ÖBIG FORSCHUNGS- UND PLANUNGSGESELLSCHAFT mbH

# ACCESS TO ESSENTIAL MEDICINES IN ROMANIA

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# ACCESS TO ESSENTIAL MEDICINES IN ROMANIA

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ÖBIG Forschungs- und Planungsgesellschaft mbH

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# Executive Summary

Access to essential medicines is a human right. Each government shall develop a regulatory framework, which supports the implementation of the right to health, including access to medicines.

The Austrian research institute ÖBIG Forschungs- und Planungsgesellschaft mbH (ÖBIG FP) was commissioned by the advocacy organisation Health Action International (HAI) Europe to investigate the pharmaceutical reimbursement system in Romania with regard to its implementation of the right to access of essential medicines.

Since 1998, Romania has operated a social health insurance system built on principles of solidarity and subsidiarity, which entitles the whole population to health care.

The overall responsibility for the pharmaceutical system lies with the Ministry of Public Health. It is responsible for setting the legal framework of the health care system; in particular also for the pharmaceutical system. The National Health Insurance Fund (CNAS) represents the third party payer and advises the Ministry of Public Health when decisions about the reimbursement status of a medicine are made.

Before a decision on the reimbursement status of a medicine is taken the Directorate for Strategies and Medicine Policy under the Ministry of Public Health sets the price of prescription-only medicines. The Ministry of Public Health sets the ex-factory price based on external price referencing for imported medicines and cost-plus pricing for locally-produced medicines. There is free pricing for OTC products, but the Ministry of Public Health needs to be notified of the price.

The Ministry of Public Health is responsible for issuing the reimbursement lists which have different reimbursement rates: List A (90%) includes mainly generics which are considered as important and cost-effective (~ essential medicines). List B (50%) includes medicines that are judged as less cost-effective and list C (100%) includes medicines for out-patient care for a group of diseases, medicines prescribed in National Health Programs, paediatric medicines and medicines used in pregnancy and after. As of the beginning of 2010 the reimbursement list includes 5,043 medicines, of which 3,170 are generics.

In addition, Romania has been operating a reference price system since 1997.

The Ministry of Public Health, assisted by the Therapeutic Strategy Commission as well as the Transparency Commission, is responsible for deciding which medicines are included in the reimbursement lists. When assessing an application for reimbursement, Commission members largely rely on the data submitted by the pharmaceutical companies. However, companies are not required to submit a pharmaco-economic analysis. Medicines with excessive prices or low therapeutic efficacy are not reimbursed. OTC products are normally not reimbursed, but there is extra separate list for children and pregnant women, which includes OTC products.

Exemptions from co-payments are made for children, students and pregnant women as well as war veterans and disabled people on low incomes.

In terms of cost-containment instruments the National Health Insurance Fund has implemented prescription guidelines, prescription limits and prescription monitoring system. However, in practice feedback on prescribing behaviour is reported months or even years later.

Doctors may prescribe by brand name or by INN. In terms of generic substitution pharmacists are permitted to exchange a prescribed medicine for a lower-priced generic equivalent, but it is not mandatory for them to do so.

The authors consider the pharmaceutical reimbursement system in Romania as appropriately defined and with a regulatory framework, in theory. However, in practice patients may not always have access to medicines unless they pay for the medicines out-of pocket. Another area for improvement is that patients should be better informed about their rights, such as on the possibility to request a less expensive generic alternative. This could be an area where civil society organisations could play a stronger role.

The authors welcome the abolition, at the beginning of 2009, of fixed pharmaceutical budgets for pharmacies, as these ceilings had caused availability problems. However, we are concerned that, as of September 2009, the overall budget for the National Health Insurance Fund had already been exhausted.

One of the possible ways forward could be the stronger enforcement of the monitoring systems.

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## List of abbreviations

| | |
|---|---|
| ANM | Agentia Nationale a Medicamentului / Medicines Agency |
| ARPIM | Asociatia Romana a Producatorilor Internationali de Medicamente / Association of Pharmaceutical Industry |
| ATC | Anatomic therapeutic chemical classification |
| CFR | Colegiul Farmaciştilor din România / Association of Pharmacists |
| CMR | Colegiul Medicilor Romania / Chamber of Doctors |
| CNAS | Casei Nationale de Asigurari de Sanatate / National Health Insurance Fund |
| DDD | Defined Daily Dose |
| EAHC | Executive Agency for Health and Consumers |
| EC | European Commission |
| 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 |
| MS | Ministerul Sănătăţii Publice / Ministry of Public Health |
| 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 Organization |

# 1 Introduction

Access to essential medicines

Access to medicines is a key component in 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

The report aims to investigate the pharmaceutical reimbursement system in Romania. There are three major chapters:

- An introduction to the organisation and funding of the health and pharmaceutical system in Romania
- An in-depth description of the reimbursement system, including key elements, such as the list of (essential) medicines, a reference price system, review and monitoring mechanisms and instruments to promote generic uptake
- An assessment of the achievements of the system with regard to realising access to essential medicines.

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 (Pharmaceutical Pricing and Reimbursement Information project) and PHIS (Pharmaceutical Health Information System project). For this project, the Austrian Health Institute was commissioned to produce the country reports; the reports on Poland and Portugal were presented at workshops in the countries.

# 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, 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 by the long-standing knowledge and experience of the authors in the field, and good collaboration with the Romanian Ministry of Public Health (see Acknowledgements) who kindly provided the latest data, updated information and assessments.

