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Pharmaceutical Pricing and Reimbursement Information

POLAND
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Pharma Profile

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Executive Summary

The Republic of Poland is the largest country in eastern Europe in terms of population and the area it covers. The total population of the country is approximately 38.15 Mio. people and the surface area covers 312,685 km². The country was devastated during the Second World War, with one fifth of the population killed. Following the war, a communist government ruled the country, until the re-emergence of a democratic government in 1989. Under communist rule, health care was declared a public responsibility. Administration of the health system was strongly centralised, as was the administration of the economy generally.

Today, Poland is a parliamentary democracy and its economy has been successfully converted to being a free market since the end of the 1980s. Nominal gross domestic product (GDP) per capita amounts to US\$ 9,593.774 and the purchasing power parity (PPPa) gross domestic product (GDP) per capita totals US\$ 15,894.367. The country enjoyed strong gross domestic product (GDP) growth in the region of 5% in the late 1990s, and then it slowed down to approximately 1% at the turn of the century, but in recent years has risen again to 3%.

The Polish health care system represents a Beveridge-type system. It is publicly funded, centralised and managed by a statutory organisational tier – the National Health Fund (Narodowy Fundusz Zdrowia (NFZ), NHF) (Central National Health Fund (NHF) and 16 regional offices). The National Health Fund (NHF) is a third-party payer in public health care. The basic source of financing for health care is income from health care contributions from personal income. Contributions for insured people and those who pay personal income tax are collected by the Social Insurance Institution (Zakład Ubezpieczeń Społecznych, ZUS) and then transferred to the National Health Fund (NHF). The National Health Fund (NHF) objective is to maximise health outcomes using available resources. The Ministry of Health (MoH) carries out most of the regulatory functions concerning pharmaceuticals and medical devices. The Minister of Health takes into account in particular the necessity to ensure protection of public health, availability of pharmaceuticals, their safe application and the financial capacity of the National Health Fund (NHF). Expenditure on reimbursement in 2004 amounted to PLN (Polish Zloty) 5.47 billion. Patient co-payments for reimbursed pharmaceuticals on average reach 33.4%, which is equal to 63% of total pharmaceutical expenditure (TPE) in Poland. Under the Polish health care system a patient receives reimbursed pharmaceuticals at the point of delivery, which means in a pharmacy. The National Health Fund (NHF) reimburses pharmacies on the basis of a reimbursement report submitted every two weeks (ex post) by the pharmacies to the regional office of the National Health Fund (NHF).

In 2005 Poland spent 6.2% of gross domestic product (GDP) on health care, of which approximately 70% was public expenditure. Private expenditure on pharmaceuticals has grown from 23% in 1994 to 35.1% in 2006. In comparison with other European countries, Poland spends a disproportionately high percentage of total health expenditure (THE) on pharmaceuticals. The Ministry of Health (MoH) is planning to undertake necessary measures to moderate expenditure on pharmaceuticals.

Poland operates positive lists of pharmaceuticals eligible for reimbursement. Only products granted a market authorisation can be included in the reimbursement lists. These include:

essential pharmaceuticals, complementary pharmaceuticals, pharmaceuticals used for chronic diseases and preparations. In Poland the reimbursement system is based on the reference price system, which means that a specific group of pharmaceuticals is allocated a reference price; a price limit, which is used as the basis for calculating the reimbursement. The reference price represents the price of the cheapest generic medicine in one group. The price of an individual pharmaceutical can be higher than the reference price set for the group, but a patient purchasing it is reimbursed solely on the basis of the reference price. The difference between the reference price and the actual price and the actual price is borne entirely by the patients.

The Minister of Health establishes a body known as the Pharmaceutical Management Team. The Minister of Health, in consultation with the Minister of Finance, makes a decision based on the Pharmaceutical Management Team's position (expressed by way of a resolution) on inclusion of pharmaceuticals into the positive lists and on official prices of pharmaceuticals. In consultation with the Minister of Public Finance and by way of an ordinance, the Minister of Health defines the official wholesale and retail prices of the pharmaceuticals and medical devices counterbalancing the interests of consumers (patients) and the entrepreneurs manufacturing and trading such pharmaceuticals and devices, while considering the payment capacity of the public health insurance system and the criteria set out in Polish legislation.

The official wholesale and retail prices are set for pharmaceuticals and medical devices included in the lists of essential and complementary medicines and the list of pharmaceuticals and medical devices used in chronic disease therapy. The official wholesale and retail prices are set for pharmaceuticals and medical devices only if they are included in the reimbursement system – in the list of essential and complementary medicines and the list of pharmaceuticals and medical devices for full reimbursement, prescribed on a flat-rate or co-payment basis in case of contagious or mental diseases/conditions, mental disability and other selected chronic congenital diseases. Official wholesale and retail prices represent the price maximum – any price below the official price is allowed. Products included in the category of non-reimbursable pharmaceuticals are freely priced.

Legislation regulating the pharmaceutical sector, in particular pricing and reimbursement matters, is composed of three principal acts: Law on health care services financed from public sources, dated 27 August 2004 and the Pricing Law, dated 5 July 2001. The Pharmacy Law, dated 6 September 2001 is the general Polish law on almost all aspects of pharmaceuticals, regulating the entire duration of product life, starting with clinical trials through to manufacturing and advertising, establishing pharmacies and all authority obligations, and including penal provisions. These matters are also regulated by ordinances of the Minister of Health, which, according to the Polish Constitution, are based on and dependent on legal acts, e.g. on the Pharmacy Law.

Recently, the Minister of Health presented an amendment to a law to the Polish Parliament – the Pharmacy Law – which also changes the provisions of the Pricing Law and the Law on health care services financed from public sources. This legislative proposition creates some changes in prices and margins provisions, making them fixed. At present it is hard to estimate which solution the Parliament will choose.

In Polish pricing and reimbursement policy, the main objectives are achieved by the regulatory authorities as described in an official document accepted in March 2004 by the Council of Ministers: "National Pharmaceutical Policy 2004-2010". The Department of Pharmaceutical Policy and Pharmacy at the Ministry of Health (MoH) is responsible for the conception and implementation of the national pharmaceutical policy.

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List of abbreviations

AOTM	Agencja Oceny Technologii Medycznych (state Agency for Health Technology Assessment)
ATC	Anatomic Therapeutic Chemical classification
CMJ	Centrum Monitorowania Jakości w Medycynie (Centre for Quality Monitoring in Medicine)
DDD	Defined Daily Dose
EAN	European Article Number
EC	European Commission
EU	European Union
GDP	Gross Domestic Product
GGE	General Government Expenditure
GP	General Practitioner
HE	Health Expenditure
HiT	Health systems in Transition
HOM	Hospital-Only Medicine(s)
INFARMA	Stowarzyszenie Innowacyjnych Firm Przemysłu Farmaceutycznego (Innovative Producers of Pharmaceutical Industry Association)
INN	International Nonproprietary Name
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
NCU	National Currency Unit
Mio.	Million
MoF	Ministry of Finance
MoH	Ministry of Health
MRP	Mutual Recognition Procedure
NATO	North Atlantic Treaty Organisation

NHF	Narodowy Fundusz Zdrowia (NFZ) (National Health Fund)
NZ	“Nie zamieniac” (“Do not substitute”)
OECD	Organisation for Economic Co-operation and Development
OOP	Out-of-pocket
OPP	Out-of-Pocket Payment
OTC	Over-The-Counter (pharmaceuticals)
PE	Pharmaceutical Expenditure
PGF	Polska Grupa Farmaceutyczna (Polish Pharmaceutical Group)
PiS	Prawo i Sprawiedliwość (“Law and Justice” party)
PLN	Polish Zloty (national currency of Poland)
PO	Platforma Obywatelska (Citizens’ Platform)
POM (Rx)	Prescription-Only Medicine(s)
PPP	Pharmacy Purchasing Price
PPPa	Purchasing Power Parity
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy Retail Price
PZPPF	Polski Związek Pracodawców Przemysłu Farmaceutycznego (Association of Employers of Pharmaceutical Industry)
R&D	Research and development
Rx (POM)	Prescription-Only Pharmaceutical
SHI	Social Health Insurance
SPFFwP	Stowarzyszenie Przedstawicieli Firm Farmaceutycznych w Polsce (Association of Representatives of Pharmaceutical Companies in Poland)
THE	Total Health Expenditure
TP	Therapeutic Programme (Medicinal Programme)
TPE	Total Pharmaceutical Expenditure
VAT	Value-Added Tax

VHI	Voluntary Health Insurance
WHO	World Health Organization
WP	Work Package
ZUS	Zakład Ubezpieczeń Społecznych (Social Insurance Institution)

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 total population of Poland is 38.13 Mio. people. The population is distributed across two major centres – the capital city of Warsaw (Mazovia region) and the southern region of Silesia, where the coal mines are located. These regions offer many more job opportunities than elsewhere in Poland, but in Silesia, where coal has not been sought since the mid-1980s, problems finding jobs may well occur. In addition, there is another region (of minor importance in terms of population distribution) – the former Prussian territories in the north-eastern part of Poland – which is inhabited by agriculturalists. Two decades ago, these people were highly subsidised by the Government, but now the economy there needs much attention in order to be improved.

The distribution of the population is not significantly related to age, but one may expect that areas of better economy and with more job opportunities will attract more individuals within their productive years, while areas of weak economy comprise mainly elderly people. The population of Poland is ageing, and this is associated with systemic and economic changes since the mid-1980s. Women have fewer children (a lower number by comparison to the level in the mid-1990s) and they give birth later (age of mother is higher in comparison the level in the mid-1990s). The new economic situation quickly developed into a capitalist style, and the social, protective mechanisms of the State, present in Poland before 1989, are no longer used. This situation demands much more creativity and activity from young people who, although conscious about the consequences of late parenthood, have dedicated time to their careers.

Table 1.1: Poland - Demographic indicators 1995, 2000-2005

Variable	1995	2000	2001	2002	2003	2004	2005
Total population	38,609,399	38,253,955	38,242,197	38,218,531	38,190,608	38,173,835	38,157,055
Population density per km ²	122	122	122	122	122	122	122
Population aged 0-14 (as a % of total)	21.6	19.1	18.4	17.8	17.2	16.7	16.2
Population aged 15-64 (as a % of total)	67.1	68.6	68.4	68.8	69.8	69.5	70.5
Population aged > 64 (as a % of total)	11.3	12.3	12.5	12.7	13.0	13.1	13.3
Life expectancy at birth, total	72.05	73.03	74.30	74.60	74.59	74.96	74.97
Life expectancy at birth, females	76.4	78.1	78.4	78.8	78.9	79.2	79.4
Life expectancy at birth, males	67.62	69.74	70.20	70.40	70.52	70.69	70.81

Source: Statistical Yearbook issued by Central Statistical Office (GUS).

The political parties of more socialist orientation propose to rebuild the safety mechanisms of the State, introduce tax discounts for married couples with more children and grant a lump sum of money to every mother for every new birth. These changes have not brought about any effects as yet – the time horizon may still be too short to judge.

The three leading causes of death in Poland are hypertension, cardiovascular event, neoplasm (women, breast; men, lung).

1.2 Economic background

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

Variable (in PLN or %)	1995	2000	2001	2002	2003	2004	2005
GDP in PLN, Mio.	337,222	744,378	779,564	808,578	843,156	924,538	982,565
GDP per capita in PLN	8,810	19,464	20,371	21,130	22,048	24,181	25,704
GDP per capita in US\$ PPPa	7,363.94	10,437.55	10,865.46	11,217.42	11,902.2	12,893.4	13,741.1
Annual economic growth rate in %	7.0	4.2	1.1	1.4	3.8	5.3	3.2
GGE, Mio.	630,270	129,831	139,456	144,651	152,826	162,656	177,785
GGE as a % of GDP	18.7	17.4	17.9	17.9	18.1	17.6	18.1
Exchange rate (PLN per €), annual rate	n.a.	4.0095	3.6700	3.8535	4.3983	4.5323	4.0230

GDP = gross domestic product, GGE = general government expenditure, PPPa = purchasing power parity, Mio. = million, n.a. = not available, PLN = Polish Zloty

Sources: Statistical Yearbook for Poland 2005 and 2006, Central Statistical Office; Rate Calculator – www.bankier.pl; OECD Health Data 2004; Human Development Report 2006, International Monetary Fund Database.

1.3 Political context

Poland is a democratic republic with two Houses of Parliament and a President. The country is comprised of 16 voivodaships, which are administrative regions with local authorities elected – like Members of Parliament and the President – in a public election. The President, who is a Supervisor of the Army, performs most of the representative functions and takes part in legislative procedure (acts proposed by the Parliament must be countersigned by the President). S/he also has the right to initiate legislation procedures with proposed solutions and acts. The Parliament is a law-giving body, which also appoints the Prime Minister, who proposes the compo-

sition of the Council of Ministers. The Government has functions in all voivodaships, which are the representation of the central authorities in regions.

The regions also have their own, self-sustained ruling authorities, elected in public and general elections. These consist of Boards of Communes, as the crucial local structure of local autonomous authorities; the county foremen; and the Voivodaships' Board, led by marshals of the voivodaships, along with presidents of towns in bigger cities.

The self-governments have to operate within a general taxation framework, but may also impose local taxes, i.e. real estate (property) tax and parking charges. The local authorities can raise or decrease such charges according to the current needs of the local community.

Since the last parliamentary elections "Law and Justice" (Prawo i Sprawiedliwość, PiS) is the ruling party with approximately 30% of public opinion support, followed by the "Citizens' Platform" (Platforma Obywatelska, PO) with approximately 28% of society's support. The third major political force is the "Samoobrona" party ("Self-defence"). Law and Justice (PiS) is an anti-communist party, and in economic and systemic solutions they propose to support the social role of the State in people's lives, while the Citizens' Platform (PO) is a far more liberal party. Law and Justice (PiS) invited other minor right-wing parties to cooperate with them in a form of parliamentary coalition. Currently, Law and Justice (PiS), together with Samoobrona and the "League of Polish Families" (Liga Polskich Rodzin) hold the majority in the Parliament, while the Citizens' Platform (PO) stands as opposition. All of the coalition parties are represented in the Government – the ministries were distributed to the parties as an outcome of internal coalition negotiations.

Presidential elections followed the parliamentary elections and the candidate of the Law and Justice (PiS) party won. Elections for local authorities were performed in autumn 2006 – presidents of cities, majors, marshals to voivodaships, members of boards of counties and county foremen were elected. Local authorities are often owners of hospitals in their regions and may have a strong influence over methods of managing such health service-providing institutions, including subsidies and other support methods. However, such influence is not generally of high importance as most decisions are made centrally in the Polish health care system and are therefore officially the health policy of the State.

Poland entered the European Union (EU) in May 2004, which required the implementation of certain European Directives into the Polish legal system. Accession to the European Union (EU) was negotiated and carried out under the previous governing coalition. Not all European Union (EU) Directives are implemented in Poland, but only a few of them have not yet been transposed into Polish law.

Poland, as a member of the North Atlantic Treaty Organisation (NATO), is currently contributing to military operations in Iraq. There are some consequences to be faced, e.g. resulting from the financial demands of the army, and war veterans coming back to the country – as a group, they are to be supported by the State (free pharmaceuticals of all kinds including those not listed as reimbursed). In addition, terrorist acts are expected in Poland, similarly to in England (explosives found in airports, some hospitals profiled as special emergencies for a case of a terrorist attack; special donations from local authorities reserved for such hospitals, etc.).

1.4 Health care system

This section includes an overview of the health system in Poland, which has been, and continues to be, in a transition period since the mid-1990s.

1.4.1 Organisation

From the Second World War onwards the system functioned as it had as part of the communist (socialist) system. Hospitals and other service-providing institutions, e.g. open out-patient specialists' surgeries, were paid for from the central budget money passed to the local authorities – and local authorities represented the central authorities in the regions of 49 voivodships. Patients did not have to pay or co-pay for the services, there was no unemployment and if some individuals did not work they were socially insured by other means (social aid state institutions). Private practice by doctors was allowed but these practices were fully paid for by the patients through out-of-pocket payments (OPP). Most pharmaceuticals were reimbursed and there were no transparent procedures for decision-making within the system. The system was corrupted and insufficiently efficient; as a result, doctors were severely underpaid and many of patients had to seek help in the private health care sector or they had to unofficially pay doctors in state hospitals, in order to be treated. This system operated in Poland until the major political, economic and administration changes that took place in the early 1990s.

In 1989 the period of communism in Poland ended. In the years that followed economic changes were introduced and state administration reform was carried out. Instead of 49 voivodships, 16 new voivodships were established, governed by local representatives (organs of the central authorities) and local self-sustained autonomous authorities (as described in 1.3).

Changes in the health care system followed much later, in 1998, when centralised funding of hospitals, overseen by the Ministry of Health (MoH), was replaced by the new system. A Common Health Insurance Law (Ustawa o Powszechnym Ubezpieczeniu Zdrowotnym), based on the rule of societal solidarity, introduced 17 sickness funds – one in each voivodship, and one which insured individuals from a variety of military bodies (i.e. fire fighters, police and other “uniformed” services). These sickness funds were managed by executive committees, members of which were nominated by local, regional self-sustained authorities and by local representatives of central authorities – the parity rule was obeyed. The Military Sickness Fund executive committee was nominated by the Ministry of Internal Affairs (police, secret service, etc.) and operated countrywide, while 16 other Regional Sickness Funds were operating in their regions only and contracted health services for inhabitants from their regions with service providers operating in regions/voivodships. The Common Health Insurance Law did not allow the operation of private health insurance companies within the obligatory health insurance system. This exclusion was intended for the first five years (during system transformation), in order to avoid competition between the state Sickness Funds (financed with public money) and private insurance companies (funded with private capital). It is worth noting that a subscriber could decide to pay her/his health insurance contribution to a different sickness fund than that of his own region of occupancy. Services provided to patients in regions other than that of their habitual occupancy were paid by their “mother” sickness fund directly to the relevant service providers, upon receipt of a

proper invoice. Sickness funds were supervised by a special institution, the Bureau of Health Insurance Supervision.

The Bureau of Health Insurance Supervision reported to the Ministry of Health (MoH) and was supposed to coordinate sickness funds' activities across the whole country. It also decided on the method of division of funds, which were commonly collected by the Social Insurance Institution (Zakład Ubezpieczeń Społecznych, ZUS) (as in more wealthy regions, sickness funds' incomes were greater than those in poor regions and a balance was desired to secure health services at a similar level across the country). Some decisions were made centrally by the Ministry of Health (MoH); namely, the pharmaceutical reimbursement list that the sickness funds were supposed to cover, and some highly specialised procedures that were paid for from the Ministry of Health's (MoH) budget (e.g. organ transplantations). The health insurance contribution was collected by the Social Insurance Institution (ZUS) in the form of 7% of the insured person's salary and was obligatorily paid by the employer to the Social Insurance Institution (ZUS), operating countrywide. Health insurance contributions were then divided and transferred to the correct sickness fund, as indicated by the employee. The Social Insurance Institution (ZUS) also collected contributions for retirement pensions, sick-leave payments and sickness pensions, but these were transferred to different institutions: the retirement contribution was transferred to the relevant retirement fund as indicated by the employee and the others remained with the Social Insurance Institution (ZUS) to be paid out by this institution when needed. According to the Common Health Insurance Law the contribution for health insurance that was originally set at the level of 7% of an employee's salary was supposed to be increased by 0.25% every year, until it reached 8.25% of salary. The obligatory health insurance donation was supposed to be fully deductible from personal income on a tax basis. It never achieved the desired level, because after almost five years undergoing the transformation of the system, another parliamentary election transferred power to more socialist forces and a change of system was decided on, completely changing the direction of the ongoing transformation.

