ÖBIG FORSCHUNGS- UND PLANUNGSGESELLSCHAFT mbH

ACCESS TO ESSENTIAL MEDICINES IN POLAND

COMMISSIONED BY
HEALTH ACTION INTERNATIONAL EUROPE

ACCESS TO ESSENTIAL MEDICINES IN POLAND

August 2009

ÖBIG Forschungs- und Planungsgesellschaft mbH

Christine Leopold
Sabine Vogler

Acknowledgements

We would like to express our appreciation to Mr. Jakub Adamski and his colleagues from the Ministry of Health. Thanks to their contributions, which they have provided within short time, this report contains the most up-dated statistical data available and information on the current situation as of August 2009.

Finally, our thanks go to Ms. Teresa Leonardo Alves and Ms. Katrina Perehudoff of Health Action International (HAI) Europe for contacting us and involving us in this remarkable project. We look forward to continuing this cooperation.

Executive Summary

Access to essential medicines is a human right. Each government should develop a regulatory framework to implement the right to health, including access to medicines.

The Austrian Research Institute ÖBIG Forschungs- und Planungsgesellschaft mbH (ÖBIG FP) was commissioned by the patients' advocacy organisation Health Action International (HAI) Europe to investigate the pharmaceutical reimbursement system in Poland in relation to access to essential medicines.

The Polish health care system is organised as a Social Health Insurance system that covers the whole Polish population, generating its funds through employee contributions.

The Polish reimbursement system in the out-patient sector is based on a positive list, which includes around 3,380 medicines. Patients contribute a co-payment for medicines, which depends on the product as well as the indication. The co-payment rates are 30% and 50%. For medicines included in the basic list, e.g. antibiotics, patients pay only a one-time co-payment of PLN 3.20 / € 0.77. However, there is also a list of medicines for specific diseases such as epilepsy, cancer and diabetes, which are free of charge for patients. In contrast, in-patients receive treatment for free, without a co-payment.

There are further regulations for vulnerable groups such as war veterans, who receive their treatment free of charge.

The Ministry of Health is responsible for reimbursement and pricing decision about medicines. The Ministry of Health is advised by the Drug Management team, who is in charge of the evaluation of the reimbursement application. The reimbursement application should include cost-effectiveness, clinical effectiveness and budget impact studies. In addition, the Health Technology Assessment Agency evaluates new expensive molecules and provides advice to the Ministry of Health. In general, medicines with excessive prices or low therapeutic efficacy are not reimbursed. Over the counter (OTC) products are not usually reimbursed.

In recent years, Poland has struggled to fully comply with the EU Transparency Directive. After an EU Twinning Project with France, Poland has implemented more transparent reimbursement criteria as well as stricter timeframes for reimbursement decisions.

With regard to the implementation of measures to promote the use of generics, Poland has already successfully achieved some outcomes. The generic market share has been quite high and remained stable over the last few years with 75% in 2008 (in volume) and 59% in value in 2008. Doctors are allowed to prescribe by INN and generic substitution by pharmacists is also permitted.

In terms of the transparency of medicines prices and levels of co-payment, the Ministry of Health offers a very well structured website. The prices of all reimbursable medicines are easily accessible and patients can obtain information on the levels of co-payment.

Currently, the Polish pharmaceutical system is undergoing reform. The legal basis for pricing and reimbursement has been redrafted by introducing more transparent criteria as well as a more unified process. It is expected that the new law will come into force by autumn 2009.

Overall, the authors consider the pharmaceutical reimbursement system in Poland to be sustainable, with a clear regulatory framework, which in general, guarantees patients access to essential medicines. However, the high co-payments are a weak point that may prevent some patients from buying high-cost medicines. This could be resolved by stronger patient demand for generics. However, patients may not be aware of the possibility of accessing the same product but at a lower price.

As an accompanying measure the authors recommend that the pharmaceutical system and rationale behind measures is better explained to patients, which may an area where civil society could play a bigger role.

Table of contents

List of tables and figures

List of abbreviations

ATC	Anatomic therapeutic chemical classification
AOTM	Agencja Oceny Technologii Medycznych / Health Technology Assessment Institute
DDD	Defined Daily Dose
EAHC	Executive Agency for Health and Consumers
EC	European Commission
EMINet	European Medicines Information Network
EU	European Union
EU-15	Member States of the European Union which acceded to the European Union before May 2004
EU-25	Member States of the European Union as before May 2006
GDP	Gross domestic product
GÖG/ÖBIG	Gesundheit Österreich GmbH/Geschäftsbereich ÖBIG / Austrian Health Institute
GP	General practitioner
ICESCR	International Covenant on Economic, Social and Cultural Rights
HAI	Health Action International
HAI-E	HAI-Europe
HiT	Health systems in transition
HTA	Health technology assessment
INN	International Non-proprietary Name
Mio.	Million
MoH	Ministry of Health
NFZ	Narodowy Fundusz Zdrowia / National Health Fund
NGO	Non-governmental organisation
No.	Number
OECD	Organisation for Economic Development
OTC	Over-the-counter medicine
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
ÖBIG FP	ÖBIG Forschungs- und Planungsgesellschaft mbH
PE	Pharmaceutical expenditure
PHIS	Pharmaceutical Health Information System project
POM	Prescription-only medicines

PPRI	Pharmaceutical Pricing and Reimbursement Information project
RPS	Reference price system
THE	Total health expenditure
TPE	Total pharmaceutical expenditure
VAT	Value added tax
Vol.	Volume
WHO	World Health Organisation
ZUS	Zakład Ubezpieczeń Społecznych / Social Insurance Institution

1 Introduction

Access to essential medicines

Access to medicines is a key component of the implementation of the human right to health. The World Health Organization (WHO) considers equitable access to safe and affordable medicines vital to the attainment of the highest possible standards of health by all.

HAI project

Access to essential medicines is also a major objective for the independent advocacy organisation Health Action International (HAI). HAI works towards a world in which all people are able to exercise their human right to health. HAI Europe seeks to increase access to essential medicines and improve their rational use in Europe.

In 2009, HAI Europe received an operating grant from the Executive Agency for Health and Consumers (EAHC) to explore various areas under the project title “Developing rational use of medicines in Europe”. One of the areas is an investigation into “access to essential medicines in Europe”. As a starting point this survey focuses on three European countries: Portugal, Poland and Romania.

Outline

For each of these countries, the project consists of two parts:

1) An investigation of the pharmaceutical reimbursement system, on which a report will be produced. There are three major chapters of the report:
   - An introduction to the organisation and funding of the health and pharmaceutical system
   - An in-depth description of the reimbursement system, including key elements, such as list of (essential) medicines, a reference price system, review and monitoring mechanisms as well as instruments to promote generic uptake
   - An assessment of the achievements of the system with regard to realising access to essential medicines
2) In a second phase, the results will be presented and discussed as part of a workshop targeting civil society organisations.

