

ÖBIG FORSCHUNGS- UND PLANUNGSGESELLSCHAFT mbH



ACCESS TO ESSENTIAL MEDICINES IN PORTUGAL

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ACCESS TO ESSENTIAL MEDCINES IN PORTUGAL

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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 Portugal in relation to access essential medicines.

In Portugal, the reimbursement system is embedded in a National Health Service, the so-called SNS, which is funded by general taxation and provides health coverage for the whole population.

Portugal has a positive list, the *Prontuário*, that includes reimbursed essential medicines and other pharmaceuticals.

The list is applied in the out-patient sector and currently includes around 7,200 medicines, where approximately 4,300 are considered essential (medicines in Category A and B of the *Prontuário*).

- Category A: Only 1% of listed medicines, mainly essential medicines that are life-saving, are fully (100%) reimbursed by the State.
- Category B: Another 10% of the medicines on the list, essential medicines for chronic diseases such as diabetes, are 95% reimbursed by the State.
- Category C: Essential medicines for the treatment of serious diseases amount to nearly half of all medicines on the list and are reimbursed up to 69% by the State. This means that co-payments for the patients taking medicines in this category may be considerable.

A special reimbursement class is applied to low-income pensioners, who are entitled to lower co-payment rates. This includes a 100% reimbursement rate for life-saving essential medicines, but also for essential medicines for chronic diseases and, since June 2009, for all generics.

Pharmaceuticals administered to in-patients at public hospitals are fully reimbursed.

INFARMED selects medicines for the *Prontuário* according to a strict and transparent regulatory framework. Pharmaco-therapeutic and pharmaco-economic evaluations are used to assess a medicine's candidacy for reimbursement. Medicines with excessive prices or low therapeutic efficacy are not reimbursed. OTC products are not usually reimbursed, but may be included in the positive list if justified on the grounds of public health.

Recently, Portugal has implemented several measures to promote generics:

- Generic substitution on a voluntary basis (i.e. substitution of an original product for a generic by the pharmacist)
- Obligation to prescribe the international non-proprietary name (INN) albeit without sanctions in cases of non-compliant physicians
- A reference price system that favors the use of less expensive generic alternatives

With this generics promotion policy, in a decade Portugal has succeeded in increasing the generic market share from 0% to 14.5% (in volume) and 19.5% (in value). However, the prices of generics remain high despite recent price cuts.

The Portuguese reimbursement system is transparent as all relevant medicines' lists are published on the Internet as soon as they have been updated. However, the overall system and specific characteristics are not fully understood by patients.

Overall, the authors consider the pharmaceutical reimbursement system in Portugal to be well-defined and sustainable, with a regulatory framework based on clear criteria and a system that in general, guarantees patients access to essential medicines. However, Portuguese citizens pay high co-payments that may prevent some patients from being able to afford high-cost medicines. The authors have identified three related areas for improvement:

- Policy makers should aim to decrease co-payments. If a reduction is not possible, the affordability of the medicines needed by the population should be monitored, particularly for vulnerable groups. If certain groups find medicines unaffordable, exemptions and/or reduced co-payments should be implemented.
- Generic promotion policies should be refined in addition to reduced generic prices. Mechanisms for better enforcement of the rules, such as sanctions or financial incentives, should be considered to encourage generic substitution.
- The Medicines Agency INFARMED have a good publication policy, however, the reimbursement system does not seem to be fully comprehensible to patients. Civil society could be more involved as educators and “translators”, who can explain the pharmaceutical system’s rationale and functioning to the general public.

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List of abbreviations

APIFARMA	Associação Portuguesa da Indústria Farmacêutica / Portuguese Association of Pharmaceutical Industry
ARS	Administração Regional de Saúde / Regional Health authority
ATC	Anatomic therapeutic chemical classification
DDD	Defined Daily Dose
DECO	Associação Portuguesa para a Defesa do Consumidor / Portuguese Consumers' Rights Association
DGAE	Direcção-Geral das Actividades Económicas / Directorate-General of Economic Activities
EAHC	Executive Agency for Health and Consumers
EMINet	European Medicines Information Network
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
HAI - E	Health Action International - Europe
HE	Health expenditure
HiT	Health systems in transition
HPF	Formulário Hospitalar Nacional de Medicamentos / National Hospital Formulary
ICESCR	International Covenant on Economic, Social and Cultural Rights
INFARMED	Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. / National Authority of Medicines and Health Products, I.P.
INN	International Non-proprietary Name
NGO	Non-governmental organisation

NHS	National Health Service
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
ÖBIG FP	ÖBIG Forschungs- und Planungsgesellschaft mbH / Austrian Health Institute, Research and Planning
PE	Pharmaceutical expenditure
PFM	Postos Farmacêuticos Móveis / Pharmacy extension
PHIS	Pharmaceutical Health Information System project
POM	Prescription-only medicines
PPR	Pharma Pricing and Reimbursement
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PTC	Pharmacy and Therapeutic Committee
RPS	Reference price system
SNS	Service National de Saúde / National Health Service
THE	Total health expenditure
TPE	Total pharmaceutical expenditure
VAT	Value added tax
WHO	World Health Organization

1 Introduction

Access to medicines is a key component for 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.

Access to essential medicines

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

HAI-E project

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.

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

Outline

- 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 national health and pharmaceutical system
 - An in-depth description of the reimbursement system, including key elements, such as a 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 achieving access to essential medicines
- 2) In a second phase, the presentation and discussion of the results as part of a workshop targeting civil society organisations.

In order to guarantee constructive project outputs, 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.

ÖBIG consultancy

2 Methodology

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

Desktop research

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

Know-how and network

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 in- and out-patient sector are provided.

Integrated view

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>

Terminology

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 Portugal stands.

Benchmarking

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).

Essential medicines’ concept

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).