In 2003 the new Minister of Health, originating from the socialist-democratic party, decided that the former system of central decision-making and centralised division of funds between the regions (and within the regions between hospitals and other service providers) was better than the system of local decision-making. He therefore initiated a new Act on Social Health Insurance – the Common Health Insurance in the National Health Fund Law (Ustawa o Powszechnym Ubezpieczeniu w Narodowym Funduszu Zdrowia) and the new Parliament approved that regulation. As consequence, a new central institution was brought into being – the National Health Fund (Narodowy Fundusz Zdrowia (NFZ), NHF), with its central office in the capital city, Warsaw. Regional Sickness Funds were transformed into regional branch offices of the National Health Fund (NHF). The President of the National Health Fund (NHF) Executive Committee is nominated by the Minister of Health and must be approved by the Prime Minister. The budget of the National Health Fund (NHF) is collected from employers by the Social Insurance Institution (ZUS) and the obligatory donation for public common health insurance is now set at the level of 8.25% of an employee's salary (paid by the employer to the Social Insurance Institution (ZUS) before the salary is delivered to the employee). The obligatory health insurance payment of 8.25% is no longer fully deductible from an employee's personal tax – only 7.5% of it is still deductible, with the remaining 0.75% paid obligatory by the employees, by means of out-of-pocket payments (OPP). A total of 8.25% of salaries are paid directly by employees to the Social Insur-

ance Institution (ZUS). Only 7.50% can be deducted from personal tax, and the remaining 0.75% must contribute to public mandatory health insurance (not deductible from tax).

The budget, divided centrally, is transferred to the regional offices of the National Health Fund (NHF) and those offices contract health services in the regions for the local populations (state hospitals can be contracted as well as private hospitals and private practices). The contracting, however, is not carried out freely – only services that are in the list of procedures contracted by the National Health Fund (NHF) may be contracted. The list is set centrally, by the National Health Fund (NHF) Department of Health Services and always after consultations with National Consultants (experts in the appropriate medical field). The National Health Fund (NHF) also reimburses pharmaceuticals in the reimbursement list – again, the list is drawn up centrally by the Ministry of Health (MoH) but in cooperation with representatives of the National Health Fund (NHF), the Ministry of Finance (MoF) and the Ministry of Economy. Usually, opinions from National Consultants are taken into consideration during this decision-making process. Some pharmaceuticals which are not listed but are needed are contracted by the National Health Fund (NHF) independently from the Ministry of Health (MoH) in the form of health services contracted within the hospitals. Each service of this kind must be – however it is individually contracted – agreed with the local branch office of the National Health Fund (NHF). Some such services are organised in therapeutic programmes (TP), also contracted by regional branches of the National Health Fund (NHF) and usually the inclusion of a patient in such a programme must be agreed individually with the payer (i.e. the local branch office of the National Health Fund (NHF)). Approval of therapeutic programmes (TP) is granted by the central office of the National Health Fund (NHF).

In late 2004 further changes were introduced with an update of the Common Health Insurance in the National Health Fund Law. It was replaced with another act called the Health Services Financed from Public Sources Act (Ustawa o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych). This new Act introduces a new demand for submission of health economics analyses together with pharmaceutical reimbursement applications. This Law (art. 250) requires the approval of these health technology assessment documents and hence the Agency for Health Technology Assessment (Agencja Oceny Technologii Medycznych, AOTM) was established by the Minister of Health. The main issue of the Agency is dealing with creating a list of health services (“basket of”, or “positive list of health services”) guaranteed within the public health insurance system. As such, pharmaceutical reimbursement issues will have to wait until that “basket” is finally completed, which may well take approximately two years. Throughout these two first years, employees in the Agency for Health Technology Assessment (AOTM) will also have to gain knowledge about health technology assessment (HTA) and its importance for Poland, as at the time of writing there is a lack of specialists in this field.

The system is constantly re-centralising and it is likely that the newly elected authorities will continue with this line of building up the system, as it corresponds with the policy of social solidarity.

Since 1998, additional voluntary health insurance (VHI) has been allowed in Poland. VHI is realised through private companies (e.g. Medicover, LIM, etc.), unlike the obligatory health insurance, which is allowed only with the National Health Fund (NHF), as mentioned above.

1.4.2 Funding

As there is only one common health insurance institution in Poland, the National Health Fund (NHF) remains the main payer for health services. As described previously, the income of the National Health Fund (NHF) is collected by another body, the Social Insurance Institution (ZUS), together with other obligatory payments for retirement pension funds, rehabilitation pension funds, and sick-leave pension funds. While most of the other funds are kept within the Social Insurance Institution (ZUS) institution (except for part of retirement pension obligatory payments: part of these payments stay within the Social Insurance Institution (ZUS) while another part is transferred to private retirement funds nominated by the person who pays the fee), the obligatory health insurance payment is transferred to the National Health Fund (NHF). This is the main source of finance for public health care.

The Ministry of Health (MoH) holds its own budget dedicated to certain special health services; these are usually highly specialised procedures, e.g. organ transplants or inherent conditions that need complicated treatments which are paid for directly to a few highly specialised centres in the country by the Ministry of Health (MoH). The Ministry of Health's (MoH) budget comes straight from the state budget and its value is decided by the Parliament at the end of every year, for the next year, according to a special Act called the Budgetary Law.

Within the local Voivodaships Offices' budgets, sums are allocated to be spent for health purposes, but those sums cannot be spent on medical services; rather, they are dedicated to being spent on prophylactic actions or to support local service providers with equipment or other modernisation works. Local government representative institutions – like Voivodaships Offices – have their budgets as well. The budgets are divided between regions by central institutions and are designated for administration purposes. Similarly, self-sustaining local authorities have sums of money in their yearly budgets for health purposes and they cannot freely buy health services with these funds. Money from these local authorities is given to local service providers – hospitals or out-patient clinics and surgeries – as the local authorities are often the owners of those institutions. This source of financing is to be spent on building renovations, purchasing medical equipment, and sometimes salaries for health centre staff, but health services cannot be paid for with these.

There are also some clinics with educational or scientific profiles, located in hospitals or out-patient clinics, or whole hospital centres belonging to educational or scientific institutions. These are university centres, which usually are paid for from the relevant university budget. This does not block the option to have a contract with the National Health Fund (NHF) at the same time – health services are paid for by the National Health Fund (NHF) and research and development (R&D) or education activities are paid for through university budgets. Some clinics, especially those responsible for postgraduate education and training for specialist doctors, are paid for through the local self-sustained authorities under the umbrella of postgraduate education of doctors, which remains within the local authorities' responsibility.

Many clinical trials are paid for by the pharmaceutical industry and they may also bring in some profits for the centre performing the trial. This is a source of financing health care institutions in Poland that is not to be forgotten.

There are many services not listed in the catalogue of National Health Fund (NHF) services which are to be contracted by hospitals and are much needed by patients. Further, there are some procedures from the negative list of services that will probably never be paid for with public funds, e.g. changing of sex. Some dental services exceeding the range of guaranteed basic procedures are not paid for by the National Health Fund (NHF) either. In such cases, patients will have to pay for those services. (Unfortunately, patients must cover the entire cost through out-of-pocket payments (OPP): no co-payments are allowed as part of this method of patients covering the cost, e.g. for the difference between a dental filling that is reimbursed (an amalgam) and one that is not reimbursed (a light-curing) – which was allowed for this type of treatment before the last change of the system and the re-centralisation of it.). There is a nationwide health services catalogue contracted by the National Health Fund (NHF) but a basic list of services is not clearly defined. This is being prepared at the time of writing. The catalogue of services contains procedures described as “non-standard” that can be administered to patients according to individual needs, previously agreed with the National Health Fund (NHF) (the extent of such services and their value), but there is a short negative list of services defined by law (including several procedures, e.g. sex change operations and cosmetic surgery).

As for pharmaceuticals, the reimbursement list details pharmaceuticals that are to be reimbursed. There are four levels of reimbursement: 100% reimbursement (oncology pharmaceuticals, chronic diseases, epilepsy, schizophrenia, other life-saving pharmaceuticals); fixed co-payment (prescription payment, lump sum) of PLN 3.2 (Polish Zloty) (equal to approximately € 0.80) to be paid by the patient and the rest of the price is reimbursed (basic pharmaceuticals, e.g. antibiotics); 70% reimbursement (chronic diseases, e.g. Parkinson's disease and Alzheimer's disease) – patients cover 30% of the pharmaceutical's price; and 50% reimbursed pharmaceuticals, when patients have to co-pay the other half of the price of a pharmaceutical (e.g. hypertension medication and new generation pharmaceuticals). There are also reimbursement limits, and therapeutic groups of pharmaceuticals are introduced to the list. The cheapest pharmaceutical in the therapeutic group sets the reimbursement limit for the whole group. If there is cross-limiting between different substances and molecules in the group, a defined daily dose (DDD) system is used for the calculations.

Over-the-counter (OTC) pharmaceuticals are not reimbursed at all and patients usually have to buy such pharmaceuticals by means of out-of-pocket payments (OPP).

According to the World Health Organization (WHO), in Poland patients co-pay (including pharmaceutical co-payments) approximately 63% of the general costs of health services spending.

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

Health expenditure (HE)	1995	2000	2001	2002	2003	2004	2005
THE in PLN, Mio.	n.a.	n.a.	n.a.	51,237.1	52,631.9	57,357.6	n.a.
THE as a % of GDP	5.6	5.7	6.0	6.3	6.3	6.2	6.2
THE per capita in US\$/PLN	423/n.a.	587/1,667.08	629/1,786.36	734/2,084.6	744/2,1123	n.a.	n.a.
Public HE as a % of THE	72,9	70	71,9	71,2	69,9	68,6	n.a.
Private HE as a % of THE	27.1	30.0	28.1	28.8	30.1	31.4	n.a.

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

Sources: OECD Health Data 2006, Paris, June 2006 ; Working together for Health, World Health Report 2006, WHO; Information for Polish Parliament on health care situation, Warsaw 31 May 2006, National Health Bill 2006, Central Statistical Office.

Access to health care

Health care in Poland can be broadly divided into two sectors: public health insurance and private sector insurance. Physicians who practise privately are paid completely with out-of-pocket payments (OPP) but, along with public service providers, they can also be contracted by the National Health Fund (NHF). Public service providers are allowed to charge people for services, provided that those services are not included in the list of procedures contracted by the National Health Fund (NHF). The contract regulates the hours during which doctors offer their services to the public and indicates a set of procedures and services that can be offered within public health insurance.

1.4.2.1 Out-patient care

Most popular out-patient care-providing doctors are general practitioners (GPs), or “family doctors” or “first contact doctors”, as they are called in Poland. Usually doctors specialising in family medicine practice in this way. Services from general practitioners (GPs) are also contracted by the National Health Fund (NHF) in public out-patient clinics or private practices.

Such practices are paid for with capitation fees. Patients choose their family doctor or the doctor of first contact by submitting a signed declaration. Doctors negotiate their contracts with the National Health Fund (NHF) based on the number of insured people that their practice takes care of. The capitation fee is highest for children under seven years, is mid-range for elderly people (over 65 years) and is lowest for others. Patients can change their family doctor once in six

months, free of charge, but if this is done more frequently the fee is fixed at PLN 50 (approximately € 15) per change of doctor.

General practitioners (GPs) (family doctors) provide services to manage common and more prevalent health problems and, if needed, to direct patients to specialists for consultations and further treatment if needed or to direct patients to in-patient care. This is how the GP gatekeeping role is manifested. There are some specialisation fields for which a written referral from a general practitioner (GP) is not required: ophthalmology, oncology, gynaecology, paediatrics, psychiatry and dentistry. General practitioners (GPs) are also obliged to perform all necessary laboratory tests and to cover the costs of these through resources obtained as part of their contract with the National Health Fund (NHF). Some additional examinations are not in the list of procedures covered by the National Health Fund (NHF) and in these cases patients have to pay for the examinations by means of out-of-pocket payments (OPP) (e.g. for orthopantomographic X-ray examinations). It is important to underline that there is no list of basic health services ("basket"). As soon as one is available, it should be referred to as the "reimbursement catalogue" or "positive list".

Specialists offer their services in hospitals as in-patient care and in "ambulatories" (ambulatory facilities) as out-patient care. These out-patient specialised practices are contracted by the National Health Fund (NHF) to provide a defined number of services within a defined budget. The services that are part of the National Health Fund (NHF) procedures list are reported in a monthly amendment to the invoice issued by each specialist practice and sent to the National Health Fund (NHF). This is the basis for the accounting and demonstrates that Polish health care is based on a mixed system of accounting that is a combination of a budgetary system and a fee-for-service system.

Table 1.4: Poland – Out-patient care 1995, 2000 - 2005

Variable	1995	2000	2001	2002	2003	2004	2005
Total no. of doctors	107,226	96,789	n.a.	98,845	n.a.	93,453	87,927
No. of doctors per 1,000 inhabitants	2.78	2.53	n.a.	2.59	n.a.	2.45	2.30
Total no. of out-patient doctors	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
<i>of which GPs</i>	n.a.	5,080	n.a.	7,004	n.a.	7,975	7,587
<i>of which dentists</i>	17,805	11,758	n.a.	10,775	n.a.	10,081	11,881
No. of out-patient doctors per 1,000 inhabitants	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of out-patient clinic departments ("ambulatories")	9,785	8,188	n.a.	7,827	n.a.	12,101	12,273

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

Source: Statistical Yearbook for Poland 2005, Central Statistical Office

Services offered as out-patient specialist care are covered by the National Health Fund (NHF) if they are included in the list of procedures accepted in the contract with the National Health Fund (NHF). If a procedure that a patient needs exceeds the range of services agreed in the contract, patients have to pay for the procedure themselves, through out-of-pocket payments (OPP). It is permitted for the same specialist out-patient practice to offer services reimbursed by the National Health Fund (NHF) at the same time as those that are not reimbursed but paid as out-of-pocket payments (OPP). If, e.g., a patient goes to the dentist and needs an X-ray, s/he has the choice of a dental X-ray – reimbursed and paid for by the National Health Fund (NHF) – or an orthopantomogram – not reimbursed. If the patient wants, s/he may pay for the orthopantomogram as an out-of-pocket payment (OPP) at the same service provider. This particular type of situation also happens as a result of limited quantities of services, and because for some health services there is a waiting list. If patients want the service to be performed faster than within a couple of months they can pay out-of-pocket payments (OPP) and have it carried out immediately; these are one and the same service, in one case reimbursed and in the other case not.

Some of the services that are not contracted by the National Health Fund (NHF) can be financed by additional voluntary health insurance (VHI), either partly or fully, depending on what is set out in the voluntary health insurance (VHI) contract and documents.

1.4.2.2 In-patient care

In-patient care in Poland is organised mainly on the basis of public hospitals. Among these, there are hospitals owned by local autonomous authorities, as well as university hospitals. Private hospitals are rare but can still be contracted by the National Health Fund (NHF). However, there is a hierarchy of hospitals in Poland, and private hospitals are not considered to be in a reference level that concerns other public institutions of that kind. Municipal hospitals and local county hospitals are usually the first level of reference, while bigger centres covering wider regions (like voivodaships) are at a higher level of reference. The last, third level of reference is restricted for the most highly specialised centres, e.g. university hospitals and clinics, post-graduate educational centres and clinics or the Ministry of Health's (MoH) research centres. If a medical problem cannot be managed by service providers at a lower level of reference, the patient is directed to a higher level for consultation, more advanced diagnostics and further treatment if needed. There are also profiled hospitals and these are usually units of a higher level of reference, e.g. paediatric hospitals, oncology clinics and haematology wards.

Hospitals are more or less evenly spread around the country, but are higher in density in big cities and areas with higher population levels. There are certainly differences in the spread of higher level, highly specialised hospitals. Hospitals of higher reference levels can only be found in big cities and they must cover huge areas of the country with their care. Plastic surgery, cranio-maxillofacial surgery, neurosurgery, and angioplasty wards are among those highly specialised clinics that can only be found in major centres.

In general, out-of-pocket payments (OPP) within in-patient care are not accepted (i.e. not given and not received). A patient treated in a hospital receives all medication free of charge and the hospital pays for it even if the administered pharmaceutical is not listed for general reimbursement. Furthermore, even if pharmaceuticals from the reimbursement list are administered in

hospital, the hospital pays the full charge for the pharmaceutical from the budget negotiated and granted from the National Health Fund (NHF). All additional required examinations (i.e., examinations not listed in the reimbursement catalogue of the National Health Fund (NHF)) are to be paid for by the ward or hospital taking care of the in-patient. Standards offered in different hospitals vary a great deal but there are no extra charges for better standards. Sometimes misunderstandings occur when hospitals demand out-of-pocket payments (OPP) from parents who want to stay overnight with their children in wards – such detailed problems are not regulated yet, but in an official statement the Ministry of Health (MoH) negated such attitudes and demanded that hospitals allow “hotel” stays for parents within their health care insurance.

Hospitals negotiate their contracts with the National Health Fund (NHF) every year in most cases. The contract's volume for the next year is anticipated based on the previous year's number of procedures carried out. Sometimes an inflation rate is considered and a contract is extended by 5% of the previous year's value. This contract is realised by the hospital or other in-patient institution by providing health services to patients. Health services are reported monthly to the National Health Fund (NHF), together with an appropriate invoice. Only services from the list of contracted procedures defined by the National Health Fund (NHF) can be reported. Hospitals may perform other procedures outside of those in the National Health Fund (NHF) list but then patients pay themselves, by means of out-of-pocket payments (OPP), or the hospital may decide to carry out the treatment at the institution's own expense and not to charge the patient. With various gathered financial sources hospitals pay their employees' wages: these usually take up approximately 60-70% of annual budgets. The rest is dedicated to pharmaceuticals (60-70%), diagnosis, or equipment purchases, and renovation works, heating, water and electricity supply, among others. As mentioned earlier, hospitals are commonly owned by local authorities – these owners are entitled to subsidise their hospitals, but it is not permitted to buy health services with that money, as health services can only be bought by the National Health Fund (NHF). If such subsidies occur, these are usually spent on renovation works, equipment and other expenditure of this kind.

Doctors are employed in hospitals mainly on the basis of a work contract. They usually receive a fixed monthly salary independently of how many patients they serve that month. Due to growing costs of employing doctors, more and more doctors deal with their own accounting and hospitals contract them as if they were self-employed. Doctors then have to pay their social insurance by themselves (obligatory health insurance, retirement insurance, sick-leave insurance and rehabilitation fund payments) but instead they may expect tax discounts, as subjects carrying out their own accounting duties, (similar to self-employment) e.g. discounts on fuel for their cars, if they drive to work. As remuneration is usually low, most doctors have to work in other places as well, outside of the hospital. Usually they work in their own private practices in the afternoons or private clinics belonging to other private parties. It also is much easier for doctors to be contracted in those other places when they are already being contracted in a hospital.

Hospitals are paid ex-post by the National Health Fund (NHF) on the basis of previously negotiated contracts. The contracts are negotiated every autumn for the following year and the sums subject to negotiation, along with the numbers/amounts of particular health services, are forecast based on the number of procedures carried out by that centre within the previous year. Extensions of contracts are rare and are usually not higher than 5% of the previous year's budget – which is meant to cover inflation of the Polish Zloty (PLN). During the execution of a negoti-

ated contract the hospital reports on how many services were supplied in the previous month from the list of services paid for by the National Health Fund (NHF) within the scope of the public health insurance, including the value of each of those services. There is no value per service, and the value per procedure is set according to a points system; the value of single point is subject to negotiation between the service provider and the National Health Fund (NHF) before the start of each year, for the coming year. A certain amount of money per service can be calculated by multiplying the point value of a service per negotiated monetary value of a point. Therefore monetary values of the same services may vary between centres. Otherwise, in out-patient care, a monetary value is set per visit which is treated as a service at a specialist practice (a per-capita sum at a general practitioner's (GP) practice is also set as a monetary value), and the specialist issues a proper invoice and sends all the documentation to the National Health Fund (NHF) every month. It is obvious that all contracted sources are usually reported as being used by hospitals. It is obvious that all contracted sources are usually reported as being used by hospitals – this is where the National Health Fund's (NHF) controls may appear

Also, as mentioned earlier, some hospitals can be subsidised by local governments. University hospitals are also remunerated by their owners; the universities. Some hospitals receive research grants if research is performed within the centre. It should be mentioned that clinical trials conducted by the pharmaceutical industry in hospitals are paid for and this is also a source of financing those institutions.