ÖBIG consultancy

In order to guarantee constructive project outcomes HAI Europe commissioned the Austrian Health Institute (ÖBIG Forschungs- und Planungsgesellschaft mbH, ÖBIG FP). The ÖBIG FP in Vienna, a subsidiary of Gesundheit Österreich Gmbh (GÖG), has over 15 years of expertise in the research and analysis of European pharmaceutical systems and the assessment of accessibility. It has been involved in various European initiatives and coordinates projects with Pan-European relevance such as PPRI, PHIS and EMINet. For this project, the Austrian Health Institute was commissioned to produce the country reports and to present and discuss them at the workshops.

2 Methodology

Desk-top research

The information and data presented in this report are primarily based on a literature review and international databases e.g. OECD or EUROSTAT, supplemented by primary information from personal contacts. As indicated in Section 6 (References), the authors have also used unpublished grey literature that has been accessed using international contacts and networks.

Know-how and network

This report was made possible due to the long-standing knowledge and experience of the authors in the field, and excellent collaboration with the Polish Ministry of Health (see Acknowledgements) who kindly provided the latest data, updated information and assessments.

Integrated view

Assessing the accessibility of a system requires a holistic approach. Therefore the health care system in which the pharmaceutical reimbursement system is embedded is outlined, and the description of the reimbursement system covers both the out-patient and in-patient sector.

Terminology

For clarity of understanding, the terms and concepts in this report are based on terminology work which ÖBIG has undertaken for several years. Most of the technical terms used in the English version of this report are defined in the PPRI/PHIS glossary, which is accessible on the PHIS website: http://phis.goeg.at

Benchmarking

In order to benchmark some results and make a European comparison, EU averages are taken from the PPRI project (PPRI 2008). Even where these averages are from earlier years, they still provide a good indication of where Poland stands.

Essential medicines' concept

A key term in this report is "essential medicines". They are defined by WHO as "medicines that satisfy the priority health care needs of the population". The WHO list of essential medicines is a model product and a model process, as the implementation of the essential medicines' concept is intended to be flexible and adaptable to many different contexts. Thus, it remains a national responsibility to determine which medicines are regarded as essential (Hogerzeil 2009).

Human rights based approach

WHO promotes a rights-based approach for assessing the accessibility of (essential) medicines, and has developed several indicators. The authors follow this human rights approach in their analysis, and apply both indicators proposed by WHO and public health indicators (e.g. PHIS indicators).

3 General background

3.1 Organisation of the health care and pharmaceutical system

Social Health Insurance

The Polish health care system is organised as a Social Health Insurance system. It is centralised and managed by a statutory body – the National Health Fund (Narodowy Fundusz Zdrowia, NFZ). Public funding is generated through employee contributions collected by the Social Insurance Institution (Zakład Ubezpieczeń Społecznych, ZUS) and then transferred to the National Health Fund (NFZ).

The health care system covers approximately 99% of the population – with either full or partial reimbursement.

Core values

In 1998, the common Health Insurance Law (Ustawa o Powszechnym Ubezpieczeniu Zdrowotnym), based on the rule of societal solidarity, was implemented. It also builds the legal basis for the introduction of the National Health Fund (NFZ) with its 16 sickness funds (one for each voivodaship, which corresponds to the regions in Poland) and one for the military services.

The Polish Constitution, which is the overarching legal framework, 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.

Regionalisation

The NFZ is organised in regional sickness funds, which are managed by an executive committee consisting of members from regional self-sustained authorities and local representatives of central authorities. They provide health services for inhabitants from their regions with service providers operating in those voivodaships[1]. Sickness funds are supervised by a special institution, the Bureau of Health Insurance Supervision, which is accountable to the Ministry of Health.

Coverage

All citizens of Poland have the right to receive health care. Even illegal migrants may receive acute health care treatment, but these services are paid directly by the Ministry of Health.

Health status

The life expectancy of the Polish population has increased since 2000, though in the last few years it has remained more or less at the same level of 75 years (see Table 3.1). However, as in other countries, Polish women have a higher life expectancy (79.7 years at birth) than men (71 years at birth, OECD 2009).

Health care delivery

In terms of health care delivery, the number of physicians per 1,000 inhabitants has increased over time, with 2.19 in the year 2007. On the contrary, the number of hospital beds per 1,000 inhabitants has decreased in the last eight years, with 4.62 beds in 2007. This tendency is

[1] Voivodaships are administrative regions or municipalities

also reflected in the decrease of hospitals (831 hospitals in 2005 and 748 hospitals in 2007).

Table 3.1: Poland – Health status and health care provision, 2000, 2005, 2008

Health system	2000	2005	2008
Total population, in million	38.65	38.17	38.12
Life expectancy at birth, total	73.83	75.04	75.37[1]
No. of physicians per 1,000 inhabitants	2.20	2.14	2.19[1]
No. of hospital beds per 1,000 inhabitants	5.10	4.69	4.62[1]
Total no. of pharmacies	n.a.	10,341[2]	10,632[1]

n.a. = not available, no = number

Data as of 31 December

[1] Year 2007
[2] Year 2006

Source: EUROSTAT, OECD 2009, information from Polish Ministry of Health

Pharmaceutical system

The Ministry of Health (MoH) carries out most of the regulatory functions concerning pharmaceuticals and medical devices. It is advised by the Drug Management Team, which makes recommendations on medicines prices. The Drug Management Team consists of three representatives from the Ministry of Health, the Ministry of Public Finance, and the Ministry of Economy and in addition, three representatives from the National Health Fund (NFZ) may also take part in the consultations.

Reimbursement decisions are taken by the National Health Fund (NFZ) whilst the National Office for Registration of Medicinal Products, Medical Devices and Biocides, a sub-ordinate of the Ministry of Health, is responsible for granting market authorisations.

Price control

As soon as a medicine receives a market authorisation, the company may apply for a maximum price from the Ministry of Health based on the recommendation of the Drug Management Team. At the same time, the company applies for the inclusion of the medicine in the reimbursement list. The reimbursement price is set on the basis of the cheapest product in the group (see Section 4.3).

Price regulations also exist in the in-patient sector. The Ministry of Health sets prices for the medicines with the highest turnover.

In addition, there is a fixed wholesale mark-up for reimbursable medicines of 8.91% on the ex-factory price[2] and regressive maximum pharmacy mark-ups[3]. There is free pricing for non-reimbursable medicines.

[2] The manufacturer's posted price. Discounts or other incentives offered by manufacturers result in an effective price that is lower than the ex-factory price. (Source: PPRI Glossary)

Availability

In 2005, there were 8,089 pharmaceutical products (including different pharmaceutical forms and package sizes) authorised. There are three different pharmaceutical categories: reimbursable pharmaceuticals, accounting for 2,151 in 2005; hospital-only pharmaceuticals (655 in 2006); and OTC products (see section 4.2.2).