Human rights based approach

3 General background

3.1 Organisation of the health care and pharmaceutical system

<p>The Portuguese health care system is organised as a National Health Service (Service Nacional de Saúde, SNS), financed through general taxation, which provides health coverage for 75% of the population. One quarter of the population (certain professions, primarily civil servants and employees of private financial institutions) are covered by one of the health sub-systems (sub-schemes), funded mainly by contributions from employers and employees.</p>	<p>National Health Service</p>
<p>The Portuguese SNS was introduced in 1979 based on the principle of universal coverage and equality of care. The revision of the Constitution in 1989 altered the principle of universal health care services to “tendentially free” meaning that health care is in general, but not always, free.</p>	<p>Core values of the SNS</p>
<p>The SNS has a strong regional structure consisting of regional health administrations. There are five regional health authorities (Administração Regional de Saúde, ARS), which have overall responsibility for supervising and allocating financial resources to SNS healthcare providers in their regions. They are accountable to the Ministry of Health, which, at a central level, is responsible for developing health policy and controlling and evaluating its implementation.</p>	<p>Strong regionalisation</p>
<p>All residents in Portugal have access to health care provided by the SNS. Thus, legal migrants have the same rights as Portuguese citizens. Even illegal migrants receive free treatment for diseases that endanger public health and for maternal care.</p>	<p>Coverage</p>
<p>The health status of Portuguese citizens has improved over the years (Barros, P.; De Almeida Simões J. 2007), which is reflected in a rise in the population’s life expectancy by 2.3 years over eight years (see Table 3.1). However, as in many countries, life expectancy for women (82.3 years at birth) is considerably better than for men (75.5 years at birth; OECD Health data 2009).</p>	<p>Health status</p>
<p>With 3.5 out-patient physicians per 1,000 inhabitants the provision of doctors is quite high in Portugal compared to the EU average (EU-25 average: 2.7 (2005), PPRI 2008). Still, the number of out-patient physicians has continued to increase in recent years. In line with other countries, Portugal has reduced the number of acute care beds in hospitals, which was already lower than the European average (Portugal: 2.9 acute care beds per 1,000 inhabitants, (2007) compared to a ratio of 4.8, (2007) for EU-25 average). During the last few years, the number of public hospi-</p>	<p>Health care delivery</p>

tals has decreased, while the number of private hospitals has increased.

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

Health system	2000	2005	2008
Total population, in millions	10.2	10.5	10.6
Life expectancy at birth, total	76.6	78.2	78.9 ¹
No. of physicians per 1,000 inhabitants	3.18	3.43	3.49 ¹
No. of hospital beds per 1,000 inhabitants	3.25	2.99	2.85 ²
Total no. of POM-dispensaries	2,795	2,909	2,905

POM dispensaries: Pharmacies and retailers that are allowed to dispense prescription-only medicines

¹ Year 2006

² Year 2007

Data as of 31 December

Source: EUROSTAT, OECD 2009, INFARMED/ PPRI 2008, INFARMED information at ÖBIG request

The key authority in the Portuguese pharmaceutical system is the Medicines Agency (Autoridade Nacional do Medicamento e Produtos de Saúde, INFARMED), which is in charge of all relevant tasks (market authorisation, vigilance, market surveillance, distribution and reimbursement of medicines) except pricing. Pricing (i.e. determining the price of a medicine) is under the competence of the Directorate-General of Economic Activities (Direcção-Geral de Actividades Económicas, DGAE). The Ministry of Health, which is the supervising authority of INFARMED, is responsible for the overall strategic framework of medicines.

Pharmaceutical system

The prices of prescription-only medicines (POM), which account for around 95% of all authorised medicines, are regulated. After a market authorisation is granted, the company may apply a maximum price to be set by the medicine to the Directorate-General of Economic Activities (DGAE) and for the inclusion of the medicine in the reimbursement tem (only relevant for the out-patient sector, see Section 4.1). Price regulation also exists at the wholesale and retail level; wholesale and pharmacy mark-ups are applied for POM and for reimbursed OTC products (for the reimbursement eligibility of OTC medicines, see Section 4.2.2).

Price control

In total, around 45,650 medicines are authorised in Portugal (data as of 1 July 2009, including different pharmaceutical forms, strengths and pack

Availability

sizes).

Patients have access to medicines through pharmacies. There are 2,664 pharmacies throughout the country (data as of 1 January 2009). The number of pharmacies has risen considerably in the first years since the millennium; however, in the recent years, the number has been stable. In 2007, the pharmacy sector was liberalised and non-pharmacists were granted permission to own a pharmacy).

Pharmacies and other retailers

In order to guarantee provisions for citizens in rural areas, pharmacies can run so-called pharmacy extensions (Postos Farmacêuticos Móveis, PFM). PFMs are dependent on a pharmacy and run by a pharmacist and they serve areas where there is no other pharmacy or PFM. There are around 240 PFMs though their number has declined in the last few years. However, in total, provisions for POM dispensaries (pharmacies and PFM) have improved in the last few years (see Table 3.1).

Additionally, since 2005 the sale of OTC products has been allowed in so-called OTC dispensaries, of which 745 exist (data as of 1 January 2009). Furthermore, pharmacies may sell medicines over the Internet.

3.2 Funding of the health care and pharmaceutical system

Per Portuguese citizen, around € 1,460 is spent on health each year (see Table 3.2). This corresponds to 10% of the GDP.

10% of GDP spent on health

Health expenditure has considerably increased in the last years (+40% from 2000 to 2006, compared to a rise of around 20% in GDP).

The Portuguese health care system is a mix of public (around 70%) and private funding (30%). The National Health Service SNS is predominantly funded through general taxation. Apart from direct transfers from the state budget, the SNS raises its own revenue (mostly generated by hospitals).

General taxation

Despite universal coverage from the SNS, approximately a quarter of the population has a second layer of health insurance coverage, e.g. by contracting voluntary health insurance.

In recent years, co-payments for health care have been increasingly applied. This might be due to cost-containment, but sometimes they are said to have been introduced in order to make “consumers more cost-aware” (INFARMED/PPRI 2008). Flat rate, out-of pocket payments are charged for consultations (primary care and visits to out-patient departments of hospitals), emergency visits, home visits, diagnostic tests and

Private funding

therapeutic procedures.

In particular, co-payments are applied to medicines, medical devices and other therapeutic products and reflect a large share of private funding (56%) of pharmaceutical expenditure. In total, pharmaceutical expenditure has risen by 33% from 2000 to 2006, amounting to € 318 per capita.

Table 3.2: Portugal – Expenditure data, 2000, 2005, 2006

Expenditure data	2000	2005	2006
GDP per capita in €	11,953	14,117	14,684
THE in % of GDP	9%	10%	10%
THE per capita in €	1,061	1,440	1,461
- Public HE in % of THE	73%	72%	71.5%
- Private HE in % of THE	27%	28%	29.5%
TPE in % of THE	22.4%	22.6%	21.3
TPE per capita in €	237	312	318
- Public PE in % of TPE	56%	58%	56%
- Private PE in % of TPE	44%	42%	44%

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

Source: EUROSTAT, OECD 2009, national statistics provided in INFARMED/
 PPRI 2008

4 Pharmaceutical reimbursement system

4.1 Framework

The pharmaceutical reimbursement system in Portugal is based on a well-defined legal framework, which is regularly updated with new legislation. The two major provisions regarding reimbursement in the out-patient sector are Decree-Law No. 129/2005, 11 August and Decree No. 1474/2004, 21 December. Decree-Law No.228/2008, 25 November is the relevant legal provision for funding pharmaceuticals in the hospital sector.