Hospitals in Poland are established in major cities by local authorities that usually remain as the owners of those. Some hospitals are founded by universities, some by the Ministry of Health (MoH). There are a few Memorial Hospitals in Poland and more and more are being established by means of private capital. Hospitals of all kind (in terms of a kind of ownership) are allowed to cooperate with the National Health Fund (NHF) if they are competitive and able to win proper tenders. Of course, standards set by the National Health Fund (NHF) must be met.

Table 1.5: Poland – In-patient care 1995, 2000 - 2005

Variable	1995	2000	2001	2002	2003	2004	2005
No. of in-patient doctors	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of in-patient doctors per 1,000 inhabitants	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of hospitals	705	716	n.a.	739	n.a.	790	n.a.
No. of acute care beds	213,969	190,952	n.a.	188,038	n.a.	183,280	n.a.
<i>of which in private sector</i>	143	1,574	n.a.	4,221	n.a.	7,649	n.a.
Acute care beds per 1,000 inhabitants	5.54	4.95	n.a.	4.81	n.a.	5.12	n.a.
Average length of stay in hospital	10.8	8.9	n.a.	7.9	n.a.	6.9	n.a.

n.a. = not available

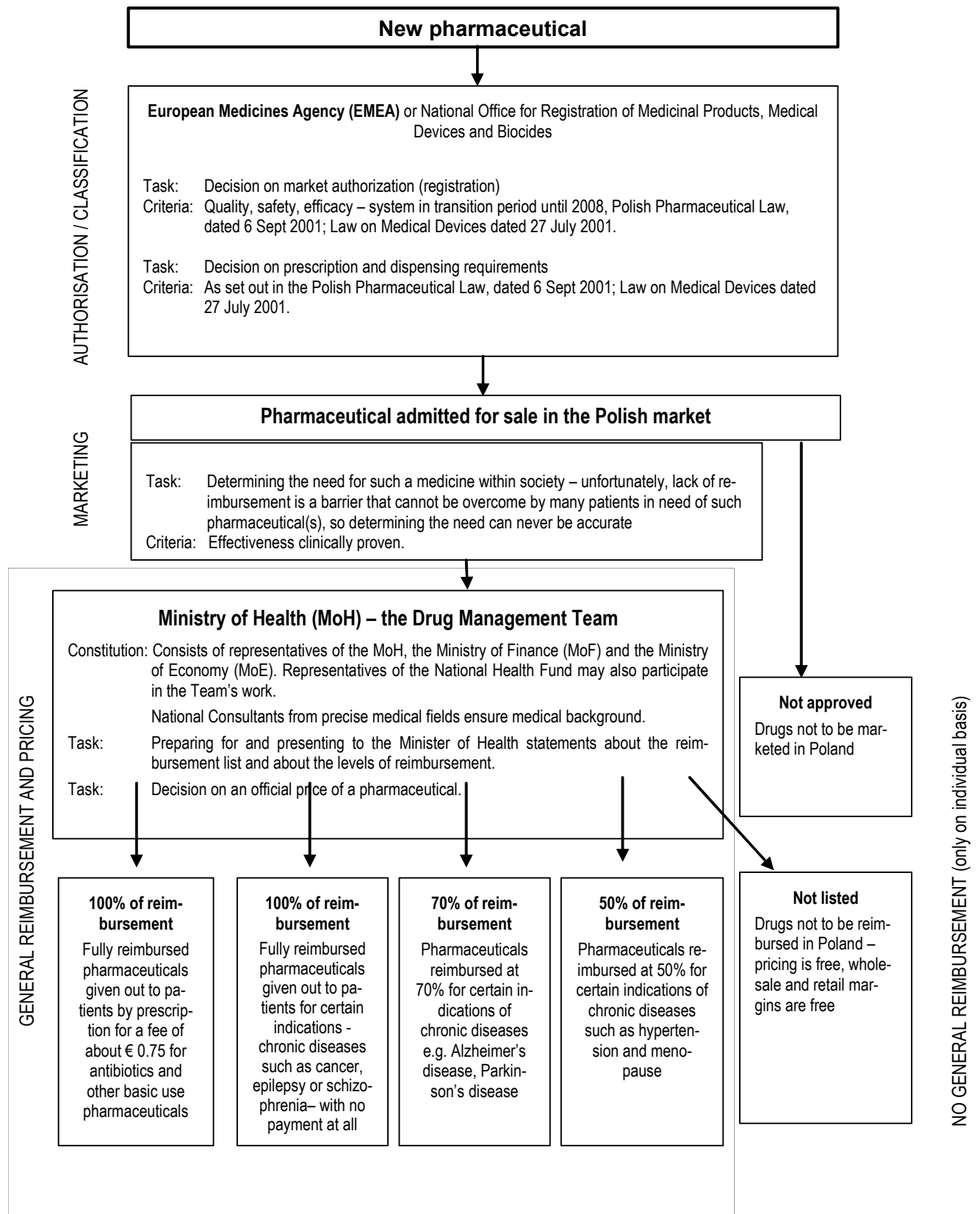
Source: Statistical Central Office (GUS)

2 Pharmaceutical system

2.1 Organisation

In the following subsections we describe, on the one hand, the regulatory framework (legal basis, main authorities and their tasks) of the Polish pharmaceutical system and, on the other hand, the Polish pharmaceutical market (key data and players).

Figure 2.1: Poland - Flowchart of the pharmaceutical system



Source: *Pricing Law, dated 5 July 2001 (O.J. No 97, Text 1050).*

2.1.1 Regulatory framework

This section includes a description of the legal framework for pharmaceutical policy in Poland, along with the principal authorities and important players within this framework and their various roles.

2.1.1.1 Policy and legislation

The pharmaceutical system in Poland is based on several legal acts with different levels of legal force, of which the Polish Constitution is the highest. The Constitution sets out that all citizens of the Republic of Poland are entitled to have equal access to health services from public sources and health services are to be free of charge.

The Law on health services financed from public sources (27 August 2004) (*Ustawa o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych*) is perceived as the principal law ruling the health care system in Poland. This is the legal basis for the National Health Fund's (NHF) actions and defines the obligatory health insurance contribution. The Law also determines the general rules of pharmaceutical reimbursement and states that pharmacoeconomic analyses of three kinds – clinical effectiveness, cost-effectiveness and budget impact – are required as part of an application for pharmaceutical reimbursement. There are specific delegations of this Law which give powers to the Minister of Health to decide on, e.g., details of certain procedures, a detailed set of requirements, etc.

The Minister of Health is obliged to prepare, announce and implement detailed rules regarding tasks delegated to his position. S/he does this by issuing a Ministry of Health (MoH) ordinance, the most important of which in terms of the pharmaceutical system are called "reimbursement lists" (updated twice a year). Others announce decisions on how a reimbursement application is to be made; bring into being state agencies, such as the Agency for Health Technology Assessment (AOTM); and decide on what set of papers are to be submitted for other regulatory actions, such as approval (national procedure), or what actions are to be taken and by whom in order to harmonise the Polish list of approved pharmaceuticals with the central European register.

Further, some chiefs of institutions are dependent on the Ministry of Health (MoH). Their edicts are issued to manage the execution of the Ministry's ordinances or to manage current issues arising in the pharmaceutical health care sector. These posts include: President of the National Health Fund (NHF), President of the National Office for Registration of Medicinal Products, Medical Devices and Biocides, Pharmaceutical Inspector or President of the Agency for Health Technology Assessment (AOTM). Usually edicts issued by such institutions require the Ministry of Health's (MoH) approval.

Legislation which regulates pharmaceutical market in Poland includes the laws and documentation listed here.

1. Pharmaceutical Law, 6 September 2001.
2. Pricing Law, 5 July 2001. In this Law, pricing criteria are mentioned that must be met by the product to be reimbursed.
3. Law on health care services financed from public sources, 27 August 2004.
4. Due to the fact that in Poland only pharmaceuticals granted a market authorisation can be included in the reimbursement list, an important source of information is also the Register of Medicinal Products approved for marketing in Poland (WYKAZ PRODUKTÓW LECZNICZYCH WPISANYCH DO REJESTRU PRODUKTÓW LECZNICZYCH DOPUSZCZONYCH DO OBROTU NA TERYTORIUM RZECZYPOSPOLITEJ POLSKIEJ).
5. Ordinance(s) of the Minister of Health, issued on the basis of and in compliance with the above-mentioned legislative acts (i.e. reimbursement lists with official wholesale and retail prices and reimbursement levels and limits – these documents are updated on a regular basis).
6. "Communicate(s)" of the Ministry of Health – document(s) of no legal value. Communicate(s) may contain some indications, mostly concerning prices, but in practice such a document is a guideline to be considered during decision-making processes.
7. The Agency for Health Technology Assessment (AOTM) has recently announced a set of criteria to be met by technology that is processed within the decision-making process. For the time being these criteria only concern hospital procedures (but include hospital pharmaceutical technologies), but there is a good chance they will also be applied to decision-making processes concerning pharmaceutical reimbursement according to reimbursement lists.

For reimbursement pricing, i.e. the setting of reimbursement limits and combining of therapeutic groups of substances with common reimbursement limits, a defined daily dose (DDD) system is applied in Poland. Reimbursement spending is growing year on year. The last changes to the reimbursement list were made in March 2007, by way of ordinance of the Minister of Health. That ordinance was issued on the basis of the Law on health care services financed from public sources. Two expert teams worked on that reimbursement list. One of the teams was obliged to have new molecules analysed, for which applications for reimbursement were submitted. The team analysed them according to pharmacoeconomic factors, and had to decide which of them were innovative molecules that would not increase reimbursement costs, as well as which could generate some savings. The other team analysed new substances according to their clinical properties. The teams' work was joined and two groups of substances emerged: a group of that, if brought into the reimbursement list, would not cause spending to increase and a group for which inclusion into the reimbursement list would generate additional costs. Price negotiations were then carried out. A total of 211 new, first generics (in the group, after the original products), were included within that particular ordinance, divided into 12 active substances; 265 new generics were included in 58 active substances and 49 original products were introduced (12 new active substances).

This update was meant to limit reimbursement spending by introducing generic pharmaceuticals; setting reimbursement limits according to the price level of generic products; introducing therapeutic groups for different pharmaceutical substances of a similar action, commonly limited to the price of cheapest generic in the group; and demanding price decreases from the pharmaceutical industry.

The transition of the system is ongoing and it seems to be going in the right direction. Creation of the Agency for Health Technology Assessment (AOTM) to recommend technologies for reimbursement is definitely a milestone for Polish pharmaceutical system.

2.1.1.2 Authorities

Key players in Polish pharmaceutical market include: the Minister of Health, the National Health Fund (NHF), the Chief Pharmaceutical Inspector, the National Office for Registration of Medicinal Products, Medical Devices and Biocides the Agency for Health Technology Assessment (AOTM), which is becoming an increasingly important topic.

The Ministry of Health (MoH) carries out most of the regulatory functions concerning pharmaceuticals and medical devices. The Minister takes into account in particular the necessity to ensure protection of public health, availability of pharmaceuticals, their safe application and the financial capacity of the National Health Fund (NHF). The Pharmaceutical Policy and Pharmacy Department at the Ministry of Health (MoH) is responsible for the conception and implementation of the national pharmaceutical policy. The National Health Fund (NHF) is a third-party payer in public health care. It concludes contracts for the supply of health services for insured citizens, manages the yearly budget, and controls the setting of contracts and pharmaceutical prescribing by doctors or in pharmacies (mainly if pharmaceuticals are prescribed within reimbursement indications approved in the reimbursement list). The National Health Fund (NHF) also has a minor influence on state health policy.

With the help of external experts, the Pharmaceutical Management Team is responsible for the evaluation of the effectiveness and safety of pharmaceuticals and medical devices to be included in the reimbursement list. The Ministry's decisions on inclusion in the reimbursement list are based on the Pharmaceutical Management Team's opinion. The Team is composed of three representatives, of the Minister of Health, the Minister of Public Finance and the Minister of Economy. Three representatives of the National Health Fund (NHF) may also take part in the proceedings of the Team. Members, their spouses and direct descendants or ancestors may not own, hold stocks or shares in, or be part of the bodies of companies or enterprises involved in the manufacturing or trade of pharmaceuticals and medical devices.

National Consultants in particular fields of medical specialisation hold an official expert position within the system. A list of National Consultants is published by the Ministry of Health (MoH), currently on the web site. National Consultants are included in the Ministry of Health's (MoH) payroll, but reside in separate clinics, advise on their own initiative when s/he decides to, or advise on certain issues when asked to by the Ministry of Health (MoH). A National Consultant may be included in expert panels at the Ministry of Health (MoH), e.g. in reimbursement committees, opinion-giving bodies, etc.

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

Name in local language (Abbreviation)	Name in English	Description	Responsibility
Ministerstwo Zdrowia	Ministry of Health (MoH)	Regulatory body	Overall planning and legislative authority
Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Materiałów Biobójczych	National Office for Registration of Medicinal Products, Medical Devices and Biocides	Market authorisation (subordinate to the MoH)	Market authorisation, classification, vigilance
Narodowy Fundusz Zdrowia (NFZ)	National Health Fund (NHF)	State-owned health insurance fund (subordinate to the MoH)	Third-party payer in public health care
Główny Inspektorat Farmaceutyczny	Chief Pharmaceutical Inspector	Controllers	Controlling body of the pharmaceutical market – in the field of pharmaceutical advertising methods (the Pharmaceutical Law provisions); issues certificates for pharmacies, approves wholesalers for their activities including licences for parallel trade, etc.
Agencja Oceny Technologii Medycznych	Agency for Health Technology Assessment (AOTM)	Opinion-giving body	Settles principles of decision-making process, is obliged to prepare a list of health services guaranteed within the public health care system
Zespół do Spraw Gospodarki Lekowej	Pharmaceutical Management Team	Functions within the MoH, consists of representatives of the Ministries of Health, Finance, and Economy, along with the NHF	Gives opinion on reimbursement of pharmaceuticals, official prices of pharmaceuticals reimbursed, reference prices, therapeutic groups, reimbursement limits and give recommendations to the Minister of Health who approves the reimbursement list and issues it
Sejmowa Komisja Zdrowia	Parliamentary Health Commission	Policy-making	Makes sure the MoH work is going in the right direction to fulfil promises set out during campaign
Konsultant Krajowy w dziedzinie medycznej	National Consultants in particular fields of medical specialisation	Recommending position or intervention when needed	Leading opinion-giving people of different medical specialties, designed by the MoH

MoH = Ministry of Health

Source: Ministry of Health 2007

The decision-making process for admission of pharmaceuticals into the Polish market starts with submission for approval, in terms of the national registration procedure. The authorisation for admission into the Polish market is issued by decision of the Minister of Health but the accompanying documentation should be submitted in full to the National Office for Registration of Medicinal Products, Medical Devices and Biocides. The Ministry of Health (MoH) makes an administrative decision on the basis of the report prepared by the President of the National Office for Registration of Medicinal Products, Medical Devices and Biocides. The set of documents required in order to start the registration procedure is set out in the Pharmaceutical Law for both innovative and generic products and is detailed in full in a Directive of the Ministry of Health. Generic registration demands the outcomes of bioequivalence tests. If a mutual recognition procedure (MRP) or centralised procedure of registration is relevant, the National Office for Registration of Medicinal Products, Medical Devices and Biocides is responsible for harmonisation of central and local lists of approved products.

According to the official terms, the national procedure is not to exceed 210 days unless there are important reasons to suspend the approval procedure (i.e. relating to missing documents, bioequivalence, stability, etc). Suspension may be granted for as long as 120 days, but usually it is only for 60 days. On the official update day the procedure re-starts from the point at which it was suspended (i.e. if suspension takes place on the 34th day, amendments are carried out 14 days later, and the day after the amendment is counted as the 35th day of the whole process; if the “proper” amendment is not carried out within the imposed suspension time, the procedure is terminated and submission is no longer processed; if the producer still intends to register their product they need to start the registration procedure again right from the beginning (day 0)). There are no interactions at this level until the procedure is finalised. As products are prepared for approval the Minister of Health makes his final decision on the basis of the above-mentioned report of the President of the National Office for Registration of Medicinal Products, Medical Devices and Biocides. Once approved by the Minister of Health, the product gains market authorisation.

As a health system in transition, Poland has been experiencing major changes over recent years. In 1997 a decision was made to decentralise the system and action was taken accordingly. Then, after another political group (left-wing) won elections and had more influence over health policy, it was decided to re-centralise the system. The Parliament accepted the proposal to make the National Office for Registration of Medicinal Products, Medical Devices and Biocides subordinate to the Ministry of Health (MoH), which is how the system remains today. Another major change worth highlighting was the implementation of the state Agency for Health Technology Assessment (AOTM), which was carried out by the Ministry of Health (MoH) in September/October 2005. The Agency plays an increasingly important role in the system.

2.1.2 Pharmaceutical market

This section gives an overview of the availability of pharmaceuticals, along with some market figures.

2.1.2.1 Availability of pharmaceuticals

Table 2.2: Poland - Number of pharmaceuticals 1995, 2000-2006¹

Pharmaceuticals	1995	2000	2001	2002	2003	2004	2005	2006
Authorised	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	8,089 ²	n.a.
On the market	n.a.	3,685	3,745	3,956	4,163	4,146	4,198	4,275
POM	n.a.	2,385	2,337	2,476	2,589	2,593	2,642	2,749
Reimbursable	n.a.	2,589	2,641	2,472	2,315	2,131	2,151	2,045
Generics	n.a.	3,077	3,140	3,318	3,492	3,457	3,502	3,537
Parallel traded	n.a.	0	0	0	0	0	6	14
Hospital-only	n.a.	517	555	606	634	630	657	655

POM = prescription-only medicine(s), n.a. = not available

¹ as of 1 January

² including different pharmaceutical forms and pack sizes

³ including hospital-only medicine(s) (HOM)

Source: IMS Data View 03/2007, © 2007 IMS Health Incorporated or its affiliates. All rights reserved.

Availability of pharmaceuticals to insured citizens is being developed. The most limiting factor is the patient co-payments that affect the acquisition of pharmaceuticals. Theoretically, the policy of the Ministry of Health (MoH) on this involves setting reimbursement limits and forcing price decreases from the authorisation holders, in order to improve access to pharmaceuticals. Still, many patients do not intend to swap pharmaceuticals they have become used to for generic equivalents, as it is often believed that generics are less effective and sometimes result in more adverse effects. Some patients are not aware that a pharmaceutical that was previously fully reimbursed now needs co-payment because it has just been included within a therapeutic group with a reimbursement limit set according to a different molecule (unfortunately, some molecules in therapeutic groups are not interchangeable). Moreover, there are several levels of reimbursement starting with full reimbursement (100%, or with a lump sum of approximately € 0.75) through to 70% reimbursement and down to 50% reimbursement. Pharmaceuticals at 50% reimbursement are usually those very commonly used in not particularly serious diseases, e.g. hypertension, hyperlipidaemia or menopause. Pharmaceuticals reimbursed at 70% are usually those in the category of not life-threatening but chronic diseases (Parkinson's disease or Alzheimer's disease) – for these, patients have to co-pay 30% of the reimbursement limit, plus the amount (if any) that is over that limit. The full reimbursement, with a PLN 3.20 lump sum to be paid with every pharmaceutical pack in a prescription (maximum of two pharmaceuticals per prescription, usually the number of packs equal to monthly therapy for each), is usually applicable to antibiotics, ophthalmic medicines or other commonly used pharmaceuticals. The section of the reimbursement list for pharmaceuticals in the full reimbursement category is of particular interest – these pharmaceuticals are free of charge, e.g. those used to treat some neurological diseases (epilepsy) or chronic fatal diseases (some oncological diseases), or other diseases of a pan-societal or industrial character, e.g. glaucoma or sometimes psychiatric disorders. Certain reimbursement indications are stipulated in the reimbursement list and may be a subject to monitoring from the National Health Fund (NHF) (cf. Table 2.1).