Pharmacies and other retailers

In Poland, medicines are generally dispensed through pharmacies. In past years, the number of pharmacies has increased offering the possibility of better access to medicines for the Polish population. There are certain rules for setting up a pharmacy, e.g. a licence from the local Pharmaceutical Chamber. A pharmacy can be owned by an individual, who can either be a pharmacist or a "pharmacy manager" with the right qualifications. Doctors are not allowed to own a pharmacy. There are no limitations on how many pharmacies can be owned by one person.

In terms of other retailers, doctors are rarely permitted to dispense medicines, and only if a pharmacist is present. No other retailers are allowed to sell prescription-only medicines. Furthermore, supermarkets or gas stations are also not allowed to sell OTC products.

3.2Funding of the health care and pharmaceutical system

6.4% of GDP spent on health

In 2007, 6.4% of the Gross Domestic Product (GDP) was spent on health care, which is around € 476 per person.

Even though the annual total health expenditure (THE) has increased over time (see Table 3.2), it is still one of the lowest in the EU-27 average. In general, the EU-10 countries, which acceded to the EU in May 2004, have a considerably lower THE per capita than the EU-15 countries (PPRI 2008).

General taxation

In Poland, health care is primarily funded from public sources (71%) and one third is funded through private contributions. As noted previously, the National Health Fund generates its funding through employee contributions.

Since 1998 voluntary health insurance is permitted in Poland, but it is not very developed, mostly in the form of private medical centre subscriptions.

Private funding

Health care services, which are outlined in a nationwide catalogue, are covered by the National Health Fund. Among other basic health care

[3] The mark-up is the percentage of the purchasing price added on to get the selling price. A mark-up is added on to the total cost incurred by the producer of a good in order to create a profit. The pharmacy mark-up is the gross profit of pharmacies expressed as a percentage add-on to the wholesale price (or pharmacy purchasing price). In case of a regressive maximum mark-up scheme these percentages get lower when the price is higher. Very often maximum pharmacy mark-ups are not fully utilised.

treatments, this list includes basics services such as dental Amalgan filling. Hence, there is also a negative list defined by law, which explicitly excludes certain services, such as cosmetic surgery.

For services that are not covered by the National Health Fund, patients have to pay the full out-of-pocket amount. In some cases the voluntary health insurance covers the costs.

In addition, patients have to pay flat out-of pocket rates for certain consultations: visits to primary care physicians or to out-patient departments of hospitals, emergency visits, home visits, diagnostic tests and therapeutic procedures[4].

Private contributions are especially high for medicines. In 2007, 62% of total pharmaceutical expenditure (TPE) was funded through private means. Total pharmaceutical expenditure has increased in recent years, whereas the percentage of total pharmaceutical expenditure as part of total health expenditure has decreased. Poland spends around 24% of total health expenditure on medicines, which is above the EU-25 average of almost 20% in 2005.

Table 3.2: Poland – Expenditure data, 2000, 2005, 2007

Expenditure data	2000	2005	2007
GDP per capita in €	4,672	6,187	7,403
THE in % of GDP	5.5%	6.2%	6.4%
THE per capita in €	255	384	476
- Public HE in % of THE	70%	69%	71%
- Private HE in % of THE	30%	31%	29%
TPE in % of THE	n.a.	28%	24%
TPE per capita in €	n.a.	108	117
- Public PE in % of TPE	n.a.	38%	38%
- Private PE in % of TPE	n.a.	62%	62%

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

Source: EUROSTAT, OECD 2009

[4] Therapeutic procedures could either be small operations that are performed in the doctor's office or small aesthetic or cosmetic surgeries.

4 Pharmaceutical reimbursement system

4.1 Framework

Legal framework

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 equal access to health services from public sources and health services are to be free of charge, funded through public funds.

The chief law in the pharmaceutical system is the Act of 27 August 2004 on health services financed through public funds. It defines the scope of the National Health Fund and determines the reimbursement conditions.

It is foreseen that in the near future, a new Act on pricing and reimbursement will be adopted. However, at the time of writing, it is unclear when it will be implemented.

Population coverage

The reimbursement policy covers the whole country and the whole population (cf. Section 3.1). In particular, there are exemptions for vulnerable groups (e.g. pensioners' scheme, cf. Section 4.2).

Linkage between pricing and reimbursement

As mentioned earlier, decisions about the price of a reimbursable medicine and the reimbursement status are very much interlinked. The Ministry of Health decides on the price and on the reimbursement limit based on recommendations from the Drug Management team. This decision is then published as a Ministry of Health Ordinance on the website.

Reimbursement authority Ministry of Health

Hence, the key authority in the pricing and reimbursement process is the Ministry of Health, advised by the Drug Management team. During that process the Drug Management team evaluates, among other criteria, if the medicine fulfils the reimbursement eligibility criteria (see section 4.1.2). After the final decision on the price and the reimbursement status, companies may start negotiations with representatives of the Ministry of Health.

Stakeholders involvement

Patients' organisations, expert panels in professional scientific societies, pharmaceutical industry representatives and public opinion (voters) can participate in influencing reimbursement decisions (PPRI Poland 2007).

Role of private sector

Even in the hospital sector, the Ministry of Health is the chief authority in terms of setting the overall framework and by issuing a list of maximum wholesale prices for 28 active substances.

The great majority of hospitals in Poland are publicly owned. Even though there are governmental incentives for privatisation; this remains very sensitive (PHIS Poland 2009).

Reimbursement in hospitals

In terms of reimbursement, the process is quite different for the in-patient sector. According to Article 35 of the Act of 27 August 2004 on health

services financed through public funds, all beneficiaries must always have their medicines (and medical devices) administered free of charge (PHIS Poland 2009). The expenses incurred for medicines in hospitals are covered by the National Health Fund for public hospitals, or by private voluntary insurances for private hospitals.

Please note that the description in the following sections primarily addresses the out-patient sector (certain reimbursement tools, e.g. a reference price system, are only relevant for the out-patient sector); and the passages on reimbursement in the hospital sector are explicitly mentioned.

4.2Reimbursement schemes

4.2.1Eligibility criteria

Reimbursement schemes

The general reimbursement scheme in Poland is based on the positive list. Medicines included in the positive list are either fully or partially reimbursed. There are no additional reimbursement schemes; hence also no individual reimbursement is possible.

However, there are exemptions for specific population groups e.g. cancer patients, patients with epilepsy and war veterans. They receive their prescribed medicines free of charge. War veterans may even ask for treatment that is not included in the positive list.

Eligibility

The major criterion for granting reimbursement of a medicine is the product itself. In a second step it is also relevant to look at the patient. Is the patient a war veteran? Or does the patient have a severe disease? All these factors determine the reimbursement category (see section 4.2.3).