Legal framework

The reimbursement policy applies across the whole country and (see Section 3.1). Within this policy, there are specific schemes for vulnerable groups (e.g. pensioners' scheme, see Section 4.2).

Population coverage

According to the understanding of the Medicines Agency INFARMED (INFARMED/PPRI 2008), the reimbursement and pricing systems in the out-patient sector are very closely linked, even though the pricing and reimbursement procedures are under the competence of two different authorities (see Section 3.1). Reimbursement refers to the coverage of pharmaceutical expenditure by a third party payer, like the SNS, whereas pricing concerns, as explained in the previous section, the setting of a price for a medicine.

Linkage between pricing and reimbursement

A medicine needs to have a price before the company can apply for reimbursement. The company producing the medicine addresses the Medicines Agency INFARMED, acting under the supervision of the Ministry of Health, which is in charge of the reimbursement process, i.e. administering and validating the reimbursement application, setting the reimbursement price of a medicine and reimbursing the patient for the pharmaceutical. In practice, INFARMED submits a proposal for the reimbursement of a medicine, while the final decision is taken by the Ministry of Health (see section 4.1.2).

Reimbursement authority INFARMED

No stakeholders (e.g. doctors', pharmacists' or patients' associations) are involved in the reimbursement procedure or decision (e.g. in committee).

Stakeholder involvement

In Portugal, where the National Health Service is funded through general taxation (see Section 3.2), public health care provision is a strong element. However, in recent years a trend in the hospital sector was observed, which saw the number of public hospitals decrease while private providers increased (see Section 3.1).

Role of private sector

The reimbursement process in hospitals is completely different from the

Reimbursement in hospitals

out-patient sector. Generally speaking, in-patients are not charged for pharmaceuticals consumed during their stay in the hospital. The penses incurred for pharmaceuticals in hospitals are covered by the SNS and its sub-schemes (see Section 3.1) for public hospitals, or by private voluntary insurance 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.

4.2 Reimbursement schemes

4.2.1 Eligibility criteria

As stated at the beginning of Section 3.1, the Portuguese National Health Service (SNS) is supplemented by five sub-schemes. The SNS reimbursement criteria are applied by the health sub-system for civil servants. The other four health sub-systems adopt the SNS reimbursement criteria as a reference but may have different lists and levels of reimbursement.

Reimbursement
schemes

Within the SNS reimbursement scheme, there is a specific reimbursement scheme (“special regime”) for pensioners on low incomes below the national minimum wage. They are granted higher reimbursement (i.e. lower co-payment, see Section 4.2.3, and higher reference prices, see Section 4.3).

Reimbursement in Portugal can be classified as having product-specific reimbursement eligibility. This means that the decision to grant reimbursement is made for each medicine (per product).

Eligibility

In order to be eligible for reimbursement, medicines must, according to Decree-Law No. 129/2005, 11 August, fulfil one of the following conditions:

- a) Innovative medicines with no direct equivalent and that demonstrate a higher level of efficacy or safety than standard treatments;
- b) New medicines that demonstrate an economic advantage over existing medicines of the same composition and pharmaceutical form, i.e. priced 5% less than the cheapest non-generic product;
- c) Medicines with a new pharmaceutical form, strength or pack size that demonstrate a higher cost-benefit ratio when compared to existing similar medicines;

- d) New medicines that neither constitute significant therapeutic innovation nor possess identical qualitative composition to already reimbursed medicines, but if they present economic advantages compared to current medicines for the same therapeutic indications;
- e) Fixed combination products made up of active ingredients already reimbursed individually with demonstrated therapeutic benefit and a price equal or lower than those of separate ingredients;
- f) Fixed combination products made up of active ingredients that do not exist as separate products on the market and that demonstrate a therapeutic advantage.

The product-specific reimbursement eligibility is supplemented by population-group eligibility (for low-income pensioners, see above) and for lower reimbursement rates – by a disease-specific component (100% reimbursement for specific diseases, see Section 4.2.3).

4.2.2 Reimbursement lists

Portugal has a positive list of medicines (Prontuário Terapêutico) used in the out-patient sector. Medicines in the “Prontuário” are reimbursed by the SNS at certain percentage rates (see Section 4.2.3).

Positive list

Criteria for the inclusion of a medicine in the positive list are enumerated in the previous sections under eligibility criteria; disease-specific criteria are additionally applied to the reimbursement rates (see Section 4.2.3). Medicines may be de-listed (i.e. excluded from the positive list and thus from reimbursement) based on the following criteria: excessive prices, lower therapeutic efficacy demonstrated by a pharmaco-epidemiologic study, the switch to an OTC product without public health reasons that would justify its reimbursement.

Criteria

After a medicine has been granted a price, companies may submit a reimbursement application by filing a formulary, sending evidence-based information to prove the therapeutic added-value related to already reimbursed products (pharmaco-therapeutic and pharmaco-economic information) and proposing a price for reimbursement (which may be equal or below the approved price).

Procedure implies two evaluations

The applications are received and validated by INFARMED, and when data is missing, companies have a defined period to submit this information. Once all documents have been validated, they are analysed by pharmacologists (external experts) in order to establish the grade of innovation and the therapeutic added-value when compared to alternatives (for the same indications) already reimbursed. The result of this evaluation consists of a pharmaco-therapeutic report with information on: pack-

Pharmaceutical evaluation

age size and strength needed, therapeutic alternatives, therapeutic value, units of the product and alternatives (for example: defined daily dose, DDD approved by WHO). Where necessary, companies are asked to provide further information in order to clarify any doubts.

After the pharmaco-therapeutic evaluation, the application is analysed by economists in order to demonstrate economic advantage. If the product does not demonstrate an added therapeutic value compared to the alternative, the economic evaluation is based only on the comparison of prices. The product under evaluation should present a lower daily price than the alternative. If the price is higher, the company is asked to lower it.

If the product demonstrates an added therapeutic value or if it is a completely new product without alternatives, the economic advantage can be demonstrated by presenting an economic evaluation study. This should be drafted according to the INFARMED guidelines for economic evaluation studies. Where necessary, companies are asked to provide clarification on doubts related to the economic evaluation study.