There is a huge gap between pharmaceuticals that are authorised and those that are actually marketed. More pharmaceuticals are granted authorisation without being marketed later. This is because many subjects (producers) gained authorisation to market their product(s) before European Union (EU) accession and still need to carry out proper amendments to their approval files. Some authorisations are granted centrally by the European Medicines Agency (EMA), but market authorisation holders (MAH) are not interested in the Polish market due to the low reimbursement levels or because reimbursement is not even expected for some molecules any time soon.

There are different classes of pharmaceuticals within the “administration and legal status” of pharmaceuticals in Poland. A status of “Rx” (prescription only) can be approved for a pharmaceutical, or an “Lz” status (“lecznictwo zamknięte”), used in in-patient care, meaning “hospital use only”. Of course, there are many over-the-counter (OTC) pharmaceuticals as well, with the appropriate status, i.e. no prescription needed. The Polish language incorporates the concept of “over-the-counter (OTC)” and uses this phrase, or sometimes another, more descriptive phrase, “leki sprzedawane bez recepty”, which means “pharmaceuticals sold with no prescription required”. There is no “specialist prescription only” status at the time of writing but incorporating such a status into the approval system is being considered.

With regard to the above-mentioned “administration and legal status”, there are no “reimbursable” or “non-reimbursable” categories at the time of writing; over-the-counter (OTC) pharmaceuticals are not eligible for reimbursement. Within “Rx” (prescription-only) and “Lz” (hospital-only) pharmaceuticals there is no “negative list” of substances or molecules that do not qualify for reimbursement, but this is being developed. Within its decision-making procedures, the Agency for Health Technology Assessment (AOTM) already assumes a class of “negative list” for pharmaceuticals that are to be negatively assessed in the future.

Generic pharmaceuticals are normally reimbursed when a positive reimbursement decision is made. However, the product itself does not need to be listed with its specific brand name to be reimbursed if the relevant original is listed and the generic comes in the same pharmaceutical presentation and does not exceed the reimbursement limit price. In such a situation, generic substitution in pharmacies is allowed and the product will be reimbursed by the National Health Fund (NHF).

Pharmaceuticals from parallel trade are not being reimbursed in Poland at the time of writing as these come in a pack with no approved Polish European Article Number (EAN) and the reimbursement list identifies pharmaceuticals by their Polish EAN numbers. However, it is planned to allow parallel importers to submit pharmaceuticals for reimbursement as well and this will probably come into effect in due course as parallel imported products are usually cheaper, which would allow a further decrease of the reimbursement limit.

The National Office for Registration of Medicinal Products, Medical Devices and Biocides is responsible for classification of pharmaceuticals. There is no clear overall policy; prescription-only medicines (POM) are sometimes switched to over-the-counter (OTC) pharmaceuticals when they appear in smaller doses. It is easy to get a switch as an over-the-counter (OTC) product does not require a doctor’s prescription and in Poland cannot be reimbursed, meaning that such a solution is convenient for the authorities.

2.1.2.2 Market data

The pharmaceutical market in Poland has grown constantly over recent years, shown by the constant increase in reimbursement spending of the National Health Fund (NHF), which grew from PLN 3.2 billion in 2002 to PLN 5.5 billion in 2005 and was expected to reach PLN 6.1 billion in 2006. Although increasingly more generics enter the market and are granted reimbursement, the availability of pharmaceuticals is therefore improved and more patients decide to be treated using generic pharmaceuticals. The number of treated patients grows and thus the share of generics is constantly growing. Parallel trade is not to be considered at the moment but it exists in Poland and will certainly increase in the future (its importance will grow rapidly with the expected decision to allow parallel importers to submit pharmaceuticals for reimbursement).

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

Pharmaceutical industry in Mio. PLN	1995	2000	2001	2002	2003	2004	2005	2006
<i>Pharmaceutical sales</i>								
Sales at ex-factory price level	n.a.	10,017.7	11,086.95	11,551.41	13,063.36	13,253.68	14,241.58	14,838.13
Sales at wholesale price level	n.a.	11,010.5	12,185.66	12,696.16	14,357.93	14,567.12	15,510.51	16,160.20
Sales at PRP level	n.a.	13,102.5	14,500.94	15,108.43	17,085.94	17,334.87	18,457.51	19,230.64
Sales at hospitals	n.a.	1,170.46	1,346.45	1,433.28	1,525.31	1,542.28	1,707.91	1,852.54
Sales of generics	n.a.	6,308.36	6,918.97	7,141.04	7,914.87	8,323.33	9,027.31	9,424.11
Sales of parallel traded pharmaceuticals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	0,708.41	14,705.69
<i>Exports and imports</i>								
Total pharmaceutical exports	n.a.	3,611.32	4,015.39	4,170.71	4,505.82	4,723.04	4,949.46	5,054.12
Total pharmaceutical imports	n.a.	6,406.42	7,071.56	7,380.70	8,557.53	8,530.64	9,292.13	9,784.00

PRP = pharmacy retail price, n.a. = not available, Mio. = million

Source: IMS Data View 03/2007, number of products sold minimum one (not registered).

As for the export and import situation there is an easy differentiation to be made. Locally produced pharmaceuticals are usually generic products and as such are not imported, as the generics market is already increasingly crowded in Poland. These locally produced generics are not subject to export to the European Union (EU) as a transition period was negotiated with the European Union (EU) accession, during which Polish pharmaceuticals cannot be sold in other European Union (EU) countries.

Still, many Polish pharmaceuticals are subject to export to the Far East, China, or closer, e.g. to Russia. Innovative products are always imported as there is no innovative industry in Poland. There are no restrictions on the import of pharmaceuticals from the European Union (EU).

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

Position	Pharmaceutical, by active ingredient
1	INS.INJECTIONEUTRALIS, INS.ISOPHANUM
2	SIMVASTATINUM
3	OMEPRAZOLUM
4	OLANZAPINUM
5	FLUTICASONUM
6	ENOXAPARINUM NATRICUM
7	FORMOTEROLUM
8	BUDESONIDUM
9	NADROPARINUM CALCICUM
10	SALMETEROLUM

Source: Remark: National Health Fund, Data of TOP 10 according to the highest costs generated by the pharmaceutical.

In Poland there are no official data on the top 10 best-selling pharmaceuticals, because data are only gathered on reimbursed pharmaceuticals. The data in Table 2.4.1, which present the top 10 best-selling pharmaceuticals in Poland in 2003, are gathered by a private source (i.e. non-official data).

Table 2.5: Poland - Top 10 best-selling pharmaceuticals, by Anatomic Therapeutic Chemical (ATC) classification, 2003, private estimation.

Position	Pharmaceutical, by active ingredient
1	A11 Vitamins
2	C09 RAA mechanism anti-hypertension pharmaceuticals
3	C05 Vasoprotectants
4	C01 pharmaceuticals for the cardiac muscle
5	J07 Vaccines
6	B01 Antitrombotic pharmaceuticals
7	C03 Diuretics
8	N05 Psycholeptic pharmaceuticals
9	S01 Ophthalmologic pharmaceuticals
10	A 02 Anti-ulceration, acid neutralising

Source: Z. Kotula, Polish pharmaceutical market in 2003, "Lek w Polsce" Vol. 14 nr 6/ 2004

2.1.2.3 Patents and data protection

Patent protection is taken very seriously in Poland at the moment. Pharmaceuticals can be protected in harmony with current European legislation. The problem is that many producers did not extend their patent certificates for the territory of Poland as they did not expect Poland to accede to the European Union (EU) before the end of their patent protection. Poland therefore has a list of products that were patent protected in the European Union (EU) but not in Poland and today these patents do not have to be obeyed. Usually, data protection expires before the patent expires, so in most cases there is no conflict with these restrictions.

In 2004 there was a court case over a situation that broke patent protection rules, won by Janssen-Cilag company versus a local Polish generic producer. However, this is the only case that has been heard and it was heard in Strasbourg, not in the local court.

A strong tendency towards winning approval for the use of existing pharmaceuticals in new indications is widely observed in the European Union (EU) and in Poland. Major companies extend their data protection period by this method. As indicated in the European Union (EU) Pharma Review (<http://www.egagenerics.com/pol-pharmarev.htm>), the data protection period (data exclusivity) is the subject of negotiations between the Polish Government and the European Commission (EC). In Poland such provisions have not been implemented.

2.1.3 Market players

This section describes the key players in the pharmaceutical system, except for the authorities that were introduced in 2.1.1.2. It gives an overview of the key players in production, distribution, dispensing, prescription and use of pharmaceuticals and their influence on pharmaceutical policy-making.

2.1.3.1 Industry

There is no originally Polish innovative pharmaceutical industry. Innovative (research-oriented) producers are importing their products to Poland, setting up separate companies there that are dependent on the mother company or only setting up their representation in Poland, but in practice pharmaceuticals are sold directly by the mother company. The common problems of taxation, budgetary limitations for payers not allowing for reimbursement of all innovative pharmaceuticals, and other similar barriers to be overcome led innovative producers to set up an interest association called the Association of Representatives of Pharmaceutical Companies in Poland (Stowarzyszenie Przedstawicieli Firm Farmaceutycznych w Polsce – SPFFwP), which has now been transformed into other company, to be more clearly differentiated from generic producers, called INFARMA (Innovative Producers of Pharmaceutical Industry Association (Stowarzyszenie Innowacyjnych Firm Przemysłu Farmaceutycznego)).

Generic companies are widely represented in Poland. Their association is called the Association of Employers of Pharmaceutical Industry (Polski Związek Pracodawców Przemysłu Farmaceutycznego, PZPPF). It is worth noting that the generics market is particularly “crowded” at the time of writing and among members of the Association of Employers of Pharmaceutical Industry (PZPPF) a price war is also being held, which is driving the market to change very quickly.

The usual distribution channel is via the wholesalers. It is not permitted to sell pharmaceuticals directly to pharmacies even if the market authorisation holder (MAH) has their own wholesaler. In such a case, only a hospital pharmacy could be a customer to an industry-owned wholesaler. This legal situation, along with huge payment delays (mostly from hospitals but some significant ones also from pharmacies) lead to distribution via wholesalers being the main channel. With this kind of distribution the full burden of the financial risk is with the wholesalers and the industry receives payments on time.

Direct distribution to patients' houses, telephone sales and those via Internet or via doctors' practices are forbidden in Poland.

The pharmaceutical industry is an important player in the Polish employment market and also an important contributor to the country's gross domestic product (GDP). This concerns Polish generics and foreign generic and innovative sectors of the pharmaceutical industry. Unfortunately, these data are not available in detail.

No representation of the pharmaceutical industry is allowed in decision-making bodies. When an update of the reimbursement list is announced there is usually a period of two weeks for extensive public consultations and the industry always uses the opportunity to send an official statement to the Ministry of Health (MoH).

Price decreases are usually decided by the Ministry of Health (MoH) and if a company does not reduce their price, the pharmaceutical will be de-listed with the next reimbursement list update.

Recently, market authorisation holders (MAH) were granted the right to initiate the approval process for therapeutic programmes (TP) (another method of reimbursement of innovative and expensive molecules, contracted by the National Health Fund (NHF) for defined group of patients – sometimes resources dedicated to such programme are not enough and not all patients qualifying for the programme are enrolled), but with an update of the approval procedure this is expected to be withdrawn. Meetings are taking place with the industry sector but these change only slightly the approach of the Ministry of Health (MoH) and pharmaceutical companies' attitudes towards possible price decreases.

Table 2.6: Poland - Key data on the pharmaceutical industry 1995-2005¹

Pharmaceutical industry	1995	2000	2001	2002	2003	2004	2005	2006
Total no. of companies	n.a.	501	525	558	586	567	569	574
- research oriented	n.a.	80	79	91	96	87	91	97
- generic producers	n.a.	421	446	467	490	480	478	477
- biotech	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of persons employed ²	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

¹ as of 1 January, ² counted per head, n.a. = not available

Source: IMS Data View 03/2007, © 2007 IMS Health Incorporated or its affiliates. All rights reserved.

2.1.3.2 Wholesalers

Wholesalers' companies in Poland differ by type of ownership. Before the transition of the system there was one state-owned company, Cefarm (Central Pharmaceutical Supply). Its divisions and regional branches were privatised and started to operate as independent companies. Then companies started to merge and what we see at the time of writing in the Polish market are huge conglomerates of pharmaceutical suppliers joined in a semi-corporation. The chains of wholesalers negotiate their contracts by common management / through representatives. The most important are the Polish Pharmaceutical Group (Polska Grupa Farmaceutyczna, PGF), Urtica and what remains of Cefarm, still holding approximately 15% of the market (other shares are not known exactly). There are wholesalers operating as single, private companies as well. In total there are 666 wholesalers in Poland today (Chief Pharmaceutical Inspector, August 2006) and this number has increased by 3 wholesalers since the end of 2005. There are no data on the number of staff employed by wholesalers at the moment. Wholesalers are obliged to report to the Ministry of Health (MoH) on the volume and composition of their sales but these data are not currently processed as the whole system is in transition.

There were 21 parallel trade licences issued for wholesalers by the Chief Pharmaceutical Inspector in January 2006 (e.g. Delfarma). At the time of writing, parallel trade is of minor importance when considering the Polish pharmaceutical market (cf. 2.1.3.1).

When contracting for distribution with pharmaceutical companies / producers / importers, wholesalers take on the full burden of the financial risk of payment delays themselves. Hospitals have a huge level of debt as they are rarely able to pay for deliveries on time. Such financial instruments as institutional debts are permitted, and wholesalers do sometimes decide to act on this right. Still, there is no hospital bankruptcy – hospitals are often subsidised by their owners.

Wholesalers do not have much influence on pharmaceutical policy-making.

Table 2.7: Poland - Key data on pharmaceutical wholesale 1995-2005¹

Wholesalers	1995	2000	2001	2002	2003	2004	2005
Total no. of wholesale companies	800	250	240	230	230	220	210
Total no. of outlets	1,100	800	780	760	740	720	700

¹ as of 1 January

Source: Chief Pharmaceutical Inspector, Jan 2006

2.1.3.3 Pharmaceutical outlets / retailers

Over-the-counter (OTC) pharmaceuticals are widely dispensed in open pharmacies and also in other pharmacies, supermarkets, tobacco shops, newspaper stands, etc. The list of such pharmaceuticals is issued by way of Ministry of Health (MoH) ordinances. Only licensed pharmacies

are allowed to dispense pharmaceuticals of “Rx” status (prescription-only medicine(s) (POM)) (cf. 2.1.2.1).

Pharmaceuticals of “Lz” status (hospital only) are distributed by hospital pharmacies and are dispensed by nursing personnel within hospital wards according to a doctor’s written order. There are no hospital pharmacies for out-patients, as hospital pharmacies will only deliver pharmaceuticals to hospital wards. The out-patients obtain their prescriptions in open pharmacies.

There is no such function as a dispensing doctor in Poland. There is only the legal possibility to buy over-the-counter (OTC) pharmaceuticals via the Internet. There are certain rules of dispensing pharmaceuticals set out in the Pharmaceutical Law. In special situations, doctors can be allowed to dispense pharmaceuticals directly to patients, but a pharmacist must be present, a prescription must be delivered by the patient and each of these actions must be approved individually by the regional branch office of the Chief Pharmaceutical Inspector (pharmaceuticals from charity aid or given as donations by pharmaceutical companies to certain groups, patients, patients’ associations, etc).

2.1.3.3.1 Pharmacies

The legal basis and requirements for establishing a pharmacy are set out in the Pharmaceutical Law. Setting up a pharmacy requires a licence from the local branch of the Pharmaceutical Chamber. There are no limitations on how many pharmacies can be owned by one owner. Each pharmacy needs to have an individual – a specialised pharmacist, the “pharmacy manager” – responsible for the pharmacy. Anyone (except for a doctor) with any kind of education, or even without any education can be an owner of a pharmacy, provided such a “pharmacy manager” is employed as the person legally responsible for all activities.

Pharmacy chains are allowed. Similarly to wholesalers, pharmacies used to be run by the State before the transition of the system, and in early 1990s they were privatised. Most pharmacies are privately owned at the time of writing. There are 11,300 open pharmacies in Poland (end of 2005, Chief Pharmaceutical Inspector).

As of 31 December 2003, 55.5% of pharmacies were owned by pharmacists; 30.5% were owned by private companies; 10.9% were owned by private persons of not pharmaceutical education; and 0.5% of pharmacies were owned by health care service-providing institutions.

The number of pharmacies for the period 2002-2005 is presented in Table 2.7. The number of inhabitants per pharmacy differs between regions and ranges between 1 per 1,500 inhabitants in major cities and 1 per 5,000 inhabitants in agricultural areas. There is an association of pharmacists but its influence on policy-making is rather weak.

Pharmacies are remunerated with margins. Margins for reimbursed pharmaceuticals are set out in the Pricing Law and are set as maximum margins. This means that pharmacies can apply rebates (discounts) within the margin. For non-reimbursed pharmaceuticals margins are freely set by each pharmacy. There are no incentives for pharmacies from the State, but as Poland has rather equal population distribution, incentives are much needed. If a local community needs a doctor, local authorities may offer accommodation to a doctor who might decide to

come and work there. Similar incentives could probably be offered for pharmacies, but this seldom occurs.

There are no specific prescription-only medicine (POM) dispensaries. In every pharmacy customers may buy over-the-counter (OTC) products as well, including in hospital pharmacies, as such pharmaceuticals are also used in hospital wards.

Some pharmacies offer delivery of products but this must be organised taking into account all rules set out for dispensing a pharmaceutical (e.g., pharmacist to deliver pharmaceuticals and to receive appropriate prescription(s) for that delivery; delivery usually agreed beforehand by 'phone, etc.).

Table 2.8: Poland - Retailers of pharmaceuticals 1995, 2000-2006

Retailers	1995	2000	2001	2002	2003	2004	2005	2006
No. of community pharmacies	6,536	8,318	9,014	9,332	9,585	9,758	10,019	12,800
No. of private pharmacies	5,994	7,739	8,449	8,757	9,512	9,736	10,002	n.a
No. of public pharmacies	n.a.	n.a	n.a	n.a	n.a	n.a	n.a	n.a
No. of hospital pharmacies for out-patients	0	0	0	0	0	0	0	0
No. of other POM dispensaries:	0	0	0	0	0	0	0	0
Total no. of POM dispensaries	n.a	n.a	n.a	9,939	10,382	10,757	11,149	11,300
No. of Internet pharmacies	0	0	0	0	0	0	15	70
No. of OTC dispensaries, such as pharmacies:	227	271	248	272	553	815	941	n.a

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

Source: Chief Pharmaceutical Inspector, Statistical Yearbook, Main Statistical Office, expert knowledge by IMS 2006, Report of the Office of Competition and Consumer Protection (UOKIK).

As described earlier, incentives may take the form of rebates (discounts) and as such are given to pharmacies by the industry. Wholesale prices of pharmaceuticals and retail prices of reimbursed pharmaceuticals are set as maximum prices in the reimbursement list. However, the Pricing Law introduces margins that are set as maximum possible margins for reimbursed pharmaceuticals. Pharmacies can therefore give rebates/discounts (in order to reduce the price of one pharmaceutical to that of its lower-priced generic, to make it competitive) and be remunerated by the industry – the pharmaceutical provider – with good prices, along with some other transactions, e.g. for other reimbursed pharmaceuticals or for non-reimbursed pharmaceuticals.

In Poland there are no hospital pharmacies (of type B) open for all patients. Also, there are no pharmacies selling only prescription-only medicine(s) (POM).

2.1.3.3.2 Other pharmacy outlets

No other methods of dispensing prescription (Rx) pharmaceuticals are allowed. Apart from in pharmacies, over-the-counter (OTC) pharmaceuticals are also distributed in supermarkets, tobacco shops, newspaper stands and through Internet pharmacies.

2.1.3.3.3 Dispensing doctors

For information on dispensing doctors, cf. 2.1.3.3. In special situations, doctors can be allowed to dispense pharmaceuticals directly to patients, but a pharmacist must be present, a prescription must be delivered by the patient and each of these actions must be approved individually by the regional branch office of the Chief Pharmaceutical Inspector (pharmaceuticals from charity aid or given as donations by pharmaceutical companies to certain groups, patients, patients' associations, etc). In general, there are no dispensing doctors in out-patient care.

