the costs of accommodation and nursing, including the necessary pharmaceuticals);
- comfort services provided under hospital treatment.

Table 1.6: Hungary – In-patient care 1995, 2000, 2002, 2004 and 2005

Variable	1995	2000	2002	2004	2005
No. of in-patient doctors	n.a.	11,933	11,894	12,149	12,436
No. of in-patient doctors per 1,000 inhabitants	n.a.	1.167	1.168	1.200	1.231
No. of hospitals	152	146	147	148	146
No. of acute care beds	73,317	65,411	61,261	60,409	60,235
of which in private sector	n.a.	n.a.	n.a.	n.a.	n.a.
Acute care beds per 1,000 inhabitants	7.09	6.39	6.02	5.97	5.96
Average length of stay in hospital	9.4	7.9	7.3	7.0	6.8

n.a. = not available, values are estimates only

Source: OEP, 2006

2 Pharmaceutical system

2.1 Organisation

2.1.1 Regulatory framework

Figure 2.1 provides an overview over the Hungarian pharmaceutical system.

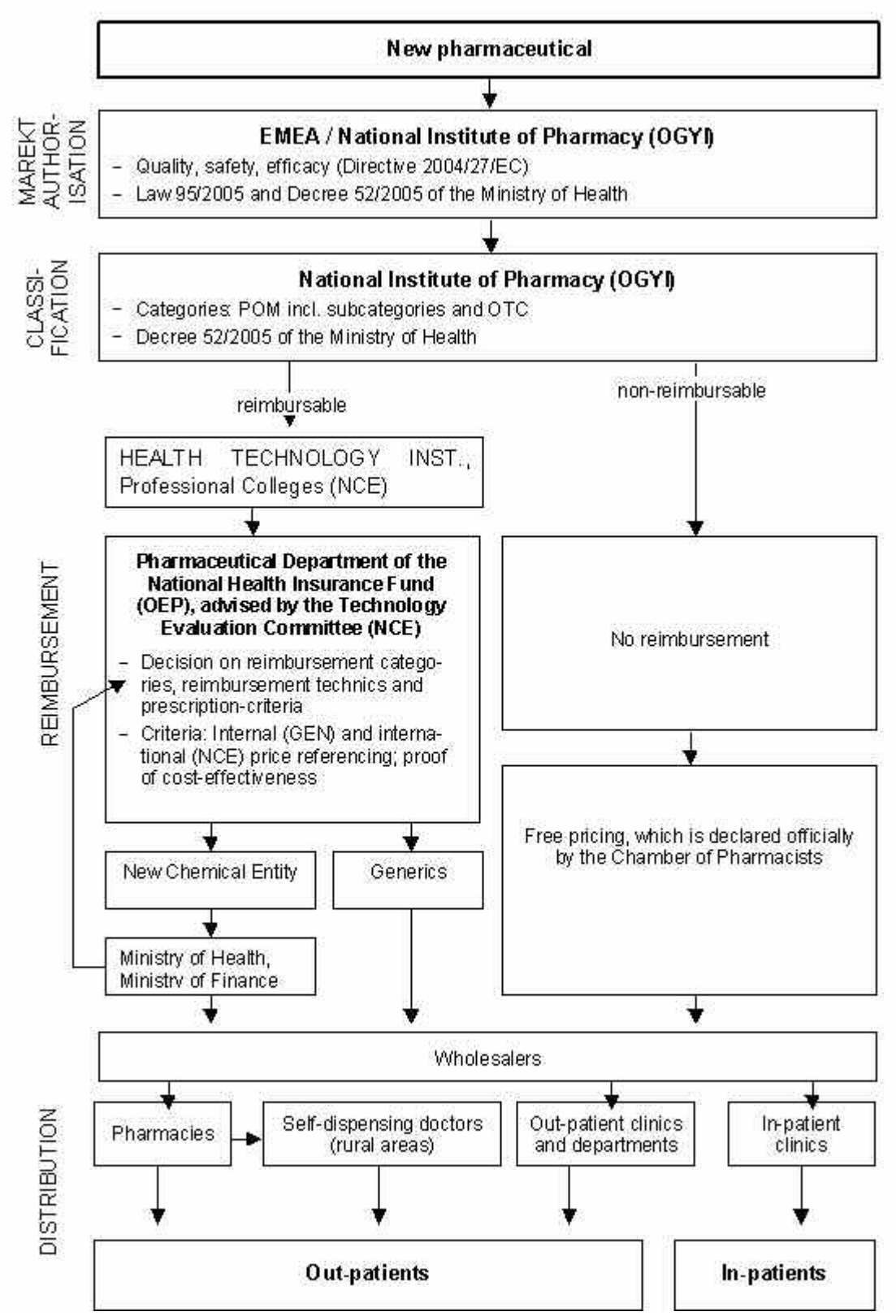
2.1.1.1 Policy and legislation

Several laws and enactments regulate the Hungarian pharmaceutical system. The principal laws are listed here.

- Law No. XCV of 2005 on pharmaceuticals for human use and on the amendment of other laws regulating the pharmaceutical market.
- Law No. LVII of 1997 on economic sales promotion activity.
- Decree of the Ministry of Health 52/2005 on the market authorisation of pharmaceuticals for human use – reclassification of all pharmaceuticals according to Art. 18 of this Decree is to be finished by 1 April 2006.
- Art. 4.2 and Art. 11.2 of Law No. XCV of 2005 on pharmaceuticals for human use and on the amendment of other laws regulating the pharmaceutical market.
- Price Act No. LXXXVII of 1990 on setting prices including those of pharmaceuticals.

- Decree of the Ministry of Health 25/1997 on pharmaceuticals marketed without social security reimbursement.
- Law No. LIV of 1994 on establishment and operation of pharmacies.
- Decree of the Ministry of Health 19/2001 on the commercial price mark up of pharmaceuticals.
- Decree of the Ministry of Health 53/2004 on the market authorisation of parallel traded pharmaceuticals.
- Decree of the Ministry of Health 30/2005 on the labelling and packaging leaflets accompanying pharmaceuticals for human use.
- Ministerial and the Self-Government of the Health Insurance Fund Statement, 1996; published in Welfare Gazette 25/1996 and Law No. LXXXIII of 1997 on compulsory health services in the framework of social security, and Decree of the Government 217/1997 on compulsory health service provision.
- Decree of the Ministry of Health 1/2003 on the pharmaceuticals co-financed by social insurance and its amount.
- Decree of the Ministry of Health 44/2004 on the order and handing over of pharmaceuticals.
- Decree of the Ministry of Health 32/2004 on the criteria of inclusion of registered pharmaceuticals and foods satisfying particular dietary requirements into social insurance coverage, and on altering coverage or reimbursement status.
- Decree of the Ministry of Health 64/2003 on the advertising and promotion of pharmaceuticals for human use and of therapeutic substances and preparations.

Figure 2.1: Hungary - Flowchart of the pharmaceutical system



Source: OEP, 2006

2.1.1.2 Authorities

The most relevant players in the Hungarian pharmaceutical system are listed here, cf. 1.4.1 and Table 2.1.

- The Ministry of Health (EüM / MoH), which is responsible for the regulatory framework in terms of pharmaceuticals.
- The National Health Insurance Fund Administration (OEP), advised by the Technology Appraisal Committee (TÉB), which is responsible for the reimbursement of pharmaceuticals.
- The National Institute of Pharmacy (OGYI), acting as a medicines agency.

The responsibility of granting market authorisation for pharmaceuticals belongs to the National Institute of Pharmacy (OGYI), which is also in charge of the classification of pharmaceuticals according to their prescription status into non-prescription pharmaceuticals (over-the-counter (OTC) pharmaceuticals) and prescription-only medicine(s) (POM) with sub-categories (e.g. prescription on hospital or specialists advice, or for use under supervision; pharmaceuticals with risk of abuse, etc.) [Act No. XCV of 2005, Decree of the Ministry of Health 52/2005]. The category of “preparations having therapeutic effect but classified as pharmaceuticals” will expire on 1 April 2011. By this date all these products are to be re-classified as pharmaceuticals or other products. Hungarian law incorporates the provisions of the Community Code with regard to market authorisation and classification.

The duration of the market authorisation procedure has been limited to 210 days from submission of the application; newly issued market authorisations are valid for five years and are then to be renewed. Further responsibilities of the National Institute of Pharmacy (OGYI) are, amongst others, quality inspections, authorisations of clinical trials and maintaining vigilance. Also, the responsibility for issuing manufacturing licences (which includes the licence for wholesale of the manufactured pharmaceuticals) and wholesaling licences rests with National Institute of Pharmacy (OGYI) in agreement with the Hungarian Trade Licensing Office (MKEH) [Art. 4.2 and Art. 11.2 Law No. XCV of 2005].

The National Health Insurance Fund Administration (OEP) is in charge of reimbursement decisions, which are made on the basis of recommendations of the Technology Appraisal Committee (TÉB), a body consisting of experts of the National Health Insurance Fund Administration (OEP), of the Hungarian Chamber of Physicians (Magyar Orvosi Kamara, MOK), the Special Body of the Presidents of the Colleges of the Medical Professionals (professional colleges) and the Hungarian Chamber of Pharmacists (MGYK). Parameters considered by the Technology Appraisal Committee (TÉB) are, among others, the proposed manufacturer price and reimbursement category, relative effectiveness compared to pharmaceuticals that are already reimbursed and prices in other countries, as well as analyses of cost-effectiveness prepared by the National Institute for Strategic Health Research (ESKI).

To oppose the decision of the National Health Insurance Fund Administration (OEP) the pharmaceutical manufacturer can turn to the Board of the National Health Insurance Fund Administration (OEP), in this case to the Appeal Committee (Fellebbviteli Bizottság, FB), consisting of representatives of the Ministry of Health (EüM / MoH), the Ministry of Finance (PM / MoF), the Ministry of Economy and Transport (Gazdasági és Közlekedési Minisztérium, GKM), the Prime

Minister's Office and the Office of Economic Competition (Gazdasági Versenyhivatal, GVH), to deal with the case. The manufacturer can appeal against the decision of the Appeal Committee (FB) (cf. 4.2.1).

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

Name in local language (Abbreviation)	Name in English	Description	Responsibilities
Egészségügyi Minisztérium (EüM / MoH)	Ministry of Health	Medicines law and policy legislation	Pharmaceutical policy, specifies indications for highly reimbursed (90%, 100%) pharmaceuticals Overall supervision of pharmaceutical policy
Országos Egészségbiztosítási Pénztár (OEP)	National Health Insurance Fund Administration	Third-party payer	Pricing and reimbursement decisions. Public procurement / tendering of pharmaceuticals; monitoring; financing
Országos Gyógyszerészeti Intézet (OGYI)	National Institute of Pharmacy	Medicines agency	Market authorisation; vigilance; possible classifications
Magyar Gyógyszerész Kamara (MGYK)	Hungarian Chamber of Pharmacists	Association of Pharmacists	Publishes the price of OTC pharmaceuticals; delegates a member to the TÉB; pricing procedures
Magyar Orvosi Kamara (MOK)	Hungarian Chamber of Physicians	Medical Doctors' Association	Expert opinions related to pharmaceutical reimbursement; delegates a member to the TÉB
Pénzügyminisztérium (PM / MoF)	Ministry of Finance	Financial policy	Covers the financial sources; specifies indications for highly reimbursed (90%, 100%) pharmaceuticals
Állami Népegészségügyi és Tisztiorvosi Szolgálat (ÁNTSZ)	National Public Health and Medical Officer Service	Authorisation	Authorises several activity, such as establishment of pharmacies
Adó-és Pénzügyi Ellenőrzési Hivatal (APEH)	State Tax Authority (Hungarian Tax and Financial Control Administration)	Supervisory body	Collects the taxes, payroll taxes

OTC = over-the-counter (pharmaceuticals), TÉB = Technology Evaluation Committee

Source: OEP, 2006

2.1.2 Pharmaceutical market

2.1.2.1 Availability of pharmaceuticals

There are special groups of pharmaceuticals, to which accessibility is limited: the group of high-tech pharmaceuticals (specially purchased through public procurement) and the groups of pharmaceuticals with special reimbursement categories (90% reimbursement (EÜ90), 100%

reimbursement (EÜ100)). In these cases the prescription is restricted by special indications defined by the Ministry of Health.

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

Pharmaceuticals	1995	2000	2001	2002	2003	2004	2005	2006[3]
Authorised[2]	3,250	5,050	5,156	5,085	5,029	4,962	5,252	5,525
On the market	1,845	2,277	2,506	2,607	2,714	2,897	3,064	3,144
POM[3]	n.a.	2,312	2,410	2,298	2,307	2,449	2,695	2,886
Reimbursable (on the market)	901	1,522	1,683	1,742	1,805	1,933	2,060	2,125
Generics (on the market)	525	871	969	992	1,030	1,130	1,230	1,271
Parallel traded	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Hospital-only (on the market)	265	449	475	496	501	513	524	528

POM = prescription-only medicine(s), [1]By product name (excluding the different pack sizes, dosages), [2] the number of authorised and on-the-market pharmaceuticals is approximately the same, [3] data of National Institute of Pharmacy (OGYI), 2006, n.a. = not available.

Source: IMS, 2006

There is a difference between the number of pharmaceuticals registered and the number of pharmaceuticals on the market. The main reasons for this can be described as follows: the medical product's application to be included in the positive list is in the process of being completed, or the manufacturer does not want to sell her/his product immediately after registration with the National Institute of Pharmacy (OGYI).

The classification categories are listed here.

- Prescription-only-medicine(s) (POM) (Hungarian abbreviation: "V") and possible subgroups; prescriptions bound to certain specialities; and over-the-counter (OTC) pharmaceuticals (Hungarian abbreviation: "VN").
- Pharmaceuticals in the out-patient sector and Hospital-Only Medicine(s) (HOM).
- Reimbursable and non-reimbursable (Hungarian abbreviation: "NT") pharmaceuticals (cf. 4.2).

The prescription status is the decision of the National Institute of Pharmacy (OGYI). The reimbursement list is supervised by the National Health Insurance Fund Administration (OEP). Switches (e.g. changes from Prescription-Only Medicine(s) (POM) to over-the-counter (OTC) products) are also feasible from the European Medicines Agency's (EMEA) point of view.

2.1.2.2 Market data

Hungary holds 15th place in the ranking of all pharmaceutical retail markets in Europe, and 3rd place in the ranking of the central and eastern European (CEE) pharmaceutical retail markets [IMS, 2005].

Approximately 60% of the total pharmacy turnover is achieved in the social health insurance (SHI) market and the remainder (40%) in the private market (cf. Table 2.8).

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

Pharmaceutical industry in Mio. HUF	1995	2000	2001	2002	2003	2004	2005
Prescriptions							
No. of annual prescriptions by volume	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n.a
No. of annual prescriptions by value	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n.a
Pharmaceutical sales							
Sales at ex-factory price level	87,580	841.8	1,016.3	1,274.7	1,445.5	1,553.7	1,845.7
Sales at wholesale price level	96,546	900.1	1,084.6	1,358.1	1,537.6	1,652.0	1,959.3
Sales at PRP level (excluding VAT)	11,7649	1,081.4	1,278.8	1,576.3	1,773.4	1,922.9	2,265.2
Sales at hospitals (at ex-factory price level)	14,091	126.7	163.3	202.0	238.2	268.0	299.7
Sales of generics (at ex-factory price level)	27,648	218	253	318	357	399	477
Sales of parallel traded pharmaceuticals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Exports and imports							
Total pharmaceutical exports[1]	36,078	104,523	127,899	124,393	162,419	224,074	n.a.
Total pharmaceutical imports[1]	55,982	164,624	190,734	210,461	266,685	309,316	n.a.

[1] finished products, data based on the Hungarian Central Statistical Office (Központi Statisztikai Hivatal, KSH), in HUF, 2005

Mio. = million, PRP = pharmacy retail price, VAT = value-added tax

Source: KSH 2005; IMS 2006

According to information of the Hungarian Chamber of Pharmacists (MGYK), parallel imported products are of no relevance in Hungary [MGYK, personal communication]. In general there are very few parallel traded pharmaceuticals in Hungary, and the market authorisation process of such pharmaceuticals is regulated by decree [Decrees of the Ministry of Health 53/2004 and 53/2005]. Parallel trade is not taken into account in terms of the decision on reimbursement status.

In the mid 1990s total pharmaceutical trade was only HUF 92,060 Mio. By 2004 this indicator had reached HUF 458,050 Mio. Since 1 May 2004, Hungary has been a member of the European Union (EU) which means that there is no restriction on trade, and further growth is therefore expected.

The number of pharmaceuticals has been increasing since 1990 when the pharmaceutical market was first opened. In 1990 there were only 1,000-1,300 products on the market; today there are approximately 13,000 (by different pack sizes and doses). Expenditure has been increasing

continuously, even in those years when there were not any price changes. The reason for the rising pharmaceutical expenditure (PE) is that sales have been strong where the modern, expensive products are concerned.

The rate of prescription of generics has been growing steadily. This is a desirable outcome for the Health Insurance Fund (E. Alap / HIF), because through generics it is possible to rationalise pharmaceutical expenditure (PE). The first reference price by active substance group was introduced in the early-to-mid 1990s. Until that date, the reference price system had been implemented for therapeutic class as well.

Table 2.4: Hungary – Top 10 best-selling pharmaceuticals[1] 2005

Position	Pharmaceutical, by active ingredient
1	Alendronic Acid
2	Atorvastatin
3	Perindopril
4	Enalapril + HCT
5	Clopidogrel
6	Fluvastatin
7	Esomeprasol
8	Ramipril
9	Risendron Acid
10	Normodipine

[1] according to reimbursement amount

Source: OEP, 2006

2.1.2.3 Patents and data protection

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

Under the recently adopted European Union (EU) legislation, authorities are also obliged to provide data protection for an 8 + 2 + 1-year period. This provides an additional protection period for patented pharmaceuticals. Only after eight years can the Medicines Agency apply for generic pharmaceuticals under the European regulation, which can then be marketed when the 10-year data protection period ends (provided that by that time the patent has also expired). Authorities may provide for an additional year of data protection (and thereby delay generic market entry) for additional innovative indications (e.g. for paediatric indications).