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 previous years, they still provide a good indication of where Romania 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

With the introduction of the social health insurance law No. 145/1997 on 1 January 1998 the health care system in Romania underwent massive changes, from a formerly centralised stated-owned health care system (Semashko model) to a decentralised health care system, which provides a distinction between health care providers and funders.

The Ministry of Public Health (Ministerul Sănătăţii Publice, MS) is the highest authority in the health care system in Romania. Apart from the legal obligation the MS has various other duties such as guaranteeing access to health care for its population.

The National Health Insurance Fund (Casei Nationale de Asigurari de Sanatate, CNAS) represents the main financial source as the third party payer of the system. It is the umbrella organisation of the 42 regional sickness funds and the two nationwide sickness funds for specific professions (such as defence, public security as well as transportation). The CNAS sets the common range of medical services provided for the insured. It is responsible for supervising the budget of the regional sickness funds and if necessary, for shifting budgets between the individual sickness funds.

Private health insurance is not yet very common in Romania and is a field with strong potential for development. Some employees of international companies receive private health insurance from their employers. However the implementation of the private health insurance was intended to make the health care system more transparent and reduce the common practice of informal payments to general practitioners. In general, private health insurance does not refund out-of-pocket payments for medicines.

Core values

Since 1998, the health care system in Romania has been based on a social health insurance system built on principles of solidarity and subsidiarity. The services that are covered under the social insurance system are regulated and include services for health care prevention, primary health care, specialised care and treatment in hospitals, dental care as well as rehabilitation services. In addition, medicines and medical devices that are included on the positive lists are either fully or partly reimbursed by the National Health Insurance Fund. Certain medical services and dental treatments are excluded from reimbursement.

The Romanian Constitution, which is the overarching legal framework, states that all citizens of the Republic of Romania are entitled to equal access to basic health services from public sources and health services

are to be free of charge. However with respect to pharmaceutical provisions, patients have to pay a lot of out-of-pocket payments. In section 3.2 this aspect is analysed in more detail.

Regionalisation

The system is organised at two main levels: national/central and district (judet). The national level is responsible for attaining general objectives and ensuring the fundamental principles of the government health policy. The district level is responsible for ensuring service provision according to the rules set by the central units.

As of 2008, there were 41 “judets”, administrative units like counties as well as one municipality in Romania, which is a special form of a “judet”. In each “judet”, there are District Public Health Authorities implementing the laws and regulations set by the Ministry of Public Health.

They implement the national laws and regulations required for services of public interest at county level, including health care, and they decide on the budget and local taxes of the county administration. According to the legislation (Emergency Ordinance 70/2002) starting from 2002, district councils are the owners of (almost) all public health care facilities and, in principle, could have an important influence on the shape of health services in Romania; in practice, owing to the lack of both financial and human resources, district councils are playing only a minor role in health policy development at present.

Coverage

The whole population is entitled to receive health care. Even people, who are not covered by the social health insurance system, may receive treatment in emergency situations as well as if it is in the public health interest (such as immunisation, TBC examinations and prevention services for pregnant women).

Health status

A decline in the population has been observed caused by emigration and a fall in the birth rates. The life expectancy of the Romanian population has, however, increased since 2000; with a life expectancy of 73 years in 2008 (see Table 3.1), which is far below the EU-average (79 years).

The main causes of death in 2007 in Romania were cardiovascular diseases (61.3%), followed by malignant tumours (17.9%), digestive diseases (5.8%), respiratory diseases (5.0%) and accidents, injuries and poisoning (4.9%). Deaths from external causes and from infectious and parasitic diseases are more common in Romania (4-5%) than in other EU Member States (Pana 2009).

Health care delivery

In terms of health care delivery, the number of physicians per 1,000 inhabitants has not increased over time, with 2.2 in the year 2007. The number of hospital beds per 1,000 inhabitants has decreased in the last eight years, to 4.5 beds in 2007.

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

| Health system | 2000 | 2005 | 2008 |
|---|---|---|---|
| Total population, in million | 22.5 | 21.7 | 21.5 |
| Life expectancy at birth, total | 71.3 | 72.2 | 73.3[1] |
| No. of physicians per 1,000 inhabitants | n.a. | 2.2 | 2.2[1] |
| No. of hospital beds per 1,000 inhabitants | 5.4 | 4.6 | 4.5[1] |
| Total no. of pharmacies | n.a. | n.a. | 5,560[1] |

n.a. = not available, no = number

Data as of 31 December

[1] Year 2007

Source: EUROSTAT, OECD 2009

Pharmaceutical system

The overall responsibility for the pharmaceutical system lies with the Ministry of Public Health. It awards licences to wholesalers and pharmacies; it is responsible for regulating and setting the prices of prescription-only medicines as well as making decisions about the inclusion of a medicine in the reimbursement system. In addition, the Ministry of Public Health initiates public tenders for selected medicines. The Ministry is supported by the Medicines Agency (Agentia Nationale a Medicamentului, ANM), a subordinate body of the Ministry, responsible for authorising and classifying medicines.

The National Health Insurance Fund (CNAS) advices the Ministry of Public Health when deciding on the reimbursement status of a medicine. Further institutions that are involved in the decision process on the reimbursement status are the Chamber of Doctors (CMR) and the Association of Pharmacists (CFR). Additionally, the National Health Insurance Fund is responsible for the compilation of the positive lists, the funding of medicines in the in- and out-patient sector as well as for the definition of specific health care programmes.