4.2.2Reimbursement lists

Positive list

Poland has a reimbursement list for the out-patient sector and an additional one for the in-patient sector.

The positive list for the in-patient sector only covers 28 active substances, which is only one part of the medicines that are reimbursed by the National Health Fund. Besides those active substances, there are several therapeutic health care programs (e.g. for very expensive treatments) for which the extra permission of the director of the regional branch of the national Health Fund is required. The majority of medicines in the in-patient sector are reimbursed according to “hospital treatment procedures” via unified groups of patients[5] and patients do not have to co-pay.

The positive list for the out-patient sector is issued by the Ministry of Health and updated quarterly.

Criteria

Criteria for the inclusion of a medicine in the positive list were already outlined in the previous section (see section 4.2.1); the main criterion being the product itself.

The reimbursement list is reviewed on a regular basis and products are de-listed and new products, included. Reasons for the exclusion of medicines include those products that were reimbursed without being used as a standard therapeutic treatment[6] or those with unproven efficiency (e.g. calcitonine salmonis for nasal administration, a particularly controversial medicine at that time) (PPRI Poland 2007). Latest de-listing of medicines was aimed at reducing expenditure.

Procedure implies two evaluations

When applying for reimbursement the marketing authorisation holder of a medicine needs to submit information on the proposed price, the manufacturing costs and pharmaco-economic analysies. If any of those documents are missing the evaluation cannot begin.

Pharmaceutical evaluation

As the first step, the application documents are verified by the Drug Policy and Pharmacy Department within the Ministry of Health. Next, the documents are forwarded to the Drug Management Team, who is in charge of evaluating the reimbursement applications. The Team proposes official reimbursement prices as well as reference prices, the clusters of therapeutic groups, and the reimbursement limits. The Drug Management Team usually seeks advices from national experts, who are also involved in the decision-making process. These recommendations are forwarded to the Ministry of Health, who takes the final decision.

In case of new active substances the reimbursement application is also sent to the Agency of Health Technology Assessment for an appraisal.

Economic evaluation

In recent years, economic analyses have become more and more important in the reimbursement process. One of the major criteria is the submission of pharmaco-economic analyses including clinical effectiveness, cost–effectiveness and budget impact studies. Guidelines for the economic evaluation were established by the Polish Agency for Health Technology Assessment.

Appeal procedure

If the Ministry of Health decides not to reimburse the medicine, the company may, at any time, appeal against the decision. The company may have to deliver extra documents or lower the proposed price.

Procedure time

In accordance with the Transparency Directive (89/105/EEC), the reim-

[5] Unified groups of patients are those grouped according to their disease, such as cancer. In the course of the treatment, doctors are allowed to prescribe and administer any type of drug that he or she finds suitable for the patients' needs.

[6] Doctors could prescribe pharmaceuticals that were not included in the positive list (= standard therapeutic treatment) and these medicines were still reimbursed. At a later stage, this type of prescribing was not possible anymore and these products were excluded from reimbursement.

bursement procedure can take a maximum of 90 days. However in Poland, there are no binding timeframes outlined in the Act of 27 August 2004 on health services financed through public funds (PPRI Poland 2007).

Infringement procedure

In December 2005, Poland was subject to an infringement procedure by the European Commission (2005/4974).

On 29 June 2007, Poland received another reasoned opinion from the European Commission on the implementation of the Transparency Directive, which is the second stage of an infringement procedure laid down in Article 226 of the EC Treaty.

In order to develop transparent and clear reimbursement criteria Poland signed an EU Twinning project with France from October 2006 to April 2008. During that period 68 experts from all over the European Union came to the Poland to establish clear decision making processes through missions, training and workshops.

The following points were recommended for consideration in the reimbursement decision:

- Impact on public health (health priorities);
- Severity of the disease;
- Proven clinical efficacy compared to gold standard;
- Proven safety profile compared to gold standard;
- Beneficial ratio of health effects vs. costs;
- Justification, proven by HTA Agency recommendation;
- Proven accessibility on the market and/or guarantee of supply;
- Impact of medicines on direct costs of treatment;
- Number of patients to whom the pharmacotherapy may refer;
- Known annual expenses for reimbursement and its potential follow-up in respective years;
- Financial feasibility for pharmaceuticals that are reimbursed through public funds should be guaranteed

These recommendations provide a stronger and more independent position for the Polish Health Technology Assessment Institute (Agencja Oceny Technologii Medycznych, AOTM).

Despite the attempts to fully implement the EU Transparency Directive, discussions are still under way (see section 4.6). Besides the planned implementation of a new Act on pricing and reimbursement, it is also important to further disseminate information about HTA and evidence-based medicine. The new Act should especially include more transparent

and clearer reimbursement criteria.

Fast-track procedure

There is a fast-track procedure for generics. If a company applies for reimbursement for a generic, it does not have to send an extra evaluation to the HTA Agency.

The prices of generics have to be at least 25% below the price of the original product. The second follower needs to reduce its price by 25% compared to the first follower.

Scope

In August 2009, there were 3,380 medicines on the reimbursement list for the out-patient sector. However, this list may include the medicines which are counted more than once due to different dosages or strengths. In general, the reimbursement list includes many generics and only few new branded medicines.

OTC are normally not covered

OTC pharmaceuticals are not reimbursed and patients usually have to buy such medicines with out-of-pocket payments.

Updates

The positive list should be updated quarterly, however, in practice updates are far less regular, resulting in patients having to pay the full price for recently launched products (PPR 2008a). A recent update was carried out on 16 July 2008, listing 23 new generics and delisting 149 presentations as well as seven parallel imported pharmaceuticals for the first time (PPR 2008b). 16 March 2009 was the most recent update of the list.

Publication

The positive list is published on the website[7] of the Ministry of Health and is freely accessible for anyone. The online database is updated on a regular basis.

Hospital formularies

As noted earlier, the Ministry of Health sets maximum prices for hospital pharmaceuticals for 28 active substances. These prices are published in the Annex of the Regulation of 6 December 2006. The prices for other medicines are set in procurement processes. The results of these tenders are published in the Public Procurement Bulletin.

4.2.3Reimbursement categories and rates

Different reimbursement rates

The positive list in the out-patient sector is divided into three sections, according to the reimbursement rates: 100%, 70% and 50%. However, there are some additional reimbursement conditions for certain groups of patients, such as cancer patients, patients with epilepsy and war veterans (see Table 4.3).

Medicines dispensed in the in-patient sector are free of charge for the patient.