Product patents have been in place in Hungary since 1994. Before that, process patents had been granted to pharmaceutical companies. Under the process patent system, only the process is protected, not the “molecule” itself; therefore copies could be manufactured if a different process was used. An agreement between the Hungarian and the multinational (“innovative”)

industry was found, granting local manufacturers the right to further sell their copies as well as to finish research that had already been started on alternative processes [ICEG EC 2003].

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

Recently, there has not been any national discussion on patent protection. Only the adaptation of the European regulation is currently being carried out.

2.1.3 Market players

2.1.3.1 Industry

Over the years the pharmaceutical industry in Hungary has been an important branch of industry. In the 1990s the Hungarian pharmaceutical industry was privatised and is nowadays mainly in the hands of foreign investors. The biggest domestic producer is Richter Gedeon, which also dominates the pharmaceutical market in terms of sales, followed by Egis.

Pharmaceutical production in Hungary amounted to HUF 356,820 Mio. / € 1,407.46 Mio. in 2003. The local pharmaceutical industry covers approximately one third of the Hungarian market in value, and more than half of the pharmaceutical market in volume. The domestic share of pharmaceutical sales has constantly declined since 1990 [MAGYOSZ, 2005]. Approximately one third of the turnover is made on the local market, and the main export markets are (besides the central and eastern European (CEE) countries) Germany, the United Kingdom, France and Italy. More than 40 pharmaceutical companies possess a manufacturing licence and the products of approximately 20 local producers are available in Hungarian pharmacies. The number of employees in the pharmaceutical industry has dropped from approximately 23,000 in 1990 to an estimated 12,000 in the year 2002.

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

Pharmaceutical industry	1995[1]	2000[1]	2001[1]	2002[1]	2003[1]	2004[1]	2005[1]
Total no. of companies	58	67	69	73	73	74	58
- research oriented	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- generic producers	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- biotech	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Number of people employed[2]	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

n.a. = not available, [1] as of 1 January of the year [2] counted per head

Source: IMS, 2006

2.1.3.2 Wholesalers

In Hungary pharmaceutical wholesale is organised in a multi-channel system. In 2005, there were approximately 80 companies holding a wholesale license [OGYI, 2006]. Quite a few pharmaceutical companies hold wholesale licenses but do not deliver to pharmacies: since 2005 the license to manufacture pharmaceuticals on Hungarian territory incorporates a wholesale license if certain conditions have been met. In fact, only four wholesalers (Phoenix Pharma, Hungaropharma, Medimpex and Pannonmedicina) dominate the market with an estimated total 85% market share. These four wholesalers are members of the Hungarian Association of Pharmaceutical Wholesalers (Gyógyszer-Nagykereskedők Szövetsége, HAPW). Besides these companies, there are approximately 8 to 10 small wholesaler companies: most of them do not provide a full range of pharmaceuticals [Hungarian Association of Pharmaceutical Wholesalers (HAPW), personal communication].

Parallel trade has no relevance in Hungary.

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

Wholesalers	1995[1]	2000[1]	2001[1]	2002[1]	2003[1]	2004[1]	2005[1]
Total number of wholesale companies[2]	65	70	74	61	49	27	14
Total number of outlets	n.a.	n.a.	n.a.	28	24	51	40

[1]as of 1 January of the year

[2] active wholesale companies

Source: GVH, 2006; OGYI, 2006

2.1.3.3 Pharmaceutical outlets / retailers

In general, pharmaceuticals are sold to patients in pharmacies. In 2005 there were 2,649 pharmacies in Hungary (cf. Table 2.7).

Geographic and demographic criteria for setting up a pharmacy are applied; the service population of a new pharmacy has to be at least 5,000 people and the minimum distance to an existing pharmacy has to be 250-300 m. Furthermore, only a trained pharmacist is allowed to own a

pharmacy, and (s/)he has to hold the majority (51%) share of the pharmacy. Up to 49% of the pharmacy may be owned by any natural or legal person (Law No. LIV of 1994). Although multiple ownership of pharmacies is not permitted, approximately 250 pharmacies are organised in the form of chains, which is allowed as a result of the fact that anyone can own 49% of a pharmacy.

In addition, some hospitals are entitled to dispense pharmaceuticals to out-patiens [MGYK, personal communication]. In Hungary only pharmacies are allowed to dispense pharmaceuticals (or in special cases in very small villages, where a pharmacy is not available, the local general practitioner (GP) can dispense). Self-service of over-the-counter (OTC) products is not allowed, nor is distance selling of pharmaceuticals, e.g. via the Internet (cf. 2.1.3.3.2) [AESGP, 2005].

The legal framework for the mail order of pharmaceuticals has been in place since November 2005. The Hungarian Chamber of Pharmacists (MGYK) has already worked out this protocol and will introduce this system at the beginning of 2007. The pharmacists are allowed to dispense all pharmaceuticals without restrictions (cf. Chapter 6).

2.1.3.3.1 Pharmacies

The Law No. LIV of 1994 (on establishment and operation of pharmacies) governs pharmacy activities. The main rules are as follows: in terms of demography, the criteria is that a new pharmacy can be opened for every 5,000 inhabitants, and geographically there must be at least 250 m distance between any two pharmacies. Pharmacists cannot operate more than one pharmacy, and the possible legal status of the pharmacy as a firm is strictly restricted. Since 2001, pharmacists have had to own more than 50% of their pharmacy. This obligatory share was 25% before 2001. In this way, there was the possibility of taking over majority ownership between 1994 and 2001, and the minority ownership can be gained since 2001 for any legal person or company. This company cannot be wholesaler or producer of pharmaceuticals. Therefore it is possible for a company to have several minority ownership shares in different pharmacies. Some experts in this field estimate that 10% of the pharmacies belong to this sort of informal chain, across four chains. The Government intends to liberalise the restrictions in the future and has handed a proposed act to the Parliament.

The main association is the Hungarian Chamber of Pharmacists (MGYK), established by the law. It is a self-governing body. The Hungarian Chamber of Pharmacists (MGYK) has the right to give its opinion in all cases that have an impact on pharmacists or pharmacies.

There are further associations, such as the Association of Private Pharmacists (MOSZ) and the Hungarian Society for Pharmaceutical Sciences (Magyar Gyógyszerésztudományi Társaság, MGYT). The Association of Private Pharmacists (MOSZ) was established in 1991. The mission of the Association is to strengthen the voice of the pharmacists and to raise the esteem of the profession among the whole society. The Hungarian Society for Pharmaceutical Sciences (MGYT) was established in 1924, with the objectives of “promoting ethical pharmacy”, “cultivating love of the natural sciences”, and “studying pharmaceutical sciences”, among others.

The only income of pharmacies is the digressive margin. Some small pharmacies receive further subsidies to their operating costs. Every pharmacy receives HUF 2.50 per receipt sent for data processing (cf. Subsection 3.5.2).

The above-mentioned incentives are not initiating the establishment of new pharmacies in rural areas (as a result of the geographic and demographic criteria).

Direct vertical integration is not allowed between the producers and the pharmacies. The legal framework for the mail order of pharmaceuticals has been in place since November 2005. The Hungarian Chamber of Pharmacists (MGYK) has already worked out this protocol and will introduce this system at the beginning of 2007.

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

Retailers	1995[1]	2000[1]	2001[1]	2002[1]	2003[1]	2004[1]	2005[1]	2006[1]
No. of community pharmacies[2]	2,335	2,603	2,606	2,627	2,652	2,642	2,649	2,654
No. of private pharmacies	915	2,599	2,602	2,623	2,648	2,638	2,645	2,650
No. of public pharmacies	1,420	4	4	4	4	4	4	4
No. of hospital pharmacies for out-patients	30	46	50	53	58	62	65	67
No. of other POM dispensaries[3]	n.a.	Ca 370	Ca 370	Ca 370	Ca 370	Ca 370	Ca 370	377
Total no. of POM dispensaries[1]	2,365	2,649	2,656	2,680	2,710	2,704	2,714	2,721
No. of Internet pharmacies	0	0	0	0	0	0	0	0
No. of OTC dispensaries, such as drugstores	0	0	0	0	0	0	0	0

POM dispensaries = including branch pharmacies, self-dispensing (SD-) doctors, and other university pharmacies (FIN), polyclinic pharmacies (NL) and hospital pharmacies acting as community pharmacies, OTC = over-the-counter (pharmaceuticals), POM = prescription-only medicine(s), n.a. = not available

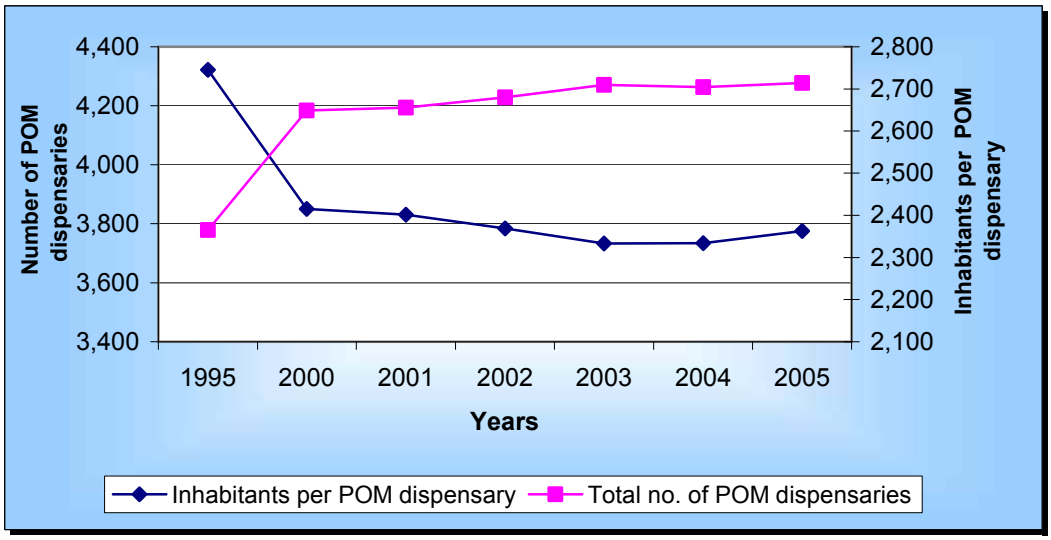
[1] as of 1 January of the year

[2] including branch pharmacies

[3] these are in self-dispensing (SD-) doctors (ca = calculation)

Source: MGYK, 2006

Figure 2.2: Hungary – Prescription-only medicine(s) (POM) dispensaries and number of inhabitants per POM dispensary 1990, 1995 and 2000-2006.



POM = prescription-only medicine(s); All POM dispensaries = including branch pharmacies, self-dispensing (SD-) doctors, and other university pharmacies, polyclinic pharmacies and hospital pharmacies acting as community pharmacies

Source: OEP, 2006

2.1.3.3.2 Other pharmacy outlets

In 2006 other pharmacy outlets were not allowed to dispense pharmaceuticals.

2.1.3.3.3 Internet pharmacies

In Hungary there have not yet been any Internet pharmacies.

2.1.3.3.4 Dispensing doctors

Besides pharmacies, self-dispensing (SD-) doctors are allowed to and do exist in rural areas; they dispense pharmaceuticals delivered by pharmacies, without any profit margin. This form of pharmaceutical distribution is of minor importance, as wholesalers are not able to hold pharmacy licenses to directly supply self-dispensing (SD-) doctors [MGYK, personal communication; HAPW, personal communication].

Only general practitioners (GPs) in small villages are allowed to dispense, where there is no pharmacy at all. They have to make a contract with a pharmacy and have to apply for permission from the National Health Service (NHS). The framework of the contracts is regulated by law.

Other people (e.g. family nurses) are not allowed to dispense pharmaceuticals.

2.1.3.4 Hospitals

In hospital pharmacies, pharmaceuticals are only supplied for internal use for the treatment of hospitalised patients – except in emergency cases – and for the employees of the hospital. Hospital pharmacies can be authorised to dispense pharmaceuticals for prescription but they have to administrate this separately.

Hospital-only medicine(s) (HOM) are also included in the positive list (0% reimbursement category), with the same coverage procedure as for out-patient pharmaceuticals. It is necessary to have a “normative 0%” reimbursement rate for inclusion into the diagnosis-related group (DRG) system.

Non-reimbursed pharmaceuticals may also be used in hospitals, but in this case, the treatment is not covered by the social health insurance (SHI) system, so the hospital has to cover the costs of these treatments.

The list (number, types) of pharmaceuticals used in a particular hospital is generally shorter than the full positive list due to professional and economical reasons. It is determined by the hospital’s chief pharmacist and the hospital’s committee of pharmaceutical therapy who take into consideration the working situation of the hospital, its needs and the time of the delivery. Purchasing, storing, distributing and control of pharmaceuticals is the responsibility of the hospital pharmacy and the chief pharmacist. Professional, economical and continuity aspects must be taken into consideration in the pharmaceutical provision of the hospital.

Each hospital establishes the committee of pharmaceuticals therapy, which has responsibility for the safe, efficient and cost-effective purchasing and use of pharmaceuticals and analyses and appraises these elements, making recommendations concerning the use of therapeutical principles.

In the in-patient sector the diagnosis-related group (DRG) system covers all the costs incurred during acute hospital care (except for investment costs), including pharmaceuticals. Thus, hospital pharmacies are maintained by the hospitals. Furthermore, every hospital has the autonomy to purchase the necessary medical products by tendering, in case of special conditions (over certain value), by public procurement. However, they have to always take into consideration the concept of rational management of public resources.

Pharmaceutical companies only have an influence over new pharmaceuticals being submitted to a particular hospital list in the event that they can offer rebates (discounts) to the hospital. The companies have right to grant rebates (discounts) in any case; this is not dependent on the reimbursement status of the pharmaceutical. For further information on hospitals cf. 3.2.4, 3.4.1 and 4.5.

2.1.3.5 Doctors

The Colleges of the Medical Professionals (professional colleges) are the highest level of professional advisory/consultative body.

Professional colleges have several responsibilities, including: working out guidelines and protocols; and offering opinions on health care developments, professional conceptual plans and financing health care provisions, etc. They advise on reimbursement decisions, including estimating the patient population with suggested indications or limitations for rational use, and offering opinions on the relative effectiveness of pharmaceuticals.

In connection with pharmaceutical policy-making doctors have a legally defined right to influence reimbursement decisions.

If the National Health Insurance Fund Administration (OEP) receives an application for the reimbursement of pharmaceutical from a special or high indication-bound reimbursement category, it requires a new disease category or indication to be listed in the Official Bulletin. This list is published by the Ministry of Health (EüM / MoH) on the basis of the National Health Insurance Fund Administration (OEP) proposal made after the opinion of the relevant professional medical college has been sought.

In the case of special reimbursed pharmaceuticals (Special Allocated Budget) the contract between the National Health Insurance Fund Administration (OEP) and the institute, with the nationwide coordinating function, allows the purchase of pharmaceuticals for the treatment of disease categories mentioned in the communiqué published by the Minister of Health and the Minister of Finance, based on protocols devised and published by the competent professional colleges. If an application is received for the reimbursement of a medical product which has an active ingredient that is not in the communiqué, the professional colleges have the same competencies mentioned above.

Pharmaceuticals that are newly included but with active ingredient(s) that is not yet reimbursed can be granted special reimbursement under a price–volume agreement or procurement procedure only if the relevant professional colleges have given a written justification in support of this.

2.1.3.6 Patients

As Hungary operates a reference price system, which has been expanded during recent years, the patient may only opt for pharmaceuticals above the reference price at her/his expense.

As the reference price system has gradually been moved from International Non-proprietary Name (INN)-based Anatomic Therapeutic Chemical ATC-5 level groups to Anatomic Therapeutic Chemical ATC-4 level (therapeutic groups), patients might be confronted with a choice between an innovative product and a selection of older brands and their generics, representing the therapeutic alternative. This is due to the fact that pharmaceuticals with different mechanisms of action and levels of effectiveness are clustered within one reference pricing group. As patients usually lack information on pharmaceuticals and the effectiveness of therapeutic alternatives, they have to rely on the advice of doctors and pharmacists concerning their treatment.

Hospital doctors can prescribe by International Nonproprietary Name (INN) when dismissing a patient; general practitioners (GPs) also have the option of doing so. There are plans to introduce compulsory International Nonproprietary Name (INN) prescribing for general practitioners (GPs) as well, though this has not been implemented yet. Pharmacists are obliged to offer generic substitution in all cases, thus the role of the pharmacist has been strengthened.

The pharmacy retail price (PRP) is uniform all over the country. The prices of the pharmaceuticals are set by the manufacturer. Pharmacies are not allowed to deviate from the co-payment charge of any reimbursable pharmaceutical. The pharmacy retail price (PRP) of all pharmaceuticals is published quarterly by the Hungarian Chamber of Pharmacists (MGYK).

2.2 Funding

2.2.1 Pharmaceutical expenditure

In 2005, expenditure on pharmaceuticals (HUF 545 billion) exceeded the amount that the Health Insurance Fund (E. Alap / HIF) had spent on in-patient care (HUF 364 billion). As a share of gross domestic product (GDP), pharmaceutical spending totalled 2.1% (2002), ranking Hungary in third place compared with the European informant Organisation for Economic Co-operation and Development (OECD). One third (32.8% in 2005) was financed by private households and two thirds through the social health insurance (SHI) and national government budget.

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

Pharmaceutical expenditure (PE)	1995[1]	2000[2]	2001[2]	2002[2]	2003[2]	2004[2]	2005[2]
TPE in HUF	104,847	250,178	295,497	344,258	408,794	458,050	545,741
TPE as a % of THE	24.99	26.63	27.02	26.49	26.52	28.04	n.a.
TPE per capita in NCU	10,151	24,501	29,006	33,888	40,357	45,319	54,103
Public PE as a % of THE	16.70	17.22	17.52	17.31	17.40	18.46	n.a.
Private PE as a % of THE	8.29	9.42	9.50	9.18	9.12	9.40	n.a.