Economic evaluation

Based on the information contained in the two reports (pharmaco-therapeutic and economic), INFARMED prepares a document with a proposal on whether or not to grant reimbursement. The final decision is taken by the Ministry of Health.

If the decision is negative, the companies are notified prior to the final resolution and may present extra information that could change the final proposal. This information is always evaluated. After the decision, the company is notified by mail. If the decision is negative, the company can appeal to the supreme administrative court.

Appeal procedure

In accordance with the Transparency Directive, the reimbursement procedure can take a maximum of 90 days, but it can be postponed if additional information is required by INFARMED (“clock-stop”).

Procedure time

Reimbursement applications for generics are evaluated faster than for other medicines, as their evaluation only considers the package and dosage dimensions and the price criteria (the price should be 3% lower than the price of the least expensive similar generic with 10% of market share in the reference cluster).

Fast-track procedure

The out-patient positive list covers around 7,220 medicines (data as of 1 July 2009, including the different pharmaceutical forms, strengths and package sizes). The number of medicines on the list has decreased in the last few years, in particular in Category B and Category C (for an planation of the reimbursement categories see the next section 4.2.3), as

Scope

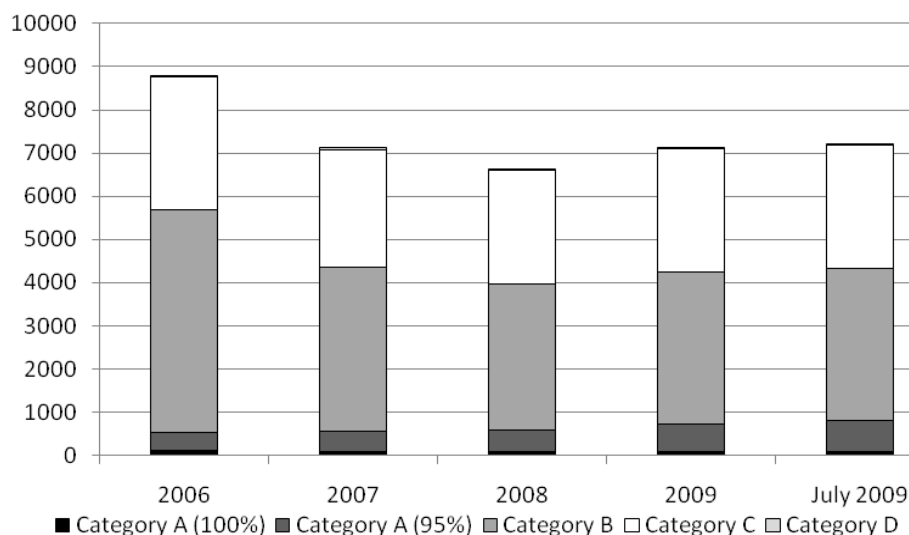
shown in Figure 4.1. According to INFARMED, the decrease may be due to two possible reasons:

- Expiry of reimbursement status due to non-marketing: According to Decree-Law No. 118/92, 25 June, the reimbursement expires in all presentations of the medicine (with the same strength and pharmaceutical form) if, within one year from the notification date of the decision, the applicant fails to market it. This was the case for around 500, 1790, 370 and 140 medicines respectively in the years between 2005 and 2008.
- Review of package sizes: Following Decree-Law No. 1471/2004, 21 December, several medicines had to change their size, for instance from three packages (with the same pharmaceutical form and dosage) to two packages.

According to legislation, OTC products are not reimbursable, except in exceptional circumstances, which have to be justified on grounds of public health. In fact, quite a number of OTC products are on the positive list.

OTC are normally not covered

Figure 4.1: Portugal – Number of Medicines per reimbursement category, 2006 - 2009



As of 1 January (or 1 July respectively), including the different pharmaceutical forms, strengths and pack sizes

Source: INFARMED information at ÖBIG request

The positive list is updated on a monthly basis by the Medicines Agency INFARMED.

Updates

The monthly updated list of reimbursed pharmaceuticals is publicly available on the website of INFARMED (www.infarmed.pt) and is also pub-

Publication

lished by the Ministry of Health in the official journal (Diário da República). The information is also accessible to the public in a database, which is updated at monthly intervals.

For the in-patient sector, a national Hospital Pharmaceutical Formulary (Formulário Hospitalar Nacional de Medicamentos, HPF) is in place and it applies to all hospitals of the SNS. In addition to this national list, many hospitals have their own hospital formulary (“addendums”). The medicines on these addendums need to be approved by the Pharmacy and Therapeutic Committee (PTC) of each hospital, but as soon as they are on the list their expenses are covered by the SNS and sub-schemes.

Hospital formularies

The national hospital formulary is publicly available at the INFARMED website (www.infarmed.pt/formulario/index.html).

4.2.3 Reimbursement categories and rates

Whilst in-patient expenses for pharmaceuticals are fully covered, only a small portion (1%) of medicines on the positive list in the out-patient sector are fully (100%) reimbursed.

Different reimbursement rates

Table 4.1: Portugal – Reimbursement of medicines, 2009

Reimbursement category	Reimbursement rate	Characteristic of category
Category A	100% and 95%	Essential medicines to treat chronic diseases (95%) e.g. diabetes, and life-saving pharmaceuticals (100%), e.g. to treat cancer
Category B	69%	Essential medicines of therapeutic value for the treatment of serious illnesses (such as anti-asthmatic or cardiovascular pharmaceuticals)
Category C	37%	Non-priority medicines, with proven therapeutic value (such as anti-infectives, vaccines not included in the National Vaccination Plan, immunoglobins, anti-parasitics)
Category D	15%	New medicines whose therapeutic value is not yet proven (a transitional category).

Source: INFARMED/PPRI 2008, GÖG/ÖBIG surveys at INFARMED 2009

The legislation provides four different reimbursement categories (A to D) with five different reimbursement rates in total for different therapeutic groups and subgroups. The reimbursement and thus co-payment categories and rates correspond with the degree to which the

Categories

medicines are essential to life of life maintenance, the level of the disease (chronic and/or serious disease), and the economic and social situation of consumers. They are explained in Table 4.1.

In February 2007, the reimbursement rates were decreased, which resulted in the rather unusual rates of 69% (previously 70%) and 37% (previously 40%). This reduction was performed following a price cut at that time, and as a consequence the reimbursement rates were adapted so that patients and consumers did not notice the price change.

Reimbursement
decreases

Already in October 2005, the 100% reimbursement category (A), originally in place, was lowered to 95% reimbursement. Only a few medicines within Category A (e.g. insulins and immunomodulators) are still 100% reimbursed.