Price control

In accordance with the Transparency Directive 89/105/EC the Romanian Ministry of Public Health implemented Price Act (No. 612/13.08.2002 adjusted by No. 569/2003; 141/2005 and 924/31.08.2005), which regulates the procedures for price control of prescription-only medicines.

For prescription-only medicines (POM) the Ministry of Public Health sets the ex-factory price based on external price referencing for imported medicines and cost-plus pricing for locally produced medicines. When comparing the prices with other EU countries (external price referencing) the prices are compared with twelve countries: Austria, Bulgaria, Belgium, Czech Republic, Germany, Greece, Hungary, Italy, Lithuania, Poland, Slovakia, and Spain.

As for pricing of generics, the price for the first generic product entering the market cannot be more than 65% of the price of the corresponding original medicine. Also the price of the original product has to be reduced by 35% as soon as a generic enters the market. In practice the realisation of these regulations is problematic.

There is free pricing for OTC products; however the Ministry of Public Health needs to be notified of the prices of OTC products.

Availability

As of 1 October 2007, 6,710 medicines were authorised (including different strengths and pharmaceutical forms), of which 917 were OTC products. However only 4,400 medicines (or 5,900 packages) were on the market. As of the beginning of 2010 the reimbursement list included 5,043 medicines, of which 3,170 were generics.

Pharmacies and other retailers

According to information from the Ministry of Public Health, there were 7,043 public pharmacies in 2009, which corresponds to one pharmacy per 3,058 inhabitants. There are huge differences between rural and urban areas: in rural areas there is one community pharmacy for approximately 4,000 inhabitants and in urban areas for 3,000 inhabitants (Pana 2009).

In addition, there were 433 hospital pharmacies in 2009 that could dispense medicines to out-patients enrolled in public health programs under certain conditions. There are additional dispensaries for civil servants from the Ministry of Defence and Transport.

Pharmacies may also be owned by other persons than pharmacists; this has enhanced the development of pharmacy chains. According to estimations around 20% of all pharmacies in Romania are part of a pharmacy chain, e.g. Sensiblu, Help Net, Dona, Catena, City Pharma, Centropharm, Remedio und Omnia.

In Romania vertical integration is allowed, for example the biggest pharmacy chain Sensiblu, with over 200 branches, is owned by the A&D company group, which also owns the wholesaler Mediplus Exim.

The interests of the pharmacists are represented by the pharmacy association (Colegiul Farmaciştilor din România, CFR). The CFR also advises the Ministry of Public Health on reimbursement decisions.

Access to medicines and to health care in general is especially difficult in the rural areas. This is also reflected in the consumption data. According to the Association of Pharmaceutical Industry (ARPIM), in 2006 pharmaceutical consumption was valued at € 50 per person in rural areas and around € 100 in urban areas. Due to poor organisation of primary health care, rural populations tend to use in-patient medical services in hospitals.

Until now, the Ministry of Public Health has implemented hardly any in-

centives to open a pharmacy in rural areas and there are no regulations regarding a minimum distance between pharmacies.

## 3.2 Funding of the health care and the pharmaceutical system

5.5% of GDP spent on health

The implementation of the health insurance scheme in 1998 increased public health expenditure (3.4% of GDP in 1999 compared to 2.8% in 1998). Compared to other European countries, Romania still has the lowest percentage of GDP spent on health. There were no further significant increases in the following years, but as general trend health expenditure in Romania as share of GDP has been increasing. The level of health care expenditure per capita is also much lower compared to countries from Western Europe and to many countries from central and south-Eastern Europe.

Employees contribution

The social health insurance contributions are around 13.5% of the income of the insured; 7% are paid by the employer and 6.5% by the employee (HiT Profile Romania 2008). Self-employed people and farmers also pay social health insurance contributions based on their income. Retired people and the unemployed are covered through specific retirement and unemployment funds.

Family members such as children, students, disabled people without an income and war veterans are covered by social health insurance for free. Additional exemptions are made for people who are in prison as well as people who are in military service.

Private funding

In general, statistics regarding pharmaceutical expenditure, especially for the private share, is not easily available. However, according to information from a World Bank report (Seiter 2007) around 80% of prescription-only medicines are reimbursed by the Health Insurance Fund (CNAS). For the remaining 20% patients have to pay out-of-pocket.

*Table 3.2: Romania – Expenditure data, 2000, 2005, 2007*

| Expenditure data | 2000 | 2005 | 2007 |
|---|---|---|---|
| GDP per capita in € | 1,810.31 | 3,684.54 | 5,742.92 |
| THE in % of GDP | 4.6% | 5.5% | n.a. |
| - Public HE in % of THE | 74.1% | 70.3% | n.a. |
| - Private HE in % of THE | 25.9% | 29.7% | n.a. |
| TPE in % of THE | 18.05% | 35.55% | 24.89% |
| - Public PE in % of TPE | n.a. | n.a. | n.a. |
| - Private PE in % of TPE | n.a. | n.a. | n.a. |

GDP = Gross domestic product, HE = health expenditure, n.a. = not available, PE = pharmaceutical expenditure, THE = total health expenditure, TPE = total pharmaceutical expenditure

Source: WHO HFA Database 2009, EUROSTAT

# 4 Pharmaceutical reimbursement system

## 4.1 Framework

Legal framework

The Ministry of Public Health as well as the National Health Insurance Fund are responsible for making reimbursement decisions. The positive lists were enacted into law. The criteria for reimbursement decisions are based on Act No. 917/2006. The reimbursement criteria are explained in more detail under section 4.2.1.