2.1.3.4 Hospitals

Hospitals negotiate their budgets yearly with local branch offices of the National Health Fund (NHF). Some hospitals are additionally financed by their founders (local authorities, the Ministry of Health (MoH) or universities) but this additional funding usually cannot be spent on health services (i.e. not for pharmaceutical acquisition, as pharmaceuticals come under health services). Additional resources are spent on renovation of buildings, purchasing technical equipment, etc. This means that all pharmaceuticals acquired by hospitals are paid for with resources contracted from the National Health Fund (NHF).

Hospitals have to pay full prices for pharmaceuticals, whether the pharmaceutical is on the reimbursement list or not.

Patients do not pay for pharmaceuticals administered in hospital. Some pharmaceuticals are administered during medical procedures (anaesthetic pharmaceuticals used for general anaesthesia, contrasts for X-rays, etc.) and as such are usually calculated into the cost of the procedure. Some pharmaceuticals are administered as additional treatment (antibiotics before and after surgical procedures) and these are not paid for by patients either.

If there are special medical needs presented by a patient, e.g. an expensive pharmaceutical that is not reimbursed by the system but is of vital importance for the patient, the hospital administers the pharmaceutical to this patient but has to agree this (as well as the price) beforehand with the local National Health Fund (NHF) office.

A total of 32.5% (PLN 6.5 billion) of total pharmaceutical expenditure (TPE) is spent within hospitals (fully reimbursed to patients, as they do not pay for pharmaceuticals in hospitals, nor are these reimbursed by the National Health Fund (NHF) separately, even if in the reimbursed list – in-patient pharmaceuticals are paid for from hospital budgets).

Pharmaceuticals reimbursed in hospitals, whether included in the general reimbursement list or not, are fully paid for by the hospitals: a therapeutic decision is made by the administering doctor and, depending on the cost of the pharmaceutical, with the director of hospital (no threshold set, no clear transparent procedure). Some pharmaceuticals that are neither reimbursed by the list nor within certain therapeutic programmes (TP) (cf. 4.1) can be administered in a hospital

and paid for by the National Health Fund (NHF), if an agreement is made to that effect with the National Health Fund (NHF) (a kind of individual consent). In the hospital procedures catalogue there is the item “non-standard pharmacotherapy”, with no value assigned to it: based on individual consent, the hospital will include this item, with an appropriate agreed value, into the accounting documents submitted to the National Health Fund (NHF). There is no transparent procedure on this kind of reimbursement and there are no criteria as to which pharmaceuticals this method applies to and which it does not; usually, expensive pharmaceuticals are reimbursed through this method, but the amount of bureaucracy involved in this kind of procedure effectively limits its usage.

If administered in hospital, all pharmaceuticals are fully reimbursed – paid for by the hospital. The hospital budget is contracted with the National Health Fund (NHF), which means that ultimately, the payer is the National Health Fund (NHF). Some hospitals have introduced their own formularies, issued by the hospitals’ management teams, listing recommended pharmaceuticals to be used by employed doctors. This is to minimise costs of pharmaceutical spending.

2.1.3.5 Doctors

There are several organisations of doctors seeking influence in policy-making in Poland.

A Doctors’ Chamber of Poland (Naczelna Izba Lekarska), located regionally, is an organisation of this professional group in Poland and has the most potential. Their involvement is rather more in administration activities (issuing licences for practising, collecting obligatory donations) than working towards improving doctors’ professional situation. Representatives from this Doctors’ Chamber are officially consulted on reimbursement lists by the Ministry of Health (MoH) for each planned edition. There are no reimbursement limits or budgets for doctors, so the Doctors’ Chamber has nothing to negotiate in this area.

On the other hand, there is a large number of scientific societies of doctors that gather together doctors specialising in certain therapeutic or medical fields. These organisations are usually consulted by health authorities on any new therapeutic methods, whether these are to be included for reimbursement or not. These societies sometimes make spontaneous suggestions, or are asked to do so by pharmaceutical companies. Sometimes these suggestions are also considered by the Ministry of Health (MoH).

National Consultants are usually asked for advice during the reimbursement decision-making process. Still, their confirmation that a certain therapeutic method is justified does not necessarily result a positive reimbursement decision. There is no organisation of National Consultants. Sometimes expert panels or advisory boards are organised to advise on a given task.

2.1.3.6 Patients

Patients’ groups, although often unofficial, have a strong influence in policy-making, and also in terms of health care and pharmaceuticals. There are many patients’ societies, e.g. the Society of Amazonians (post-mastectomy women), the Spartacus Society (prostate cancer), the Polish Union of Oncology (gathering patients and doctors in a united front against cancer), the Leukaemia Society, the Multiple Sclerosis Society, Parkinson’s disease societies (both at local level

and a national board for these), and the Polish Association of Alzheimer's' Disease Caregivers' Societies. Stakeholders of the health care system are gathered in the abovementioned and similar organisations to put forward their expectations to decision-makers in a formal way.

Sometimes patients' groups can be particularly effective in their struggle for reimbursement. The more support these organisations have, the more effective they can become. Support often comes from the pharmaceutical industry in the form of organising logistics, and financial support (although the latter is rare as this is perceived as not ethical and dangerous, and can be easily disclosed to media, threatening the credibility of any actions undertaken by the organisation). Some health-policy programmes, lobbied by patients, are approved by the Ministry of Health (MoH), e.g. the national programme against cancer and the national programme for multiple sclerosis treatment and rehabilitation. However, except for declarations of good will for co-operation, no major resources are dedicated to supporting such programmes.

Many patients do not agree to replace their pharmaceutical therapy with generic products. Some patients, on the contrary, demand a substitution for financial reasons, substituting their current treatment with other pharmaceuticals of the same therapeutic group (the one limiting the group), resulting in no co-payment or a generic substance with no out-of-pocket (OOP) co-payment (sometimes out-of-pocket payments (OPP) are required in full for services).

Pharmacies' margins for non-reimbursed pharmaceuticals are freely set by the pharmacy (while there are no officially approved and executed prices for non-reimbursed pharmaceuticals), so all marketing activities are implemented (except for public advertising which is forbidden for prescription pharmaceuticals). Reimbursed pharmaceuticals are officially priced and margins are set, but while official prices are set and are unchangeable, official margins are set as maximum values and can be freely decreased by pharmacies or earlier in the process by wholesalers. In this way, price lowering can be carried out to encourage patients to use a particular pharmacy or to buy a particular pharmaceutical over a competitor. In addition, loyalty programmes are put in place by some pharmacy chains, whereby regular customers can obtain certain discounts, not only for over-the-counter (OTC) pharmaceuticals and sanitary products but also for prescription pharmaceuticals. For margin details, cf. 2.1.3.2 and 2.1.3.3.

In some pharmacies patients are even "paid" for buying their pharmaceuticals there. When a patient buys her/his medicine there the pharmacist can divide his margin between the pharmacy and the patient and give some of it, in cash form, to the patient, together with the desired pharmaceutical (part of the reimbursable margin is therefore recouped, as a kind of claw-back).

Patients can freely receive medical information about over-the-counter (OTC) pharmaceuticals. Information on prescription pharmaceuticals is restricted for professionals only (doctors and pharmacists). However, patients carry out research on the Internet and find out on their own initiative information that they are not likely to really understand but still want to make some use of it. Doctors remain a source of information for patients on pharmaceuticals and, although it is not allowed, patients are informed about other available pharmaceuticals in pharmacies (i.e. generic substitution). Information obtained by patients can often be wide ranging, and they want much more information than the necessary minimum. Also, information on price decreases in pharmacies is distributed in leaflets or via newspaper adverts, or is advertised in pharmacies' windows.

2.2 Funding

This section provides an overview on the funding of pharmaceuticals, including pharmaceutical expenditure (PE) and the allocation of funds for pharmaceuticals.

2.2.1 Pharmaceutical expenditure

Total pharmaceutical expenditure (TPE) in Poland is expected to reach a level of PLN 20 billion (approximately € 5.13 billion) in 2006; 50% of this total pharmaceutical expenditure (TPE) value is spent on prescription (Rx) pharmaceuticals ("Rx" status standing for "prescription only").

Table 2.9: Poland - Total pharmaceutical expenditure (TPE) 1995, 2000-2005

Pharmaceutical expenditure (PE) in Mio. PLN	1995	2000	2001	2002	2003	2004	2005
TPE in Mio. PLN	n.a.	12,335.88	13,523.40	13,935.85	15,813.23	16,099.26	17,245.09
TPE as a % of THE	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
TPE per capita in Mio. PLN	n.a.	322.47	353.63	364.64	414.06	421.74	451.95
Public PE as a % of TPE	n.a.	34.2	35.3	36.4	37.0	35.0	35.1
Private PE as a % of TPE	n.a.	65.8	64.7	63.6	63.0	65.0	64.9

GDP = gross domestic product, TPE = total pharmaceutical expenditure, THE = total health expenditure, PE = pharmaceutical expenditure

Source: IMS Data View 03/2007, © 2007 IMS Health Incorporated or its affiliates. All rights reserved.

A proportion (30%) of total pharmaceutical expenditure (TPE) is spent on reimbursement of prescription (Rx) pharmaceuticals (PLN 6 billion budgeted for 2006 by the National Health Fund (NHF)), while the next 20% of total pharmaceutical expenditure (TPE) (PLN 4 billion) is made up of out-of-pocket payments (OPP) (co-payments for reimbursed pharmaceuticals, at 95% or full out-of-pocket payment (OPP) for prescription (Rx) pharmaceuticals that are not reimbursed at all – 5% qualified as direct payments, as shown in Figure 2.3).

A total of 32.5% (PLN 6.5 billion) of total pharmaceutical expenditure (TPE) is spent within hospitals (fully reimbursed to patients, as they do not pay for pharmaceuticals in hospitals, nor are these reimbursed by the National Health Fund (NHF) separately, even of in the reimbursed list – in-patient pharmaceuticals are paid for from hospital budgets).

Finally, 17.5% of total pharmaceutical expenditure (TPE) consists of spending on over-the-counter (OTC) pharmaceuticals, covered by full out-of-pocket payments (OPP).

When considering reimbursed products it is worth noting that out-of-pocket (OOP) co-payments for reimbursed pharmaceuticals have reached an average of 43-45% in Poland.

Health expenditure (HE) in Poland for reimbursed services has reached the level of approximately PLN 34 billion (National Health Fund (NHF) spending on services and pharmaceuticals). If it is assumed that patients co-pay an average of 60% for health services, then total health expenditure (THE) can be assessed at the level of approximately PLN 85 billion (€ 22.5 billion).

2.2.2 Sources of funds

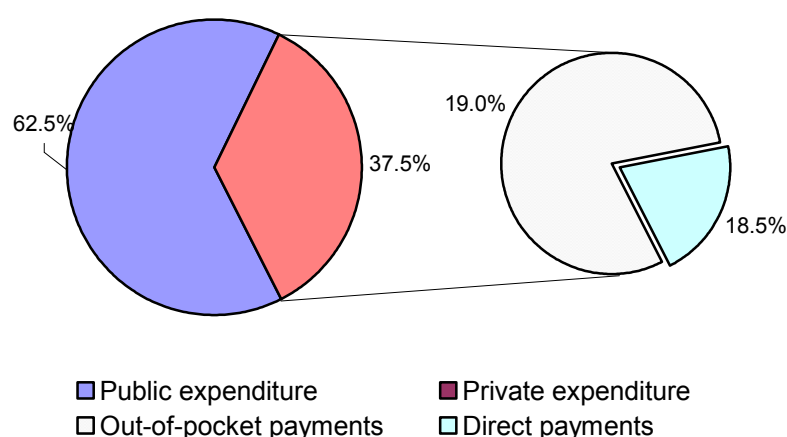
Social insurance contributions are a source of funding for the National Health Fund (NHF). The National Health Fund (NHF) reimburses 30% of total pharmaceutical expenditure (TPE) for reimbursed prescription (Rx) pharmaceuticals and a further 32.5% for pharmaceuticals given to patients in hospitals (via hospital budgets) (cf. 1.4.2). The financial engagement of the National Health Fund (NHF) is being lowered by the consequent policy of cost-containment in recent years. Although global spending on pharmaceutical funding is growing, the percentage of public funding for it is decreasing.

There are no other methods of financing pharmaceuticals from public sources. As for private sources, voluntary supplementary insurance does not contribute to pharmaceutical spending of the insured individuals in those institutions.

Most out-of-pocket payments (OPP) are percentage co-payments and fixed co-payments (lump sums for fully reimbursed pharmaceuticals – cf. 1.4.2). This kind of spending is not deductible. More out-of-pocket payments (OPP) consist of spending for non-reimbursed prescription pharmaceuticals and over-the-counter (OTC) pharmaceuticals, as mentioned in 2.2.1.

There are no informal payments directly for pharmaceuticals, unlike for health services. Where some health services administer pharmaceuticals themselves, informal co-payments for quicker access to such health services may arise. In any case, neither the amount nor any percentage of these is reported.

Figure 2.2: Poland - Share of private and public pharmaceutical expenditure (PE) 2006



Source: Statistical Yearbook, Central Statistical Office 2006

2.3 Evaluation

There are two major institutions, both state dependent, to assess the state pharmaceutical policy.

The Centre for Quality Monitoring in Medicine (Centrum Monitorowania Jakości w Medycynie, CMJ) based in Krakow has been functioning for approximately 10 years at the time of writing. The Institute for Public Health (Instytut Zdrowia Publicznego) is another expert body. The two institutions advise the Polish Government on the health care policy of the State. There are no programmes to monitor access to pharmaceuticals or the impact of changes in the health care policy. It is possible that such programmes have been carried out (e.g. from European Union (EU) funds) but outcomes of these are not announced in public because the health care system is still a strong tool in political campaigns and outcomes of such surveys are probably very weak. Neither of the aforementioned institutions, subordinate to the Ministry of Health (MoH) (directly or indirectly), will announce anything without the Ministry of Health's (MoH) approval.

That said, an independent survey has been carried out and the report from it was entitled "Poles Apart".

3 Pricing

3.1 Organisation

Legal acts by which pharmaceutical pricing is regulated mainly comprise the Pricing Law, dated 5 July 2001, and certain ordinances of the Minister of Health. There are also documents with no legally binding value that determine specific rules of price setting for reimbursed pharmaceuticals (guidelines), in the form of "Communicates". However, these are not available anymore, having been removed from the Ministry of Health's (MoH) web site in early 2005.

The Pharmaceutical Management Team is entitled to make recommendations on the shape of the reimbursement list and official prices to the Minister of Health but the Minister is in a position to make the final decision about the content of the reimbursement list. The Pharmaceutical Management Team does not work on a regular basis. Agendas of the meetings are kept secret "to protect members from the industry's potential influence attempts". The whole procedure of official price setting is managed and decided by the same set of people who decide on reimbursement, during the same process. The process lasts until the reimbursement decision is made. The Team judges according to the Anatomic Therapeutic Chemical (ATC) classification of molecules and decides on inclusion of molecules into therapeutic groups with common reimbursement price limits. The limit price is set at the level of the cheapest substance in the group. Other substances of the same Anatomic Therapeutic Chemical (ATC) code are priced according to their "strength of biological action" based on the defined daily dose (DDD) system (cf. 4.3).

- Data on clinical effectiveness, cost-effectiveness and budget impact are required with reimbursement and pricing submission, but are not taken into consideration within the price setting process.
- Budget impact is taken into consideration by the Ministry of Health (MoH) and also by the National Health Fund (NHF). This will probably change due to the emergence of the state Agency for Health Technology Assessment (AOTM) now operating in Poland, and its development will probably also increase the importance of pharmacoeconomic data in the reimbursement procedure.
- If a company does not accept the pricing proposal from the regulator, the pharmaceutical is not reimbursed (not even partly) and no co-payment is accepted (only when the price limit is set at the level of the prices of comparable pharmaceuticals).
- Even if it is higher than assumed at the beginning of the process, clinical effectiveness is not a major criterion for price setting.

When the official price is set, the Pharmaceutical Policy and Pharmacy Department of the Ministry of Health (MoH) that coordinates activities of the Pharmaceutical Management Team sends a price proposal to the producer / market authorisation holder (MAH). The price must then be accepted or the product will not enter the reimbursement list (cf. 3.2.2).

Recently, the Ministry of Health (MoH) decided to impose official prices for hospital-use products as well. Consultants helped to compile a list of hospital products that generate the greatest turnover in hospitals and official prices were imposed on those products. During short negotia-

tions some market authorisation holders (MAH) or producers managed to obtain prices somewhere between what was proposed by the Ministry of Health (MoH) and actual prices.

Hospital products which are not among those that generate the top 40% of hospital turnover (cf. 3.4.1) are obtained via public procurement. Prices are set by agreement between the buyer and seller, the tendering procedure offers (from sellers) are presented and the best deal wins.

3.2 Pricing policies

Table 3.1: Poland - Ways of pricing pharmaceuticals

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free pricing	All non-reimbursed pharmaceuticals All OTC pharmaceuticals		1. for OTC pharmaceuticals sold in and outside pharmacies 2. for all non-reimbursed pharmaceuticals in pharmacies
Statutory p	Statutory pricing increasingly concerns hospital pharmaceuticals – after negotiations a list of official prices for hospital pharmaceuticals is published. All reimbursed pharmaceuticals, along with official manufacturers' prices and official wholesale and retail prices are published as a Directive of the Ministry of Health, commonly called the "reimbursement list"		
Price negotiations	Officially there are price negotiations between producers/MAH and the Pharmaceutical Management Team of the MoH during the reimbursement and pricing procedure	Not applied	Not applied
Discounts / rebates	Not allowed	Not allowed on product prices; originally allowed on margins but not anymore	Not allowed on product prices; originally allowed on margins but not anymore
Public procurement	➤ For pharmaceuticals used in hospitals, except for "hospital use only" pharmaceuticals for which the official price is settled officially by the MoH (see above)		
Institution in charge of pricing	➤ MoH Pharmaceutical Management Team, final decision by the Minister of Health in consultation with the MoF		
Legal basis	➤ Ustawa o cenach (Pricing Law, 5 July 2001)		

MoH = Ministry of Health, MoF = Ministry of Finance, MAH = market authorisation holder(s)

Source: Polish acts – Pharmacy law, Pricing Law

The Pricing Law entered into force in June 2001 and remains valid at the time of writing. Procedures vary among groups of products, as shown in Table 3.1.

As for the reimbursement list, pricing of generics varies just as much, as there is a demand of a minimum 25% price decrease on an original product's price when entering the list. The next generics must then decrease their price by a further 20% and any generics introduced into the list after that cannot be any more expensive than the cheapest generic in the therapeutic group. Unfortunately, the Ministry of Health's "Communicates", establishing the rules of price setting for reimbursed pharmaceuticals, is no longer available. It has also not been clearly stated whether new original pharmaceuticals being introduced into the reimbursement list are also to be governed by these rules. Furthermore, it is not clear how an original pharmaceutical entering the list should be priced if a molecule is new in terms of the reimbursement list, but there is an adequate therapeutic group in the list already.

Prices, if set, are set on three levels: the manufacturers' level, the wholesalers' level and the pharmaceutical retail price (PRP) level for pharmacies. Hospital prices are set as manufacturers' prices and margins are official as well (although margins are set as a maximum, so rebates (discounts) are still possible from the margin). Prices in the hospital list include the wholesalers' margin but no retailers' margin – hospital pharmacies do not put any extra margins on pharmaceuticals. Changes in prices are possible. Market authorisation holders (MAH) can always ask for a price decrease; this happens sometimes when a generic pharmaceutical enters the market.

Price cuts are very commonly used by the decision-makers in the pharmaceutical sector. All price changes are decided by the Pharmaceutical Management Team, and finally approved by the Ministry of Health (MoH).

3.2.1 Statutory pricing

The statutory pricing system was implemented in July 2001. Some amendments were introduced later, but since 2002 the system has remained unchanged. Statutory pricing applies to all pharmaceuticals reimbursed by the list. At the time of writing, 3,300 pharmaceuticals are included in that list.