[7] http://www.mz.gov.pl

Table 4.3: Poland – Reimbursement of medicines, 2009

Reimbursement category	Reimbursement rate	Characteristic of category
List of supplementary medicines	50%	Disorders such as menopause, cardiovascular disorders, hypertension
List of supplementary medicines	70%	Disorders such as Parkinson's disease, Alzheimer's disease, etc.
List of basic medicines	100% and lump sum of PLN 3.20 / € 0.77	E.g. antibiotics
List of medicines for specific indications	100% (no lump-sum)	Diseases such as epilepsy, oncology, diabetes

Source: Ministry of Health/PPRI Poland 2007

Categories

If a medicine receives a positive reimbursement status, it is then categorised according to the reimbursement indication, e.g. medicines for Parkinson disease are reimbursed at 70%.

In Poland, certain diseases have a high treatment priority, such as cancer, epilepsy and cardiovascular conditions. The medicines used to treat these conditions are fully reimbursed - either without any co-payments or with a co-payment of PLN 3.20/ € 0.77.

Reimbursement decreases

There have been no changes to the reimbursement rates since the mid 1990s.

However, the positive list has changed over time especially in terms of volume (cf. section 4.2.1). More generics have been included in the positive list in order to reduce costs.

Exemptions for vulnerable groups

Certain groups of patients are exempt from any kind of co-payment. These patient groups are: cancer patients, patients with epilepsy and war veterans. Disabled war veterans can even receive expensive medicines that not included in the reimbursement list.

Generics promotion

In Poland, there are no lower reimbursement rates for generics. However, through the introduction of the reference price system, there has been a consistent policy of promoting generic alternatives.

4.3Reference price system

RPS since 1998

Since 1998, Poland has had a reference price system (RPS), which is a reimbursement tool for the out-patient sector. For medicines included in the reference price system, the National Health Fund refunds up to the reference price (= reimbursement limit), whereas the difference between reference price and actual pharmacy retail price has to be covered by the

patients.

The Act of 27 August 2004 on health services financed through public funds and the Pricing Law form the legal basis for the RPS.

As described earlier, the relevant authorities are the Ministry of Health and the Drug Management team.

Scope

In Poland, reference groups (groups of homogenous products) are clustered at ATC 5 level (grouping reimbursable medicines of the same active ingredient and the same dosage, pack size and method of administration) and at ATC 4 level (grouping reimbursable medicines at similar therapeutic indications).

In some rare cases the reference groups are also clustered at ATC 3 level.

Increasing number of medicines included

The scope of the medicines included in the reference price system has increased in the last couple of years, as more and more generics are included in the reimbursement list. Thus, the reference price system is mainly applied to medicines where generic alternatives exist. However, since March 2009, for the first time, seven parallel imported pharmaceuticals were included in the reimbursement list (PPR 2008b).

Technical procedure

The Drug Management team suggests how to cluster the medicines and proposes a reference price. The final decision is taken by the Ministry of Health. This process is based on the legal Act of 27 August 2004 on health services finances from public funds as well as the Pricing Law.

Reference price

The reference price (reimbursement limit) is set according to the lowest price per unit in the cluster. This is calculated based on the defined daily dose (DDD) by the WHO.

If the patient chooses the cheapest medicine in that cluster, they only have to co-pay the percentage co-payments as mentioned earlier (cf. section 4.4). However, if the patient wants to have other more expensive medicines from that cluster, he/she has to co-pay the difference between the reference price (reimbursement limit) and the actual pharmacy retail price.

Exemptions for vulnerable people

Within the reference price system, the same rules apply regarding vulnerable groups; hence there is no co-payment for cancer patients, patients with epilepsy and war veterans.

Regular updates

Reference groups and prices are updated biannually.

Publication

The reference prices are published on the Ministry of Health website on a regular basis.

4.4Co-payments

% co-payments

As mentioned in section 4.2.3, there are three different reimbursement

for out-patients

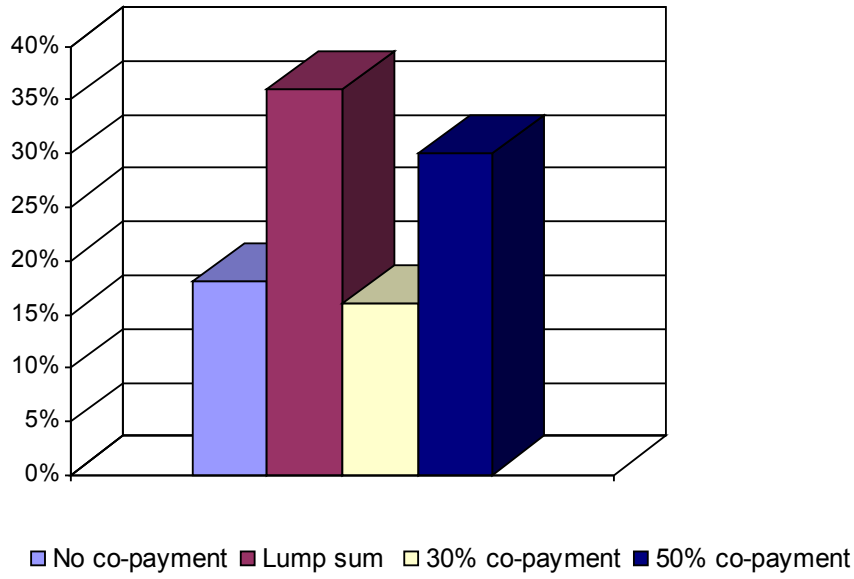
rates for reimbursable medicines. Hence, the percentage co-payment rates for reimbursable medicines for patients are: 0%, 30% and 50%.

According to information from the Ministry of Health (Błaszczyk, P; 2006), in 2005 the division of reimbursable medicines on the positive list according to the different co-payments rates was as follows:

- No co-payment: 504 reimbursable medicines
- Lump sum of PLN 3.20 / € 0.77: 997 reimbursable medicines
- 30% co-payment: 430 reimbursable medicines
- 50% co-payment: 837 reimbursable medicines

This can also be illustrated according to percentages, as shown in Figure 4.1.

Figure 4.1: Poland – Division of reimbursable medicines according to co-payment rates, 2005



Source: Błaszczyk, P; 2006

In general, the patient co-payment is high in Poland compared to other European countries. As already mentioned under section 3.2, private pharmaceutical expenditure accounts for 63% of the total pharmaceuticals expenditure in 2007.

Different prices

Due to the fact that pharmacy mark ups are maximum mark-ups the pharmacists may lower the price and so patients may be able to shop around for the cheapest medicines. However, the co-payment rates remain the same no matter how the price is set.

Apart from the percentage co-payments, there are no other forms of co-

payment in Poland. Although it is important to note that in the reimbursement category for basic medicines (e.g. antibiotics), patients have to co-pay a flat fee of PLN 3.20 / € 0.77. This is not seen as a prescription fee, but rather as part of the reimbursement process, which is paid to the National Health Fund.

For medicines dispensed to in-patients during their stay in hospitals no co-payments are applied.