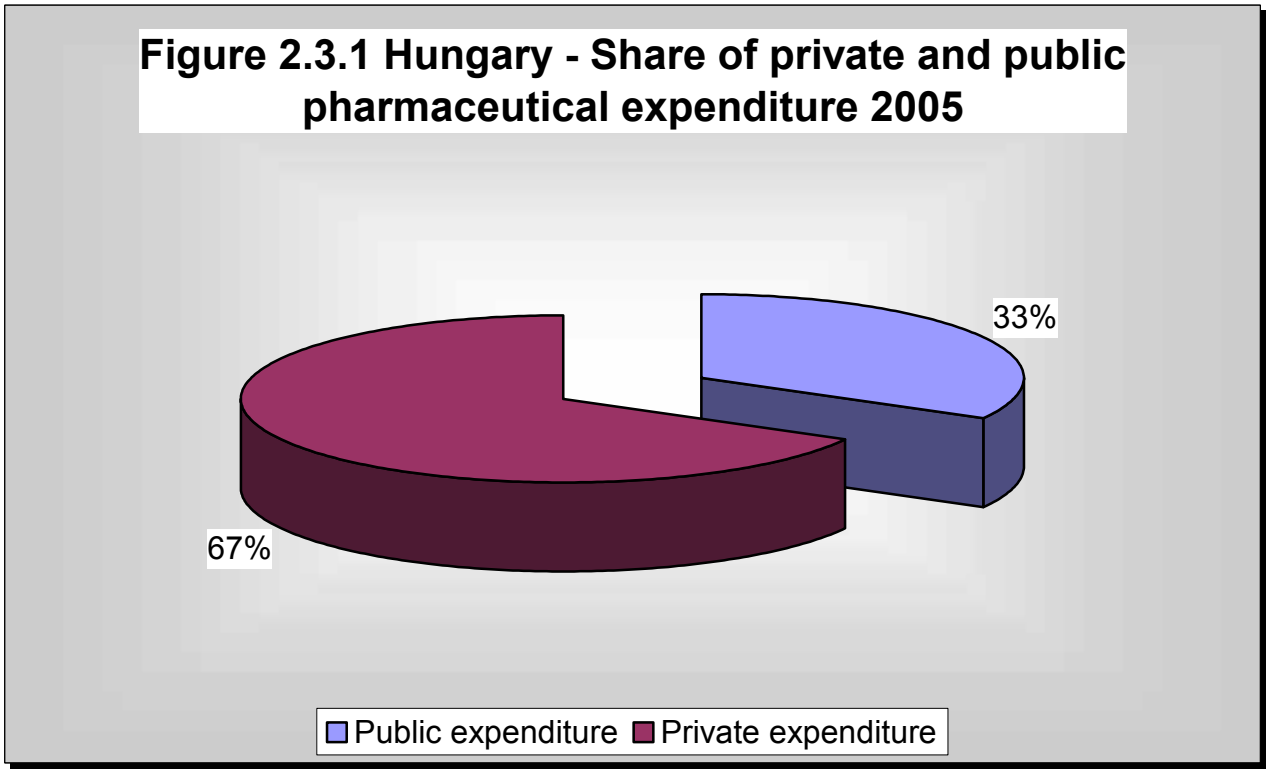
TPE = total pharmaceutical expenditure, NCU = national currency unit (HUF), PE = pharmaceutical expenditure, THE = total health expenditure, PE = pharmaceutical expenditure

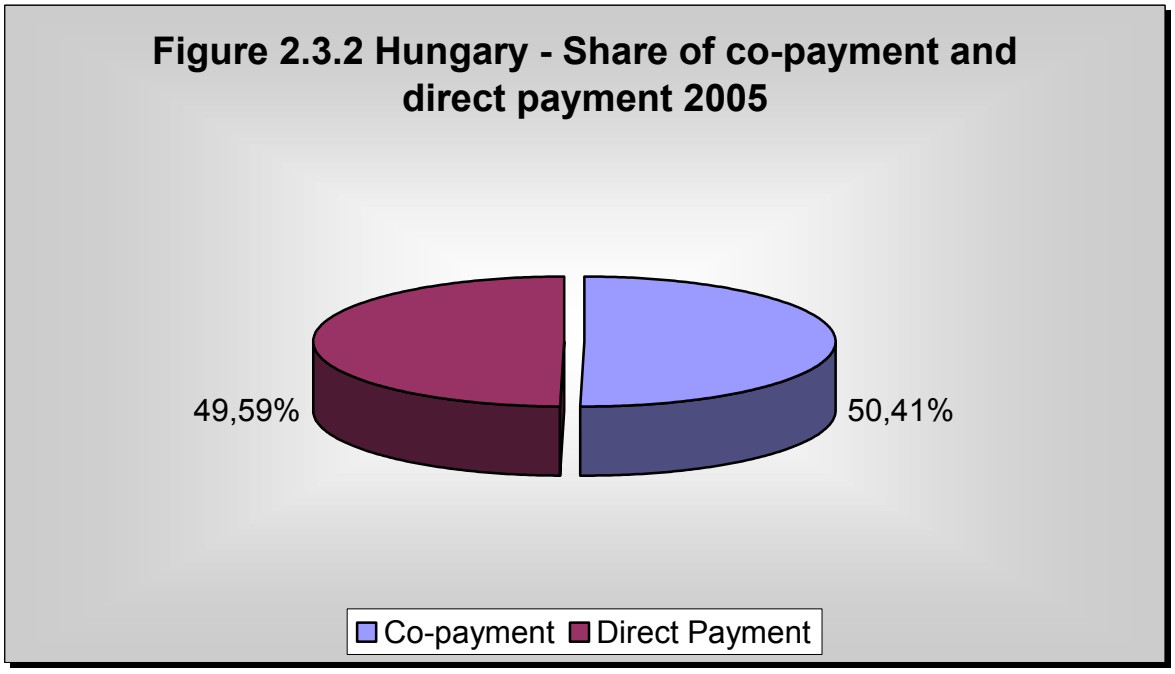
Sources: [1]OECD Health Data 2006, [2]OEP, 2006

2.2.2 Sources of funds

The main sources of public pharmaceutical funding are the health insurance contribution and health taxes paid by the employers and employees. In addition to this, an essential part of the funding is financed by the national Government from taxes, covering the yearly deficit (HUF 64 billion in 2005) which arose in the pharmaceutical budget (HUF 348 billion, 2005) of social health insurance (SHI), and the pharmaceutical co-payment exemption system (HUF 18 billion, 2005), which aims to help the very low income inhabitants.

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





Source: OEP, 2006

The proportion of reimbursement products as a share of the reimbursement scheme allocated to private households is far less (19.82% in 2005) than in the total turnover (32.8% in 2005) and it has been decreasing moderately since 2003 (20.48%). Public expenditure on pharmaceuticals rose faster (37.8%) than private expenditure (27.7%) between 2003 and 2005. In 2005, the total

reimbursed pharmaceutical turnover made up 83.69% of the total turnover of the pharmaceutical market.
The Ministry of Health (EüM / MoH) determines the percentage level of subsidy (cf. 4.6.3), which the producers can apply for, for certain substances. The regulation of the Ministry of Health (EüM / MoH) and the decision of the social health insurance (SHI) authorities determine together what co-payment the patient will have to pay for the product(s). Private and voluntary health insurance (VHI) do not play an essential role in the financing of pharmaceuticals in Hungary.

2.3 Evaluation

At the moment there is no established system for monitoring of the outcome of pharmaceutical policy. However, Law No. XCVIII of 2006 on the safe and economic supply and distribution of pharmaceuticals rules that the outcome and impact of the new measures introduced in December of 2006 have to be evaluated by 30th September of 2007.

3 Pricing

3.1 Organisation

At manufacturer level, the system includes free pricing for all pharmaceuticals regardless of their prescription status (prescription-only medicine(s) (POM) or over-the counter (OTC) products). Thus, pharmaceutical companies are free to set their own prices for non-reimbursable pharmaceuticals. There is no other price-setting procedure.

With regard to pharmaceuticals applying for reimbursement, the legal framework for pricing is set out in the Decree of the Ministry of Health 32/2004, together with the reimbursement-related regulation. If a product is included in the positive list, the manufacturer has to apply for reimbursement to the National Health Insurance Fund Administration (OEP). However, the application has to include the proposed manufacturer price. The National Health Insurance Fund Administration (OEP) may accept or reject the reimbursement at the proposed price. Negotiations between the National Health Insurance Fund Administration (OEP) and the pharmaceutical companies start when a pharmaceutical has been accepted for reimbursement but the proposed price is considered to be (too) high.

In summary, the National Health Insurance Fund Administration (OEP) never sets the prices: it is the responsibility of the pharmaceutical company to adjust its prices, and the National Health Insurance Fund Administration (OEP) to accept or reject them.

The reimbursement process takes 90 days (cf. Chapter 4). As stated above, over-the-counter (OTC) prices are free priced. For over-the-counter (OTC) products which are included in the list for socially disadvantaged people, prices are negotiated with the National Health Insurance Fund Administration (OEP).

Prices for hospital products are agreed in the same way as prices for reimbursable pharmaceuticals, but this price functions as a maximum limit, thus leaving hospitals and manufacturers or wholesalers the possibility to negotiate.

Before the enforcement of the new transparent pharmaceutical reimbursement and coverage policy system, price negotiations were the main method behind pharmaceutical pricing in Hungary.

Pharmaceutical prices are notified by the manufacturer to the Hungarian Chamber of Pharmacists (MGYK).

3.2 Pricing policies

Law No. LXXXVII of 1990 on setting prices was implemented in 1990. The price margins of the pharmaceutical are regulated by the Decree of the Ministry of Health 19/2001. The present form of the Decree entered into force on 1 January 2004.

There is no difference in pricing mechanism between the different types of pharmaceuticals (e.g. prescription-only pharmaceuticals, me-too products, generics, parallel traded pharmaceuticals). It rather depends on the type of reimbursement or the level of the pharmaceutical within the pricing system.

There are no pricing decisions at any level, including at manufacturer level, wholesale level, pharmacy level or other. Only the price margins (retail and wholesale) are regulated by the Decree mentioned above.

Price changes are possible for all pharmaceuticals. There are only procedural differences between the reimbursed and the non-reimbursed ones.

All pharmaceuticals are free priced, according to Decree of the Ministry of Health 32/2004. At the beginning of the reimbursement procedure, the reimbursed pharmaceuticals have to accomplish the (main) criteria listed here.

- For innovative pharmaceuticals, companies have to indicate, along with other information, the prices in selected European Union (EU) Member States and pharmacoeconomic studies in their application form. Where there is a non-reimbursed active substance, the new pharmaceutical's price is not approved when the price is higher than the lowest price of the listed countries. The Decree contains this list (cf. 3.3.1).
- For generics, the terms of inclusion into the reimbursement lists stipulate that the product's price must be lower by at least 30% than the original one until the first reference price evolves (cf. 3.3.2) [Decree of the Ministry of Health 32/2004].
- When a fixed group is available, the new pharmaceutical can only be reimbursed at the price equal to the reference preparation daily cost of therapy (DCT / NTK) or the reference price daily cost of therapy (DCT / NTK), or at a lower price. Any preparation that is not eligible to be placed in a fixed-amount group (not equivalent) can only be reimbursed at the price equal to the reference daily cost of therapy (DCT / NTK) of the fixed group having the same active ingredient and the same strength or lower price (cf. 3.3.2) [Decree of the Ministry of Health 32/2004].

Among the non-reimbursed pharmaceuticals the manufacturer has to announce the price change to the Hungarian Chamber of Pharmacists (MGYK). This procedure can be repeated month by month. According to the Law No. LXXXVII of 1990 on the establishment of prices, the non-reimbursed pharmaceuticals have free pricing, so the manufacturer only has an obligation to announce the price. The Hungarian Chamber of Pharmacists (MGYK) has to adopt the announced price (on each occasion).

Among the reimbursed products the manufacturer has to request the price change from the National Health Insurance Fund Administration (OEP). The duration of the procedure is 90 days, so the number of announcements is limited. In case of reimbursement changes, the National Health Insurance Fund Administration (OEP) has the right to accept or decline the appeal. The National Health Insurance Fund Administration (OEP) is obligated to publish all accepted changes in every quarter.

Table 3.1: Hungary - Ways of pricing of pharmaceuticals

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free pricing	All pharmaceuticals regardless of their prescription status	Not applied	Not applied
Statutory pricing	Prices for pharmaceuticals applying for inclusion in the reimbursement lists may be negotiated with the OEP	All pharmaceuticals regulated via a regressive mark-up scheme	All pharmaceuticals regulated via a regressive mark-up scheme
Price negotiations		Not applied	Not applied
Price–volume agreements, discounts/rebates	Yes (Price freezes 2004-2006 and claw back for 2005 and 2006) ,cf. 3.2.4	Not applied	Not applied
Institution in charge of pricing	Manufacturers EüM / MoH sets the legislative framework Price of reimbursable pharmaceuticals is agreed between the OEP and the pharmaceutical companies		
Legal basis	Law No. LXXXVII of 1990 on the establishment of prices Decree of the Ministry of Health 19/2001 on the commercial price mark up of pharmaceuticals Decree of the Ministry of Health 32/2004 on the criteria of registered pharmaceuticals Contract between the Government and the pharmaceutical industries – set out in the Decree of the Government 217/1997		

OEP **=** National Health Insurance Fund Administration, EüM / MoH = Ministry of Health

Source: OEP, 2006

3.2.1 Statutory pricing

Statutory pricing is not applied at manufacturer level, but at wholesale and pharmacy levels. All pharmaceuticals are regulated via a regressive mark-up scheme [Decree of the Ministry of Health 19/2001 on the commercial price mark up of pharmaceuticals].

Three main authorities are involved in the procedure: the Ministry of Health (EüM / MoH), the National Health Insurance Fund Administration (OEP) and the Hungarian Chamber of Pharmacists (MGYK). Both internal and external price referencing are applied but only among the reimbursed pharmaceuticals. This process is legislated by Decree of the Ministry of Health 32/2004. Cf. 3.3 for details of the different pricing procedures.

The current system was implemented on 1 May 2004, when Decree 32/2004 entered into force. This Decree – as mentioned above – regulates only the reimbursed medicals. Decree 19/2001 on the commercial price mark up of pharmaceuticals has been in operation since 01 July 2001. The legal framework is further supported by the Price Act [Act No. LXXXVII of 1990 on setting prices].

Enforcement is not relevant in terms of non-reimbursed pharmaceuticals. Decree of the Ministry of Health 32/2004 defines exactly the requirements which gives the possibility for exclusion of certain medicines (cf. Chapter 4).

In summary, all the terms of statutory pricing are written into the law, and the parties concerned have to observe these laws in practice. However, the pricing procedure and the process of inclusion of pharmaceuticals into the positive list can be difficult to separate from each other (cf. Chapter 4 for further procedural information).

3.2.2 Negotiations

Price negotiations are only used at manufacturer level. For pharmaceuticals that should be included in the positive list, manufacturers have to apply for reimbursement to the National Health Insurance Fund Administration (OEP). The application has to include, among other things, the proposed manufacturer price. The proposed price is either approved by the National Health Insurance Fund Administration (OEP) or negotiations take place and the pharmaceutical company may then reduce the proposed price. The National Health Insurance Fund Administration (OEP) therefore does not set any price, but accepts or rejects price proposals from pharmaceutical companies.

For this kind of pricing policy there are three relevant parties. The main authority is the National Health Insurance Fund Administration (OEP), which operates within the supervisory authority of the Ministry of Health (EüM / MoH). The Pharmaceutical Department of the National Health Insurance Fund Administration (OEP) conducts the negotiations with the producers on its behalf. The Technology Appraisal Committee (TÉB) gives advices to the Pharmaceutical Department on the negotiation. On the other side of the process are the manufacturers.

The pricing procedures and the legal framework are the same in the case of statutory pricing (cf. 3.2.1).

This system has been operating since 01 May 2004, when Decree of the Ministry of Health 32/2004 entered into force. This decree regulates the exact procedure (cf. Chapter 4).

If the negotiations fail, the pharmaceutical will not be included in the positive list. This therefore means that the manufacturers are often keen to compromise.

3.2.3 Free pricing

Free pricing is only applied at manufacturer level. This is the case for all pharmaceuticals regardless of their prescription status. In case of reimbursement, free pricing is also permitted, regulated by Decree of the Ministry of Health 32/2004.

This procedure was implemented in 1990, when the Price Act came into effect.

Manufacturer prices may be set freely. The manufacturers have to notify the National Health Insurance Fund Administration (OEP) of their reimbursement prices, and for non-reimbursed

pharmaceuticals they must notify the Hungarian Chamber of Pharmacists (MGYK). Prices of non-reimbursed pharmaceuticals may be altered monthly. Owing to a provision in an agreement between the manufacturer associations and the Ministry of Health (EüM / MoH) / National Health Insurance Fund Administration (OEP), since June 2004 prices of reimbursed pharmaceutical have not been allowed to change unless the exchange rate drops by more than 6.25%. This agreement is to last until the end of 2006.

3.2.4 Public procurement / tendering

Tendering is relevant in two pharmaceutical groups: in the group of hospital-only medicine(s) (HOM) (cf. 3.4.1); and in the group of special reimbursed pharmaceuticals (Special Allocated Budget). In either case, however, tendering is only available for reimbursed pharmaceuticals.

The National Health Insurance Fund Administration (OEP) grants 100% reimbursement to the purchase price of special reimbursed pharmaceuticals with the understanding that in other cases the provisions of Decree of the Government 130/2004 on the detailed and special rules of the procurement of pharmaceuticals and medical devices shall apply.

The volume of this kind of procedure is approximately 5% of the total pharmaceutical budget. It is carried out for pharmaceuticals that are very expensive or required by a limited number of patients (e.g. multiple sclerosis, haemophilia, HIV).

According to the Hungarian experiences, the tendering process has a cost-containment effect. For some diseases (e.g. haemophilia), tendering results in a price reduction. In the case of hospital-only medicine(s) (HOM), the competent hospital is responsible for the whole process.

3.3 Pricing procedures

Table 3.2: Hungary - Pricing procedures

Pricing procedure	In use: Yes / No	Level of pricing	Scope
Internal price referencing	Yes	Price accepted as the basis for public funding (VAT added retail price)	Reimbursable pharmaceuticals
External price referencing	Yes	Price accepted as the basis for public funding (VAT added retail price)	Reimbursable pharmaceuticals
Cost-plus pricing	No	n. app.	n. app.
Other, e.g. indirect profit control	No	n. app.	n. app.