Statutory pricing also applies to hospital-only products that generate the top 40% of hospital turnover. The first hospital price list was issued in August 2005 and regulated prices of products that generate the top 20% of hospital turnover; then in December 2006 an ordinance was issued by the Minister of Health introducing a new list of products and regulating the prices of the products which generate the next 20% of hospital turnover. This means that statutory pricing exists for the products generating the top 40% of hospital turnover (270 pharmaceuticals).

Statutory pricing concerns manufacturers' prices, wholesale prices and retail prices. Margins are also statutorily set.

Within the Ministry of Health (MoH), the Pharmaceutical Policy and Pharmacy Department is a coordinating body. The Pharmaceutical Management Team consists of representatives of the Ministry of Health (MoH), the Ministry of Finance (MoF), the Ministry of Economy and potentially also representatives of the National Health Fund (NHF). The Pharmaceutical Management Team is a kind of working group, but final decisions are made by the Minister of Health. External

referencing, internal referencing and cost-minimisation (cost-containment) policies are used as pricing methods.

At the time of writing, there are no binding time frames. In the Law on health care services financed from public sources there are time frames for reimbursement procedures that run alongside pricing procedures, so that the same terms are maintained.

Formally, there is a 180-day decision period granted by the Law on health care services financed from public sources, plus suspension periods to be granted when a full and correct set of documents had not been submitted.

The information that is required from the applicant is listed in the application form (partially based on art. 6 of the Pricing Law of 5 July 2001 and the Decree of the Minister of Health of 17 May 2002 “on the scope of information and applications necessary to set official prices” (Official Journal 03.69.643)). Except for legal status (prescription (Rx) / hospital only), data on price in the manufacturer’s country are required, along with information on prices of the product in other European countries (not only the European Union (EU)), the cost of manufacturing of a single pack of the pharmaceutical(s) and the proposed manufacturer price.

3.2.2 Negotiations

Price negotiations are conducted for all reimbursed products.

As far as the reimbursement list is concerned, negotiations are ongoing, alongside the reimbursement decision-making process. A pricing application accompanies the reimbursement application (based on the submission form). There is a special pricing form, which is very similar to the reimbursement one; these are required to be submitted jointly (as parts of the same submission). A price proposition from the manufacturer / market authorisation holder (MAH) is also inserted into the documentation to be submitted. After it is decided that a pharmaceutical is to be introduced into the reimbursement list, a price proposal from the Ministry of Health (MoH) is sent to the applicant. The price should be confirmed; if it is not, talks may take place. Most often the price is accepted by the applicant. This is also true for the level of reimbursement, i.e. 100% or partial reimbursement, the level of which (100%, 70% or 50%) is dependent on the Ministry of Health’s (MoH) decision, and also stated in the official offer letter. Prices (in this process of “negotiation”) are usually given at the level of the cheapest generic’s price, or if there are either no generics or no therapeutic group with generics then the manufacturer’s price minus 20% is likely to be offered.

Margins are set by the Pricing Law and are not a subject to negotiations. Margins are likely to be changed from “maximum margins” to “fixed margins”.

As for pricing of hospital pharmaceuticals, the process for products that generate the top 40% of hospital turnover has started recently. Free pricing, existing until 2005, is now controlled by the Ministry of Health (MoH). Prices of transactions are checked across the country and, based on invoices (especially those including rebates/discounts), a price proposal is offered to the manufacturer, followed by negotiations.

The Ministry of Health (MoH) is involved at the stage when reimbursement list is considered and the Ministry of Health (MoH) together with external consultants (experts on health care systems) are involved if negotiations on hospital products are taking place.

If negotiations fail, the pharmaceutical is not admitted for reimbursement. This applies to both the out-patient and in-patient sectors.

3.2.3 Free pricing

Free pricing is applicable for over-the-counter (OTC) pharmaceuticals and for prescription (Rx) pharmaceuticals that are not reimbursed. Free pricing is also applicable for hospital-use pharmaceuticals if the pharmaceutical does not generate turnover from the top 40% of the hospital pharmaceuticals turnover. With the current policies of the Ministry of Health (MoH), all hospital pharmaceuticals will probably soon have negotiated “hospital prices”. Hospital pharmaceuticals negotiations started in 2005 (cf. 3.2.2).

3.2.4 Public procurement / tendering

Tendering procedures are applied to hospital pharmaceuticals (and other hospital products, materials, and services for hospitals). Health services are also contracted in a tendering procedure by the National Health Fund (NHF).

Hospitals must use a public procurement procedure, but it can be omitted in certain specific conditions, e.g. if there is only one supplier of a particular pharmaceutical (but usually there are many, as a product from one producer is distributed by many wholesalers and wholesalers are suppliers, not producers themselves). Tenders should always be carried out when the planned purchase exceeds the sum of € 6,000 (this is intended to be changed to € 11,000 in June or July 2007).

Tenders apply for all types of pharmaceuticals used in hospitals. Within tenders, best prices (or best deals; an offer for a tender may include different types and amounts of pharmaceuticals and in these cases the whole package can be considered) are achieved for hospitals (unless there are some “backdoor agreements”). For pharmaceuticals where a maximum hospital price is set by the Ministry of Health (MoH) (cf. 3.2) the resulting/negotiated price has to be below that limit in order to be reimbursed, but the hospital can buy those pharmaceuticals at a higher price and co-pay the difference from its own resources. The National Health Fund (NHF) will only reimburse the agreed/permitted price (not all pharmaceuticals can be checked or monitored by the National Health Fund (NHF), which is why such differences occur).

3.3 Pricing procedures

Different methods are applied for pricing of pharmaceuticals in Poland.

Referencing against prices in other countries is most common and there is clearly a strong demand for the cheapest price in Europe (not only the European Union (EU)) (but is not articulated in any official document).

A cost-minimisation approach by the Ministry of Health (MoH) is apparent and this is set out in the Pricing Law (one of criteria mentioned there is “best competitive price”). Internal price referencing is used within the reference price system, with reimbursement limits placed on generics and therapeutic groups with common reimbursement limits set for prices of the cheapest generic substances in the whole group (cf. 3.3.2). A kind of internal price referencing is applied as well, especially when pricing negotiations are held for hospital-use only products (cf. 3.2.2). For this, prices documented in different transactions (invoices) across the whole country are taken into consideration. This semi-negotiation pricing procedure – a kind of internal price referencing for hospital pharmaceuticals – is a major change in the system, introduced in 2005.

Table 3.2: Poland - Pricing procedures

Pricing procedure	In use: Yes / No	Level of pricing ¹	Scope ²
Internal price referencing	Yes	Manufacturers prices (and consequently wholesaler's and retail prices) as margins are set officially as well	Reimbursable and hospital
External price referencing	Yes	Manufacturers prices (and consequently wholesaler's and retail prices) as margins are set officially as well	Reimbursable and hospital
Cost-plus pricing	No		
Other, e.g. indirect profit control	Yes, cost-minimisation (see text)	Manufacturers prices (and consequently wholesaler's and retail prices) as margins are set officially as well	Reimbursable and hospital

¹ Level of pricing = the stage of the pricing process at which the pricing takes place (e.g. at the retail price level)

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

Source: Ministry of Health

3.3.1 External price referencing

External price referencing is applicable to all reimbursable pharmaceuticals. Pricing concerns all levels – manufacturer's price, wholesaler's and pharmaceutical retail price (PRP), as these can be consequently computed (margins are officially set).

External price referencing is only one of the criteria set. A pharmaceutical of a lower European price does not automatically qualify for reimbursement. Among others factors, the most important is the affordability of a pharmaceutical, in terms of budgetary limitations of the National Health Fund (NHF). Presence of generics in the market is another important factor, as this makes the reimbursement limit easier to set.

There is a list of countries that Polish decision-makers intend to refer to during reimbursement and pricing decisions. The list of countries include: Belgium, the United Kingdom, Ireland, France, Germany, the Netherlands, Sweden, Denmark, Spain, Portugal, Italy, Greece, the Czech Republic, Hungary, Luxembourg, Lithuania and Switzerland.

Why this set of countries? Spain: probably because its economy is similar to that in Poland. Hungary and the Czech Republic: because of similar political and economic situations and history. Italy and Greece: because of a strong demand for the cheapest price in the European Union (EU) to be proposed there. It is obligatory to disclose this information, but if data are missing, the application still proceeds. No alternative countries are taken into consideration in this case. The comparison influences pricing in Poland. Usually the decision-makers' proposal is at the level of the lowest prices.

Comparisons are made without considering purchasing power parity (PPPa). The amount in € is subject to comparison. The manufacturer provides the information in written format along with the reimbursement and pricing application form. The decision-maker compares it with their own data, the source of which is not disclosed. Changes of prices in other countries are not subject to constant monitoring.

As the Polish price is set in PLN based on the exchange rate of the National Bank of Poland (Narodowy Bank Polski, NBP), if an appreciation of local currency takes place, manufacturers are encouraged to lower prices. This "encouragement" comes in the form of a new official price proposal for the forthcoming reimbursement list update, and in practice cannot be rejected.

3.3.2 Internal price referencing

Internal comparisons are carried out for all reimbursable pharmaceuticals, mainly for the general reimbursement list.

The manufacturer's price is subject to comparisons – the wholesale price and pharmaceutical retail price (PRP) are a consequence of this manufacturer's price (following the officially set margins). Prices are compared between the original pharmaceuticals and the generic equivalents of those. Also, prices are compared between pharmaceuticals of the same therapeutic group (with one reimbursement price limit (cf. 4.3)).

Therapeutic groups of substances are based on Anatomic Therapeutic Chemical (ATC) classifications down to level 5. However, sometimes Anatomic Therapeutic Chemical (ATC) level 4 is applied. Formulations are taken into consideration but criteria are not known.

Packs of the same product (the same brand), the same pack size but different dosage are priced according to the following correlation: twice as much of a substance yields a price limit (for the bigger dose) of 1.6 times the price limit of a smaller dose – this is an observation, as no criteria have been officially announced. If a pharmaceutical has no reimbursement limit, its own price would therefore be a limit, but in cases where there is other limiting product, which limit will be calculated is decided according to the above-mentioned observed rule. Companies are obliged to supply data on the costs of manufacturing of a single pack of a pharmaceutical. Research and development (R&D) costs are not considered by decision-makers as part of the

manufacturing costs. If the data are not submitted, the whole reimbursement and pricing procedure is not processed any further. The Pharmaceutical Management Team, and Pharmaceutical Policy and Pharmacy Department in the Ministry of Health (MoH) carry out this internal pricing referencing.

3.3.3 Cost-plus pricing

No cost-plus pricing policy is applied in Polish pricing procedures.

3.3.4 (Indirect) Profit control

There is no (indirect) profit control in the pharmaceutical industry in Poland.

3.4 Exceptions

3.4.1 Hospitals-only

Hospitals used to carry out their own procurement, but this is no longer the case. Since 2006 the Ministry of Health (MoH) controls the prices of the top 40% of pharmaceutical turnover. The official prices for these pharmaceuticals are set in a negotiation procedure.

Changes are monitored. The official prices for hospital products will decrease over time, resulting in pharmaceuticals that generate increasingly less turnover. When these hospital prices are reduced, due to official price setting, the 40% limit will move “down” from year to year, so more and more hospital pharmaceutical are included in the process of official price setting. Information of official prices of hospital pharmaceuticals is available in the relevant Minister of Health ordinance, issued after negotiations.

There are no procedures established so far; pricing is set on basis of negotiations, opinions of external consultants hired by the Ministry of Health (MoH) and decision by arbitration.

3.4.2 Generics

There are no differences for generics, apart from strictly referring to prices of other, already reimbursed generics of the same substance (or substance in the therapeutic group). A 25% reduction in price is demanded for a generic entering the list as a first generic, another 25% reduction is required for the next, and from then on generics entering the list must not have a higher price than the cheapest generic in the group. This procedure was announced by the Ministry of Health (MoH) in a “Communicate” (document of no legal value).

3.4.3 Over-the-counter pharmaceuticals

There is no system of pricing for over-the-counter (OTC) pharmaceuticals – pricing for this type of pharmaceutical product is free.

3.4.4 Parallel traded pharmaceuticals

Parallel traded pharmaceuticals are not subject to reimbursement at the time of writing, so there are no pricing procedures for this type of pharmaceutical – they are priced freely, as only non-reimbursable pharmaceuticals are parallel traded.

3.4.5 Other exceptions

No other exceptions exist.

3.5 Margins and taxes

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

Table 3.3: Poland - 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	Linear maximum mark ups	All reimbursable pharmaceuticals	Yes	Regressive maximum mark ups	All reimbursable pharmaceuticals

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

Source: Pricing Law (Ustawa o cenach), July 2001

3.5.1 Wholesale remuneration

Wholesalers are remunerated according to what is settled in contractual relations between manufacturers and wholesalers, where non-reimbursed pharmaceuticals are concerned.

For non-reimbursed pharmaceuticals, an average wholesale margin of 12% up to 14% exists. The 14% margin is usually calculated into the price of the pharmaceutical.

The officially set margin is applied when a reimbursed product is traded. This margin is announced in the Pricing Law (Ustawa o cenach, July 2001). The margin is rarely changed and the last update took place in 2004 (changed in the Minister of Health's legal act). The wholesaler's margin is set at 9.78153% of the ex-factory price plus 7% value-added tax (VAT). This is

a maximum margin. There are plans to set all official margins as fixed, to allow full control of pharmaceutical prices by closing the last remaining method of granting rebates/discounts on products.

Sometimes wholesalers can move away from their margin if their agreement with the manufacturer is such that pharmaceutical can be provided cheaper. Such a mechanism is used for rebates (discounts), e.g. in the case of a generics price war. Wholesalers are then remunerated by the manufacturer in other ways, by e.g. granting rebates (discounts) on other products.

The calculation of a wholesaler's price is carried out as follows:

(Ex-factory price) x 1.07 (7% value-added tax (VAT)) x 1.0978153 (for 9.78153% of wholesaler's margin).

3.5.2 Pharmacy remuneration

Pharmacy margins are free to be set by the pharmacist for non-reimbursable pharmaceuticals (over-the-counter (OTC) pharmaceuticals, or prescription (Rx) pharmaceuticals not listed in the reimbursement list in the relevant Minister of Health's ordinance ("reimbursement list")).

For reimbursed pharmaceuticals, margins are officially set (as shown in Table 3.4) in the Pricing Law. Margins are set as maximum and can be lowered by the pharmacist (cf. 2.1.3.6).

Such margins are defined as maximum values allowing the pharmacist to grant discounts if appropriate. Sometimes this opportunity is used for decreasing the cost of purchasing a pharmaceutical limited by a generic (the patient co-payment may be reduced and patients may therefore buy an original pharmaceutical instead of a generic). Usually, pharmacists are remunerated for such discounts in different ways by manufacturers and by wholesalers.

Also, with many reimbursed pharmaceuticals there is a lump sum of PLN 3.20 charged for fully reimbursed pharmaceuticals that may resemble a "prescription fee". These fees are not to be treated as part of the pharmacy's margin as these are two totally different things. The lump sum of PLN 3.20 for some fully reimbursed products goes to the National Health Fund (NHF), while the patient does not even see the pharmacy's margin as this is paid as part of the reimbursement process, by the National Health Fund (NHF) to the pharmacy.

Table 3.4: Poland - Pharmacy mark-up scheme 2006

Wholesale price in PLN (includes value-added tax (VAT))	Pharmacy mark up as a % of pharmacy purchasing price (PPP) in PLN
0.00 – 3.60	40%
3.61 – 4.80	1.44 PLN
4.81 – 6.50	30%
6.51 – 9,75	1.95 PLN
9.76 – 14.00	20%
14.01 – 15.55	2.80 PLN
15.56 – 30.00	18%
30.01 – 33.75	5.40 PLN
33.76 – 50.00	16%
50.01 – 66.67	8.00 PLN
66.68 – 100.00	12%
over 100.00	12.00 PLN

Source: Pricing Law

To calculate the official pharmacy price for reimbursed pharmaceuticals, we need to add the appropriate value from Table 3.4 to the wholesaler's price (as calculated in 3.5.1). The Ministry of Health (MoH) intends to fix margins for wholesalers and pharmacies.

For non-reimbursable pharmaceuticals the retail margin is freely set by pharmacists, usually at 25% of the wholesaler's price.

3.5.3 Remuneration of other dispensaries

No other methods of dispensing are allowed in Poland. Hospital pharmacies are not remunerated with standard official pharmacy margins as these pharmacies do not sell pharmaceuticals. Pharmacies of this kind are a part of a hospital and employees there are paid by the hospital, usually in the form of standard wages. There are special dispensing arrangements, as described in 2.1.3.3, but no remuneration, as these are usually related to charity activities.

3.5.4 Value-added tax

Value-added tax (VAT) for pharmaceuticals in Poland is set at 7%. This is the first step (from the manufacturer's price) and then the wholesale and pharmacy margins are added. E.g. product Lovasterol from company Polpharma, active ingredient Lovastatin 20 mg, pack size 28, costs (retail price) PLN 29.11; wholesale price including value-added tax (VAT) amounts to PLN 24.67, manufacturer price including value-added tax (VAT) totals PLN 22.47, manufacturer price excluding value-added tax (VAT) amounts to PLN 21.00.

The scheme detailed in 3.5.1 is binding. Value-added tax (VAT) is calculated at a level between the manufacturer's ex-factory price and manufacturer's wholesale price. The manufacturer ex-factory price plus 7% value-added tax (VAT) results in the manufacturer wholesale price, then multiplied by 1.0978153 gives the wholesale gross price which already includes value-added tax (VAT). Then, only the retail margin must be added, according to Table 3.4 (cf. 3.5.2).

3.5.5 Other taxes

There are no other taxes on pharmaceuticals in Poland.

3.6 Pricing-related cost-containment measures

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

3.6.1 Discounts / Rebates

No discounts in cash are allowed for reimbursed pharmaceuticals – that is what officially set prices are for. Official prices are not set as maximum values, while margins set are of maximum character and therefore some discounts/rebates on lowered margins are possible (cf. 3.5.1). However, this is soon to be discontinued as the Ministry of Health (MoH) intends to impose official margins set at certain levels, not at a maximum level anymore.

Natural discounts/rebates are allowed in Poland, although an invoice of zero value is still to be issued for transactions involving goods that are free of charge, if the goods are reimbursed pharmaceuticals. There is also still some risk that a lowered price will be taken into consideration by the Ministry of Health (MoH) during official price negotiations in the future.

Natural rebating is much safer for the industry, as those involved do not show the real value of their products which could then be used for price re-negotiations by the Ministry of Health (MoH), if a major price decrease concerns other non-reimbursed pharmaceuticals bought by the wholesaler in a package together with the reimbursed pharmaceutical from the manufacturer.

Payments are usually made within the time frame of two weeks to one month. Extending this term is not perceived by the wholesalers or pharmacists as a discount or rebate of any kind. No statutory discounts exist.

The National Health Fund (NHF) monitors all invoices for all hospital pharmaceutical transactions and therefore all rebates/discounts are easily visible. This may be a basis for negotiating a lower than currently marketed official price for a rebated/discounted pharmaceutical (cf. 3.2.3). For information on claw-backs, cf. 2.1.3.6.

3.6.2 Margin cuts

In 2003 the statutory wholesale margin on reimbursable pharmaceuticals was decreased from 9.91% to 8.91% of the wholesale price. There have been no other changes.

As discussed earlier, wholesale and retail margins for reimbursed pharmaceuticals are set as maximum margins. Therefore, decreases in these, as a form of discount/rebate (cf. 3.6.1), is allowed both for wholesalers and for pharmacists.

The Ministry of Health (MoH) intends to fix both wholesale and retail margins, so discounts will no longer be possible. Margins for non-reimbursed pharmaceuticals or over-the-counter (OTC) products are freely set by wholesalers and pharmacists and can also be decreased freely.

3.6.3 Price freezes / Price cuts

There is no price freeze in Poland at the time of writing. Price cuts are often used tool of cost-minimisation by the Ministry of Health (MoH). The last price cut was applied in July 2006 due to Polish Zloty (currency) appreciation. The cut was decided on by the Ministry of Health (MoH) and prices were lowered by 13%.