No co-payment for in-patients

4.5Further instruments

4.5.1Pharmaceutical budgets

The system of using pharmaceutical budgets for physicians, which would define a maximum amount of expenditure for prescribed medicines, is not applied in Poland.

Limiting expenditure

4.5.2Reviews and monitoring

The reimbursement list should be updated quarterly, but in reality it is not updated as regularly. When updating and reviewing the reimbursement list, new medicines are added and others are de-listed. The criteria for de-listing were stated under Section 4.2.2.

Reviews in outpatient and in-patient sector

The National Health Fund routinely checks the prescriptions written by contracted physicians. Those inspections are intended to confirm whether the physician has prescribed the correct indication, which has consequences for the reimbursement rates. The inspectors check the patients' files at physicians' offices to confirm if the reimbursement corresponds with the right indication. In the case of inappropriate prescribing, physicians must pay back the sum that was spent incorrectly. Additional sanctions are rare.

Prescription monitoring

In general, physicians must adhere to certain prescribing rules indicated by the National Health Fund. For instance, contracted physicians are allowed to prescribe five different medicines per prescription, although some pharmaceuticals need to be prescribed as the only medicine per prescription (those with major side effects).

The National Health Fund has developed prescription guidelines for contracted physicians. Those guidelines are like therapeutic recommendations indicating which reimbursable medicines are best to prescribe for certain indications. They have no financial implications.

Prescription guidelines

In addition, there are therapeutic guidelines issued by doctors or scientific associations, which also include recommendations for pharmaco-therapy, but very often those therapeutic guidelines do not correlate with the

real prescribing habits of physicians.

4.5.3Generics promotion

INN prescribing

INN (International Non-proprietary name) prescribing is voluntary in Poland. Physicians may prescribe as they wish, either by generic name, by brand name or by INN.

In any case, the pharmacist is obliged to inform the patient about the cheapest medicines in the therapeutic cluster.

Generic substitution

Generic substitution is allowed in Poland. However, the physician may prohibit substitution by adding the code “NZ” (Nie zamieniac) on the prescription, meaning “Do not substitute”. Patients also have the right to oppose generic substitution – in both cases they have to pay a higher price.

Further generic promotion

As mentioned earlier, when applying for reimbursement for a generic, a fast-track procedure is applied, meaning that there is no further reimbursement evaluation.

In general (generic) pharmaceutical companies communicate directly with physicians or pharmacists to inform them about generic products. However, authorities have not undertaken any specific measures to promote generic uptake.

Generic market

The generics market in volume as well as in value has been fairly stable over the past few years. In terms of volume, it has declined (2000: 1,190 packs per year; 2008: 1,067 packs per year). However, there have been efforts to include more generics in the reimbursement list in the last year (PPR 2008b).

Table 4.4: Poland – Trends for the generics market in volume and value, 2000 - 2005

Generic market	2000	2003	2005
Volume (no. of packs sold per year in Mio.)	1,190.29	1,078.46	1,067.34
Value (in Mio. PLN)	6,308.36	7,914,87	9,027.31

Source: PPRI Poland 2007

4.6Future developments

New reimbursement and pricing law

There are plans to implement new reimbursement and pricing laws, covering the in- and the out-patient sector.

Currently, the Drug Policy and Pharmacy Department at the Ministry of Health are preparing these new regulations. Both Acts are expected to be implemented in autumn 2009. The plan is to unify the reimbursement process and to introduce more transparent criteria. These criteria will be valid for the in- and the out-patient sector. The Ministry of Health will still hold the final decision-making power.

Future decision-making bodies

In future, the Ministry of Health will no longer receive reimbursement recommendations from the Drug Management team, and instead there will be two new decision-making bodies: the Transparency Council and the Economic Commission.

Recommendations

The Transparency Council will be in charge of offering recommendations on the reimbursement of medicines, in particular on reimbursement rates and the inclusion/exclusion on the reimbursement list. The Council will consist of 26 representatives from the Ministry of Health, the National Health Fund, the Agency for Health Technology Assessment, the Chief Sanitary Inspector, the Patient Ombudsman, the Polish Pharmaceutical Chamber, the Polish Chamber of Physicians and Dentists and the Medical University.

The Economic Commission will be responsible for price negotiations. The plan is for 12 members representing the Ministry of Health, the National Health Fund and the Transparency Council.

5 Analysis

5.1 Human rights approach

Analysis for the civil society

In this chapter, the authors discuss the implications for access to essential medicines based on the facts and figures of the Polish health and pharmaceutical system, which were presented in the previous sections. This analysis is undertaken from a public health and human rights perspective, which should correspond with the interests of civil society.

Essential medicines as a human right

In an article published in 2003 (Hogerzeil, H. 2003), Hans Hogerzeil, Director of the Department of Essential Medicines and Pharmaceutical Policies of WHO, stressed that access to essential medicines is a human right. He referred to the Committee on Economic, Social and Cultural Rights, which is in charge of the implementation of the International Covenant on Economic, Social and Cultural Rights (ICESCR). The ICESCR specifies availability, accessibility, acceptability and quality as interrelated and essential components for the fulfilment of the right to health in all its forms.

In the last few years, there have been some initiatives driven by WHO to specify and define criteria from a rights-based perspective. This analysis follows this human rights based approach and applies several previously proposed indicators (Hogerzeil, H. 2006; Hogerzeil, H.; Samson, M.; Casanovas, J. V., Rahmani-Ocoro L. 2006), and additionally integrates some criteria that the authors of this report consider to be useful and relevant.

5.2 Discussion

The Polish pharmaceutical reimbursement system will be discussed with regard to nine components; including transparency, the role of stakeholders and beneficiaries, availability and affordability, which are relevant for the implementation of the access to essential medicines. For each of these components, indicators have been developed. A brief assessment of the indicators is provided in Table 5.5 in order to offer at a glance information.

Government commitment

In Poland, the government is committed to implementing equitable and consistent access to health care. One central measure was the introduction of the National Health Fund (cf. Section 3.1).

The regulatory framework also guarantees the right to equal access to health care and medicine. Poland does not have an explicit essential medicines policy document.

Nevertheless, Poland is still struggling to implement all relevant laws re-

lating to the EU Transparency Directive. During the EU Twinning Project signed between Poland and France (see section 4.2), one of the core outcomes was a list of recommended reimbursement criteria that should be implemented. It explicitly mentioned that proven accessibility should be guaranteed.

Health care reform is still in progress, and outcomes can only be assessed a later stage.

Population coverage

Health care is available for the whole population. There is universal health care coverage (99% of the population), and reimbursable medicines through the National Health Fund, although patients still have to pay a large share of their medicines costs out-of-pocket.

List of essential medicines

Poland has a reimbursement list in the out-patient sector. In addition, there is a separate reimbursement list (budget) for therapeutic programs in the in-patient sector.