Furthermore, it is worth mentioning that Category D is a category of a transitory character for medicines whose therapeutic value is not yet proven, which was created in 2000 to facilitate the entry of new medicines onto the market. Medicines may stay in Category D no longer than two years.

Pensioners with incomes under a certain threshold (below the national minimum wage) receive an additional 5% reimbursement on the rate of Category A (thus 100% reimbursement) and an extra 15% reimbursement on the Categories B, C and D rates (i.e. 84%, 52% and 15% percent respectively).

Higher reim-
bursement rates
for pensioners

In order to promote generics (see Section 4.5), Portugal once had 10% higher reimbursement for generics, which resulted in reimbursement rates of 100% for Category A, 80% for Category B, 50% for Category C, and 30% for Category D at that time. This measure, introduced in 2000, was withdrawn in September 2005.

Generics promo-
tion

However, a similar measure that combines generics promotion with protection for vulnerable groups was recently introduced. Since June 2009, 100% reimbursement on all generics has been applied for pensioners under the “special regime” (low-income).

4.3 Reference price system

Portugal has a reference price system (RPS), which is a reimbursement tool for the out-patient sector. For medicines included in the reference price system, the SNS 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.

RPS since 2002

The reference price system was introduced in 2002, with the first list of homogenous medicines being published in March 2003. As there needs to be a sufficient number of generics available on the market for the implementation of a reference price system, several measures for generics promotion preceded this reimbursement tool, including

- higher reimbursement rates for generics (see Section 4.2.3),
- the introduction of INN prescribing (2002),
- the introduction of generics substitution (2002) and
- promoting the switch of copy-products into generics.

At the time of the RPS implementation, stakeholders were consulted, but not involved.

The reference groups (groups of homogenous products) are clustered at ATC 5 level, thus grouping reimbursable medicines of identical active ingredients with the same quantitative and qualitative composition.

Scope

The reference price system is only applied to medicines where generic alternatives exist. Portugal started with around 35 active ingredients in 143 reference groups. Today (July 2009), there are around 158 active substances (5,200 medicines) in 595 reference groups.

Increasing number of medicines included

The Medicines Agency INFARMED is in charge of setting and adapting the reference groups and reference prices. It is a technical process, based on legal rules, with no involvement from committees or stakeholders. As soon as INFARMED is informed of the planned market entry of a generic, they start the technical preparation for building a new reference group or adjusting a group. However, INFARMED observed several cases where, despite the announcement, the generic was not then brought on the market, even though it had already been considered for the creation of a cluster. To prevent such instances in future, INFARMED is now allowed to impose a fine on companies for wrongful notification.

Technical procedure

Portugal defines the reimbursement limit (reference price) as the unit price of the most expensive generic in the cluster. The reimbursable centage for medicines on the positive list (see Sections 4.2.3 and 4.4) is also applied to the reference price, thus the co-payment for patients is not only the difference between the reference price and the actual macy retail price, but also a percentage co-payment of the ment limit that is calculated on the basis of the reference price.

Rather high reference price

For pensioners on low incomes (already mentioned as the “special regime”), the reference price is increased by 20%. Initially, the increment was 25%; but it was reduced in autumn 2006.

Exemptions for vulnerable people

Reference groups and reference prices are updated on a quarterly basis.	Regular updates
The updated versions of the reference price system are accessible on the Medicines Agency's website. Additionally, paper versions are produced and sent to all physicians and pharmacists four times a year.	Publication

4.4 Co-payments

As explained in Section 4.2.3, Portugal has different reimbursement categories and rates for reimbursable medicines. Based on this system, co-payment percentages of 0% (in a few cases), 5%, 31%, 63% and 85% are applied to reimbursable medicines.	% co-payments for out-patients
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For pensioners on low incomes, lower co-payments are applied. They amount to 0% (for all Category A medicines, thus covering a greater range than for the other insured), 16%, 48% and 70% for Category B, C, and D, respectively. Recently, co-payments have been eliminated for generics dispensed to this group.

In the past few years, Portugal has twice decreased reimbursement rates and thus increased co-payments (in 2005 and 2007).	Rising co-payments
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There are no other co-payments (such as prescription fees or deductibles) for reimbursable medicines in the out-patient sector. However, co-payments also arise to the reference price system (see Section 4.3).

For medicines dispensed to in-patients during their stay in hospital, no co-payments are applied.	No co-payment for in-patients
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4.5 Further instruments

4.5.1 Pharmaceutical budgets

Pharmaceutical budgets for physicians, which would define a maximum amount of expenditure for prescribed medicines, are not applied.	Limiting expenditure
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However, at an overall level, there are limits on public pharmaceutical expenditure. They are stipulated in the framework agreements between the pharmaceutical industry (through the Portuguese Pharmaceutical Industry Association, APIFARMA) and the Ministry of Health. The first agreement was signed in 1997 and several new agreements have since been made, committing both parties to reforms, establishing limits of public pharmaceutical expenditure and industry pay-backs in case of excess. The latest agreement was signed in 2006 (Protocol No. 7/2006, 10

February) and is valid from 2006 to 2009. This protocol limited the growth rates of medicines in the out-patient sector to 0% in 2006 and to the foreseen nominal growth rate of the GDP in 2007. It also, for the first time, limited the growth rates of medicines in the in-patient sector to 4% in 2006. According to the protocol, the targets for 2008 and 2009 are set according to mutual agreement, but they have not, as yet, been set. In principle, they should be consistent with the maximum growth rates allowed in the national budgets for out-patient care (2008: 2.9%; 2009: 3.5%) and in-patient care (2008: 3.9%, 2009: 4.5%).

A maximum target for an individual company's pharmaceutical sales, including the option for pay-back in case of excess, may be set if a medicine is reimbursed on the basis of an agreement between INFARMED and a company, and if justified by public health and patients' interests.

4.5.2 Reviews and monitoring

After inclusion in the positive list, the Medicine's Agency is required to re-assess the medicine's reimbursement status within three years. The criterion for de-listing a medicine is stated in Section 4.2.2 (e.g. excessive prices). During the evaluations between 2000 and 2004 covering 353 active substances, corresponding to 536 brands, 381 products lost their reimbursement status due to lack of efficacy or unwillingness to prove absolute efficacy in comparison to a placebo.

Reviews in out-patient and in-patient sector

In Portugal, reimbursement reviews for new medicines used in hospitals are also required by legislation (introduced at the end of 2006), which includes an evaluation of both therapeutic and economic effectiveness.