VAT = value-added tax

Source: OEP, 2006

3.3.1 External price referencing

In the case of innovative pharmaceuticals, companies have to indicate external prices in their reimbursement application. The manufacturer price of a newly included preparation containing active ingredient(s) that is not yet reimbursed cannot be higher than the lowest of the existing manufacturer prices in the countries listed in the application (France, Ireland, Germany, Spain, Portugal, Italy, Greece, Poland, Check Republic, Slovenia, Slovakia, Belgium, Austria, one additional country) [Art. 7 and Annex. No. 3/a of Decree of the Ministry of Health 32/2004].

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

Besides the prices, information has to be given on the market share of the pharmaceutical at Anatomic Therapeutic Chemical ATC-4 level in the referenced countries.

3.3.2 Internal price referencing

With application for reimbursement, pharmaceutical companies have to submit information on (among other things) the proposed manufacturer price and on daily treatment costs in comparison with therapeutic alternatives at Anatomic Therapeutic Chemical ATC-4 level.

The inclusion and reimbursement criteria are listed here.

a. New packaging should be included in the same manufacturer price and with the same reimbursement extent as the previous packaging.
b. A new pack size should be included in the price of the unit dose of the active ingredient, calculated at the same or lower manufacturer price.
c. A new strength may be included in the price of the unit dose of the active ingredient, calculated at the same or lower manufacturer price of an already reimbursed preparation with the same brand name.
d. A new formulation may be reimbursed at the same therapeutic cost as pharmaceuticals with the same mode of application or same brand name, or at a lower price.
e. A second brand product of an original preparation for which a generic version has not yet been produced can be reimbursed at the price of the active ingredient, calculated on the unit dose of the manufacturer price, or at a lower price.
f. Newly reimbursed preparation’s generics eligible for fixed-amount reimbursement, can only be reimbursed at the price equal to the reference preparation daily cost of therapy (DCT / NTK) or the reference price daily cost of therapy (DCT / NTK), or at a lower price. Any preparation that is not eligible to be placed in a fixed-amount group (not equivalent) can only be reimbursed at the price equal to the reference daily cost of therapy (DCT / NTK) of the fixed group having the same active ingredient and same strength, or at a lower price.
g. A condition for the inclusion of generics is that the manufacturer price of the preparation should be at least 30% below the manufacturer price of the original preparation as long as the first reference product or reference price is set.

h. If the preparation has major therapeutic benefit, the market authorisation holder can apply, under normal procedure, for reimbursement at a higher price and for the applying for inclusion to the positive list.

i. If the gross pharmacy retail price or the daily cost of therapy (DCT) of a unit dose of the active ingredient – in a combination product, with the same dosage form but cheaper, with the same mode of application, and with the same or similar strength and pack size – does not exceed 10% of the total gross pharmacy retail price, the price of the combination product cannot be higher than the price of the product containing a more expensive active ingredient.

j. If the gross pharmacy retail price or the daily cost of therapy (DCT) of a unit dose of the active ingredient(s) in a combination product exceed 10% of the total gross pharmacy retail price per active ingredient, the price of the combination product cannot be higher than the maximum amount of the gross pharmacy retail price of the active ingredients in a mono-component product containing the active ingredient(s) in the combination product and having the same dosage form, same mode of application or the same or similar strength and pack size.

k. If the combination product has major therapeutic benefit compared to the combined use of the previous same active ingredients and if the market authorisation holder applies for a higher price or reimbursement as outlined in paragraphs (i)-(j) (above), the application should be processed according to the normal procedure.

l. As far as galenic preparations are concerned, if they were registered by the National Institute of Pharmacy (OGYI), as defined in a separate piece of legislation, reimbursement is to be 90% of the price that is accepted as the basis for public financing.

3.3.3 Cost-plus pricing

In Hungary cost-plus pricing procedures have not yet been applied.

3.3.4 (Indirect) Profit control

The profits of pharmaceutical companies are indirectly influenced by the above-mentioned cost-containment measures (cf. 4.6) and most directly by price stops and the claw back and individual price–volume agreements. However, there are no direct company profit controls, such as those that are in place e.g. in the United kingdom.

3.4 Exceptions

3.4.1 Hospitals-only

In the in-patient sector the diagnosis-related group (DRG) system covers all the costs that occur during acute hospital care (except for investment costs), including pharmaceuticals. Furthermore, every hospital has the autonomy to purchase the necessary medical products by tender-

ing, in case of special conditions (over certain value), by public procurement. However, they have to always take into consideration the concept of rational management of public resources.

Pharmaceutical companies only have an influence over new pharmaceuticals being submitted to a particular hospital list in the event that they can offer rebates (discounts) to the hospital.

Hospital-only medicine(s) (HOM) are also included in the positive list (0% reimbursement category), with the same coverage procedure as for out-patient pharmaceuticals.

Information concerning prices and costs of pharmaceuticals in hospitals is collected in the reports about the real monthly use of hospital pharmaceuticals which is to be sent to the county health insurance administrations and the National Programme of Statistical Data Acquisition (Országos Statisztikai Adatgyűjtési Program, OSAP).

3.4.2 Generics

In Hungary there is no different price-setting procedure for generics, but there are some specific regulations in terms of reimbursement (Decree of the Ministry of Health 32/2004), which determine the maximum prices of the generics applying for reimbursement (cf. 3.3.2).

- Newly reimbursed preparation's generics, eligible for fixed-amount reimbursement, can only be reimbursed at the price equal to the reference preparation daily cost of therapy (DCT / NTK) or the reference price daily cost of therapy (DCT / NTK), or at a lower price. Any preparation that is not eligible to be placed in a fixed-amount group (not equivalent) can only be reimbursed at the price equal to the reference daily cost of therapy (DCT / NTK) of the fixed group having the same active ingredient and same strength, or at a lower price.
- A condition for the inclusion of generics is that the manufacturer price of the preparation should be at least 30% below the manufacturer price of the original preparation as long as the first reference product or reference price is set.

3.4.3 Over-the-counter pharmaceuticals

There is a free pricing system in Hungary, so the price of the over-the-counter (OTC) pharmaceuticals is only regulated by Act No. LXXXVII of 1990.

3.4.4 Parallel traded pharmaceuticals

According to information of the Hungarian Chamber of Pharmacists (MGYK), parallel imported products are of no relevance in Hungary [MGYK, personal communication].

In general, there are only a very few parallel traded pharmaceuticals. The market authorisation process of such pharmaceuticals is regulated by decree [Decree of the Ministry of Health 53/2004]. Parallel trade is not taken into account as part of the decision on reimbursement status.

Parallel traded products are not taken into account for internal price referencing.

3.4.5 Other exceptions to the pricing schemes

Pharmaceuticals may be reimbursed on behalf of individual applications. Such applications may be filed because of the social situation involved, or due to a disease that needs special, expensive treatment. Furthermore, pharmaceuticals not authorised, or else not available, in Hungary, or excluded from general reimbursement, may be reimbursed under certain circumstances on individual application.

Individual applications are considered on a case by case basis, although there are certain trends as to what kind of pharmaceuticals are reimbursed.

There are two pricing methods for pharmaceuticals reimbursed on behalf of individual applications:

- In cases in which the pharmaceutical is authorised in Hungary but not included in the positive list (or reimbursed only in other indications, or because of the social status of the patients there is a need for higher reimbursement), the price is determined in accordance with the lists of non-reimbursed (NT) (or reimbursed) pharmaceuticals maintained by the National Health Insurance Fund Administration (OEP) or the Hungarian Chamber of Pharmacists (MGYK).
- In cases in which the pharmaceutical is not authorised in Hungary the price is derived from the price in the country where the pharmaceutical is on the market and from where the pharmaceutical would be imported by the particular pharmacy (individual import).

3.5 Margins and taxes

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

Wholesale mark up			Pharmacy mark up		
Regulation (yes / no)	**Content**	**Scope***	**Regulation (yes / no)**	**Content**	**Scope**
Yes	Regressive mark ups	All pharmaceuticals	Yes	Regressive mark ups	All pharmaceuticals

Source: OEP, 2006

3.5.1 Wholesale remuneration

In Hungary the wholesalers are remunerated via regressive mark ups (cf. Table 3.4), which are regulated by Decree of the Ministry of Health 19/2001. The law applies to all pharmaceuticals. In the Hungarian system both the percentage and the fixed amount are used.

Table 3.4: Hungary - Wholesale mark-up scheme 2006

Ex-factory price in €[1]	Maximum mark up as a % of ex-factory price	Wholesale price in €[1]
0.01-0.60	12.0	n. app.
0.61-0.73	n. app.	0.07
0.74-1.21	10.0	n. app.
1.22-1.34	n. app.	0.12
1.35-2.02	9.0	n. app.
2.03-2.42	n. app.	0.18
2.43-4.03	7.5	n. app.
4.04-4.65	n. app.	0.30
4.66-8.06	6.5	n. app.
8.07-10.48	n. app.	0.52
Over 10.48	5.0	n. app.

[1] average exchange rate, 2005

Source: Decree of the Ministry of Health 19/2001, 2001

3.5.2 Pharmacy remuneration

Pharmacists are remunerated via regressive mark ups, regulated by Decree of the Ministry of Health 19/2001. The law applies to all pharmaceuticals. The average margin, assessed by the turnover data in 2005, was 19.46%. In the Hungarian system both the percentage and the fixed amount are used.

Table 3.5: Hungary - Pharmacy mark-up scheme 2006

Pharmacy purchasing price (PPP) from … to… in HUF / €	Pharmacy mark-up coefficient as a % of pharmacy purchasing price (PPP) or a fixed amount
Up to HUF 500 / € 2.02	26%
From HUF 501 / € 2.03 – To HUF 590 / € 2,38	HUF 130 / € 0.52
From HUF 591 / € 2.04 – To HUF 1500 / € 6.05	22%
From HUF 1501 / € 6.06 – To HUF 1737 / € 7.00	HUF 330 / € 1.33
From HUF 1738 / € 7.01 – To HUF 3500 / € 14.11	19%
From HUF 3501/ € 14.12 – To HUF 3911 / € 15.77	HUF 665 / € 2.68
From HUF 3912/ € 15.78 – To HUF 5000 / € 20.16	17%
From HUF 5001/ € 20.17	HUF 850 / € 3.43
Average mark up	**19.46%**[1]

[1] average margin, turnover data in 2005 by the National Health Insurance Fund Administration (OEP)

Source: Decree of the Ministry of Health 19/2001, 2001

The pharmacy retail price (PRP) for reimbursable pharmaceuticals is uniform throughout the country; pharmacies are not allowed to deviate from the co-payment charge of any reimbursable pharmaceutical.

For non-reimbursable pharmaceuticals, since summer 2005 pharmacies have to pass on discounts received during procurement to the patients, thus calculating the pharmacy retail price (PRP) according to the pharmacy mark-up scheme based on the discounted wholesale price [Art. 31.b of Law 95/2005 on pharmaceuticals for human use and on the amendment of other laws regulating the pharmaceutical market]. The pharmacy retail price (PRP) of non-reimbursable pharmaceuticals might therefore vary slightly between pharmacies according to the negotiated wholesale discounts they receive. Therefore, the pharmacy retail price (PRP) published is of an informative nature, but according to the Hungarian Chamber of Pharmacists (MGYK), in practice the pharmacy retail price (PRP) of non-reimbursable pharmaceuticals is uniform throughout the country as well, as the law does not specify according to which method wholesale discounts are to be broken down to a product basis and then passed on to the customers [MGYK, personal communication, May 2006].

The pharmacy retail prices (PRPs) of all pharmaceuticals are published quarterly by the Hungarian Chamber of Pharmacists (MGYK).

3.5.3 Remuneration of other dispensaries

There are no other remuneration techniques in Hungary (cf. 2.1.3.3).

Besides the pharmacies, self-dispensing (SD-) doctors supply patients with pharmaceuticals in rural areas. They have to procure the pharmaceuticals through a pharmacy, without being granted a profit margin.

3.5.4 Value-added tax

In the last few years there have been several changes in the value-added tax (VAT) rates in Hungary.

- Although in the year 2003 there were no changes in value-added tax (VAT) rates (0%, 12%, 25%), some tax exempt goods and services were shifted to reduced or standard value-added tax (VAT) rate, in accordance with the European Union (EU) legal harmonisation.
- In the year 2004 modifications to the value-added tax (VAT) system in Hungary had essentially two objectives: legal harmonisation with the regulations of the European Union (EU) and strengthening the balanced position of the budget. The 0% value-added tax (VAT) rate was replaced by the 5% minimum rate – according to the 6th Directive (77/388/EEC) of the European Union (EU) – e.g. in the case of pharmaceuticals and textbooks. There were some measures regarding transposition of certain goods and services among the tax rates, including some, for which no derogation was granted. The 12% reduced value-added tax (VAT) rate was increased to 15% for purposes of balancing the budget.

- From 1 January 2006, the 25% standard value-added tax (VAT) rate has been decreased to 20%. Moreover, the reduced 15% value-added tax (VAT) rate has also been increased to 20% from 1 September 2006. These measures are to simplify the value-added tax (VAT) system without any considerable decrease of value-added tax (VAT) revenue.

At the time of writing, the standard value-added tax (VAT) rate was 20% in Hungary. For pharmaceuticals (human registered medicines), a 5% rate is applied, which is the allowed minimum level of reduced value-added tax (VAT) rate in the European Union (EU) according to the 6th VAT Directive.

For the time being there are no amendments planned concerning the current value-added tax (VAT) rates (5%, 20%).

3.5.5 Other taxes

There are no other taxes on pharmaceuticals in Hungary.

3.6 Pricing-related cost-containment measures

Hungary has been struggling with its publicly funded pharmaceutical expenditure (PE) for quite some years. Pharmaceutical expenditure (PE) ranks second place on the list of expenditure categories and accounts for over 30% of the National Health Insurance Fund Administration's (OEP) budget. As the National Health Insurance Fund Administration's (OEP) pharmaceutical budget has been overspent in the past, the Ministry of Health (EüM / MoH) and the National Health Insurance Fund Administration (OEP) have been looking for ways to reduce public pharmaceutical expenditure (PE). Both price-related and volume-related cost-containment measures have been set, including price stops/freezes; price–volume agreements and claw backs; and agreements binding prices of imported pharmaceuticals to exchange rate fluctuations.

3.6.1 Discounts / Rebates

There is not legal basis for rebates (discounts). There are individual cases when a manufacturer gives rebates (discounts) to pharmacies or hospitals, but there is no set model for how this should be carried out.

Furthermore, there are no statutory fixed rebates (discounts) that the industry must grant to the National Health Insurance Fund Administration (OEP) or any other public body. However, there is a history of claw backs between the pharmaceutical industry and the National Health Insurance Fund Administration (OEP).

Besides the claw back scheme for the pharmaceutical industry, there are individual price–volume agreements with manufacturers for certain pharmaceuticals. Depending on the contract there are yearly paybacks based on the monetary yearly sales volume; above certain defined limits the manufacturer has to pay back an increasing percentage share to the National Health Insurance Fund Administration (OEP), up to 100% of the exceeded volume. Monthly paybacks

may also be agreed in individual contracts, with the payback sum depending on the monthly sales volume (cf. 4.6.4 for further details of the contracts).

3.6.2 Margin cuts

The pharmacy mark-up scheme was last modified with effect from 1 January 2004, which resulted in an increase of the average pharmacy margin from 15.42% in 2003 to 16.64% in 2004, rather than in a margin cut, after a decrease in the average pharmacy margins since the year 2000.

Wholesale mark ups remained practically unchanged from 1993 to 1999. In 1999, the wholesale mark ups were lowered (an average decrease of 1.5%), and again in 2002.

3.6.3 Price freezes / Price cuts

A price stop was introduced by the political decision-makers in the year 2000; following this price stop, pharmaceutical prices were only allowed to be raised below the inflation rate between 2000 and 2003. Under this agreement between the Government and the pharmaceutical industry associations, the prices of all pharmaceuticals were only allowed to rise on three occasions.

After the elections of 2002, the new Government introduced another price stop, to last until the end of 2002. Prices of non-reimbursable pharmaceuticals were allowed to be changed quarterly from January 2003 onwards, while for reimbursable pharmaceuticals only a modest price increase was put into effect on 1 February 2003. Prices went up by an average of 4.5%, whereas more expensive pharmaceuticals were raised by a smaller percentage than pharmaceuticals priced HUF 550.00 / € 2.17 (in 2003) or below. The price hike of 1 July 2003 under this agreement failed to materialise and prices of reimbursable pharmaceuticals remained frozen until February 2004.

In addition, a price–volume agreement was introduced from September to December 2003 to control pharmaceutical expenditure (PE).

A further industry claw back was proposed for the first half of 2004. According to an agreement, from January to June 2004 manufacturers should pay back 15% of the revenue of pharmaceutical sales to the National Health Insurance Fund Administration (OEP). As only a small part of the manufacturers signed the agreement (whilst 138 manufacturers representing 85% of the Hungarian market opposed it); the Government imposed a price cut of 15% from 1 April 2004 for a period of six months on all pharmaceuticals (reimbursable and non-reimbursable), with a pharmacy retail price (PRP) above HUF 600.00 / € 2.38 (2004) for manufacturers not signing the contract. After legal complaints filed by the pharmaceutical industry associations, the price cut was ruled unconstitutional and lost its validity, as did the agreement signed by some manufacturers, on 30 June 2004.

A new agreement between the pharmaceutical industry associations and the Government entered into force from July 2004, valid until July 2006. Under this agreement both local and multinational manufacturers set wholesale prices in € at a fixed exchange rate of HUF 251.24 to the

€ and contracted to refrain from raising HUF prices, unless HUF drops more than 6.25% against the €. Any resulting price increase has to be reported by 30 April before entering into force on 1 July each year. In return the Government promised to increase the National Health Insurance Fund Administration's (OEP) pharmaceutical budget. In January 2005, as agreed in the above-mentioned contract, prices of pharmaceuticals below HUF 600.00 / € 2.42 (2005) were raised by HUF 45.00 / € 0.18; pharmaceuticals priced between HUF 600.00 / € 2.42 and HUF 1,000.00 / € 4.03 were increased by HUF 70.00 / € 0.28. In July 2005 prices of 1,200 reimbursable pharmaceuticals were raised again.

In addition, claw back was signed for 2005 and 2006 (cf. Chapter 6).