Population coverage

As mentioned earlier, the whole population is entitled to receive health care.

Most of the population is covered by the public health insurance scheme. In general, the reimbursement lists are only valid for the out-patient sector. However, there is a separate list of reimbursable OTC products for children and pregnant women. This list is published in the Act No. 678/2006.

Linkage between pricing and reimbursement

Before a decision on the reimbursement status of a medicine is made the Directorate for Strategies and Medicine Policy under the Ministry of Public Health sets the price of the medicine. The pricing strategies are explained in detail under section 3.1.

Reimbursement authority Ministry of Public Health and National Health Insurance Fund

The National Health Insurance Fund (CNAS), the umbrella organisation for all sickness funds, is responsible for the reimbursement of all medicines included in the positive lists. Until the end of 2008 the regional sickness funds and those for special employment groups concluded monthly budgets with pharmacies. Within those budgets, the pharmacy dispensed medicines at the expense of the sickness fund.

If the monthly budget was exhausted before the end of the period, the pharmacy could not dispense any more prescription-only medicines (with some exceptions). This led to insufficient supplies in some pharmacies (Seiter 2007).

By 2009 the regulation on pharmacy budget ceilings was abolished, meaning that all pharmacies could dispense the real quantity of medicines needed by the population. However, this led to the paradoxical situation that, by the end of September 2009, the overall state budget for medicines for the year had already been exhausted.

Stakeholders involvement

When deciding whether a medicine should be included in the reimbursement list, different stakeholders are part of the decision making process. Pharmaceutical companies send their application for reimbursement to the Therapeutic Strategy Committee within the Ministry of Public Health. This Committee includes representatives of the Ministry of Public Health, of the National Health Insurance Fund as well as many

medical experts. The members of this committee, other experts, and their duties and procedures are defined in Acts No. 131/2005 and No. 466/2006.

In addition, the Association of Doctors (CMR) and the Association of Pharmacists (CFR) may assist the Ministry of Public Health and the National Health Insurance Fund with decisions about the reimbursement status of a medicine (cf. section 4.2.2). Associations of patients, producers and wholesalers have observer status.

The National Transparency Commission endorses the list, which is signed by the Minister and the head of the National Health Insurance Fund, and approved through governmental decision. However, the Transparency Committee has been criticised because experts may sometimes face conflicts of interests (see section 5.2).

Role of private sector

In Romania, where the social health insurance system is funded by employee contributions (cf. section 3.2), public health care provision is key. Health care is still largely provided by public health facilities.

## 4.2 Reimbursement schemes

### 4.2.1 Eligibility criteria

Reimbursement schemes

The Romanian health care system is based on a social health insurance system. The Ministry of Public Health as well as the National Health Insurance Fund are responsible for deciding on the reimbursement status of a medicine. All reimbursable medicines are included in one of the three reimbursement lists (list A, B, C).

Children and pregnant women are eligible to receive additional non-reimbursable OTC products free of charge. These medicines are paid out of public budgets, separately from the National Health Insurance Fund.

Eligibility

Reimbursement in Romania is a mix of product-specific and disease-specific reimbursement eligibility criteria. In List A and List B the reimbursement status is decided per medicine (product) and in List C reimbursement is based on the underlying disease, the age group of the population or personal condition (pregnancy).

### 4.2.2 Reimbursement lists

Positive list

For the out-patient sector the National Health Insurance Fund publishes three different reimbursement lists. As mentioned earlier, the updating and the publishing of the lists are the responsibility of the Ministry of Pub-

lic Health and the National Health Insurance Fund.

The reimbursable medicines are listed according to their active substance on one of the three positive lists including the maximum reimbursement price. The reimbursement price corresponds to the reference price of a cluster plus the respective reimbursement rates (cf. section 4.2.3). In case a medicine is not included in the reference price system the reimbursement price is set based on the pharmacy retail price taking into account the reimbursement rates.

The reimbursement rates are 50%, 90% and 100% (cf. section 4.2.3). The clusters (reference groups) are built at ATC (Anatomic therapeutic chemical classification) level 5 (cf. section 4.3).

For some specific medicines on list B and C a separate approval from the National Health Insurance Fund is needed.

Criteria

Criteria on the reimbursement decision are described below. The product needs to fulfil the following criteria to be eligible for reimbursement:

- New chemical entity, with new therapeutic indication and bringing a major clinical benefit;
- Known chemical entity, with new therapeutic indication and bringing a major clinical benefit;
- Chemical entity with superior effectiveness than other chemical entities in the same therapeutic group / subgroup, demonstrated in controlled clinical studies
- Chemical entity with enhanced safety compared to other existing chemical entities in the same therapeutic group / subgroup, according to the data presented by the holder of the authorization for marketing / sales within the benefit / risk ratio according to the ministerial Act No. 406 / 2005 for approval of guidelines to the procedure to be followed by holders of the authorisation for marketing / sales, in actions of pharmaco-vigilance.
- Chemical entity / associated chemical entities, in the same therapeutic group, with the same therapeutic indication with the scope of existing products for a certain disease, when bringing a decrease of the therapy cost. Therapy cost means the cost of a daily therapeutic dose (DDD).

Procedure implies three evaluations

As mentioned earlier, the reimbursement procedure is composed of different review procedures set by the Ministry of Public Health. Firstly, experts from a specialist commissions prepare a first draft list (so called “wish list”).