Market surveillance is commonly undertaken: the Medicines and Health Products Observatory of INFARMED regularly monitors consumption of, and expenditure on, medicines in the out-patient market (which includes the reimbursement market, generics market and OTC market) and in the public in-patient sector. It then publishes monthly reports on its website.

Market monitoring

Additionally, a few specific studies were published, in which the prescribing habits of doctors were evaluated for pre-determined issues (e.g. GP prescriptions of antibiotics) or policies adopted (e.g. monitoring INN prescribing by physicians, see below).

Prescription monitoring

Prescription patterns are not regularly monitored by INFARMED. Instead, this is done at a regional level by the Regional Health Authorities (see Section 3.1).

There are some prescription guidelines to facilitate more rational

Prescription

cian prescribing, but the guidelines are not mandatory. At a national level, INFARMED publishes a National Prescribing Formulary and, for the in-patient sector, a National Hospital Pharmaceutical Formulary (HPF, see Section 4.2.2), to give prescribing guidance to doctors.

guidelines

4.5.3 Generics promotion

INN prescribing

Physicians in Portugal are obliged to prescribe by the International Non-proprietary Names (INN), but there are no sanctions if doctors do not adhere to this rule.

Generic substitution is also in place in Portugal on an indicative basis. Physicians can 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.

Generic substitution

Portugal has undertaken several measures to promote generics. Besides INN prescribing and generic substitution these include:

Further generic promotion

- an additional 10% generics reimbursement level from 2000 to 2005 (see Section 4.2.3),
- the introduction of the reference price system in 2002 (see Section 4.3),
- incentives to convert “copies” to generics (also mentioned in Section 4.3),
- a simplification of the reimbursement process in 2006;
- a price revision in 2007 (the generic price changed from a difference of 35% to 20% related to the original price for new generics where the originals have the maximum ex-factory price of 10 Euros in all packages),
- an exemption from any co-payment on reimbursed generics if dispensed to low-income pensioners in June 2009 (see Section 4.2.3).

Additionally, INFARMED has been actively committed to information campaigns in order to promote generics as an alternative. Since 2000, several public information campaigns were carried out to promote generics through television, radio, billboards and Internet. Various information leaflets were distributed to hospitals, health care centres and pharmacies. At the start of the decade, INFARMED organised information sessions for doctors at a regional level, where doctors who were sceptical about generics as an alternative were informed about quality generics and their role in the control of pharmaceutical expenses.

The Generics Guide (Guia dos Genéricos), which contains information on prices and reimbursement levels for all generics on the market, is up-

Information on generics

dated quarterly by INFARMED and accessible on their website.

Portugal has increased its generic market share from less than 1% (in volume and value) in 2000 to 14.8% in volume (expressed in packs) and to 19.5% in value (expenditure in comparison to total market value (PRP)) in 2007 (INFARMED).

5 Analysis

5.1 Human rights approach

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

Analysis for the civil society

In an article published in 2003 (Hogerzeil, H. 2003), Hans Hogerzeil, the current 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 Covenant specified availability, accessibility, acceptability and quality as interrelated and essential components for the fulfilment of the right to health in all its forms.

Essential medicines as a human right

In the last few years, there have been some initiatives, driven by WHO, to specify and define criteria from a rights based perspective. The following analysis applies this human rights based approach, several indicators proposed in literature (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 as useful and relevant.

5.2 Discussion

The Portuguese 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.

In Portugal, governments have been committed to the implementation of an equitable and consistent access to health care. A major indicator was the introduction of the National Health Service (SNS), supplemented by five sub-schemes, in 1979 (see Section 3.1).

Government commitment

Portugal has a well-developed regulatory framework for the implementa-

No essential medicines policy

tion of the right to health and to medicines, even though it has no explicit essential medicines policy document.

document

Access to essential medicines is defined as a core value of the pharmaceutical reimbursement system, as a report of the Medicines Agency INFARMED stresses: “The current Portuguese reimbursement system of pharmaceuticals is the result of a long process in which, the principles of accessibility, therapeutic value, essentiality, equity, universality and effectiveness were introduced” (INFARMED/PPRI 2008). The same report elaborates on the rationale behind regulation: “Reimbursement rules have come to be used as an instrument of price negotiation, because the per capita income is low, and the companies do not risk placing most of the pharmaceuticals on the market without

Universal coverage is in place in Portugal: All residents enjoy coverage of health care, including essential medicines (SNS and sub-schemes, see Section 3.1). The fact that around a quarter of the population has acquired voluntary health insurance might, however, suggest that barriers to access exist or that SNS quality is perceived not as sufficient.

Population coverage

In the out-patient sector, Portugal has a positive list (the so-called *tuário Terapêutico*). It includes around 7,200 medicines (including the different pharmaceutical forms, strengths and pack sizes) which are – at least partially – reimbursed. Within this positive list, two categories are explicitly devoted to essential medicines (Category A and B), and these two categories comprise around 4,340 medicines. Thus, essential medicines account for around 60% of the reimbursed medicines (see also Table 5.2). The critical point in this respect concerns the rather high co-payments (see below on affordability). The positive list is updated on a monthly basis, which allows for the inclusion of new products (those with therapeutic added value, but also generics) on short notice.

List of essential medicines

Additionally, Portugal is among the few European countries with a nation-wide hospital positive list. This is a basic list providing guidance for the in-patient doctors when prescribing, and it is complemented by individual hospital pharmaceutical formularies.