The reimbursement list in the out-patient sector includes 3,380 medicines (including the different pharmaceutical forms, strengths and pack sizes) which are – at least partially – reimbursed. The list should be updated quarterly, but in reality it is not updated as often. In recent years there have been attempts to include more new products with added therapeutic value.

Table 5.5: Poland – Assessment of the pharmaceutical reimbursement system

Indicator	Assessment	
	In brief	**Discussion**
Government commitment		
Access to health	Yes	Access to equitable health care is recognised in several laws, decrees and legal provisions and implemented by the Social health insurance.
Access to essential medicines	Yes	The right to receive medical treatment including medicines is ensured in several laws, acts and legal provisions covering the whole population.
Essential medicines policy	No	Poland has no explicit essential medicines policy.
Coverage of the population		
Health care	Yes	The Social health insurance system covers the whole population of Poland. In addition, migrants also have the right to receive medical treatment.
Medicines	Yes	The right to health care treatment includes access to (essential) medicines.
List of essential medicines		
Positive list	Yes	Poland has a positive list in the out-patient sector and a national Hospital Pharmaceutical Formulary in the in-patient sector.
Scope	~ 3.380 medicines	The Polish reimbursement list for the out-patient sector includes around 3.380 medicines. Additionally, there is a list with maximum prices of 28 active substances for the in-patient sector as well as special budgets for therapeutic programs for the in-patient sector.
Updates	quarterly	In practice, the reimbursement list is not updated quarterly.
Transparency		
Publication of lists	Yes	The reimbursement list for the out-patient sector is published and freely accessible on the internet. In the out-patient sector the budgets for some therapeutic programs such as for chemotherapy (which are similar to reimbursement lists) are published in orders of the National Health Fund.
Publication of prices	Yes	Prices of medicines used in the out-patient sector are published and freely accessible on the internet.
Rational selection of medicines		
Positive list	Point of criticism	In theory, there should be transparent criteria for selecting medicines, but in recent years this has been one of several reasons why Poland was subject to an infringement procedure by the EC.
Reference price system	Yes	There are clear criteria and rules; however, pharmaceutical companies have not always observed the rules.

Indicator	Assessment	
	In brief	Discussion
Mechanisms for enforcement		
Appeal procedure in reimbursement	Yes	Pharmaceutical companies that have received a negative decision on the inclusion into the reimbursement list may appeal to the supreme administrative court.
Fines and sanctions	No	There is no authority for the National Health Fund to fine contracted physicians if they do not adhere to prescription guidelines.
Beneficiaries and stakeholders		
Involvement and consultation	Low	In general, the Polish reimbursement system is based on technical criteria rather than stakeholders committees.
Role of stakeholders	Physicians	The role of physicians is crucial, since they decide which medicines to prescribe. This has an impact on the level of co-payment for the patient.
Patients understanding the system	Low	The reimbursement system is complex thus patients need to be very well informed to ask for the right medicine e.g. with lower co-payment. However patients do not seem to fully understand the system.
Vulnerable groups	Special groups	There is free treatment for certain population groups: cancer patients, epileptic patients and war veterans.
Availability		
Medicines launched	8,089 authorised (2005) 4.198 on the market (2005)	Poland has a high number of medicines authorised; however only half of the number is actually on the market.
Pharmacies	Depending on the region	In general, the number of inhabitants per pharmacy differs between regions. In 2007, there were 10,632 pharmacies in Poland.
Affordability		
Price level	Rather low	Prices of medicines in Poland are amongst the lowest in Europe (IPF 2008), compared at ex-factory price level.
Co-payments	% co-payments	Co-payments are fairly high in Poland. There is no patient co-payment on only 18% of the reimbursable medicines.
Private funding of pharmaceutical expenditure	Rather high	The share of private funding in pharmaceutical expenditure (62%) is very high compared with the EU average (36%).
Promotion of less expensive medicines	Yes	Through the introduction of the reference price system there has been a consistent policy of promoting generic alternatives.

Source: ÖBIG

Transparency

Prices of medicines are easily available in Poland. They are published on the Ministry of Health's website.[8] There is even a possibility for patients to enter the name of their medicine and patient status (e.g. if the patient is a chronic patient) and then the co-payment of the patient is automatically calculated. Additionally, the Ministry of Health offers a hotline for patients to receive information on the product and on the level of co-payment. This system seems to be very transparent and informative for the patient.

In the in-patient sector medicines are free of charge. The Ministry of Health publishes a list of 28 active substances with maximum prices, which are in reality much lower due to procurement procedures of hospitals. However, the prices of medicines used in hospitals, which are bought individually by hospitals, are usually not shared by the hospitals and thus, not publicly available.

However, it seems that, in general, patients are not very well informed about the functioning of the pharmaceutical reimbursement system and the prices. Furthermore, the information to patients policy might require customisation for target groups of patients.

Rational selection of medicines

Poland has defined criteria for the rational selection of medicines. Nevertheless, there has been criticism that those criteria do not comply with the EU Transparency Directive. The criticism focuses on the ambiguity of the criteria, deadlines, the lack of information and the lack of an appropriate appeal procedure against a decision.

In 2007 and 2008, these weak points were discussed in several expert meetings and workshops resulting in the implementation of more transparent criteria (cf. section 4.2.1). Within this reform process, the importance of the independent reimbursement assessment for new molecules by the Health Technology Agency was emphasised.

Despite this, the fast-track procedure foreseen for generics seems to be very efficient and allows for a quicker generic uptake without a loss in quality.

Poland has many years of experience with the reference price system. It seems that the procedure for setting the reference price (reimbursement limit), which is the cheapest DDD per reference group, is very transparent and clear. Nevertheless, the criteria for the inclusion of a medicine in a reference group do not seem to be clearly defined. The groups are either built based on the same active ingredient (AT 5 level) or the same therapeutic group (ATC 4 level) with similar therapeutic indications. It is not clearly defined what "similar" therapeutic indication really means.

Mechanisms for enforcement

Public authorities in Poland have only limited possibilities to enforce cost-containment mechanisms, such as INN prescribing by contracted physicians.

[8] http://bil.aptek.pl/servlet/pacjent/fupraw;jsessionid=C407B1B58F65E9D4B2C1E80231B83FE6.GENTOO

This is due to the fact that these provisions, such as INN prescribing and prescription guidelines for physicians or generic substitution for pharmacists, are not mandatory. There are neither financial incentives to adhere to those measures nor budgetary sanctions in case of non-adherence.

There is evidence (PPRI 2008) that countries that have introduced mandatory generic substitution and/or obligatory INN prescribing including sanctions and/or other enforcement mechanisms, have had a considerable increase in the generics uptake.

Beneficiaries and stakeholders

In Poland, decisions on pricing and reimbursement of medicines are based mostly on formal criteria rather than on the expert opinions of representatives from the pharmacists or doctors association. The reimbursement decision is taken by the Ministry of Health. The decision is based on an evaluation process by the Drug Management Team as well as assessment by the Health Technology Agency in case of new molecules.