3.6.4 Price reviews

The National Health Insurance Fund Administration (OEP) has no authority to change the reimbursed price of pharmaceuticals, but through the internal reference pricing it regularly (once in 2006, four times in 2007) revises the list of the pharmaceuticals which belong to the different therapeutic or active substance fixed groups.

4 Reimbursement

4.1 Organisation

The reimbursement policy is regulated by several decrees and acts, including those listed here.

- Law No. LXXXIII of 1997 on compulsory health services in the framework of social security Decree 217/1997 on compulsory health service provision.
- Decree of the Ministry of Health 1/2003 on the pharmaceuticals co-financed by social insurance and its amount.
- Decree of the Ministry of Health 32/2004 on the criteria of inclusion of registered pharmaceuticals and foods satisfying particular dietary requirements into social insurance coverage, and on altering coverage or reimbursement status.

The reimbursement scheme only differentiates the simplified and the normal procedure. It is not dependent on the type of pharmaceuticals (e.g. over-the-counter (OTC) products). The simplified procedure is adaptable, to accommodate the changes (e.g. new combination) in active substances which have been already reimbursed or for the generic equivalents of these products. The normal procedure is applicable in other cases (e.g. new active substance, new indication, new combination, etc.) [Decree of the Ministry of Health 32/2004].

The policy covers the whole population and the whole country. Differences are only noticeable in the group of hospital-only medicine(s) (HOM) and the Special Allocated Budget. In these situations the Pharmaceutical Department of the National Health Insurance Fund Administration (OEP) gives a 0% reimbursement rate, but the Department of Curative-Preventive Provisions finances in another way, calculating these into the point value rate of the diagnosis-related group (DRG).

The final reimbursement decision is made by the Head of the Pharmaceutical Department of the National Health Insurance Fund Administration (OEP) (in the case of hospital-only medicine(s) (HOM) by the Head of Department of Curative-Preventive Provisions) based on the pre-opinion of the Transparency Secretariat, the Health Technology Assessment Institute, and the Technology Appraisal Committee (TÉB). At the end of the appeal procedure (cf. 4.2.1) a Superior Committee (comprising delegates of the Ministry of Health, the National Health Insurance Fund Administration (OEP), the National Institute of Pharmacy (OGYI), etc.) has the right to decide. Pricing and reimbursement policy are always interlinked during the procedure.

The reimbursement status can be changed by two sources: by application, or ex officio according to Decree 32/2004, which declares that the Pharmaceutical Department has an annual right to review the reimbursement categories of all pharmaceuticals.

4.2 Reimbursement schemes

The current system – called Transparency – has been operating since 2004. The current scheme was implemented on 1 May 2004, as a consequence of the European Union's (EU) admis-

sion of Hungary, which in fact forced the newly acceded country to adapt the 89/105/EEC Transparency Directive into reimbursement policy. Thus Hungary has to ensure a transparent, accountable process of pharmaceutical coverage, applied by the National Health Insurance Fund Administration (OEP), based on the strict deadlines and forms required by the Directive. The legal framework is the same in 4.1.

Approximately 50% of the available pharmaceuticals (pharmaceuticals on the market) are covered by this method (transparency). The total Hungarian population is covered by social health insurance (SHI) and is thus eligible for reimbursement of pharmaceuticals under this scheme.

Both in the case of the normal procedure and in the case of the simplified procedure, the reimbursement decision takes 90 days, starting at the receipt of the complete application. In case of appeal there is a 60-day procedure, starting at the receipt of the appeal, which can be submitted 15 days after the enactment of the decision of the first instance. The first day of the reimbursement cannot be more than 365 days later than the enforcement of the reimbursement order.

4.2.1 Eligibility criteria

There are several criteria which are applied to pharmaceuticals in the decision on inclusion to the reimbursement lists in Hungary (responsible actor given in parentheses).

- Product-specific criteria:
  - medical and therapeutic value (Health Technology Assessment Institute, Colleges of Medical Professionals, Technology Appraisal Committee (TÉB), Ministry of Health (EüM / MoH));
  - safety (National Institute of Pharmacy (OGYI));
  - lack of alternative therapies (Health Technology Assessment Institute);
  - prescription status (National Institute of Pharmacy (OGYI));
  - patent status (Hungarian Patent Office).
- Economic criteria:
  - cost-effectiveness (Health Technology Assessment Institute, Technology Appraisal Committee (TÉB));
  - reference price (Pharmaceutical Department of the National Health Insurance Fund Administration (OEP));
  - budget impact (Health Technology Assessment Institute and the National Health Insurance Fund Administration (OEP)).
- All of the patient-specific and disease criteria (e.g. age, sex, chronic or terminal illness, severity of illness, special medical needs, etc.) are appraised by the Health Technology Assessment Institute and the professional medical colleges.

Each manufacturer has to apply for a reimbursement category (the terms of the different categories are regulated by the Ministry of Health (EüM / MoH)). After the usual procedure has taken place the Head of the Pharmaceutical Department of the National Health Insurance Fund Ad-

ministration (OEP) makes the reimbursement decision (in the case of hospital-only medicine(s) (HOM) the Head of Department of Curative-Preventive Provisions has this role).

These criteria are important because they operate as a filter. A pharmaceutical that does not correspond to these terms will probably not be included into the positive list. E.g. if a pharmaceutical is not cost-effective, the Health Technology Assessment Institute will not support the reimbursement. On the other hand, because of the percentage reimbursement scheme, out-of-pocket payments (OPPs) depend on the category.

In the case of reimbursement being denied the manufacturer has the right to appeal. When lodging an appeal the client has to pay a legal fee by postal order or bank transfer to the National Health Insurance Fund Administration's (OEP) account kept within the Hungarian Treasury.

The decision on the appeal is done by the Appeal Committee. The Committee consists of one member nominated by each of the following ministers: the Minister of Health, Minister of Finance and the Minister of Economy and Transport, as well as the Director of the National Institute of Pharmacy (OGYI), the President of the Health Insurance Supervisory Body, and the Director of the National Health Insurance Fund Administration (OEP).

The decision of the Appeal Committee (FB) has to be made within 60 days from receipt of the appeal.

4.2.2 Reimbursement categories and reimbursement rates

According to Art. 5 of Decree 32/2004, the National Health Insurance Fund Administration (OEP) can use the following reimbursement techniques to reimburse pharmaceuticals included in the scope of the health insurance system:

- percentage-based reimbursement;
- fixed-amount reimbursement:
  - fixed-amount reimbursement based on the active ingredient;
  - reimbursement based on therapeutic groups;
- reimbursement-volume agreement;
- contract for the supply of specially reimbursed pharmaceuticals purchased through public procurement.

Different reimbursement categories are applied, as described here.

Pharmaceuticals on the positive list are generally reimbursed in kind, at rates of 90%, 70% and 50% of the pharmacy retail price (PRP) (so-called normative reimbursement). Normative reimbursement accounts for approximately one quarter of the National Health Insurance Fund Administration's (OEP) pharmaceutical expenditure (PE).

Furthermore, expensive pharmaceuticals with approved special indications are reimbursed at 100%, or 90% if prescribed by a specialist or on the recommendation of a specialist, otherwise

they fall under the lower reimbursement levels of normative reimbursement (preferential reimbursement category). These maximum reimbursement categories apply to individuals suffering from severe chronic diseases such as cancer, multiple sclerosis or diabetes (100%), or epilepsy, rheumatoid arthritis or asthma (90%), and are only applicable with treatment of these diseases. The list of disease conditions is defined by Ministry of Health (EüM / MoH) along with Ministry of Finance (PM / MoF).

Table 4.1: Hungary - Reimbursement of pharmaceuticals

Reimbursement category	Reimbursement rate (%)	Characteristic of category
Normative	**90**	High reimbursement category (normative 90%): Pharmaceuticals which offer the most successful and effective treatment for severe and chronic diseases and disorders that are of high priority from a public health point of view – diseases and disorders which trigger reversible (but without treatment irreversible) processes with lifelong consequences and which have a moderately adverse impact on life expectancy and quality of life.
Normative	**70**	Higher than average reimbursement category (normative 70%) – pharmaceuticals which: (a) offer effective treatment for moderately severe, chronic diseases and disorders that (i) entail considerable deterioration in the quality of life and require prolonged therapy; or (ii) result in a reduced ability to take care of oneself; (b) are used in the supplementary therapy of chronic diseases that imply a major burden of disease, which ensure considerable health gain on reasonable investment
Normative	**50**	Average reimbursement category (normative 50%) – pharmaceuticals which: (a) offer successful and effective treatment for chronic diseases and disorders which partially affect one's ability to take care of oneself for a prolonged period; (b) offer successful treatment for moderately severe chronic diseases and disorders which adversely affect the quality of life or the ability to take care of oneself temporarily or for a prolonged period; (c) are used in the supplementary therapy of chronic and acute diseases which have demonstrated assessable health gain on reasonable investment
Special Reimbursement Category (EÜ90)	**90**	High reimbursement category (90%) bound to indication EÜ90 – pharmaceuticals which offer the most effective treatment in a given indication for chronic diseases and disorders that are severe and usually require ongoing or lifelong therapy, and which: (a) trigger reversible (but without treatment irreversible) processes with lifelong consequences; (b) have a moderately adverse impact on life expectancy and on quality of life; (c) are used in the supplementary therapy of diseases that are severe and imply a high burden of disease, which ensure consid-

Reimbursement category	Reimbursement rate (%)	Characteristic of category
		erable health gain on reasonable investment
Special Reimbursement Category (EÜ100)	**100**	Special reimbursement category (100%) bound to indication (EÜ100 and special fund) – pharmaceuticals which offer the most successful and most effective treatment and prevention (hereinafter collectively described as "treatment") in a given indication for chronic diseases and disorders that are severe and usually require ongoing or life-long therapy, and which: (a) without continuous medicinal therapy endanger life; or (b) trigger irreversible processes and adversely affect life expectancy and quality of life to a significant degree; or (c) are rare and/or a rare manifestation of hereditary diseases but result in a heavy burden of disease
Non-reimbursable (00)	**0**	Category without reimbursement value. Pharmaceuticals which: (a) are prescribed and/or dispensed for health care providers only; (b) OEP – on application – enrols into reimbursement without reimbursement value (not corresponding to individual applications)

OEP = National Health Insurance Fund Administration, EÜ90 = Reimbursement category bound to indication. Reimbursed by 90%, EÜ100 = Reimbursement category bound to indication. Reimbursed by 100%

Source: OEP, 2006

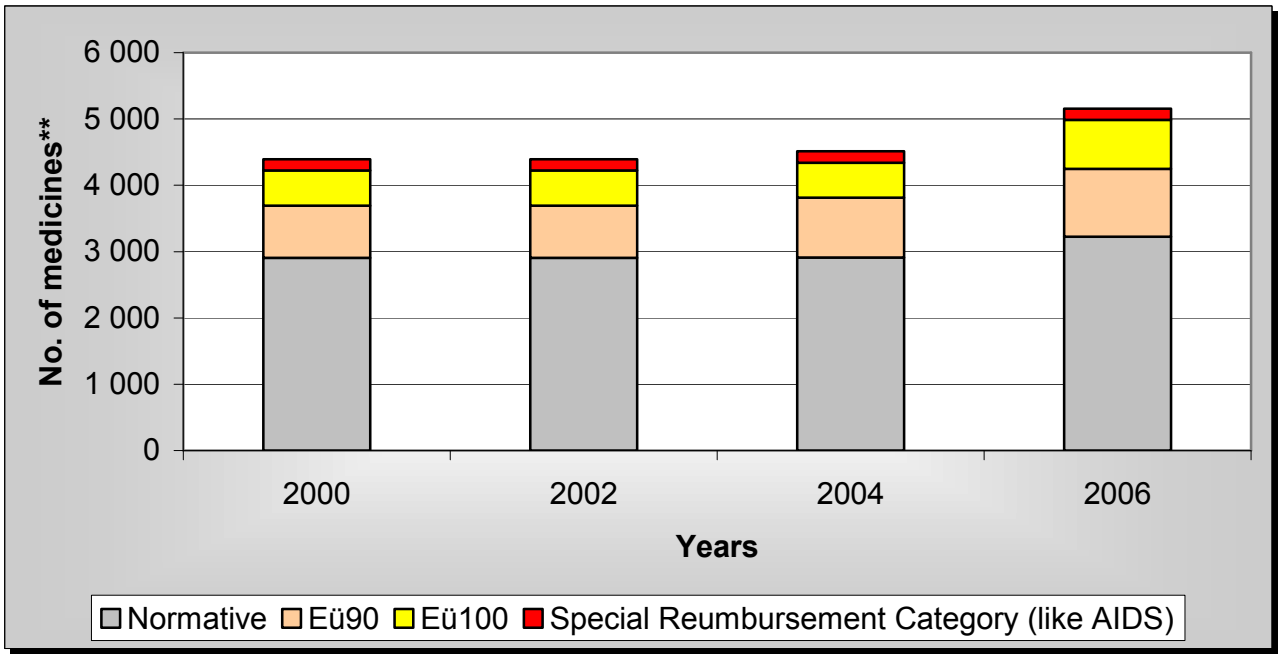
A Decree of the Ministry of Health defines which Anatomic Therapeutic Chemical (ATC) classification groups qualify for the category of normative and/or preferential reimbursement.

In addition, there is a special reimbursement level for people with low income (reimbursement for socially disadvantaged people). Approximately 5% of the population are eligible to receive pharmaceuticals reimbursed at 100% according to a separate list, revised each year by a committee with representatives of the National Health Insurance Fund Administration (OEP), the Ministry of Health (EüM / MoH), the Hungarian Chamber of Physicians (MOK) and the Hungarian Chamber of Pharmacists (MGYK). This list also comprises approximately 100 over-the-counter (OTC) products.

Furthermore, pharmaceuticals can be reimbursed on behalf of individual applications. Individual applications for reimbursement may be filed because of the social situation or as a result of a medical condition that needs special treatment.

The National Health Insurance Fund Administration (OEP) provides very expensive pharmaceuticals through a special budget; these pharmaceuticals are purchased centrally by the National Health Insurance Fund Administration (OEP) via tenders (e.g. for haemophilia treatment).

Figure 4.1: Hungary- Development of pharmaceuticals, 2000, 2002, 2004 and 2006[1]



[1] Only estimated data, because several pharmaceuticals are reimbursed at different categories at the same time (e.g. CALCO 50 NE injection is available at normative, 90% (EÜ90) and 100% (EÜ100) categories); data as of 1 July each year ** by different packages and different active ingredients

Source: OEP, 2006

4.2.3 Reimbursement lists

There is a positive as well as a negative list, both of which are registered by the National Health Insurance Fund Administration (OEP). If the market authorisation holder of the reference preparation cannot show that it can meet its supply obligation for three consecutive months, the National Health Insurance Fund Administration (OEP) will delist the preparation from reimbursement and that preparation cannot be included in reimbursement procedures for two years effective from the next setting of the reference price. If the meeting of a supply obligation is delayed by six months, this provision is also to be applicable to other preparations receiving fixed-amount reimbursement, to the extent that this is not likely not jeopardise patient care. Any pharmaceutical that is deleted from registration should be removed from reimbursement consideration by the National Health Insurance Fund Administration (OEP) at the latest by the end of the second calendar year following its deletion.

Accordingly, the National Health Insurance Fund Administration (OEP) should delist from social security reimbursement any pharmaceutical:

(a) that is without valid market authorisation;

(b) about which doubts have arisen as to its efficacy;

(c) that disproportionately burdens the budget of the Health Insurance Fund (E. Alap / HIF) compared to the health gains that can be achieved with its use;

(d) for which the market authorisation holder was sanctioned twice within a year in respect of the very same reimbursed pharmaceutical (for breach of the provisions relating

to promotion and presentation of pharmaceuticals) by a competent authority in an advertisement control case;

(e) for which the cost-effectiveness cannot be proven;

(f) that is not on the market for over six months (for three months in the case of reference products);

(g) that has had its market authorisation withdrawn;

(h) for which its market authorisation holder has asked for its delisting from reimbursement;

(i) belonging to fixed-amount reimbursement groups based on active ingredients, where the pharmaceutical's daily cost of therapy (DCT) or the price calculated for a unit dose of the active ingredient surpasses by at least 20% the reference preparation's daily cost of therapy (DCT), or, in the case of average price groups, where this surpasses the reference price;

(j) belonging to a therapeutic fixed-amount reimbursement group, where the pharmaceutical's daily cost of therapy (DCT) is three times the average daily cost of therapy (ADCT) in the group.

In the event that the National Health Insurance Fund Administration (OEP) decides to abolish or cut the amount of reimbursement of a pharmaceutical, the first day of the new reimbursement measure or the deletion cannot be earlier than the first day of the second quarter after the decision.

A detailed flowchart of the Hungarian reimbursement procedure is provided in Chapter 2 (cf. 2.1). The main bodies are listed here.

- The Director-General of the National Health Insurance Fund Administration (OEP) set up a Technology Appraisal Committee (TÉB) to evaluate the applications for the inclusion in the positive list.
- The National Health Insurance Fund Administration (OEP) also decides about inclusion of pharmaceuticals within the scope of the health insurance system and their reimbursement rate (in typical circumstances) after consultation with the National Institute of Strategic Health Research (ESKI). The Pharmaceutical Department deals with decisions and administration.
- The special reimbursed category is regulated by the Ministry of Health (EüM / MoH) and the Ministry of Finance (PM / MoF).

The inclusion of pharmaceuticals within the reimbursement scheme is continuous. There is a regular weekly meeting of the Health Care Technology Appraisal Committee (TÉB) where the preparatory work takes place. In every quarter information on pharmaceuticals is disseminated. The official Health Bulletin contains detailed information about the reimbursed and excluded pharmaceuticals and it is readily available to patients and doctors, so they can easily obtain such information.

Inclusion of pharmaceuticals within the scope of the health insurance system is carried out by means of reimbursement categories defined with a view to equity and accessibility. All reim-

bursement techniques can be used for all reimbursement categories. The criteria for inclusion are listed here [According to the Decree of the Ministry of Health 32/2004].