Table 5.1: Portugal – 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 National Health Service (SNS).
Access to essential medicines	Yes	There are several laws, decrees and further legal provisions that ensure equitable access to medicines, including those considered as essential, for all residents.
Essential medicines policy	No	Portugal has no explicit essential medicines policy.
Coverage of the population		
Health care	Yes	The SNS and its sub-schemes cover all residents in Portugal.
Medicines	Yes	Coverage with SNS also means access to (essential) medicines.
List of essential medicines		
Positive list	Yes	Portugal has a positive list in the out-patient sector and a national Hospital Pharmaceutical Formulary in the in-patient sector.
Scope	~ 7.220 medicines	The “Prontuário” (positive list for the out-patient sector) includes in two of its four sections (Category A and B) medicines that are considered essential.
Updates	Monthly	The monthly updates allow a quick response and short-term inclusion of new medicines.
Transparency		
Publication of lists	Yes	All reimbursement lists are published and freely accessible on the Internet.
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	Yes	There are transparent criteria in the legal provisions which guarantee a rational and sound selection of medicines to be included in reimbursement.
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 in reimbursement may appeal to the supreme administrative court.
Fines and sanctions	Few	There are only few possibilities for the authorities to impose fines. Non-adherence to generics promotion tools like INN prescribing and generic substitution does not entail sanctions.
Beneficiaries and stakeholders		
Involvement and consultation	In general, no	In general, the Portuguese reimbursement system is based on defined technical criteria than on committees involving stakeholders.
Role of stakeholders	Doctors impact patients' choice of medicine	The prescribing behaviour of physicians (in particular their exclusion of generic substitution, no INN prescribing) has a major impact on patients' access to less expensive generic alternatives.
Patients understanding the system	Not sufficient	Despite a very transparent publication policy, patients do not seem to fully understand the system.
Vulnerable groups	Specific scheme	There is the "special regime", allowing lower co-payments for low-income pensioners.
Availability		
Medicines launched	Not known	Portugal has a high number of authorised medicines; however the number of pharmaceuticals on the market is not available.
POM dispensaries	Above EU average	The provision with POM dispensaries (3,655 inhabitants per POM dispensary, year 2008/2009) is better than the EU-average (EU-25: 4,405 inhabitants per POM dispensary, year 2005). Besides pharmacies, there are specific POM dispensaries (Postos Farmacêuticos Móveis, PFM) to guarantee pharmaceutical provision in rural areas.
Affordability		
Price level	Below OECD average	Prices of medicines are below the OECD average; however, generic prices are quite high in Portugal.
Co-payments	% co-payments	99% of all medicines on the positive list in the out-patient sector are only partially reimbursed. Most medicines are subject to a co-payment of 31% or 63%.
Private funding of pharmaceutical expenditure	Quite high	The share of private funding in pharmaceutical expenditure (44%) is quite high compared to the EU average (36%).
Promotion of less expensive medicines	Yes	There has been a consistent policy of promoting generic alternatives.

Source: ÖBIG

From a technical point of view, Portugal rates as outstanding with regard to the publication of medicines lists: both the “Prontuário” for the out-patient sector and the Hospital Pharmaceutical Formulary are published and made available on the Internet (on the website of the Medicines Agency www.infarmed.pt). In addition, INFARMED publishes the updated versions of the reference price system and a “Generics Guide” on their website. Furthermore, the Ministry of Health publishes the “Prontuário” in the official journal. The publication policy is supplemented by regular publications on statistics.

Transparency

Regarding the prices of medicines for the out-patient sector, INFARMED runs a database on its website, where the public can easily access the pharmacy retail price of a medicine. 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.

Despite the basically robust publication policy, patients are, in general, not very well informed about the functioning of the pharmaceutical reimbursement system and the prices (ÖBIG FP 2008). This may be due to the fact that the prices paid (reimbursement price) differ from the pharmacy retail prices. Furthermore, the patients’ information policy might need to be customized for targeted groups of patients.

The Portuguese reimbursement system is well-defined in decrees and other legal provisions, and it has transparent criteria on the inclusion and exclusion of medicines for reimbursement. The authors appreciate that there is a provision under which a medicine normally excluded according to the formal criteria, can be included on the positive list on public health grounds. The assessment of reimbursement applications is a two-tier procedure, which may be classified as a quality assurance process. Like other reimbursement agencies, INFARMED undertakes two evaluations – a pharmacotherapeutic assessment and a pharmaco-economic evaluation (see Section 4.2.2). The fast-track procedure foreseen for generics does not seem to result in a loss of quality, but is possible due to the nature of these products and allows for a quicker generics uptake (see also below the discussion on generics promotion under affordability).

Rational selection of medicines

The rules regarding the inclusion of medicines in the reference price system are clearly specified and have to be followed by INFARMED. In practice, however, INFARMED was confronted with the problem that as soon as they were informed by the company about the planned market entry of a generic they reacted, for example, by building a new reference group. But, if the company did not go on to launch the product, it undermined the reference price system. The possibility of fining companies (sanctioning), which was introduced in 2008, may help to resolve this problem.

Pharmaceutical companies that have received a negative decision on the inclusion for reimbursement of a medicine can appeal to the preme administrative court (see Section 4.2.2). In the European Union, according to the Transparency Directive, reimbursement systems must have an appeals procedure.

Mechanisms
for enforce-
ment

On the other hand, the authorities can only rarely enforce penalties. For ample, fining companies in case of wrongful information. Another sanction is the option for pay-back where a pharmaceutical company has exceeded the limit of the individual maximum sales target (see Section 4.5.1).

Generic promotion tools (see Section 4.5.3) lack mechanisms for enforcement. Though INN prescribing is mandatory, there are no sanctions for physicians who do not adhere to the rule. Generic substitution is in place on an indicative basis, without sanctions, but also without financial incentives. There is evidence (PPRI 2008) that countries that have introduced mandatory generic substitution and/or obligatory INN prescribing, including tions and/or other enforcement mechanisms, had a considerable increase in generics uptake. The low generic market share in Portugal could be creased effectively if mechanisms for enforcement, including sanctions, were implemented.

The Portuguese pharmaceutical system is organised around several technical rules. Committees (e.g. reimbursement committees) involving stakeholders such as doctors or pharmacists are not common in Portugal; the technical work is carried out by DGAE, in the case of pricing and by INFARMED, for the remainder.

Beneficiaries
and stake-
holders

Stakeholders are sometimes consulted prior to the implementation of measures, however, these consultations are often criticised as insufficient. For example, doctors were unhappy that they were only consulted, but not involved in the implementation of the reference price system, see ÖBIG FP 2008). Patients and consumers are represented in some consultant groups of INFARMED, but not involved in the policies regarding pharmaceutical reimbursement.

According to the consumers' organisation DECO, the most urgent bility issue stems from the low generic prescription rate, thus excluding tients from less expensive and therefore, more affordable medicines. cording to a survey of nearly 5,000 consumers undertaken by DECO in 2007, around 40% of the patients said that they had some difficulties in ing medicines and around 12% did not buy all the medicines prescribed cause they were too expensive. At least in the cases where generic tives are on the market, the affordability problem could be solved if cians observed the rule of obligatory INN prescribing or if they would only

exclude generic substitution on reasonable grounds. There are indications (see ÖBIG FP 2008) that some patients simply do not dare to oppose or doubt a physician's decision not to prescribe generics or by active stance, and so patients do not ask for a generic.