Previously, price cuts were imposed with new generic pharmaceuticals entering the reimbursement list. Also, after the introduction of generics into the list, the next update was designed to cut off pharmaceuticals that had not decreased their prices if the price was more than 50% greater than the price of the cheapest generic in the reimbursement therapeutic group.

3.6.4 Price reviews

Pricing procedures are not reviewed regularly. The last regulation took place together with the Pricing Law in July 2001 and the Ministry of Health (MoH) ordinances that followed.

An an independent survey was carried out and the report from it was entitled "Poles Apart" (cf. 2.3). Data gathered from this need further investigation. No legal action has been taken with regard to non-compliance with European Union (EU) legislation.

4 Reimbursement

4.1 Organisation

There are basically three ways of reimbursing pharmaceuticals in Poland.

The positive reimbursement list is the method that covers the majority of patients' pharmaceutical acquisitions and is described in most detail in this section.

Those of minor volume, but still significant in terms of budget, are:

1. pharmaceuticals administered in hospitals as part of hospital procedure, e.g. photodynamic therapy in some ophthalmic disorders, where, before laser exposition, certain pharmaceuticals must be administered intravenously;
2. pharmaceuticals reimbursed in hospitals, given to in-patients staying within wards (pharmaceuticals paid by the hospitals' budgets);
3. pharmaceuticals administered in hospitals or clinics (in- or out-patient, depending on the nature of the medical or therapeutic problem) as pharmaceutical technology procedures, called therapeutic programmes (TP) or medicinal programmes.
 - In terms of point 1 above: Procedures administered to patients within health insurance are collected in a catalogue of contracted procedures and contracted in hospitals by the National Health Fund (NHF). The cost of a pharmaceutical, in cases where administration is necessary as part of the procedure, is calculated and included in the price of the procedure.
 - In terms of point 2 above: Pharmaceuticals reimbursed in hospitals, whether or not they appear in the general reimbursement list, are paid for in full by the hospitals: the therapeutic decision is made by the administering doctor and, depending on the cost of the pharmaceutical, with the director of hospital as well. Some pharmaceuticals that are neither reimbursed nor available within therapeutic programmes (TP) can be administered in a hospital and paid for by the National Health Fund (NHF), if such an agreement is made with the National Health Fund (NHF) (a kind of individual consent). In the hospital procedures catalogue there is the item "non-standard pharmacotherapy", with no value assigned to it: based on individual consent, the hospital will include this item, with an appropriate agreed value, into the accounting documents submitted to the National Health Fund (NHF). There is no transparent procedure on this kind of reimbursement and there are no criteria as to which pharmaceuticals this method applies to and which it does not; usually, expensive pharmaceuticals are reimbursed through this method.
 - In terms of point 3 above: Therapeutic programmes (TP) are created to reimburse the most expensive (no threshold on this) and most therapeutically important pharmaceuticals. Therapeutic programmes (TP) are a "reimbursement element"; a solution of sorts that the National Health Fund (NHF) has undertaken. This way of reimbursing pharmaceuticals did not require Minister of Health's approval. At the time of writing, the therapeutic programmes (TP) are still contracted by the National Health Fund (NHF) but it has been agreed that new therapeutic programmes (TP) will require the Ministry of Health's

(MoH) approval, and a legal solution is being worked on. A therapeutic programme (TP), legally, is a hospital procedure of pharmaceutical technology, with detailed inclusion and exclusion criteria and monitoring of the benefit to patients during the therapy.

The most popular method of pharmaceutical reimbursement is via the reimbursement list, issued by the Minister of Health periodically (recently updated in March 2007).

The list consists of several chapters, each one for a different reimbursement level. There are four levels of reimbursement: 100% reimbursement (oncology pharmaceuticals, chronic diseases, epilepsy, schizophrenia, other life-saving pharmaceuticals); fixed co-payment (prescription payment, lump sum) of PLN 3.2 (Polish Zloty) (equal to approximately € 0.80) to paid by the patient and the rest of the price is reimbursed (basic pharmaceuticals, e.g. antibiotics); 70% reimbursement (chronic diseases, e.g. Parkinson's disease and Alzheimer's disease) – patients cover 30% of the pharmaceutical's price; and 50% reimbursed pharmaceuticals, when patients have to co-pay the other half of the price of a pharmaceutical (e.g. hypertension medication and new generation pharmaceuticals). There are also reimbursement limits, and therapeutic groups of pharmaceuticals are introduced to the list. The cheapest pharmaceutical in the therapeutic group sets the reimbursement limit for the whole group. If there is cross-limiting between different substances and molecules in the group, a defined daily dose (DDD) system is used for the calculations. There is no automatic reimbursement procedure after the approval (market authorisation). The producer, or rather the market authorisation holder (MAH) – prepares the reimbursement application and submits it to the Ministry of Health (MoH). The Minister of Health is addressed in the proposal and the procedure is then delegated to the Pharmaceutical Policy and Pharmacy Department of the Ministry of Health (MoH). The whole decision-making process is regulated in two legal acts the Pricing Law and the Law on services of public health care financed from public sources, and several acts of a lower reference level, i.e. the appropriate ordinances of the Minister of Health.

The Pharmaceutical Management Team was set up according to the Pricing Law (cf. Table 2.1). It combines representatives of the Ministry of Health (MoH), Ministry of Finance (MoF), Ministry of Economy and the National Health Fund (NHF). Activities of the Team are managed by the Deputy Minister of Health, and their role is to agree on the reimbursement of pharmaceuticals. The Team sets official prices for the pharmaceuticals to be reimbursed, as well as reference prices, therapeutic groups and reimbursement limits (a reimbursement limit is not strictly a reference price – it may differ, but is usually also set by looking at other prices that are considered as references); at the end of process the Team give their recommendation(s) to the Minister of Health, who grants final approval of the reimbursement list and issues it as a Minister of Health Ordinance on pharmaceutical reimbursement. Price negotiations are only possible with Ministry of Health (MoH) representatives. During proceedings, the Team usually seeks expert advice and National Consultants are involved in such discussions.

Patients' organisations, expert panels in professional scientific societies, pharmaceutical industry representatives and public opinion (voters) can try to influence reimbursement decisions.

Over-the-counter (OTC) pharmaceuticals are exempt from reimbursement. The system described above covers the whole country. As described in 3.1, 3.2 and 3.2.1, reimbursement de-

cision-making is a parallel process to official pricing and is carried out by the same group of stakeholders.

The set of documents required for submission for reimbursement and pricing is declared in the relevant Minister of Health's ordinance and includes data on: first registration/approval date, expiry date of approval certificate, patent status and its expiry date, reimbursement status in other countries (by the submitting party's choice, the party submitting the documents is the market authorisation holder (MAH)), price in the country of manufacture, proposed price for Poland, and prices in other European countries (as described in 3.3.1: Belgium, the United Kingdom, Ireland, France, Germany, the Netherlands, Sweden, Denmark, Spain, Portugal, Italy, Greece, the Czech Republic, Hungary, Luxembourg, Lithuania and Switzerland). Also, information on the manufacturing costs for a single pack is required and recently, pharmacoeconomic analyses have been included into the set of required papers to support the reimbursement application (with no pharmacoeconomic analyses the submission is considered incomplete and is not processed at all). Clinical effectiveness, cost-effectiveness and budget impact analyses are required (for therapeutic programme (TP) applications and hospital procedures as well).

Reimbursement status, once granted, does not usually change unless the therapy is no longer used, the pharmaceutical is too expensive or the market authorisation holder (MAH) submits an application for it to be de-listed.

The procedure that precedes reimbursement changes (e.g. de-listing, cut offs because of price cuts and others) is always determined ad hoc and usually communicated in "Communicate" of the Minister of Health (an act of no legally binding value).

Details of the reimbursement scheme are listed here.

- The scheme (cf. 4.1) was introduced in 2002/2003. The scheme that existed before that was very similar; instead of the Pharmaceutical Management Team there was the Reimbursement Committee within the Ministry of Health (MoH), consisting of experts of different therapeutic fields, empowered by the Minister of Health, that made reimbursement decisions.
- The scheme as it functions at the time of writing covers approximately 80% of prescriptions issued and is beneficiary to approximately 99% of population – all the insured that use pharmaceuticals in some capacity are reimbursed either fully or partially.
- Special reimbursement of a different formulation of a pharmaceutical because of an individual patient's problems is not applicable, although for diseases that may cause swallowing problems, a liquid form of the pharmaceutical can generally be reimbursed.

4.1.1 Eligibility criteria

Where the reimbursement list is concerned, the Ministry of Health (MoH) Pharmaceutical Management Team categorises pharmaceuticals into proper reimbursement levels. Depending on the reimbursement indication, a pharmaceutical is likely to be placed in the appropriate cluster, e.g. pharmaceuticals for Parkinson's disease reimbursed at 70%, pharmaceuticals for menopause reimbursed at 50% and those for epilepsy reimbursed fully (without even lump-sum payment). No clear criteria have been articulated. Certain diseases are considered to be the most

urgent to treat in Poland, i.e. oncological disorders, epilepsy and cardiovascular conditions. Oncology and epilepsy pharmaceuticals are fully reimbursed, while cardiovascular pharmaceuticals only have 50% reimbursement. Life-saving therapies are usually reimbursed at 100% (e.g. insulin injections for diabetes).

The company may appeal to the Ministry of Health (MoH) using the appeal procedure.

Table 4.1: Poland - Reimbursement of pharmaceuticals

Reimbursement category	Reimbursement rate	Characteristic of category
List of supplementary pharmaceuticals	50%	Disorders such as menopause, cardiovascular disorders, hypertension
List of supplementary pharmaceuticals	70%	Disorders such as Parkinson's disease, Alzheimer's disease, etc.
List of basic pharmaceuticals	Full lump sum of PLN 3.20	E.g. Antibiotics
List of pharmaceuticals for specific indications	Full, 100% with no lump-sum payment	Disorders such as epilepsy, oncological disorders, diabetes

Source: Ministry of Health

There are no specified inclusion criteria for each group. Life-saving therapies are likely to be reimbursed fully. Others are likely to remain in line with tradition. Special cases (i.e. reimbursement rate for vulnerable patients) are described in 4.4.

4.2 Reimbursement lists

There is a positive list ("reimbursement list") in place. No negative list of pharmaceuticals has been issued in Poland at the time of writing. There is negative list of health services not to be covered by the public mandatory insurance, but this does not concern pharmaceuticals.

There is no automatic reimbursement procedure after the approval (market authorisation). The producer, or rather the market authorisation holder (MAH) – prepares the reimbursement application and submits it to the Ministry of Health (MoH). The Minister of Health is addressed in the proposal and the procedure is then delegated to the Pharmaceutical Policy and Pharmacy Department of the Ministry of Health (MoH). The whole decision-making process is regulated in two legal acts the Pricing Law and the Law on services of public health care financed from public sources, and several acts of a lower reference level, i.e. the appropriate ordinances of the Minister of Health.

The Pharmaceutical Management Team was set up according to the Pricing Law (cf. Table 2.1). It combines representatives of the Ministry of Health (MoH), Ministry of Finance (MoF), Ministry of Economy and the National Health Fund (NHF). Activities of the Team are managed by the Deputy Minister of Health, and their role is to agree on the reimbursement of pharmaceuticals. The Team sets official prices for the pharmaceuticals to be reimbursed, as well as reference prices, therapeutic groups and reimbursement limits (a reimbursement limit is not strictly a ref-

erence price – it may differ, but is usually also set by looking at other prices that are considered as references); at the end of process the Team give their recommendation(s) to the Minister of Health, who grants final approval of the reimbursement list and issues it as a Minister of Health Ordinance on pharmaceutical reimbursement. Price negotiations are only possible with Ministry of Health (MoH) representatives. During proceedings, the Team usually seeks expert advice and National Consultants are involved in such discussions.

The list is not updated regularly, although it is requested that this be carried out a minimum of twice a year by law (Law on health care services financed from public sources, 2004).

There is no category of conditional temporary reimbursement for pharmaceuticals not fulfilling all criteria for inclusion in the reimbursement list.

Specific procedures for reimbursing pharmaceuticals in hospitals (equal to nursing homes in terms of legal status) are described in detail in 4.1.

4.3 Reference price system

Pricing and reimbursement approval procedures run parallel to each other, overseen by the same bodies (cf. 3.1 and 3.2.)

Since 1998 there has been a reference pricing system in place in Poland. The legal framework is the same, as described earlier, governed by the Law on health care services financed from public sources, and the Pricing Law. In the first, criteria are defined for inclusion into reference price groups (either pharmaceuticals with the same active ingredient or therapeutic groups) with a common reimbursement limit: same dosage, pack size, method of administration, and – in the case of therapeutic groups – similar therapeutic indications (“similar” is not defined clearly; in practice, Anatomic Therapeutic Chemical (ATC) classification level 5 and sometimes level 4 are included (cf. 3.3.2)). The reference price (reimbursement limit) is in general equal to the price of the cheapest available pharmaceutical. Dose equivalency is defined by the defined daily dose (DDD) system. Pricing is essentially equal to setting the reimbursement price limit, based on the price of cheapest molecule in the group, then calculated using the defined daily dose (DDD) proportion for other substances.

Doctors are allowed to prescribe pharmaceuticals priced above the set reimbursement limit and patients co-pay the difference. In addition, generic substitution is allowed in pharmacies, but only the same molecule can be substituted; changing the molecule, even for one of the same therapeutic group, is prohibited (cf. 5.5.1).

As described before, the relevant authorities are the Ministry of Health (MoH) and the Pharmaceutical Management Team. No parallel traded pharmaceuticals are eligible for reimbursement in Poland.

4.4 Private pharmaceutical expenses

Private pharmaceutical expenditure (PE) totals approximately 40% of total pharmaceutical expenditure (TPE), including co-payments for reimbursed pharmaceuticals and payments for pharmaceuticals that are not covered by the public health insurance.

Decisions on private spending are made by doctor and patient: the doctor can propose a pharmaceutical that is not reimbursed and patient then decides if they want to purchase it or not. If not, the doctor prescribes a pharmaceutical from the reimbursed list.

In terms of reimbursed pharmaceuticals, the patient can always ask the doctor to prescribe a cheaper product of the same therapeutic group or a cheaper generic product. Also, a generic substitution is allowed in pharmacies but only with generics. When this occurs, the substitute must contain the same molecule in the same dose, with the same pack size and the route of administration must be the same. This is only allowed if doctor does not indicate otherwise on the prescription (i.e. "NZ" ("Nie zamieniac"), meaning "Do not substitute").

There are no mechanisms to educate patients about rational consumption of pharmaceuticals. Indirect tools include a lump-sum payment and some levels of co-payment required for most reimbursed pharmaceuticals – patients will think twice before building up a "private stock" of reimbursed pharmaceuticals at home that often expire before being administered for treatment.

Changes in the co-payment system are ongoing. The cost-containment policy for payers and decision-makers is intended to limit pharmaceutical usage and is going to ensure better control of reimbursement spending that is growing year on year. There are, however, some mechanisms to protect some vulnerable groups of patients and these can be found in the construction of the reimbursement list. The list, as mentioned in 4.2.2. is divided into three general sections according to different levels of reimbursement: 100%, 70% and 50%. However, there are also some additional reimbursement clusters designed especially for particular groups of patients, e.g. for cancer patients, epileptic patients or for war veterans. These groups of patients have pharmaceuticals prescribed completely free of charge (normally with full reimbursement, but a required lump-sum payment of PLN 3.20 per pack). This is the case for epileptic or cancer patients when it comes to pharmaceuticals used in this particular indication. War veterans that are also disabled are entitled to be given any pharmaceutical free of charge (even if it is a very expensive therapy that is not included in any reimbursement list).

4.4.1 Direct payments

Pharmaceuticals of new classes that are not reimbursed must be paid for directly by patients (meantime in Alzheimer's disease, entacapone in Parkinson's disease, Keppra in epilepsy). No over-the-counter (OTC) pharmaceuticals are reimbursed. There are no data sources on average payments – these are not set.

4.4.2 Out-of-pocket payments

There are no deductibles within payments for pharmaceuticals in Poland. Out-of-pocket payments (OPP) and co-payments have been described in detail earlier (cf. 1.4.2; 2.1.1.1; 2.1.2.1; 2.1.3.6; and 3.2.1).

Table 4.2: Poland - Reimbursement rates and patient co-payment rates 2006

Reimbursement classification	Co-payment	Reimbursement
100%	PLN 3.20	100% – PLN 3.20
100% in specific indication (e.g. oncological disorders, epilepsy, glaucoma, diabetes)	0	100%
70% (specified indications such as Alzheimer's disease, Parkinson's disease)	30%	70%
50% (specified indications such as menopause, hypertension)	50%	50%

Source: Polish Reimbursement List, July 2006

4.4.2.1 Fixed co-payments

There is no prescription fee used in Poland. Pharmacies are remunerated via their margins (in case of reimbursable pharmaceuticals, reimbursed by the National Health Fund (NHF)).

For most fully reimbursed pharmaceuticals, a lump-sum payment of PLN 3.20 is applied per pack of pharmaceutical. There is no monthly or annual ceiling set to be spent by the patient.

4.4.2.2 Percentage co-payments

No annual or monthly ceiling co-payment is set. A minimum co-payment is set, not as a percentage, but rather as a lump sum of PLN 3.20 per pack (with certain exceptions).

A percentage co-payment is dependent on the reimbursement category in which the pharmaceutical is placed (50%, 70% or 100%).

Also, reimbursement limits exist in Poland. In the event that a prescribed pharmaceutical exceeds the reimbursement limit, patients have to co-pay the remaining 50% or 30% of the reimbursement limit (depending on the category of the list the pharmaceutical is in) and then the difference between the two prices (the pharmaceutical price and the limit).

4.4.2.3 Deductibles

There are no deductibles within spending on pharmaceuticals in Poland.

4.5 Reimbursement in the hospital sector

Reimbursement of pharmaceuticals is described in detail in 2.2.1 and 4.1.

A total of 32.5% (PLN 6.5 billion) of total pharmaceutical expenditure (TPE) is spent within hospitals (fully reimbursed to patients, as they do not pay for pharmaceuticals in hospitals, nor are these reimbursed by the National Health Fund (NHF) separately, even of in the reimbursed list – in-patient pharmaceuticals are paid for from hospital budgets).

Pharmaceuticals reimbursed in hospitals, whether included in the general reimbursement list or not, are fully paid for by the hospitals: a therapeutic decision is made by the administering doctor and, depending on the cost of the pharmaceutical, with the director of hospital (no threshold set, no clear transparent procedure). Some pharmaceuticals that are neither reimbursed by the list nor within certain therapeutic programmes (TP) (cf. 4.1) can be administered in a hospital and paid for by the National Health Fund (NHF), if an agreement is made to that effect with the National Health Fund (NHF) (a kind of individual consent). In the hospital procedures catalogue there is the item “non-standard pharmacotherapy”, with no value assigned to it: based on individual consent, the hospital will include this item, with an appropriate agreed value, into the accounting documents submitted to the National Health Fund (NHF). There is no transparent procedure on this kind of reimbursement and there are no criteria as to which pharmaceuticals this method applies to and which it does not; usually, expensive pharmaceuticals are reimbursed using this method.

If administered in hospital, all pharmaceuticals are fully reimbursed – paid for by the hospital. The hospital budget is contracted with the National Health Fund (NHF), which means that ultimately, the payer is the National Health Fund (NHF). There are no deductibles. Some hospitals have introduced their own formularies, issued by the hospitals’ management teams, listing recommended pharmaceuticals to be used by employed doctors. This is to minimise costs of pharmaceutical spending.

4.6 Reimbursement-related cost-containment measures

4.6.1 Major changes in reimbursement lists

As described earlier, new reimbursement lists have been introduced many times since the mid-1990s. The most recent innovations (those pharmaceuticals entering the reimbursement list for the first time) were introduced into the reimbursement list in 2007.

There have been no major changes in terms of quality of the list, but many in terms of volume. As for quality, a “cleaning” of the lists was started in 2002 and many pharmaceuticals were de-listed (molecules that were reimbursed but not used in therapeutic standards/traditions (there are not many standards, official guidelines or procedures in Polish medicine)). Some molecules that were considered to be of unproven efficacy were also de-listed (e.g. Calcitonine salmonis for nasal administration, a particularly controversial medicine at that time).