Reimbursement-volume agreements:

Art. 11

(1) In order to ensure that the budgetary limits are respected, the National Health Insurance Fund Administration (OEP) may conclude reimbursement-volume agreements for preparations that are already reimbursed, as well as for products that are newly included for reimbursement, if the pharmaceutical is to be used for the treatment of diseases with patient numbers that can be properly estimated (prevalence) and incidence rates that can be properly defined. The scope of the reimbursement-volume agreement shall depend on whether the patient numbers are suitable for treatment, as recommended by the competent professional medical college with a view to disease prevalence and incidence.

(2) The detailed payment rules shall be outlined in the reimbursement-volume contract concluded between the manufacturer and/or the distributor and the National Health Insurance Fund Administration (OEP).

Special fund pharmaceuticals

Art. 12

(1) Social security reimbursement linked to the price of pharmaceuticals from the special fund is to be accounted according to a contract made between the National Health Insurance Fund Administration (OEP) and the health care institutions performing the treatment, whose names are published annually by the National Health Insurance Fund Administration (OEP) in a communiqué.

(2) The National Health Insurance Fund Administration (OEP) grants 100% reimbursement to the purchase price of special reimbursed pharmaceuticals with the understanding that in other cases the provisions of Decree of the Government 130/2004 on the detailed and special rules of the procurement of pharmaceuticals and medical devices shall apply.

(3) The list of special fund pharmaceuticals referred to in Subsection (2) of Art 12 – with the names of the active ingredient and the disease category – shall be published by the Minister of Health and the Minister of Finance on the first day of each calendar quarter in a communiqué.

(4) The contract between the National Health Insurance Fund Administration (OEP) and the institute with the nationwide coordinating function allows, up to the yearly limit, purchase of pharmaceuticals for the treatment of disease categories figuring the communiqué in Subsection (3) of Art 12, based on protocols devised and published by the relevant professional colleges.

(5) If an application is received for the reimbursement of a pharmaceutical which has an active ingredient that is not in the communiqué as referred to Subsection (3) of Art 12, with the indication of the special reimbursement technique for pharmaceuticals purchased via public procurement, the method described in Art. 4, Subsections (10)-(11) need to be applied, as appropriate.

Special issues

Art. 13

(1) Newly included pharmaceuticals with active ingredient(s) that is not yet reimbursed can be granted special reimbursement only under a reimbursement-volume agreement or procurement procedure, where:

(a) the preparation's efficacy and cost-effectiveness have been demonstrated by good-quality evidence; and

(b) the relevant professional colleges have given a written justification in support thereof.

(2) Preparations already receiving fixed-amount reimbursement can be assigned special reimbursement if:

(a) in the already reimbursed group containing the same active ingredient the pharmaceutical's daily cost of therapy (DCT) is not higher than the reference preparation's daily cost of therapy (DCT); or

(b) in an average price group the price of the pharmaceuticals when projected to a unit dose of the active ingredient is not higher than the reference price; or

(c) in a 5-digit Anatomic Therapeutic Chemical ATC-4 level category, the pharmaceutical's daily cost of therapy (DCT) is not higher than the group's average daily cost of therapy (ADCT).

(3) In the case of indication-bound special or high reimbursement category pharmaceuticals, the reimbursement of pharmaceuticals receiving fixed-amount reimbursement under the indication "on specialist's direction" cannot be lower than the normative reimbursement amount. The reimbursement should be adjusted according to the daily cost of therapy (DCT).

Art. 14. Other inclusion and reimbursement criteria

(a) New packaging should be included in the same producer's price and with the same re-imbursement extent as the previous packaging.

(b) A new pack size should be included in the price of the unit dose of the active ingredient, calculated at the same or lower producer's price.

(c) A new strength may be included in the price of the unit dose of the active ingredient, calculated at the same or lower producer's price for an already reimbursed preparation with the same brand name.

(d) A new formulation may be reimbursed at the same therapeutic cost as pharmaceuticals with the same mode of application or same brand name, or at a lower price.

(e) A second brand product of an original preparation for which a generic version has not yet been produced can be reimbursed at the price of the active ingredient, calculated on the unit dose of the manufacturer price, or at a lower price.

(f) Newly reimbursed preparation's generics, eligible for fixed-amount reimbursement, can only be reimbursed at the price equal to the reference preparation daily cost of therapy (DCT) or the reference price daily cost of therapy (DCT), or at a lower price. Any preparation that is not eligible to be placed in a fixed-amount group (not equivalent) can

only be reimbursed at the price equal to the reference daily cost of therapy (DCT) of the fixed group having the same active ingredient and same strength, or at a lower price.

(g) A condition for the inclusion of generics is that the manufacturer price of the preparation should be at least 30% below the manufacturer price of the original preparation as long as the first reference product or reference price is set.

(h) Newly reimbursed generics that are not eligible for fixed-amount reimbursement can only be included at a price lower than the average daily cost of therapy (ADCT / NTKÁ).

(i) If the preparation has major therapeutic benefit, the market authorisation holder can apply, under normal procedure, for reimbursement at a higher price and for the applying for inclusion in the positive list.

(j) If the gross pharmacy retail price or the daily cost of therapy (DCT) of a unit dose of the active ingredient – in a combination product, with the same dosage form but cheaper, with the same mode of application, and with the same or similar strength and pack size – does not exceed 10% of the total gross pharmacy retail price, the price of the combination product cannot be higher than the price of the product containing a more expensive active ingredient.

(k) If the gross pharmacy retail price or the daily cost of therapy (DCT) of a unit dose of the active ingredient(s) in a combination product exceed 10% of the total gross pharmacy retail price per active ingredient, the price of the combination product cannot be higher than the maximum amount of the gross pharmacy retail price of the active ingredients in a mono-component product containing the active ingredient(s) in the combination product and having the same dosage form, same mode of application or the same or similar strength and pack size.

(l) If the combination product has major therapeutic benefit compared to the combined use of the previous same active ingredients and if the market authorisation holder applies for a higher price or reimbursement as outlined in paragraphs (i)-(j) (above), the application should be processed according to the normal procedure.

(m) As far as galenic preparations are concerned, if they were registered by the National Institute of Pharmacy (OGYI), as defined in a separate piece of legislation, reimbursement is to be 90% of the price that is accepted as the basis for public financing.

For the terms of the reference system, cf. 4.3. There are no special conditions for pharmaceuticals used in hospitals or nursing homes.

4.3 Reference price system

In Hungary two types of reference price system are in operation (based on active ingredient(s) and on therapeutic groups) under the supervision of the Pharmaceutical Department of the National Health Insurance Fund Administration (OEP). The legal basis is the same as that which regulates the whole reimbursement system, namely Decree of the Ministry of Health 32/2004.

Reference price system based on active ingredient(s) [Decree 32/2004, Art. 8]

(1) In the case of fixed-amount reimbursement based on active ingredient(s), the basis of the (fixed) amount of reimbursement for a given product category shall be the price of reference preparation that has been accepted as the basis for public financing.

(2) The (fixed) amount of reimbursement for pharmaceuticals with the same active ingredient, having the same dosage form, the same mode of administration and the same strength and classified equivalent according to the National Institute of Pharmacy (OGYI) shall be calculated in conformity with Subsection (4) of Art. 8. In the case of preparations with the same mode of administration but with a strength that is different from the existing fixed groups (+/- 20%), these shall be reimbursed according to the daily therapeutic cost (DCT) of the reference value for a fixed-amount group that is closest in terms of strength (having higher strength).

(3) The reference preparation shall be a pharmaceutical belonging to a defined (fixed-amount) group, where

(a) it has not been deleted from registration;

(b) its equivalence has been established by the National Institute of Pharmacy (OGYI);

(c) it has the lowest daily cost of therapy (DCT) related to gross pharmacy retail price, or if that cannot be determined, has the lowest gross pharmacy retail price when projected to a unit dose of the active ingredient (daily cost of therapy (DCT)) among the pharmaceuticals in the given group;

(d) it has been on the market for at least six months preceding the setting of the reference price for the given year;

(e) as regards the indication underlying the reimbursement it does not exceed the quantity defined in the valid instructions for use (for one month's therapy) or the pack size closest to it;

(f) its market share within the group reached 3% in directly observed treatment (DOT) during the last six months of the year preceding the year in question, provided that the daily cost of therapy (DCT) calculated from the price of the pharmaceutical does not exceed the average daily cost of therapy (DCT) calculated according to Subsection (6) of Art 8.

(4) The reference preparation, according to its Anatomic Therapeutic Chemical (ATC) classification, shall receive percentage reimbursement as shown in Annex No.1 of Decree 32/2004, calculated for the Anatomic Therapeutic Chemical (ATC) classification containing the given active ingredient(s). Reimbursement of the other products in the group shall be based on the reimbursement amount calculated for the daily cost of therapy (DCT) of the reference preparation. Pharmaceuticals whose daily cost of therapy (DCT) is lower than the reference preparation shall be exempt from this rule. In this case the reimbursement extent (percentage) shall equal the percentage extent of the reference preparation's reimbursement.

(5) Non-equivalent generic preparations will not be considered for the definition of the reference preparations or reference price. If their daily cost of therapy (DCT) (in the case of a reference preparation or average price group) is higher than the daily cost of therapy (DCT)

of the reference price, they will be reimbursed according to the daily cost of therapy (DCT) of the reference price. Otherwise, they will receive the percentage extent of the reimbursement allocated to the reference price.

(6) If none of the pharmaceuticals in a fixed-amount group satisfy the criteria set out in Subsection (3) of Art. 8, the basis of the fixed-amount reimbursement in that group (the average price group) – based on data from the past six months of the year preceding the year in question – will be the mean arithmetic average of the daily cost of therapy (DCT) for those pharmaceuticals that attained at least 2% market share in directly observed treatment (DOT) and satisfied points (a)-(e) of Subsection (3) of Art. Pharmaceuticals whose cost of daily therapy (DCT) is lower than the average calculated will receive a group-specific percentage reimbursement.

(7) If the market authorisation holder of the reference preparation cannot show that it can meet its supply obligation for three consecutive months, the National Health Insurance Fund Administration (OEP) shall delist the preparation from reimbursement and that preparation can not be included in reimbursement for two years effective from the next setting of the reference price. If meeting supply obligation is delayed by six months, this provision will also be applicable to other preparations receiving fixed-amount reimbursement, to the extent that this is not likely not jeopardise patient care.

(8) The National Health Insurance Fund Administration (OEP) shall publish a breakdown of the public pharmacy sales data and directly observed treatment (DOT) market shares needed for the calculations, organised according to preparations and reimbursement titles, on the first day of each calendar quarter in its official journal and on its home page. This system is used at Anatomic Therapeutic Chemical ATC-5 and ATC-7 levels.

Therapy-based reference price system

Art. 9

(1) Fixed-amount reimbursement based on therapeutic groups can be assigned to products which are equally suitable for the treatment of certain specific diseases (conditions), if the registration authority determined their use for clinically identical indications and if the same therapeutic result can be achieved, with their use, on the patients.

(2) The conditions of fixed-amount reimbursement based on therapeutic groups and its calculation methods shall be outlined in Annex No.2 of Decree 32/2004.

(3) The maximum reimbursement accessible in the 5-digit Anatomic Therapeutic Chemical ATC-4 level categories shall be defined in Annex No.1 of Decree 32/2004.

(4) Pharmaceuticals used in the treatment of the same diseases or disease categories can be subdivided on the basis of:

(a) mode of application

(b) different strengths

(c) duration of effect

(d) pharmaceuticals with approximately the same impact on the quality of life

(e) proven clinical advantage

(f) early identical side-effect profile.

(5) Calculation of reimbursement based on the therapeutic groups fixed-amount principle shall be carried out as described here.

(a) Pharmaceuticals for which the daily cost of therapy (DCT) is equal to or lower than the average daily cost of therapy (ADTC) determined in accordance with Paragraph (a) of Subsection 1.1 of Annex No. 2 of Decree 32/2004 (average daily cost of therapy (ADCT) shall receive a group specific percentage reimbursement.

(b) Preparations for which the daily cost of therapy (DCT) is higher than the average daily cost of therapy (ADTC) determined in accordance with Paragraph (a) of Subsection 1.1 of Annex No. 2 of Decree 32/2004 (average daily cost of therapy (ADCT)) shall receive, as reimbursement value, an amount calculated on the basis of the reimbursement value given to the average daily cost of therapy in the group (ADCT), as shown here:

$$\text{Reimbursement value} = \frac{\text{ADCT x given packaging}}{\text{value of DOT}}$$

(6) For those reimbursement groups which are based on the therapeutic groups fixed-amount principle, the National Health Insurance Fund Administration (OEP) shall publish a breakdown of the public pharmacy sales data and market shares needed for the calculations, organised according to preparations and reimbursement titles, on the first day of each calendar quarter in its official journal and on its home page.

(7) On 1 July each year the National Health Insurance Fund Administration (OEP) shall publish in its official journal the therapeutic fixed-amount groups planned for 1 July of the next calendar year (5-digit Anatomic Therapeutic Chemical ATC-4 level groups), including any subdivisions and the maximum percentage extents pertaining to them.

Art. 10

(1) The therapeutic fixed-amount groups may experience a correction when calculating the reimbursement of preparations with various strengths and pack sizes, in the form of an index number generated as a result of the group's price proportions. The index numbers shall be defined for each therapeutic group.

(2) In order to ensure that the active ingredient-based groups and the therapeutic fixed-amount groups are manageable and that the inclusions are realised as described, the National Health Insurance Fund Administration (OEP) shall announce on 1 July every year – within the framework of its quarterly announcement as set forth in a separate piece of legislation – the reference prices and preparations, and the price and reimbursement of all the preparations in the given groups, effective from 1 July. Reference values determined at that time shall remain in effect without change for one year after the announcement, with mid-year price changes not able to influence the setting of the reference values.

(3) The July reference values shall be set on the basis of the prices in effect on 1 April of the respective calendar year. The National Health Insurance Fund Administration (OEP) shall

send the reference prices and reimbursements (calculated on the basis of these prices) for the preparations in the given group to the market authorisation holders by 20 April of the given calendar year. With this knowledge, the market authorisation holder can apply for one price change by 30 April of the given calendar year. Prices applied for until 30 April will not influence the reference values set by 20 April.

The price groups have an annual review and evaluation by the Pharmaceutical Department, and if there are no matching pharmaceuticals to compare, the external price system is acceptable. There are approximately 1950 pharmaceuticals in an active ingredient group and another 350 in a therapy group.

If a patient opts for pharmaceutical other than the one priced at (or below) the reference price level (s/)he does not have to pay the difference.

4.4 Private pharmaceutical expenses

The system of private pharmaceutical expenses has two important elements in Hungary since the introduction of the current cost-sharing system in 1988: direct payment for over-the-counter (OTC) pharmaceuticals, and non-reimbursed pharmaceuticals:

- co-payment for reimbursable pharmaceuticals;
- in the case of over-the-counter (OTC) pharmaceuticals and non-reimbursed pharmaceuticals there is no price control – the patients have to pay the full amount of the gross pharmacy retail price.

The data for private pharmaceutical spending as a share of the total health expenditure (THE) was shown earlier (cf. 2.2). The share of private pharmaceutical expenditure (PE) has been increasing faster than public spending in recent years, but the co-payment share for reimbursed pharmaceuticals has essentially not changed. In exceptional cases, the patients can apply individually for reimbursement for expensive pharmaceuticals that are not reimbursed in the positive lists. This individual procedure can exempt them from paying the co-payment or the direct payment.

4.4.1 Direct payments

The share of direct payments compared with co-payments was also detailed earlier (cf. 2.2). There are a couple of groups of pharmaceuticals which are not covered by the social health insurance (SHI) scheme: over-the-counter (OTC) pharmaceuticals, lifestyle pharmaceuticals, and pharmaceuticals that are prescribed but not reimbursed. Patients have to pay the full amount of the gross pharmacy retail price for these pharmaceuticals.

4.4.2 Out-of-pocket payments

An important element of out-of-pocket payments (OPPs) is the co-payment, which has to be paid by the patients. The co-payment and the reimbursement categories are now regulated by

Decree of the Ministry of Health 32/2004 on the reimbursement categories and procedure of registered pharmaceuticals. For further details on the categories, cf. 4.4.4.2 and 4.6.3.

The share of co-payments compared with direct payments was detailed earlier (cf. 2.2). The reference pricing system for the active substance therapeutic classification (cf. 4.6.2 for a more detailed presentation) and the co-payment exemption system for low-income residents essentially modify the level of out-of-pocket payments (OPPs) that the patients have to contribute in order to receive prescribed pharmaceuticals.

Table 4.2: Hungary - Reimbursement rates and patient co-payment rates (not used)

Annual expenses for patients in terms of reimbursement price	Co-payment rate (%)	Reimbursement rate (%)
Adults	*These kinds of reimbursement rates and patient co-payment rates are not applicable*	
Children up to 18 years		
Chronically ill		
Terminally ill		

Source: OEP, 2006

4.4.2.1 Fixed co-payments

In Hungary there fixed co-payments are not relevant.

4.4.2.2 Percentage co-payments

The co-payment and the reimbursement categories are regulated by Decree of the Ministry of Health 32/2004 on the reimbursement categories and procedure of registered pharmaceuticals.

Table 4.3: Hungary - Reimbursement and co-payment categories 1995

Year	Reimbursement categories as a % of the gross pharmacy retail price of the pharmaceuticals						Legal basis
1995	100	90	70	50	0		174/1995 Government Decree
Year	**Co-payment categories as a % of the gross pharmacy retail price of the pharmaceuticals**						**Legal basis**
1995	0	10	30	50	100		174/1995 Government Decree

Source: OEP, 2006

The system is applied for all reimbursed pharmaceuticals and the structure of the categories has been the same since 1995. The patient has to pay the amount above the reimbursement, which is given as a percentage of the gross pharmacy retail price. The 100% category is available for pharmaceuticals prescribed by specialists with restricted indications. The 0% category is for hospital use and not for out-patients.

4.4.2.3 Deductibles

Deductibles are not used in Hungary.

4.5 Reimbursement in the hospital sector

In Hungary, reimbursement in the in-patient sector differs from that in the out-patient sector. In the in-patient sector the Hungarian diagnosis-related group (DRG) system covers all the costs incurred during acute hospital care (except for investment costs), including pharmaceuticals. The type of pharmaceutical can often be an aspect for classification in a diagnosis-related group (DRG) (e.g. solid tumours). The cost of medical and accommodation services for average hospital cases is based on a cost-assessment study carried out in 1998. The systematic maintenance of codes and financial parameters is an essential part of the diagnosis-related group (DRG) financing systems.