Patient attitudes towards their doctor's prescribing might also be attributable to the fact that many patients do not fully understand the system. This perception from the monitoring of the Portuguese system for several years is also supported by a consumers' representative. As stated above, in spite of several publications by INFARMED, there seems to be some confusion and misunderstanding about the system. From a patient's point of view, the most important issue is the amount of money s/he has to pay for a medicine. Information on the pharmacy retail price, which is published and also printed on the boxes of the medicines, is not of primary interest for patients.

Therefore an information policy that addresses patients as the main target group in a customized way might be useful. In the case of generics, regular and sustainable information campaigns, undertaken by INFARMED, have heightened public awareness of generics. Today, according to DECO data, around 70% of the Portuguese consumers consider generics as effective as the equivalent original products.

Within the SNS, Portugal provides a "special regime" for pensioners whose income is below the national minimum wage. These pensioners have lower co-payment rates for several products (see Section 4.2.3) and a higher reimbursement price (reference price) in the reference price system (see Section 4.3). Additionally, since June 2009, generics have had 100% reimbursement in the special scheme, and the authors learned that generic substitution has increased in the pensioners group since the implementation of this measure.

Other vulnerable groups are protected by the disease-specific components in the reimbursement system (see Section 4.2.1), allowing 100% (e.g. for HIV/AIDS patients) or 95% reimbursement for serious diseases (e.g. ics). Illegal migrants have 100% reimbursement for medicines to treat diseases that endanger public health.

With around approximately 45,650 medicines (including different pharmaceutical forms, strength and pack sizes) the number of authorised pharmaceuticals is rather high in comparison to other countries (see PPR1 2008; comparison is limited due to different calculation methods in each country). This figure has increased 2.5 fold since the year 2000. The authors assume that this is due to a large rise for generics within the group of authorised medicines (from around 700 generics in 2000 to approximately 24,200 in July 2009).

Availability

However, the number of marketed medicines is not available, which would allow for a grounded availability assessment. Availability problems were reported to the authors during another study on the reference price system (ÖBIG FP 2008) when generic companies did not launch their product as announced, even though it had been considered for a new reference price group. Today, INFARMED can react by imposing a fine on the company for wrongful notification (see Section 4.3).

Access to retailers that dispense prescription-only medicines (POM) in the out-patient sector is guaranteed due to around 2,700 community pharmacies and 240 PFM in rural areas (see Section 3.1). The provision of POM dispensaries (3,655 inhabitants per POM dispensary, year 2008/2009) is better than the EU average (EU-25: 4,405 inhabitants per POM dispensary, year 2005).

Around 3,100 medicines (as of July 2009) are classified as hospital-only medicines and are only accessible for in-patients. Their number more than doubled in 2005, which may be an indicator of improved accessibility to newer medicines.

Prices of medicines are not considerably lower than the OECD average; however, the prices of generic medicines are still quite high (OECD 2008). Portugal's generic market share is higher in value than in volume (see section 4.5.3), unlike all other European countries (PPRI 2008). The guese authorities, in particular INFARMED, are aware of this discrepancy. Annual price cuts are made to generics that gain more than 50% of the active ingredient market share. The third and latest price cut occurred in April 2009.

Affordability

One of the major concerns for the authors is the relatively high co-payments in Portugal (see Table 5.2). Only 1% of all medicines on the "Prontuário" are fully reimbursed to the general public. Most medicines are charged a co-payment of either 31% or 63%, which, expressed in Euro, may be able for certain medicines. For 98% of all essential medicines on the list, co-payments of 5% or 31% are charged.

There are lower co-payments for the vulnerable group of low-income pensioners, but nevertheless the out-of pocket payments are still quite high. As stated above, there is evidence from a survey undertaken by DECO that patients choose not buy a medicine simply because they cannot afford it. In this context, the recently introduced measure of an exemption from co-payment for generics bought by low-income pensioners is welcome. The fact that the generic consumption has increased within this pensioners' group suggests that vulnerable groups are price-sensitive.

Table 5.2: Portugal – Assessment of co-payments for medicines in the positive list

Category	Co-payments – General Regime	Co-payment – Special Regime	% of reimbursed medicines
A – life-saving	0%	0%	1.1%
A – others	5%	0%	10.1%
B	31%	16% or 0% (G)	48.9%
C	63%	48% or 0% (G)	39.5%
D	85%	70% or 0% (G)	0.4%

General Regime: common system under the SNS

Special Regime: system for low income pensioners under the SNS

G = generics

Source: INFARMED, ÖBIG analysis

The pharmaceutical consumption of in-patients in public hospitals is not subject to any out-of pocket payments. This contributes to improving accessibility and affordability, but it might result in costs being shifted from one sector of the system to another.

The concern about co-payments limiting the affordability of medicines, is evidenced by the quite large share of private funding in pharmaceutical expenditure. It amounts to 44% (year 2007) in Portugal compared to 36% in the EU-average (EU-25, year 2004). Usually, high private funding is attributed to the new EU Member States; for the EU-15 average (“old” EU Member States) private funding amounts to around 28%, which is considerably lower than in Portugal.

Given these concerns about affordability, the Portuguese authorities are advised to implement a sustainable policy for granting access to less expensive medicines. The generics promotion package (see section 4.5.3) being applied is a promising approach. As discussed in this analysis, the lack of mechanisms for enforcing INN prescribing and generic substitution and high generic prices are other limiting factors. Additionally, more savings for the public sector could be achieved if the reference price was not measured according to the highest priced generic in a reference group (see Section 4.3).

5.3 Conclusions

The authors consider the Portuguese reimbursement system to be an elaborate and sustainable system, based on the core values of accessibility, essentiality, equity, universality and effectiveness and on a well-defined and founded regulatory framework with transparent rules. There

are regular updates, which allow the system to be flexible and to easily incorporate new developments.

In general, access to medicines, in particular to essential medicines, seems to be guaranteed by both the regulatory framework and the actual implementation.

Room for improvement

However, the authors have identified three major fields where there is room for improvement:

- Affordability might be restricted, as co-payments are rather high, and Portuguese citizens pay considerable out-of pocket amounts. If budgetary restraints do not allow for decreased co-payments, then policy-makers are advised to monitor the population's ability to buy the medicines they need, particularly the vulnerable groups. Where certain groups are experiencing difficulty, exemptions and/or reduced co-payments should be made available.
- Portugal is advised to continue to refine their generics promotion policies, accompanied by reduced generics prices. Mechanisms (e.g. sanctions or financial incentives) for better enforcement of the rules should be considered.
- The authorities, in particular the Medicines Agency INFARMED, have good publication policies. However, the system does not seem to be fully understood by the patients. This could be an area where civil society is more involved in acting as “translators” between regulators and the general public.

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