Secondly, the Therapeutic Strategy Commission, which includes members of the National Health Insurance Fund (CNAS) and the Ministry of Public Health as well as observers from industry and distribution assess

the proposed reimbursement lists.

In a final step, the Transparency Commission clears the decision document and passes it to the minister for his/her signature.

The process relies to a large extent on data submitted by the manufacturers and the limited human resources of the Commission to read and digest these data. Commission members are not accountable for the economic or public health impact of their decisions. There is no systematic assessment of pharmaco-economic data or arguments (cf. section 4.5.2).

Pharmaceutical evaluation

When a pharmaceutical company applies for reimbursement of its product then the company needs to submit a dossier including information on the marketing authorisation, classification, relevant clinical studies, cost-effectiveness studies as well as pricing and reimbursement information from 12 other EU countries (cf. section 3.1). Furthermore, the dossier needs to include information on the superior safety (fewer adverse reactions) and efficacy of the product in comparison to other medicines of the same cluster already included in the reimbursement list.

Economic evaluation

However, it is not explicitly required to include a pharmaco-economic analysis in the reimbursement application. In addition, there are no pharmaco-economic guidelines in Romania.

Appeal procedure

If the Ministry of Public Health or the National Health Insurance Fund returns a negative reimbursement decision, they have to inform the applying company within ten days. The company may then appeal against the decision within three days at the Transparency Committee.

Procedure time

In accordance with the Transparency Directive, the reimbursement procedure can take a maximum of 90 days, but it can be extended if more information is required by the Ministry of Public Health.

Scope

The number of medicines on the different reimbursement lists varies. As of 2008. List A included 156 clusters with around 1,460 medicines (mainly unbranded generics), with around 9 different products in each cluster. List B had 216 clusters with around 650 medicines (mainly branded original products), which is around 3 products per cluster. List C consists of three sub-lists, however information was only available on the scope of list C3, which includes 150 clusters (Rusu 2009).

All in all 5,043 medicines were included in the reimbursement list in 2010.

OTC are normally not covered

According to legislation OTC products are not reimbursable, unless in exceptional circumstances that have to be justified on grounds of public health. However, there is an additional list including OTC products, which are reimbursable for pregnant women and children.

Updates

The Ministry of Public Health and the National Health Insurance Fund

update the three reimbursement lists each quarter.

The reimbursement lists are publicly available on the website of the Ministry of Public Health.

Publication

### 4.2.3 Reimbursement categories and rates

Reimbursement of medicines by the National Health Insurance Fund is based on three positive lists with different rates and categories. The lists are categorised according to the International Non-proprietary Name (INN):

Different reimbursement rates & categories

- List A consists of medicines (mainly generics) that are seen as important and cost-effective, with a reimbursement rate of 90%.
- List B includes medicines that are judged as less essential or less cost-effective; the reimbursement rate is 50%.
- List C is divided into three sub-lists, all of which are 100% reimbursed
  - C1 including medicines for ambulatory care for a group of diseases (mainly for severe and chronic diseases)
  - C2 including medicines that are reimbursed as part of the national treatment programs delivered only through hospitals. These programs cover conditions such as HIV/AIDS, certain tumours, tuberculosis, multiple sclerosis, diabetes mellitus, renal insufficiency, osteoporosis, transplantation etc.
  - C3 including medicines from list A and B with additional OTC-products limited only to persons under the age of 18, students and other apprentices aged 18-26 if they are without income, pregnant women and young mothers.

Certain medicines on the three lists in category C need to be prescribed by a specialist or require a pre-approval by the regional sickness fund. Table 4.1 gives an overview of the reimbursement categories and rates.

*Table 4.1: Romania – Reimbursement of medicines, 2009*

| Reimbursement category | Reimbursement rate | Characteristic of category |
|---|---|---|
| List A | 90% | Includes medicines that are necessary and cost-effective. |
| List B | 50% | Includes medicines that are of less importance and less cost-effective. |
| List C | 100% | Includes three sub-lists: |
| List C1 | | Includes specific medicines for ambulatory care for a group of diseases (mainly severe and chronic diseases). |
| List C2 | | Includes medicines, that are reimbursed as part of the national treatment programs delivered only through hospitals; treating conditions such as HIV/AIDS, certain tumours, tuberculosis, multiple sclerosis, diabetes mellitus, renal insufficiency, osteoporosis, transplantation etc. |
| List C3 | | Including medicines for young people, students, pregnant women and young mothers. |

Source: Rusu 2009

Exemptions for vulnerable groups

List C3 is especially designated for vulnerable groups such as children, students and pregnant women. In addition to the other positive lists, this list also included non-reimbursable OTC products only for this population group.

Generics promotion

Generics are very much promoted by the National Health Insurance Fund, since this is a possible tool to decrease public spending. Positive list A, in particular, includes a lot of generic essential medicines.

## 4.3 Reference price system

RPS since 1997

Since 1997, Romania has been operating a reference price system, which is a reimbursement tool for the out-patient sector. For medicines included in the reference price system, the National Health Insurance Fund refunds up to the reference price (= reimbursement limit), whereas the difference between reference price and actual pharmacy retail price plus percentage co-payments has to be covered by the patients.

Scope

The reference groups (groups of homogenous products) are clustered at ATC 5 level, thus grouping reimbursable medicines of the identical active

ingredient of the same quantitative and qualitative composition.