In chronic care the costs of the pharmaceuticals are covered by the daily fees. Consequently, the pharmaceuticals are fully reimbursed for in-patient care and this covers a significant part of the hospitalisation costs.

The main "payer" for pharmaceuticals in hospitals is the National Health Insurance Fund Administration (OEP), which finances pharmaceutical costs through the diagnosis-related group (DRG) system (in case of chronic care, daily fees are used) and the management of the hospitals ensure the supply of pharmaceuticals. Often they can receive discounts, rebates or other kinds of benefits, such as pharmaceuticals received free.

Hospital products are also included in the positive list (0% reimbursement category), thus being evaluated by the Technology Appraisal Committee (TÉB). Price agreements apply to hospital pharmaceuticals as well.

Ideally, the cost of the diagnosis-related groups (DRGs) referring to pharmaceuticals is calculated with the prices of generics, and protocols have been established for the utilisation of pharmaceuticals. Aside from this measure, the National Health Insurance Fund Administration (OEP) also provides very expensive pharmaceuticals through a special budget; these pharmaceuticals are purchased centrally by the National Health Insurance Fund Administration (OEP) via tenders (e.g. for haemophilia). There are some efforts to cut down the role of this special budget and to calculate the prices of hospital-only medicine(s) (HOM) within the diagnosis-related group (DRG) (e.g. for oncology treatments).

The reimbursement criteria for pharmaceuticals in the hospital sector are actually the same as in the out-patient sector. The same coverage policy system is to be applied for hospital pharmaceuticals with the same procedure, so only the decision-maker differs; in this case, the decision-maker is the Head of Department of Curative-Preventive Provisions.

With regard to pharmaceuticals for regular hospital treatment, there are no out-of-pocket payments (OPPs) to be borne by the patient. Out-of-pocket payments (OPPs) occur in hospitals in the case of those provisions for which only partial fees can be charged, as listed here.

- Extra meal and accommodation when these are available in the hospital.
- Sanitaria provisions.
- Requisition of services, which are liable for referral, without referral.
- Requisition of services by a different health care provider from the location at which the physician initiated the treatment.
- Requisition of services for self-initiation, differing from standard protocols and/or incurring extra costs.
- Accommodation with the aim of nursing by the relevant provider (for the costs of accommodation and nursing, including the necessary pharmaceuticals).

4.6 Reimbursement-related cost-containment measures

4.6.1 Major changes in reimbursement lists

The main changes that have been carried out in the reimbursement lists in recent years are listed here.

- The reimbursement category of the group of “statins” changed from Normative 70% to Normative 90% in September 2003.
- The reimbursement category of the group of “antihistamines” changed from the 90% Special Reimbursement Category (EÜ90) to the 70% Special Reimbursement Category (EÜ90) in October 2003.
- The Special Reimbursement Category (90% (EÜ90)) of the group of “H_2-receptor blockers” has been abolished since July 2005.
- The reimbursement category of the group of “sartans” (angiotensin receptor blockers – ARBs) changed from Normative 50% to Normative 70% in January 2006.
- The reimbursement category of the group of “aspirins” (ASP) changed from the 90% Special Reimbursement Category (EÜ90) to the 70% Special Reimbursement Category (EÜ90) in July 2006.
- The reimbursement category of the active ingredient “theophyllin” changed from Normative 90% to the 70% Special Reimbursement Category (EÜ90) in July 2006.
- The following products have been removed from the positive list since July 2006:
  - topical antimycotics;
  - Simvor 5mg (because the defined daily dose (DDD) of this active ingredient is 15 mg);
  - minor analgetics in oncological indications;

4.6.2 Introduction / review of reference price system

Table 4.4: Hungary – Reference pricing system development

Year	Description of measure	Legal basis
1991	The first step of the reference pricing system was launched, organised by active substance. The measure made it possible to allocate the same fixed amount as the reimbursement amount for those pharmaceuticals which contained the same substance, in the same dosage and form. The status of bioequivalence was presumed.	Government Decree No. 133/1991
1992	The reference pricing system, organised by active substance, can be applied in the event of the same substance being used and for the same application.	Government Decree No. 106/1992
1995	The reference pricing system, organised by active substance, can be applied for pharmaceuticals, if the OGYI stated their bioequivalent status. The pharmaceuticals had to contain the same substance in equivalent form, and their application methods had to be the same. The pharmaceuticals above the price of the reference product could receive a fixed amount of reimbursement, derived from the reimbursement level of the reference product.	Government Decree No. 11/1995
1998	The next step in forming the reference pricing system involved the allocation of fixed amounts of subsidies to pharmaceuticals with a comparable therapeutic effect and with a similar route of administration for treating the same indication. These conditions had to be defined by the OGYI. An essential restriction was enforced through the regulation that the fixed subsidy could be given only in subgroups according to the active substance in the therapeutic class.	Government Decree No. 217/1997
2000	This main step introduced the reference pricing system, arranged according to therapeutic class, to define that the fixed subsidy can be given to pharmaceuticals with a comparable therapeutic effect, when treating for the same indication. These conditions should be defined by the relevant authority.	Government Decree No. 111/2000
2000	The conditions of selecting the reference product and calculating the reference price were clarified. The reference product was selected based on the cheapest DCT. The reference product had to reach a defined 1% market share in the previous six months, before it was selected as reference product. Above the price of the reference product the pharmaceuticals could receive a fixed amount derived from the subsidy of the reference product; under the price of the reference product they could receive the same proportional subsidy as the reference product.	Government Decree No. 111/2000
2001	Further clarifications of the reference price definition were reached. The reference product had to reach 5% market share and it should have been on the market in the previous nine months, before being selected as a reference product. If a generic product was selected as a reference product the bioequivalence should be stated by the OGYI.	Government Decree No. 71/2001
2003	Further clarifications of the reference price definition were reached. The reference product had to reach 3% market share calculated on a DOT basis.	Government Decree No. 295/2002

2004	Further clarifications of the reference price calculation were reached, particularly concerning therapeutic class. The regulation made it possible to create therapeutic subgroups based on the profile of side-affects, the route of administration for treating the same indication and the length of the effect. During the calculation of the reference price, those pharmaceuticals that could reach minimum 1% market share could be taken into account. These products should reach between 10% and 50% market share. The reference price is calculated as a mathematical average of the daily DCT of the pharmaceuticals derived from the gross pharmacy retail price.	Decree of the Ministry of Health 32/2004
2004	Further clarifications of the reference price calculation were reached. During the calculation of the reference price, those pharmaceuticals which could reach minimum 2% market share could be taken into account. These products should reach at least 50% market share, calculated on a DOT basis.	Decree of the Ministry of Health 32/2004

OGYI = National Institute of Pharmacy, DOT = directly observed treatment, DCT = daily cost of therapy

Source: OEP, 2006

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

The present version of the system for out-of-pocket payments (OPPs) for pharmaceuticals was introduced in Hungary at 1988 within the framework of the reformed cost-sharing system. Since then the structure of the out-of-pocket payment (OPP) categories have been changed several times, but the governing logic of the system remains untouched (cf. Table 4.5).

Table 4.5: Hungary - Reimbursement categories as a percentage of gross pharmacy retail price 1998, 1990, 1992, 1995

Year	Reimbursement categories as a % of the gross pharmacy retail price of the pharmaceuticals						Legal basis
1988	100	90	80				85/1988 Government Decree
1990	100	95	80				49/1990 Government Decree
1991	100	95	80	0			49/1991 Government Decree
1991	100	95	80	50	0		133/1991 Government Decree
1992	100	95	80	50			106/1992 Government Decree
1995	100	95	90	70	40	0	11/1995 Government Decree
1995	100	90	70	50	0		174/1995 Government Decree

Source: OEP, 2006

Table 4.6: Hungary – Co-payment categories as a percentage of gross pharmacy retail price 1988, 1990, 1991, 1992, 1995

Year	Co-payment categories as a % of the gross pharmacy retail price of the pharmaceuticals					Legal basis
1988	0	10	20			85/1988 Government Decree
1990	0	5	20			49/1990 Government Decree
1991	0	5	20			49/1991 Government Decree
1991	0	5	20	50		133/1991 Government Decree
1992	0	5	20	50		106/1992 Government Decree
1995	0	5	10	30	60	11/1995 Government Decree
1995	0	10	30	50	100	174/1995 Government Decree

Source: OEP, 2006

The reference pricing system, which was introduced in terms of active substance in 1991 and in terms of therapeutic class in 2000 (cf. 4.6.2), essentially modifies the level of out-of-pocket payments (OPPs) that the patients have to contribute in order to receive prescribed pharmaceuticals.

4.6.4 Claw-backs

There were three main periods when claw-backs were in use:

4.6.4.1 Global Reimbursement Volume Contract – September to December 2003

In 2003 the planned pharmaceutical budget was overspent in the first half of the year. As a result the manufacturers had a choice between two versions of a contract:

- market growth
- company growth
  - Version A: company growing < market growing
  - Version B: company growing > market growing

The claw-back was calculated according to the pharmaceutical turnover of the month, the ratio of the reimbursement level of a company, and the actual monthly budget deficit. The overall payment was HUF 6 billion.

4.6.4.2 Price Cut – April to July 2004

The aim was to keep the yearly pharmaceutical budget. Companies were invited to sign a 15% claw-back contract. In the absence of a signed contract, 15% of the manufacturer price cut was carried out. The result was that the reimbursement level and co-payment were reduced as well. However, this price cut was eventually ruled unconstitutional by the Constitutional Court.

4.6.4.3 2.5-year Agreement – July 2004 to December 2006

During this period the claw-back was calculated according to the ratio of the pharmaceutical turnover of the period from July 2003 to June 2004. Companies had to pay in full HUF 9 billion in 2004, HUF 20 billion in 2005 and HUF 22.5 billion in 2006. All the companies signed this contract.

According to the agreement, the price increase is regulated in the following way:

- +/-6.25% HUF/€ exchange rate moving from the base rate, which was 251 HUF/€;
- 7% increase for very low-priced products on the 1 January 2005 and 2006 (HUF 600, HUF 1,000).

Table 4.7: Hungary - Effects of implementing a claw-back system

Year	Support plan (billion HUF)	Realised payments (billion HUF)	Growth compared to previous year (billion HUF)	Manufacturer claw-backs (billion HUF)	Manufacturer claw-backs (%)	Adjusted payments (billion HUF)	Growth compared to previous year (billion HUF)	Adjusted payments compared to previous year (%)
2001	147	179.5	28.7	0	0.00	179.5	28.7	19.03
2002	153	209	29.5	0	0.00	209	29.5	16.45
2003	217	251.8	42.8	6	2.38	245.8	36.8	17.61
2004	238.9	289	37.2	7.9	2.73	281.1	35.3	14.32
2005	284	348.8	64.8	23	6.6	325.8	44.7	15.9

Source: OEP, 2006

4.6.5 Reimbursement reviews

The reimbursement decisions are evaluated by the Pharmaceutical Department of the National Health Insurance Fund Administration (OEP). There is a negative list which contains those pharmaceuticals that are excluded from the positive list.

All criteria for revision are declared in Decree of the Ministry of Health 32/2004 (cf. 4.2.3).

In Hungary, third-party payers are not allowed to request a review of a reimbursement decision. If pharmaceuticals are delisted, the Official Publications (e.g. Health Bulletin) will simply not contain them anymore.

5 Rational use of pharmaceuticals

5.1 Impact of pharmaceutical budgets

Monitoring of the prescribing habits of doctors has been intended, and the “top prescribers” have received feedback about their activities and some incentives have been planned, to be built into the system. However, at the time of writing there were no systematic information systems in operation.

Special prescribing procedures are applied at the 90% reimbursement category (EÜ90), at the 100% category (EÜ100) and for special reimbursed pharmaceuticals. In these cases only the relevant specialists have right to prescribe those pharmaceuticals (cf. 5.2).

5.2 Prescription guidelines

In Hungary the Minister of Health is authorised to stipulate regulations on the proceedings of the working out, construction and conciliation of the reimbursement, examination, and therapy related to the major disease groups and pharmacotherapeutic recommendations (Decree of the Ministry of Health 23/2006). Examination and therapeutical proceedings must be published in the form of professional guidelines and protocols. The professional medical colleges are charged to work out these papers but the Ministry involves several professional bodies (i.e. other relevant professional colleges, the Chief Medical Officer, the Director of the National Health Insurance Fund Administration (OEP), etc.) in the reconciliation process.

The National Methodological and Professional Supervisory Centre (OSZMK), which has been established and is supervised by the Ministry of Health (EüM / MoH), is responsible for conveying the professional guidelines and quality requirements, and for following up and managing their common execution: it examines both plans for, and particularly the implementation of, professional guidelines and protocols by professional inspectors (Decree of the Ministry of Health 15/2005).

Obligatory guidelines have been established since 2005, but previously professional bodies also published guidelines for different fields. Decree of the Ministry of Health 23/2006 provides a comprehensive regulatory framework for the proceedings of the working out, construction and conciliation of these guidelines. According to further guidelines, protocols are to be enforced on the basis of this regulation. These professional guidelines and protocols are to be assessed once in three years from their inception. The above-mentioned Decree sets out strict requirements for the form and content of the guidelines and protocols, and on the whole the previous guidelines also fit into these criteria. Protocols need to contain: essential considerations; definitions; diagnostic procedures; and information about treatment (including pharmaceutical treatment, i.e. prescription guidelines: algorithm of the therapy; the recommended pharmaceutical treatment, with evidence; and alternative/supporting treatment). They must also contain information on rehabilitation, nursing, eligibility indicators and a bibliography. The aim is that prescription guidelines would appoint only the International Non-proprietary Name(s) of the active ingredient(s), rather than the brand name(s), for the sake of substitution.

Adherence to guidelines and protocols is supervised by the professional supervisory system by means of clinical studies. In the case of deficiencies in implementation, the professional inspectors bring the problems to the providers' attention, but in serious cases they can withdraw the operating licence of the provider or they can prohibit the physician from practising for a longer period of time.

Protocols and guidelines are published in the Official Bulletin of the Ministry of Health (EüM / MoH) and in professional journals, and are also available on the web site of the Ministry of Health (EüM / MoH) or in CD-ROM format. Information about diagnostic limits and dose limits for pharmaceuticals can be also obtained from the brochures of the National Institute of Pharmacy (OGYI) (i.e. Compendium, Pharmindex), which are updated yearly. In Hungary, doctors are allowed to prescribe only 1-month doses of pharmaceuticals, or in special cases 3-month doses.

It has been intended to translate and reformulate these guidelines and protocols for the patients as a form of patient information (cf. 5.3).

5.3 Information to patients / doctors

Marketing directives, as stated in Directive 2001/83/EC, were implemented in Hungary through acts and regulations. Under certain conditions (e.g. for over-the-counter (OTC) or curative products with name and international name, giving a brief, etc.) Hungarian law allows the advertising of over-the-counter (OTC) products in all media except children's channels (Decree of the Ministry of Health 64/2003). Requirements for the labelling of pharmaceuticals and handouts for patients in packs are also regulated (Decree of the Ministry of Health 30/2005).

No measures have been implemented in order to restrict or control manufacturers' promotional spending.

Audits of the sales promotion material sent to doctors and on advertisements in journals is regulated by law. The professional/scientific audit and sanctioning of false and biased promotional materials is the National Institute of Pharmacy's (OGYI) responsibility. The other, nonscientific part of promotion is regulated by the Advertising Act and the Ethical Codex of the pharmaceutical industry, accepted by every pharmaceutical company in Hungary.

Regulations and restrictions on the activities of representatives of pharmaceutical companies are set out in acts and regulations of the Ministry of Health (EüM / MoH). If the representative has the required qualification, gets a certificate and can perform her/his job. A representative is allowed to give pharmaceuticals for free to hospitals and doctors through personal encounters, but only two packs of a pharmaceutical in a year are allowed to change hands in this way and minutes have to be drawn up to document it.

There is no control over the quantity of sales promotion activities undertaken by pharmaceutical companies and no action has been taken to inform patients on the rational use of pharmaceuticals, except information on the medication prescription. There are no specific regulations regarding information (that must be given) to patients in the in-patient sector.

5.4 Pharmacoeconomics

In Hungary the development of health economics began in the 1990's as several young researchers were in the process of obtaining the M.Sc. degree in health economics and related fields.

It was a major challenge for the Hungarian health care financing system to integrate the results of pharmacoeconomics into the public administration decision-making processes. In 2000 the Government issued two Orders (No. 2150, No. 2329), through which it revealed its aims, as listed here.

- During the price negotiations the adherence to the pharmaceutical budget must have been taken into consideration.
- The reimbursement system must have been based on the principles of the 89/105/EC Directive.
- The decisions made within the reimbursement and coverage policy system must have been based on the outcomes of health economics analyses.
- Only cost-effective and essential pharmaceuticals can be reimbursed.

In 2002, the Ministry of Health (EüM / MoH) released guidelines for conducting health economic analyses. These guidelines determine the methodological issues of health economic evaluations. The guideline groups included in the Ministry of Health (EüM / MoH) directive are concerned with the following issues: description of interventions, patient population and the health service needs should be addressed in the analyses; analytic perspective; type of economic evaluation; measurement of health improvement; costs; handling time in economic evaluation studies; synthesis of health gain and costs; examining robustness and generalising study results; impact on health care, expenditure and equity; conclusions; and information on authors, sponsors and competing interests [Szende et al, 2002]. In order to update the guidelines the Ministry of Health (EüM / MoH) reviews them once every two years.

The Hungarian Health Economics Association (Magyar Egészség-gazdaságtani Társaság, META) was founded in 2003 and has a current membership of approximately 100. It holds monthly assemblies at which presentations are made on different areas of health economics, followed by discussions [Boncz et al, 2006].

In 2004, the National Institute for Strategic Health Research (ESKI) was established, which assists with decision-making in four major areas of health policy and financing: medical informatics and information policy; health economics; health services research; and health technology assessment.