Even in the redrafting process of the legal basis for pricing and reimbursement in the last couple of years, there does not seem to be increased participation from groups such as patient organisations or other stakeholder representatives.

The Ministry of Health offers a very useful service for independent information on reimbursable medicines, generics and co-payments. Patients can either obtain information via the Ministry's website or call the Ministry's telephone hotline directly. This service seems to be very helpful for finding out what the patient has to pay. The patient even has the option of including his/her status (e.g. war veteran) after which the co-payment information adjusts accordingly.

Availability

A trend has been observed that there is a high number of authorised medicines and yet, a low number of medicines actually available on the market. More medicines are granted market authorisation without later being marketed. Among other explanations, one is that some authorisations are granted centrally by the European Medicines Agency (EMEA) but market authorisation holders later decide not to launch the product in the Polish market due to low prices.

Few medicines are considered as hospital-only medicines, only around 655 (in 2006). Compared with other European countries, this number is not very high. This could mean that the uptake of new molecules is not very fast in the in-patient sector.

In the out-patient sector, patients have access to medicines through 10,632 pharmacies (2007). Depending on where the patient lives, he/she has different access to medicines. Patients living in major cities have many more options for visiting a pharmacy nearby, whereas patients living in rural areas have more limited access to medicines.

Affordability

In terms of affordability, the patient co-payment has been noted as very high in Poland. In 2007, private pharmaceutical expenditure amounted to 62% of

the total pharmaceutical expenditure.

Through the implementation of the reference price system and the use of generics, the Ministry of Health has implemented a cost-containment strategy in order to decrease prices and co-payments. In fact, the Polish pharmaceutical prices at ex-factory level are among the lowest in the European Union (IPF 2008).

However one major problem is that patients are very often not aware that they could ask for a generic. In fact, some patients still believe that generics are less effective and induce more adverse effects. Hence, patients receive the original product and have to contribute a higher co-payment.

Another reason for high co-payments is that patients are not aware that the reimbursement limit of a medicine might change over time, when a cheaper alternative becomes available in the reference group.

In addition, there are several levels of co-payment, such as 30% co-payment for non life-threatening diseases (e.g. Parkinson's disease or Alzheimer's disease), and 50% co-payment for very commonly used medicines such as for hypertension, hyerlipidaemia or menopause. Even for medicines with 100% reimbursement, a lump sum of PLN 3.20 / € 0.77 is charged.

The high out-of pocket payments on pharmaceuticals may also result from the fact that Poland has quite high consumption rate of medicines.

5.3Conclusions

In general, it can be concluded that the Polish reimbursement system is sustainable and based on a well-defined and founded regulatory framework, with core values of accessibility, equity, universality and effectiveness. In recent years, there have been many attempts to make the system more transparent and structured according to clear criteria.

Access to essential medicines is provided through in-patient and out-patient care.

Room for improvement

Nevertheless, the authors have identified some room for improvement.

- The role of HTA has already improved in recent years; in particular through the establishment of the Health Technology Assessment Agency. This valuable assessment should be strengthened, especially for decisions on the inclusion of new molecules into the reimbursement list.
- Affordability might be restricted, as co-payments are rather high, and Polish citizens pay a considerable out-of pocket amounts. If budgetary restraints do not allow for a decrease in co-payments, policymakers should monitor the situation to see if the population, in partic-

ular vulnerable groups, are discouraged from buying the medicines they need. Should there be indications of such a trend, exemptions and/or reductions of co-payments should be made available for at least these groups.

- Policy-makers are advised to put more emphasis on the enforcement of certain measures that have already been implemented (such as generic substitution). This should contribute to achieving the expected outcomes.
- The Ministry of Health has already implemented strong measures to inform patients and consumers about medicines prices and levels of co-payment. However, the system does not seem to be fully understood by the public. There is room for greater civil society involvement here, to act as “translators” between the regulators and the general public.

6 References

Błaszczyk, P.; Ministry of Health, 2006
Presentation of the Polish Pharmaceutical Market at the PPRI Meeting in Warsaw, Oct. 2006 (unpublished)

Espin, J.; Rovira, J. 2007
Analysis of differences and commonalities in pricing and reimbursement systems in Europe. DG Enterprise and Industry of the European Commission. Brussels, June 2007

Eurostat 2009
Eurostat database (online). Accessible at:
http://epp.eurostat.ec.europa.eu/portal/page/portal/eurostat/home/

Gericke, C.; Kuszewski K.; 2005
Health Systems in Tranistion (HiT). Poland 2005. Vol. 7. No. 5. European Observatory on Health Systems and Policies

GÖG/ÖBIG 2007
Pharmaceutical Systems in the European Union. Fact Sheets. Vienna

GÖG/ÖBIG 2009
Generics Matrix. EMINet, compiled for DG Enterprise (unpublished)

IPF 2008
Der österreichische Pharmamarkt: ein europäischer Preisvergleich. Wien

Hogerzeil, H. 2003
Access to essential medicines as a human right. In: Essential Drugs Monitor, published by WHO. Issue No. 33: 25-26

Hogerzeil, H. 2006
Essential medicines and human rights: what can they learn from each other? In: Bulletin of the World Health Organisation. May 2006, 84: 371-375

Hogerzeil, H.; Samson, M.; Casanovas, J. V., Rahmani-Ocoro L. 2006
Is access to essential medicines as part of the fulfillment of the right to health enforceable through the courts? In: The Lancet 2006, Vol. 368, July: 305-311

Hogerzeil, H. 2009
Access to essential medicines as part of the Right to Health. Presentation at Utrecht Summer Course, July 2009 (unpublished)

ÖBIG 2006
Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States. DG Competition of the European Commission, Vienna, July 2006

OECD 2009
OECD Health Data (online version)

OECD 2008
Pharmaceutical Pricing Policies in a Global Market. OECD Health Policy Studies, Paris

PHIS 2009
PHIS Hospital Pharma Report Poland 2009 (unpublished)

PPR 2008a
Poland: New Reimbursement List takes effect. In: PPR 1/2008, p. 17-18

PPR 2008b
Poland: Reimbursement List updated. In: PPR 9/2008, p. 278

PPR 2009a
Polish reimbursement list update effective. In: PPR 3/2009, p. 88

PPRI Poland 2007
PPRI Pharma Profile Poland 2007. Available as pdf:
http://ppri.goeg.at ->publications ->country information

PPRI 2008
PPRI Report. GÖG/ÖBIG and WHO. Vienna, July 2008

Simoens, S.; Coster, S. 2006
Sustaining Generics Medicines Markets in Europe. Research Centre for Pharmaceutical Care and Pharmaco-economics. Leuven University, April 2006