Technical procedure

The Ministry of Public Health is in charge of setting and adapting the reference groups and reference prices. It is a technical process, based on legal rules. As soon as the Ministry of Public Health is informed by the companies about the planned market entry of a generic, they start the technical preparation for building a new reference group or adjusting a group.

Reference price

According to the Ministry of Public Health the reference price (= reimbursement limit) is defined as the price of the cheapest generic in the cluster. The percentage reimbursement rate for reimbursable medicines (cf. sections 4.2.3 and 4.4) is also applied at the reference price, thus the co-payment for patients is not only the difference between the reference price and the actual pharmacy retail price, but also a percentage co-payment of the reimbursement limit that is calculated on the basis of the reference price.

Exemptions for vulnerable people

Children and pregnant women as well as war veteran and disabled people on low incomes are exempt from any co-payments (cf. section 4.4).

Regular updates

Reference groups and reference prices are updated on a yearly basis. However, according to information from the association of industry (ARPIM) the list of reference prices has not been updated for three years.

Publication

The list of reference prices is published on the website of the Ministry of Public Health site.

## 4.4 Co-payments

% co-payments for out-patients

There are three forms of co-payment for reimbursable medicines in Romania:

- Percentage co-payment (10%, 50% or 0%) depending on the different reimbursement list the medicine is included
- Co-payment due to the reference price system (difference between the reference price and the actual pharmacy retail price)
- And direct co-payments in case the monthly prescription limit of physicians is exhausted.

Additional out-of pocket payments may occur in case a contracted physician prescribes more medicines per month as he/she is allowed according to the prescription guidelines (cf. section. 4.5.2).

Exemptions from out-of pocket payments are only possible for children or pregnant women. Additional exemptions are made for war veterans and for disabled people on low incomes. However, there are no exemptions for other vulnerable groups such as people with chronic diseases.

## 4.5 Further instruments

### 4.5.1 Pharmaceutical budgets

Budget ceiling for pharmacies

The tool of pharmaceutical budgets for physicians, which would define a maximum amount of expenditure for prescribed medicines, is not applied in Romania. However, as already mentioned in section 4.1, there used to be annual budget ceilings for pharmacies. The ceiling referred to the amount of reimbursable medicines that a pharmacy was allowed to dispense within a month. The value of ceiling was set by the National Health Insurance Fund based on a score of each pharmacy that included the number of pharmacists and their professional status, the number of pharmacy assistants, the opening hours and the urban/rural location.

The budget ceilings for pharmacies were criticised by the Association of Pharmacists since the pharmacists could not influence the number prescribed medicines by physicians. Hence, the pharmacy budget was often spent for fewer patients and the budget was already used in the first half of the month. This led to a situation where patients had to go from one pharmacy to the next to find a pharmacy with a remaining budget. However, in many cases patients decided to pay out-of pocket for their medicines.

In the beginning of 2009 the pharmaceutical budget ceilings for pharmacies were abolished. Since then, pharmacists have been allowed to dispense the quantity of prescribed medicines without a budget limit. However, this led to the paradoxical situation that, by the end of September 2009, the 2009 medicines budget of the National Health Insurance Fund was exhausted. This development was mainly driven by the fact that the existing monitoring systems did not manage to curb potential over-prescriptions within the system.

As a short-term solution, the Romanian government introduced the following strategies:

- Introduction of a claw-back system (5-11% of the sales of pharmaceutical companies) as well as a prolongation of the payment period to pharmacies.
- Generating additional funds through tobacco and alcohol taxes.
- Enforcement of monitoring measures.
- Combating corruption.

### 4.5.2 Reviews and monitoring

No regular price reviews – Price freezes

The prices of reimbursable medicines should be reviewed by the authorities every quarter. This review can lead to a reduction in prices. However, it is not clear if this time period is really enforced.

However, in 2008 the authorities refused to make price adjustments, keeping the exchange rate to calculate the regulated prices for imported reimbursable medicines frozen at the level of April 2007. This exchange rate was maintained until January 2009. In the meantime the local currency had depreciated by more than 30%. At the beginning of each year a new exchange rate is defined, but it is still lower than the expected rate for the current year. This measure affected the pharmacy market significantly.

Prescription monitoring

General practitioners as well as specialists who have contracts with the sickness funds receive feedback on their prescribing behaviour on a regular basis. When monitoring the prescription behaviour, the sickness funds check whether the physicians follow the prescription guidelines. Nevertheless, the National Health Insurance Fund has no right to implement sanctions where physicians have not adhered to the prescription guidelines. However, in practice the feedback on prescribing behaviour is reported months or even years later and therefore has a more informative than sanctioning character. The existing monitoring system does not match expectations and needs, as the message is delivered too late, or not at all.

Prescription guidelines

The National Health Insurance Fund tries to control the prescription behaviour of physicians through prescription guidelines, education and information. Thus, physicians may prescribe only a limited number of reimbursed medicines per patient per month depending on the reimbursement list: a maximum of four list A medicines, three from list B and three from list C1 or four from list C3 per month. If the patient needs more medicines within the month, he/she has to co-pay for these medicines even if they are included on the reimbursement list.

There are exemptions to the monthly prescription limitations, for example if the limitation would severely damage the life of a patient or risk serious health damage. In these cases, written approval of the Ministry of Public Health is needed.

For children under the age of 18 there is no value- or volume-based limitation on prescriptions.

### 4.5.3 Generics promotion

INN prescribing

Physicians in Romania are allowed to prescribe by the International Non-

proprietary Names (INN) as well as the brand name.