Later, changes took place aimed at cost-minimisation. The list grew in volume, with the introduction of many new generic products (registered in Poland in national procedure, very quickly, before European Union (EU) accession). This allowed reimbursement limits to be set for original products and also enabled decision-makers to establish therapeutic groups of common reimbursement limits (price reference groups). When this was done, a price cut off was imposed; new official prices were proposed to the industry and if they were not accepted by the market authorisation holders (MAH), de-listing was carried out. The general rule was that pharmaceuticals more than 50% more expensive than the price of the cheapest generic substance in the reference group were cut off.

Accessibility to pharmaceuticals increased together with the introduction of cheaper generics (e.g. pharmaceuticals reimbursed with 50% or 70% co-payments in absolute value decreased, allowing many patients to start such treatment) – the market was growing in volume.

Further price cuts were imposed, based on PLN appreciation – a 13% official price decrease was proposed to all members of industry that had official prices of their reimbursed products set before 1 January 2004. The list of lower prices was introduced in July 2006. The most recent changes to the reimbursement list were made in March 2007, when, by way of an ordinance, the Minister of Health issued the updated reimbursement list. That ordinance was issued on the basis of the Law on health care services financed from public sources. Two expert teams worked on that reimbursement list. One of the teams was obliged to have new molecules analysed, for which applications for reimbursement were submitted. The team analysed them according to pharmacoeconomic factors, and had to decide which of them were innovative molecules that would not increase reimbursement costs, as well as which could generate some savings. The other team analysed new substances according to their clinical properties. The teams' work was joined and two groups of substances emerged: a group of that, if brought into the reimbursement list, would not cause spending to increase and a group for which inclusion into the reimbursement list would generate additional costs. Price negotiations were then carried out. A total of 211 new, first generics (in the group, after the original products), were included within that particular ordinance, divided into 12 active substances; 265 new generics were included in 58 active substances and 49 original products were introduced (12 new active substances).

At the time of writing, reimbursement spending seems to have stabilised and new molecules are expected for introduction to the new list (probably together with their generics).

4.6.2 Introduction / review of reference price system

There are no formal procedures for reference pricing in Poland. Anatomic Therapeutic Chemical (ATC) level 5 is taken into account, and sometimes even Anatomic Therapeutic Chemical (ATC) level 4 as well. There is no reimbursement for parallel traded pharmaceuticals yet, although this is planned.

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

There have been no changes in out-of-pocket payments (OPP) since the mid-1990s. Patients need to pay a proper co-payment of 50% or 30%, depending on the reimbursement level

granted for the pharmaceutical concerned, and if a pharmaceutical is more expensive than the reimbursement limit price, the patient must pay the difference between the prices, in addition to the 50% or 30% co-payment (cf. 1.4.2; 4.1; 4.2.3; and 4.4.2.2).

4.6.4 Claw-backs

For information on claw-backs, cf. 2.1.3.6. In some pharmacies patients are “paid” for shopping there, e.g. if a patient buys her/his medicine there the pharmacist can divide his margin between the pharmacy and the patient and give some of it, in cash form, to the patient, together with the desired pharmaceutical (part of the reimbursable margin is therefore recouped, as a kind of claw-back). Such a situation seems to be obviously illegal, but it is not strictly prohibited by the law and so the Chief Pharmaceutical Inspector finds no basis on which prosecute. However, the Tax Office would be interested in such a source of “income” and how it is taxed – or rather, why it is not taxed. This is not a widely used promotional tool but the mechanism is enabled and it is difficult to be proven as illegal, as margins are set as a maximum and are therefore divisible.

4.6.5 Reimbursement reviews

Reimbursement decisions are required by law to be updated twice a year, as described in 2.1. The Minister of Health is to approve reviews. Reviews are not published.

Until recently, reviews were carried out to achieve certain goals, e.g. minimising the cost of reimbursement. Criteria were therefore set ad hoc before each of the planned changes to the lists.

Anyone can request a reimbursement decision review and supply proper documentation. Most interested parties are doctors, scientific societies and pharmaceutical companies.

5 Rational use of pharmaceuticals

5.1 Impact of pharmaceutical budgets

There are no obligatory budgetary constraints for prescribing doctors. The only measure that is sometimes checked is compliance with the reimbursement indications in the list and this happens when a lot of prescriptions are written by the same doctor for one specific reimbursed pharmaceutical. When this happens, a special inspection is carried out by the National Health Fund (NHF) at the prescriber's practice to find out from patient files if reimbursement is entitled and in accordance with the reimbursement list.

If any incorrectness in clinical records (i.e. reimbursement indications) come to light, the doctor is obliged to pay back the sums spent on inappropriate reimbursement. There are not usually further sanctions.

Doctors are given guidelines by the National Health Fund (NHF), similar to a reimbursement top 10 or equivalent benchmarks; they are classified according to the general reimbursement rules and according to the specialisation.

Prescribing is the same in the out-patient sector as in hospitals. Prescription of narcotics (like morphine) is restricted to hospitals and a limited number of licensed doctors, but reimbursement of such pharmaceuticals does not differ. Reimbursement in pharmacies, as per the list, is delivered to the National Health Fund (NHF) by the pharmacy. In hospitals, patients are given pharmaceuticals free and these are paid for from the hospitals' budgets; if a patient leaving hospital is given a prescription it is reimbursed in an open pharmacy in the usual way and dispensing pharmaceuticals from hospital for out-patient use is not allowed.

Changes in these terms are in the planning stage at the time of writing. When a specialists' ordination list is introduced (for reimbursement only in case of prescription by certain specialists), a problem with chronically ill patients is likely to occur, as access to specialists is limited and for certain chronic diseases, one visit to a specialist in six months is enough. Therefore, general practitioners (GPs) should be allowed to continue, once treatment has been initiated by the specialist. However, proper tools to control this complex method of reimbursement have not yet been developed to a level that is efficient.

5.2 Prescription guidelines

Basically there are no prescription guidelines in Poland in terms of reimbursement or budget control.

There are therapeutic guidelines from doctors' professional and scientific societies that also include pharmacotherapy. These often do not correlate with the realities of reimbursement.

Doctors' prescribing is monitored for compliance with reimbursement indications, as described in 5.1. Also, there are some general rules of prescribing: doctors are allowed to prescribe five

different pharmaceuticals per prescription; some pharmaceuticals must be prescribed as the only pharmaceutical per prescription (those with central effects) and the amount of pharmaceutical prescribed shall not exceed one month of therapy according to the dosage indicated by the doctor.

There are no regular audits for doctors. Therapeutic guidelines issued by professional and scientific societies of doctors are announced in conferences, congresses or symposia, and/or published later in the professional press. Guidelines among other scientific materials from conferences are often delivered to doctors by medical representatives of pharmaceutical companies.

Inter alia, information on duration of therapy and dosage limits is something that doctor learns about while practising; some prescriptions are simply not reimbursed and patients come back from a pharmacy with feedback on what went wrong with the prescription.

5.3 Information to patients / doctors

In Poland all provisions of the European Union (EU) Pharma Review are implemented with regard to pharmaceutical marketing. Advertising of over-the-counter (OTC) pharmaceuticals is allowed to patients, as well as via the Internet (unlike prescription-only medicine(s) (POM)). The provisions of the Pharmacy Law regulate pharmaceutical advertising.

There is no control over manufacturers' promotional spending. Certain tools are intended to be introduced, e.g. a certain percentage of the company's income (rather than a budget ceiling). Also, ideas are being raised repeatedly on total prohibition pharmaceuticals promotion, along with prescription-only medicine(s) (POM) for doctors. Some decision-makers propose publicly that contact between medical representatives and doctors should be prohibited and sponsored attendances at medical conferences should be punished, but only when such contact is illegal, i.e. has a background based in corruption. At the time of writing, doctors who attend conferences or receive medical books of a value over PLN 100 (gross) are obliged to pay income tax on these items. This is commonly obeyed.

As for samples, there are some restrictions: only the smallest pack of a pharmaceutical can be given out as a sample, and one doctor can only receive five packs of one kind of sample per year (doctors confirm acquisition of samples on special forms). The Chief Pharmaceutical Inspector is obliged to monitor this and is entitled to carry out appropriate monitoring/inspections.

No action is taken to inform patients on the rational use of pharmaceuticals in Poland. Sometimes doctors or pharmacists explain, but nothing is available in the form of a written publication.

5.4 Pharmacoeconomics

Pharmacoeconomic data are not required for the approval procedure if the pharmaceutical has gone through the national registration procedure. Nor are they necessary for obtaining market authorisation.

Pharmacoeconomic analyses are required as an integral part of the reimbursement dossier, for the list, for therapeutic programmes (TP) or for hospital procedures (cf. 2.1.3.1 and 4.1). This is based on the Law on health care services financed from public sources, the appropriate ordinance of the Minister of Health (reimbursement list), an Edict of the President of the National Health Fund (NHF) (therapeutic programmes (TP)) and an Edict of the President of the state Agency for Health Technology Assessment (AOTM) (for hospital procedures). In all cases, three types of analysis are required:

- clinical effectiveness analysis
- cost–effectiveness analysis
- budget impact analysis.

As over-the-counter (OTC) pharmaceuticals are generally not reimbursed in Poland, these analyses are not required for that type of pharmaceutical. As for other pharmaceuticals, independently of the type of reimbursement, the same types of analysis are required (unless it is not possible to perform a full cost–effectiveness analysis for some reason; sometimes a cost–consequence analysis can be submitted instead of cost–effectiveness, but at the time of writing there are no legal regulations on this).

For pricing procedures, only the budget impact is taken into account and usually only the simplified budget impact analysis that unfortunately does not take into account health outcomes and their value in terms of savings.

Health economics documents are required for submissions to the reimbursement list, as of 2004. The submitting party is responsible for preparing the proper analyses. The Agency for Health Technology Assessment (AOTM) checks the quality and credibility of the submitted papers, rather than producing their own, as there is too much work to be done, and quickly, with defining a list of guaranteed health care services, which is the Agency's main task. There are also companies that can prepare such analyses commercially.

A Polish guideline on economic analyses, to be introduced in April 2007, is proposed by the Polish branch of ISPOR (International Society for Pharmacoeconomics and Outcomes Research).

5.5 Generics

Legal regulations allow generic substitution in pharmacies (cf. 2.1.2.1; 2.1.3.6; 4.3; and 4.4).

Also, a regulation (not legally binding, in the form of a “Communicate”) sets out the rules for the introduction of generics to the reimbursement list and establishment of therapeutic groups (TP) in the list with a common reimbursement limit. This is the principal way in which generics perceived as a cost-containment tool are manifested.

Use of generics is relevant in both the out-patient and in-patient sectors, although there are no consolidated data on this. Still, some hospitals create formularies and these usually contain generics, due to their much lower cost.

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

Generics market share	2000	2001	2002	2003	2004	2005
Volume (no. of packs sold per year in Mio.)	1,190.29	1,160.74	1,069.60	1,078.46	1,051.15	1,067.34
Value (in Mio. PLN)	6,308.36	6,918.97	7,141.04	7,914.87	8,323.33	9,027.31

Source: IMS Data View 03/2007, © 2007 IMS Health Incorporated or its affiliates

In Poland, many generics were introduced into the local market just before the country's accession to the European Union (EU). Some pharmaceuticals have not been marketed, although they have been approved.

5.5.1 Generic substitution

Generic substitution is allowed and the legal basis for it is described in 2.1.2.1, 2.1.3.6, 4.3 and 4.4. Generic substitution in pharmacy is allowed but only with generics and not products with molecules from the same therapeutic group. In such a case, the substitute must contain the same molecule in the same dose, the pack must be of the same size and the route of administration must be the same. This is only allowed if the doctor does not indicate otherwise on the prescription (i.e. "NZ" ("Nie zamieniac"), meaning "Do not substitute").

5.5.2 Generic prescription

There is no official demand for generic prescription, although ideas like this have been raised. Doctors do not profit from prescribing generics. They are allowed to prescribe as they see fit – by generic name, brand name or International Nonproprietary Name (INN). Pharmacists are obliged to inform patients of the possibility of receiving the cheaper counterparts of the pharmaceuticals.

5.5.3 Generic promotion

No promotion among patients of prescription (Rx) pharmaceuticals is allowed in Poland. Generics are promoted among doctors, carried out as usual by pharmaceutical companies. Generics are also promoted among pharmacists, as generic substitution in pharmacies is allowed (cf. 2.1.2.1; 2.1.3.6; 4.3; 4.4; and 5.5.1).

Generics are promoted for a variety of reasons: to ensure access for patients to a greater variety of pharmaceuticals; to support local generic manufacturers; and for cost-containment reasons. Also, as generics are cheaper they allow even less wealthy patients to undergo certain therapies, due to the fact that the required co-payments are reduced together with the price decreases. One of the promotional messages in generics marketing strategies is cost-containment or savings for the state budget.

5.6 Consumption

Individual consumption of pharmaceuticals is essentially not monitored, or rather, it is monitored but there are no consequences as a result of this monitoring. The National Health Fund (NHF) monitors prescriptions and reimbursement spending assigned to war veterans and those disabled as a result of military service. The information is updated monthly; pharmacies have to report all prescriptions to the National Health Fund's (NHF) regional branch office.

A document has been produced called the Green Book (Zielona Ksiega¹). It is a general policy statement on essential pharmaceutical and health system policy in Poland. Unfortunately, it was produced before the most recent elections and it is not known if anything from this document will ever be implemented.

¹ See> http://www.mz.gov.pl/wwwfiles/ma_struktura/docs/raport_zk_211204.pdf

6 Current challenges and future developments

6.1 Current challenges

More formal and rigid procedures need to be introduced into the Polish pharmaceutical system in all aspects of its operations: approval procedures, pricing procedures and reimbursement procedures. These aspects should be introduced through:

- clarified, published procedures;
- the possibility to take decisions to independent institutions of higher instance;
- “silent approval”, in case of the lack of an official answer regarding officially submitted papers.

6.2 Future developments

As Poland is a health system in transition there are many changes either being discussed, that have just been decided upon or that are just being implemented. Most important are:

- Setting up of the state Agency for Health Technology Assessment (AOTM), carried out by the Minister of Health's edict of 1 September 2005, following one of 30 June 2006. The Agency for Health Technology Assessment (AOTM) is at the time of writing educating and training employees as there are not many pharmacoeconomists in Poland. The first strategic and political task is already assigned to the Agency for Health Technology Assessment (AOTM) by the Ministry of Health (MoH) – drawing up a list of health care services guaranteed within the public social health insurance (SHI).
- Drawing up a list of health care services guaranteed within the public social health insurance (SHI) will allow a basic level of health safety within the defined budget; this will also allow equality of citizens' access to health care. Once the services are defined a market for voluntary health insurance (VHI) will consequently be defined as well.
- Setting out criteria – the Agency for Health Technology Assessment (AOTM) has defined a decision-making process of inclusion of health services into a list of guaranteed services. A guideline for economic assessment has already been established and is available on the Agency for Health Technology Assessment AOTM web site². When the system or process is defined and transparent it will be applied to all decision-making issues in health care, including pharmaceutical technologies (some of which are currently being assessment by the Agency for Health Technology Assessment (AOTM) among other hospital health services) and the reimbursement list. The decision-making process of the Agency for Health Technology Assessment (AOTM) can be seen in Figure 6.1, with the specific criteria and thresholds remaining undefined for the time being.

² www.aotm.gov.pl

- Guidelines for economical analyses were prepared by the Agency for Health Technology Assessment (AOTM), as health technology assessment (HTA) is becoming increasingly more important in the decision-making process (official reimbursement submission requirements include clinical effectiveness, cost-effectiveness and budget impact analyses to be submitted as part of the reimbursement application).
- Fixed margins for wholesalers and pharmacies which are currently under discussion (those provisions are placed in the new Pharmaceutical Law) will allow better control of marketing tools for pharmaceuticals (discounts/rebates). Prices for reimbursed pharmaceuticals are official and, due to price referencing, price decreases are not welcomed by the industry. Therefore, reducing margins (based on contracts with manufacturers, wholesalers and retail pharmacies) is a convenient way of lowering the final cost of pharmaceuticals. When margins are fixed this will not be possible anymore. Generic pharmaceuticals can easily compete by lowering even official prices, as there is not much cross-country referencing for generics.
- Together with above change in the Pharmaceutical Law, another change is planned on the legal categorisation of pharmaceuticals ("legal and administrative status" of a pharmaceutical). For the time being, pharmaceuticals are categorised as Rx (prescription only) and Lz (hospital only), but unfortunately not all pharmaceuticals are assigned to the right categories. The update of the Pharmaceutical Law is meant to change this and to introduce new classes, i.e. "restricted prescription only" for pharmaceuticals to be qualified as for specialists' ordination only. However, there are other corresponding laws that will also have to be changed to enable the changes in the Pharmaceutical Law to be effective in its execution.
- Restriction of prescription of pharmaceuticals to specialists' ordination only is planned (in order to control reimbursement pharmaceutical spending), although there are no tools in place as yet to effectively monitor the correlation between prescribing, patient diagnoses and the prescribing doctor's specialisation.
- A register of medical services (e-card) provided is under construction and will allow the fast identification of a patient, monitoring of pharmaceuticals prescribed and other health services supplied.

7 Appendixes

7.1 References

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2. Kotula Z. Polish pharmaceutical market in 2003. (Polski rynek farmaceutyczny w roku 2003). *Lek w Polsce*, Vol 14 nr 6/04.
3. IMS Data View, IMS Health Incorporated or its affiliates. (All rights reserved.)
4. OECD. OECD Health Data 2006. Paris, Organisation for Economic Co-operation and Development, 2006.
5. WHO. Working together for Health. The World Health Report 2006. Geneva, World Health Organization.

7.2 Further reading

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2. Kuszewski K, Gericke CH. *Health Systems in Transition: Poland*. Brussels, European Observatory on Health Systems and Policies (Vol. 7 No.5), 2005.
3. OECD. Economic Survey Poland. Paris, Organisation for Economic Co-operation and Development, 2004.
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8. J, Groyecki K, Nowicki D. Wpływ polityki lekowej na dostępność leków oraz finanse publicznej ochrony zdrowia. *Zdrowie i Zarządzanie*, No.6/2001, p.89.

9. National Health Bill 2006. Central Statistical Office, 2006.

7.3 Web links

Most legal acts on the Polish reimbursement system can be found on the Internet – please use the web links listed here.

- Ministry of Health (MoH): <http://www.mz.gov.pl/>
- National Health Fund (NHF): <http://www.nfz.gov.pl>
- Medicinal Products, Medical Devices and Biocides Registration Office: <http://www.urpl.gov.pl/>
- Agency for Health Technology Assessment (AOTM): <http://www.aotm.gov.pl/>
- Chief Pharmaceutical Inspectorate: <http://www.gif.gov.pl/>
- Parliamentary Health Commission: http://www.sejm.gov.pl/komisje/www_zdr.htm
- National Institute of Public Health: <http://www.il.waw.pl/>
- Poland's Pharmaceutical Policy, document from 2004:
http://www.mz.gov.pl/wwwfiles/ma_struktura/docs/plekp2004_2008_230304.pdf
- Report of Polish Health Care Insurance System "The Green Book":
http://www.mz.gov.pl/wwwfiles/ma_struktura/docs/raport_zk_211204.pdf
- Ministry of Health (MoH) Directive on Agency for Health Technology Assessment establishment: http://www.aotm.gov.pl/pliki/spr/pl/zarzadzenieMZ_AOTM.pdf
- Ministry of Health (MoH) Directives on Lists of Reimbursed Medicines – archive of acts and current List: <http://www.mz.gov.pl/wwwmz/index?mr=b4&ms=0&ml=pl&mi=0&mx=0&ma=2151>
- Ministry of Health (MoH) Directives on medicines – prescriptions, reimbursement lists, parallel trade, others – archive:
<http://www.mz.gov.pl/wwwmz/index?mr=b4&ms=311&ml=pl&mi=311&mx=6&ma=55>

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