The Office of Health Technology Assessment of the National Institute for Strategic Health Research (ESKI-TÉI) is a new organisational unit of the Institute, focused primarily on assessment of pharmaceuticals to determine their eligibility for social insurance funding, but as the new institutional structure becomes more firmly established, it is increasingly able to perform thorough, comprehensive assessments of other health technologies. Comprehensive health technology appraisals have been created for Positron Emission Tomography (PET) and Gamma Knife, and

also larger expert-led studies were made on featured professional areas such as cardiology and oncology.

Besides the National Institute for Strategic Health Research (ESKI), university units and private advisory firms perform health-economic analyses. As a result of this development, Hungary has moved towards introducing the “Fourth Hurdle” for pharmaceuticals. This development is fully supported by Act No. CLIV of 1997 on health, which clearly states among the basic principles that health care services have to be evidence based and cost effective.

On 1 May 2004, Hungary joined the European Union (EU), and it was thus necessary to adopt the European Commission (EC) Transparency Directive. As a result of the introduction of the Transparency Directive, decisions on pricing and reimbursement of pharmaceuticals are made in accordance with the regulations and practices of the European Union (EU). Accompanying the National Health Insurance Fund Administration (OEP), the Technology Appraisal Committee (TÉB) has been set up to prepare decisions on reimbursement applications.

Since the enforcement of the new transparent pharmaceutical coverage and reimbursement system (in normal procedure) the applicants are obligated to submit pharmacoeconomic analyses in order to obtain reimbursement status for their pharmaceuticals (to be accepted into the positive list).

In the event that the application is classified as a normal procedure, the Pharmaceutical Division of the National Health Insurance Fund Administration transfers the complete documentation to the Office of Health Technology Assessment of the National Institute for Strategic Health Research (ESKI-TÉI) in order to carry out a critical evaluation, with specific regard to health economic analyses.

Debates on the applications take place before the Technology Appraisal Committee (TÉB), taking account of the above-mentioned assessment, the preliminary opinion of the Pharmaceutical Division, and the opinion of Colleges of the Medical Professionals.

Parameters considered by the Technology Appraisal Committee (TÉB) are, among others, the proposed manufacturer price (applied by the applicant) and reimbursement category, benefits compared to pharmaceuticals that are already reimbursed and prices in other countries, as well as analyses presented by the National Institute for Strategic Health Research (ESKI).

The National Health Insurance Fund Administration (OEP) is in charge of reimbursement decisions (in the case of out-patient pharmaceuticals the decision-maker is the Head of the Department of Pharmaceuticals; in the case of hospital pharmaceuticals the Head of Department of Curative-Preventive Provisions), which are made on the basis of recommendations of the Technology Appraisal Committee (TÉB).

Recently, pharmaceutical reimbursement and health care financing have been of the highest priority in terms of health economics topics in Hungary.

As in all European Union (EU) countries, in Hungary, in order to obtain market authorisation, the manufacturer has to support with documentation the quality, safety and efficacy of the pharma-

ceutical. The authorisation bodies (European Medicines Agency (EMEA), National Institute of Pharmacy (OGYI)) are in charge of the evaluation of these three aspects.

In Hungary, no maximum is applied in terms of an agreed amount to "pay" for one quality-adjusted life year (QALY), but efforts are being made to develop the methodology of priority setting and financing thresholds.

Hopefully, the development of health economics in Hungary since the early 1990s will continue.

5.5 Generics

5.5.1 Generic substitution

In Hungary, generic substitution by pharmacists is allowed, but is not obligatory since 1995. Decree of the Ministry of Welfare 8/1995 introduced the possibility for pharmacists to substitute the pharmaceuticals based on the same substance, strength and forms. The issue is now regulated by Decree of the Ministry of Health 44/2004, which states that products involved in generic substitution should be included in the bioequivalence list issued by the National Institute of Pharmacy (OGYI). Substitution is permitted for the same substances, strength and forms, so so-called analogous substitution is not possible.

Table 5.1: Hungary - Development of the generics market in the out-patient sector, 2000-2005

Generic* market share	2000	2001	2002	2003	2004	2005
Volume (UNIT per year) (%)	44	43	43	4	42	42
Value (%)	26	25	25	25	26	26

* Product, not molecule category, i.e., an original brand will remain original, even after patent expiry

Source: OEP, 2006

If the pharmacist intends to substitute a pharmaceutical, (s/)he has to offer the cheapest available version of the pharmaceutical for the patient, who has the right to refuse the substitution. The prescribing doctor can indicate on the prescription that (s/)he prohibits the substitution. The pharmacist receives a proportional share of the price of dispensed products, which means that (s/)he does not have any financial incentive to prescribe generic pharmaceuticals.

5.5.2 Generic prescription

At the time of writing neither regional nor individual pharmaceutical budgets for physicians had been introduced, although there are government plans to this effect. There is no regular feedback or audit that could improve attitudes to, and the amount of, generic prescription. In practice, prescribing guidelines for cost-effective prescription are not widely used. It is permitted to use an International Non-Proprietary Name (INN) pharmaceutical on the prescription, but this is not common practice. In spite of the weak incentives on the demand side, the value of the Hungarian generics market was 26.20% according to IMS data, which is a surprising fact. This fact shows that physicians have accepted generic pharmaceuticals for use in therapies.

5.5.3 Generic promotion

Generic pharmaceuticals are promoted very strongly in journals aimed at physicians. In the mid-1990s the Government applied the tools of mass media in some instances, to inform patients, but this policy tool did not became a regular way of informing the public. There is no central Internet-based information centre for patients, where they can compare their pharmaceuticals with alternatives. The strongest financial incentives for patients to opt for generic pharmaceuticals are the reference pricing system based on active substance and similar therapeutic indication, applied within the reimbursement system. The higher co-payments on the original pharmaceuticals are a clear (but sometimes just theoretical) encouragement to select the generic pharmaceuticals. Pharmacists are obliged, according to Government Decree 217/1997, to inform patients of the possibility of substitution for a cheaper pharmaceutical.

5.6 Consumption

The individual consumption data is not monitored and there is therefore no Essential Drug Policy in place.

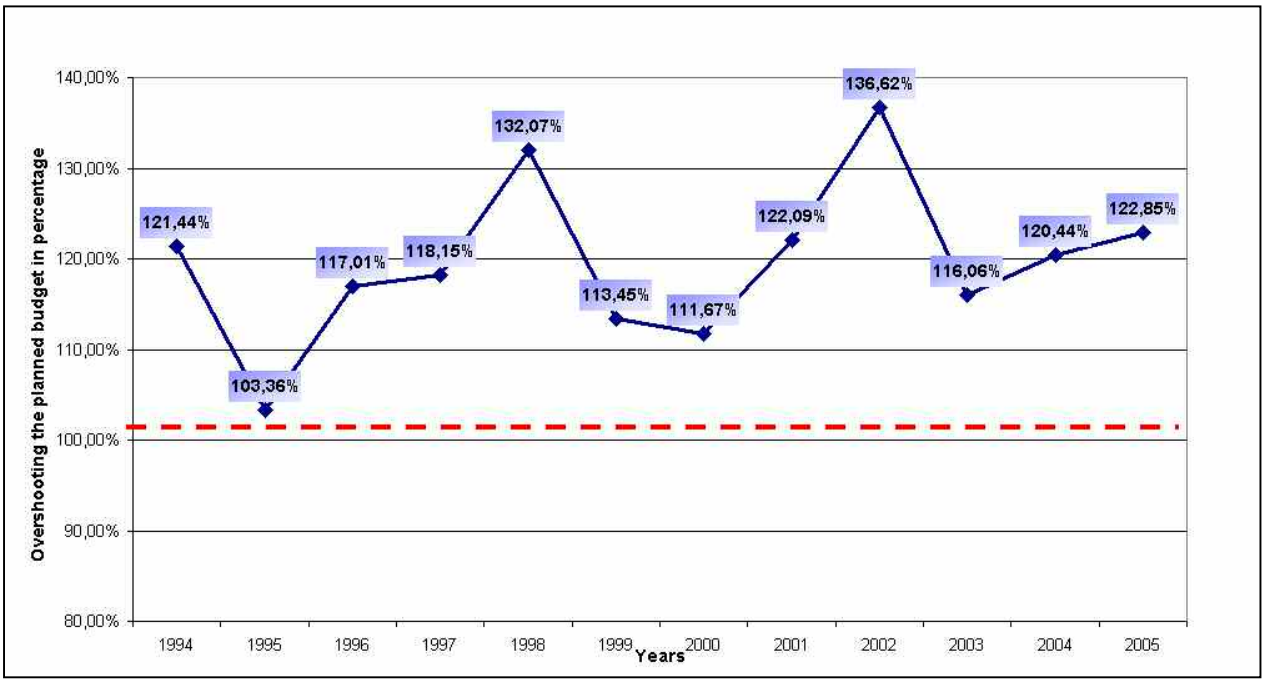
In the case of individual reimbursement, different consumption data are allowed to be used (e.g. a patient who has difficulties swallowing large tablets can receive reimbursement for more expensive, smaller pharmaceuticals).

6 Current challenges and future developments

6.1 Current challenges

Although in Hungary the total pharmaceutical expenditure (TPE) per capita in US$ – in exchange rate – according to the Organisation for Economic Co-operation and Development (OECD) 2006 Health Data is far lower (US$ 137 per capita per year) than in other countries in the European Union (EU), the proportional spending for pharmaceuticals in the budget of the (social) Health Insurance Fund (E. Alap / HIF) and as a share of the total health expenditure (THE) is extremely high (cf. 2.2.1). The (social) Health Insurance Fund (E. Alap / HIF) spent more on pharmaceuticals than on active hospital care. Despite this high disproportionate spending, the actual pharmaceutical spending has overshot the planned expenditure every year since the mid-1990s (cf. Figure 6.1). The pharmaceutical budget became the most important governing factor behind the financial instability of the (social) Health Insurance Fund (E. Alap / HIF), which is a cause of great concern for the Government, considering the potential accession of Hungary to the European Monetary Union.

Figure 6.1: Hungary - Overspending of the planned pharmaceutical budget as a percentage of the social health insurance (SHI) budget



Source: OEP, 2006

In spite of the disproportionately high pharmaceutical social health insurance (SHI) expenditure, there is large share of private household spending in the form of co-payments and direct payments in Hungary (cf. 4.4.2). This is also high in comparison with other European countries. It therefore follows that the financial techniques that were introduced could not ease the financial burden for patients and could not decrease the overspending on the planned budget limit within the pharmaceutical budget of the social health insurance (SHI) over the decade past.

With the introduction of the so-called Transparency Directive for reimbursement decisions (89/105/EGK) in 2004 the (social) Health Insurance Fund (E. Alap / HIF) began to use pharmacoeconomics and technology assessment widely in the decision-making process. An adequate institutional and methodological framework was set up (cf. 5.4) in 2004 and 2005, but some important developments have to be made to improve the efficiency of the decision-making process, such as creating a sound epidemiological database background, educating the experts carrying out the evaluations, establishing a sound informatics supporting system, creating a more transparent evaluation process, and involving the patient organisations.

The rules for establishing and operating pharmacies were liberalised and reformed by the Government at the end of 2006 with the annulment of the Law No. LIV of 1994 on establishing and operating pharmacies (cf. 2.1.3.3 and 2.1.3.3.1). Previously, only the Hungarian Chamber of Pharmacists (MGYK) could grant a permit to establish and operate a new pharmacy. The new Law (No. XCVIII of 2006 on the safe and economic supply and distribution of pharmaceuticals) essentially changed the legal status and competence of the Hungarian Chamber of Pharmacists (MGYK), and there is therefore no longer any need for the approval of the Hungarian Chamber of Pharmacists (MGYK) in establishing and supplying pharmaceuticals in Hungary. In future the state authorities will grant permits and control the foundation and operation of the pharmacies. It will be possible, after fulfilling certain conditions, for some of the over-the-counter (OTC) pharmaceuticals to be supplied outside of pharmacies, in shops. The restriction of ownership was annulled, but leading and operating pharmacies is permitted exclusively by trained pharmacists.

The new Law No. XCVIII of 2006 on the safe and economic supply and distribution of pharmaceuticals regulated the pharmaceutical market from a couple of points of view, with the aim of decreasing the deficit in the pharmaceutical budget of the social health insurance (SHI).

- The suppliers of the pharmaceuticals have to pay certain amount – HUF 5 Mio. – by each of their promotion agent on a yearly basis. They have to send a summary report to the recently established Health Insurance Authority on the gifts and other promotional items given to subscribing doctors.
- The suppliers of the pharmaceuticals have to pay certain amount – 12% of their revenue from the reimbursed pharmaceuticals – to the budget of the social health insurance (SHI). This amount can be decreased, if the supplier cuts back the prices of the products and maintains this price level for three years. There is no payment obligation for pharmaceuticals that were involved in the reference pricing system and when their prices are at least 15% below the reference price. There are also some other conditions that reduce this burden.
- Through claw-back regulations, the general payback scheme for the industry became the general rule (cf. 3.6.1 and 4.6.4). Up to 9% in excess of the planned pharmaceutical expenditure of the social health insurance (SHI), the supplier and the social health insurance (SHI) itself share the additional cost, with the supplier bearing a higher percentage. If the planned expenditure is exceeded by more than 9%, the supplier alone has to bear the additional cost of the pharmaceutical spending.
- The wholesalers have to pay 2.5% of their total revenue from the wholesale margins based on the publicly financed pharmaceuticals.

- The pharmacies have to pay a so-called “solidarity fee” on any revenue over HUF 30 Mio. from the publicly financed pharmaceuticals. The fee is progressive from 0.5% (above HUF 30 Mio. per year) to 2% (above HUF 75 Mio. per year). From the collected fee the Ministry of Health (EüM / MoH) can support pharmacies which have to operate alone in certain geographical areas and are not able to operate economically.

The doctors have to inform the patients about cheaper therapeutic alternatives and about the possibilities of substitution. In contrast with the earlier situation (cf. 5.5.1), the pharmacists are obliged to inform the patient about cheaper alternatives and to substitute the more expensive pharmaceuticals if the patient gives her/his approval to do so. The doctors have the right to prohibit the substitution. The social health insurance (SHI) authorities launched such a computer programme, which has to be used by the subscribing doctors.

The newly established Health Insurance Authority can evaluate the safe and efficient prescribing practices of the providers, and in contrast with the earlier situation it can fine them if necessary.

From 1 January 2007 the Ministry of Health (EüM / MoH) introduced new out-of-pocket payment (OPP) categories (cf. 4.6.3). Patients with exemptions have to pay a fixed co-payment (HUF 300), even for pharmaceuticals that are reimbursed at the 100% level. The pharmaceuticals with special indications can be reimbursed at 100%, 90%, 70% and 50%; those without restrictions at 85%, 55% and 25%. The latter measure is essentially an increase in the share of the patient’s co-payment.

For internal price referencing (cf. 3.3.2), the reference product has to reach 1% of the turnover of the group, instead of 3% as calculated in the directly observed treatment (DOT). The creation of the groups is to be carried out continuously. To influence the reference price of the group any supplier in the group can tender publicly and permanently. Based on the tenders, the social health insurance (SHI) gives a deadline for any supplier in the group to compete with counter offers. The new reference price gained from the tender is announced quarterly.

The new measures introduced the stepped pricing system for pharmaceuticals, which is not part of internal reference pricing. The first generic product has to offer a 30% price reduction compared to the reimbursed one, the following one a further 10% and the third one also 10%. The earlier regulation on reimbursing combination products (cf. 3.3.2) was annulled.

6.2 Future developments

In the next few months an evaluation of the implemented policies will take place. If it is necessary, the policy-makers will carry out the required corrections.

7 Appendixes

7.1 References

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The most important laws and decrees:

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2. Decree of the Ministry of Health 1/2003 on the pharmaceuticals co-financed by social insurance and its amount.

3. Decree of the Ministry of Health 19/2001 on the commercial price mark up of medicinal products.

4. Decree of the Ministry of Health 25/1997 on pharmaceuticals marketed without social security reimbursement.

5. Decree of the Ministry of Health 30/2005 on the labelling and packaging leaflets accompanying pharmaceuticals for human use.

6. Decree of the Ministry of Health 32/2004 on the criteria of inclusion of registered pharmaceuticals and foods satisfying particular dietary requirements into social insurance coverage, and on altering coverage or reimbursement status

7. Decree of the Ministry of Health 44/2004 on the order and handing over of medical products.

8. Decree of the Ministry of Health 52/2005 on the market authorisation of pharmaceuticals for human use in accordance with Directive 2001/83/EC.

9. Decree of the Ministry of Health 53/2004 on the market authorisation of parallel traded pharmaceuticals.

10. Decree of the Ministry of Health 64/2003 on the advertising and promotion of pharmaceuticals for human use and of therapeutic substances and preparations.

11. Law No. CLIV of 1997 on hygiene.

12. Law No. LIV of 1994 on establishment and operation of pharmacies.

13. Law No. LVIII of 1997 on economic sales promotion activity.

14. Law No. LXXXIII of 1997 on compulsory health services in the framework of social security and Decree of the Government 217/1997 on compulsory health service provision.

15. Law No. LXXXVII of 1990 on setting prices including those of pharmaceuticals.

16. Law No. XCV of 2005 on pharmaceuticals for human use and on the amendment of other regulations related to pharmaceuticals.

17. Law No. XXXIV of 2001 on specialised care obligation.

18. Ministerial and the Self-Government of the Health Insurance Fund Statement, 1996; published in Welfare Gazette 25/1996 and Law No. LXXXIII of 1997 on compulsory health services in the framework of social security and Decree of the Government 217/1997 on compulsory health service provision.

7.2 Further reading

Gaal P (2004). *Health Care Systems in Transition*. Peter Gaál
Available at http://www.euro.who.int/Document/E84926.pdf

7.3 Web links

www.oep.hu	(National Health Insurance Fund Administration)
www.eum.hu	(Ministry of Health)
www.mgyk.hu	(Hungarian Chamber of Pharmacists)
www.aipm.hu	(Association of Innovative Pharmaceutical Manufacturers)
www.magyosz.org	(Hungarian Pharmaceutical Manufacturers Association)
www.mok.hu	(Hungarian Chamber of Physicians)
www.pm.gov.hu	(Ministry of Finance)
www.ksh.hu	(Central Statistical Office)
www.ogyi.hu	(National Institute of Pharmacy)

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