Generic substitution

In Romania, there is indicative generic substitution, meaning that the physician may prescribe generically. However, physicians may exclude generic substitution (by ticking a box on the prescription), and patients can also oppose generic substitution – in both cases patients have to pay a higher price.

Further generic promotion

It is recommended that physicians prescribe a generic by using the national computerized system for decision support and monitoring of prescription patterns.

Generic market

*Table 4.2: Romania – Generics market in volume and value, 2007*

| **Generic market** | **2007** |
|---|---|
| Volume (no. of packs sold) | approx. 70% |
| Value (expenditure) | approx. 40% |

Source: Data gathering by GÖG/ÖBIG, estimations by the Romanian Ministry of Public Health

## 4.6 Future developments

Recession and unstable political environment

The financial crisis in 2009 has, as in Hungary, Latvia and Iceland, put the country in an even more difficult economic situation than before. Not only has the recession had a big influence on public spending for health care but also the unstable political environment. In October 2009 the coalition government collapsed and a new government was elected.

Increase transparency

As already recommended by others (Seiter 2007) the criteria for medicines to be included in the reimbursement lists as well as the pricing procedures should be more transparent. The government has promised to put a particular focus on this. Possible solutions may be the introduction of rebates for the sickness funds or the enlargement of the reference price system on ATC 4 level.

According to the Ministry of Public Health there is a plan to review the country basket for external price referencing and to reduce the number of countries (at the moment twelve countries are included). There is also a plan to change the price calculation to the average of the lowest three prices in the basket.

Additionally the implementation of an e-health system (introduction of e-health record, e-prescription, e-health card) is currently being prepared. Experts have high expectations for the e-health system (e.g. improved monitoring etc.).

Recommendations

As experiences from other countries show, it helps to learn from neighbouring countries with similar economic situations. Good ways of involving international experts in a reform process is to apply for TWINNING projects funded by the European Commission.

Another possible way of exchanging experiences on certain pharmaceutical policies is active participation in non-commercial, Member States' funded initiatives such as PPRI (Pharmaceutical Pricing and Reimbursement Information, http://ppri.goeg.at). The Romanian Ministry of Public Health joined the PPRI network in 2009.

# 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 Romanian health and pharmaceutical system, which were presented in the previous sections. This analysis is undertaken from a public health and human rights perspective, which correspond with the views of many civil society organisations.

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 Romanian pharmaceutical reimbursement system will be discussed with regard to nine components (e.g. transparency, role of stakeholders and beneficiaries, availability, affordability) which are relevant for the implementation of access to essential medicines. For each of these components, indicators have been developed. A brief assessment of the indicators is provided in Table 5.1 in order to offer information at a glance.

Government commitment

In Romania, the government has committed to implementing equitable and consistent access to health care. A major measure in this context was the introduction of the National Health Insurance Fund (cf. section 3.1).

However, the political environment in Romania is quite unstable. Consequently, certain policy measures may not be implemented in timely way,

to an appropriate degree of quality, or without accountability.

However, the regulatory framework in Romania refers to the right to health and to medicines for the whole population, even though it has no explicit essential medicines policy document.

Population coverage

In theory, there should be universal coverage for the population in Romania. All residents enjoy health care coverage, including all reimbursable medicines in the different reimbursement lists (cf. section 4.2.2).

List of essential medicines

Romania has different reimbursement lists in the out-patient sector. The different lists include different amounts of substances which are reimbursed either at 100%, 90% or 50%.

List A, in particular, includes a lot of essential medicines. A critical point here is that there are still high out-of-pocket payments due to unavailability of certain medicines (see below on availability) and poor transparency of the reimbursement process (see below transparency).

*Table 5.1: Romania – Assessment of the pharmaceutical reimbursement system*

| Indicator | Assessment | |
|---|---|---|
| | **In brief** | **Discussion** |
| **Government commitment** | | |
| Access to health | Yes | Access to equitable health care is recognized in several laws, decrees and legal provisions and implemented by the Ministry of Public Health. |
| Access to essential medicines | Yes | There are several laws, decrees and further legal provisions which ensure equitable access to medicines for all residents, including those considered as essential. |
| Essential medicines policy | No | Romania has no explicit essential medicines policy. |
| **Coverage of the population** | | |
| Health care | Yes | The predominately public system covers almost the entire population (94%). |
| Medicines | Yes | In theory, the whole population is covered by the reimbursement lists of the National Health Insurance Fund. |
| **List of essential medicines** | | |
| Positive list | Yes | The reimbursement lists (A, B and C with its sub-lists) cover the whole population. |
| Scope | Around 520 clusters | As of 2008, list A includes 156 clusters with around 1,460 medicines (mainly unbranded generics) with around 9 different products in each cluster; list B 216 clusters with around 650 medicines (mainly branded products) which represent around 3 products per cluster. List C consists of three sub-lists, however only information on the scope of list C3 could be found; it includes 150 clusters. |
| Updates | Quarterly | The reimbursement lists should be updated each quarter. |
| **Transparency** | | |
| Publication of lists | Yes | The lists are published on the Ministry of Public Health's website. |
| Publication of prices | Yes | The reimbursement lists include the prices of the reimbursable medicines, which are published on the Ministry's of Public Health website. However, the prices of non-reimbursable medicines are not published, since they are set freely, but the Ministry of Public Health has to be notified. |
| **Rational selection of medicines** | | |
| Positive list | ~ | The reimbursement criteria have been criticised for not being transparent. The new government is working on the implementation of more transparent criteria. |
| Reference price system | Since 1997 | The reference groups are clustered at ATC 5 level and The reference price is defined as the price of the cheapest generic in the cluster. |

| 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 reimbursement may appeal to the Transparency Committee. |
| Fines and sanctions | No | Public authorities may not impose fines in case of non-adherence; there are no fines if physicians do not prescribe by INN. |
| **Beneficiaries and stakeholders** | | |
| Involvement and consultation | Yes | Experts from the Transparency Committee, which is the advising body of the Ministry of Public Health in the reimbursement process, have been criticised for receiving some sponsorship from pharmaceutical companies for research. This could represent a conflict of interest. |
| Role of stakeholders | Physicians impact patients' choice of medicine | Physicians either prescribe by INN or by original brand name. This may have a negative impact on the patients' access to less expensive generic alternatives. |
| Patients understanding the system | Not sufficient | It seems that patients do not fully understand the system. |
| Vulnerable groups | Not sufficient | Exemptions from co-payments are made for children and pregnant women as well as for war veterans and disabled people on low incomes. However, there are no exemptions for older people or people with chronic diseases, as in many other countries. |
| **Availability** | | |
| Medicines launched | 4,400 on the market (2007) | In Romania a much higher number of medicines are authorised (6,710 in 2007) than there are actually on the market (4,400 in 2007). |
| Pharmacies | 7,043 (2009) | In 2009, there were 7,043 pharmacies in Romania. This corresponds to 3,058 inhabitants per pharmacy (EU-average (EU-25: 4,405 inhabitants per POM dispensary, year 2005). |
| **Affordability** | | |
| Co-payments | Yes | For most of the medicines included in either one of the reimbursement lists patients have to co-pay. |
| Private funding of pharmaceutical expenditure | Not known | No exact data are available on private funding of medicines, but it is expected that the share is high. |
| Promotion of less expensive medicines | Yes | Reimbursement list A, in particular, includes a lot of generics. However, INN prescribing for physicians is only on a voluntary basis: very often physicians still prescribe by brand name. This is accompanied by an inconsequent generic substitution policy, which is however not always consequently enforced. |

Source: ÖBIG

Transparency & rational selection of medicines

According to Rusu (2009), the Romanian pharmaceutical system lacks transparency in two main areas:

Firstly, experts of the Transparency Committee, which advices the Ministry of Public Health in the reimbursement process, have been criticised for having been employed by industry as collaborators or experts to promote particular medicines. This could represent a conflict of interests. In addition, those experts have little or no knowledge of pharmaco-economics. Hence, throughout the whole reimbursement process pharmaco-economic or impact analyses have not been applied.

Secondly, poor transparency characterised by a lack of public information. Patients are not aware of the fact that they might ask their doctors for a cheaper alternative medicine, this lack of awareness might contribute to higher out-of-pocket payments for patients. Even though reimbursement lists are publicly available, on the Ministry of Public Health's website, patients are still not aware of them.

Mechanisms for enforcement

Pharmaceutical companies that have received a negative decision regarding reimbursement of their medicine can appeal to the Transparency Committee (cf. section 4.2.2). In the European Union, according to the Transparency Directive, a reimbursement system has to foresee the possibility to appeal.

On the other hand, the public authorities rarely implement measures, since they have no power to sanction companies, for example reporting incorrect information.

Since neither generic substitution for pharmacists nor INN prescribing for physicians are mandatory, public authorities have no right to enforce those measures.

Beneficiaries and stakeholders

As mentioned earlier, in the Transparency Committee different experts are included. However, in some cases these experts might have a conflict of interest (see under transparency).

In terms of patients the pharmaceutical system does not sufficiently protect vulnerable groups. There are exemptions from co-payments for children and pregnant women. However, people with chronic diseases or people on low incomes are not protected from out-of pocket payments.

In addition to the few out-of-pocket payment exemptions, patients are not aware of the fact that they may ask their physician for cheaper equivalents. Patients trust their physicians. But physicians have no incentives to prescribe by INN; they therefore very often prescribe brand names.

Availability & Affordability

The reimbursement lists in Romania do include enough essential medicines.

In terms of availability it is reported that especially in rural areas it is be difficult for patients to get their medicines in time (Pana 2009).

## 5.3 Conclusions

The authors believe that the Romanian reimbursement system has room for improvement. First attempts regarding an elaborated and sustainable system have been made. However, the focus should increasingly be based on core values of accessibility, essentiality, equity, universality and effectiveness and on a well-defined and founded regulatory framework with transparent rules.

Room for improvement

In general, better access to medicines, in particular for essential medicines, could be guaranteed by considering the following points:

- The establishment of an independent institution responsible for pharmaco-economic and impact analysis in the long run. This would guarantee quality assurance in the reimbursement decision process. The composition of the institution should include economists and social scientists trained in cost-benefit analysis and pharmaco-economics as well as medical experts.
- Access to affordable medicines could be improved by promoting generic policies that increase competition and contain pharmaceutical expenditure both for patients and third party payers. The objective could be achieved by implementing mandatory generic substitution for pharmacists and mandatory INN prescribing for physicians.
- Enforcement of the monitoring mechanism for the prescribing behaviour of physicians.
- Finally, active participation in a European non-commercial network on pricing and reimbursement, such as the PPRI network, is recommended. Active participation will give representatives of public authorities in Romania the opportunity to exchange with their fellow colleagues and to learn from experiences with certain policy measures in other countries.

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