

Portugal's reimbursement system Critical assessment of the access to essential medicines

Sabine Vogler
ÖBIG / Austrian Health Institute

HAI Workshop
Lisbon, 15 October 2009



This arises from the Developing Rational Use of Medicines in Europe project, which has received funding from the European Union, in the framework of the Health programme

Gesundheit Österreich / Geschäftsbereich ÖBIG



- **ÖBIG Health Economics / Pharma**
- Know-how on pharmaceutical pricing and reimbursement systems in the EU Member States and beyond
- Pharma Price Information (PPI)
- Advising MoHs, Social Insurance institutions; World Bank missions, WHO, European Commission, Council of Europe
- EU projects: EUROMEDSTAT, PPRI, PHIS, EMINet
- Involved in Pharmaceutical Forum

Introductory remarks

- You are the experts in Portugal – as professionals and in your personal capacity.
- All health care and pharmaceutical systems have their strengths and weaknesses.
- Historical developments, traditions and culture have a large influence on how a reimbursement system is set up.
- Nonetheless: There is always room for improvement.
- A human rights approach is applied to assess the right to access to essential medicines.

Outline

- The Portuguese reimbursement system - an overview on key characteristics in a European comparison
- Criteria for assessing a reimbursement system
- Assessing the reimbursement system
- Recommendations & the way forward

Health care - characteristics

- National Health Service (Service National de Saúde, SNS), financed through general taxation
- Strong regionalisation five regional health authorities (Administração Regional de Saúde, ARS)
- Coverage for all residents in PT
- Principle of universal coverage and equality of care of SNS
 - Principles defined in 1979 at introduction of SNS
 - 1989: “tendentiously free”

Health system and status

Health system	2000	2005	2008	EU average
Life expectancy at birth, total	76.6	78.2	78.9 (2006)	75.8 (2006)
No. of physicians per 1,000 inhabitants	3.18	3.43	3.49 (2006)	2.7 (2005)
No. of hospital beds per 1,000 inhabitants	3.25	2.99	2.85 (2007)	4.8 (2007)
Total no. of POM-dispensaries	2,795	2,909	2,905	-
Inhabitants per POM-dispensary			3,655	4,405

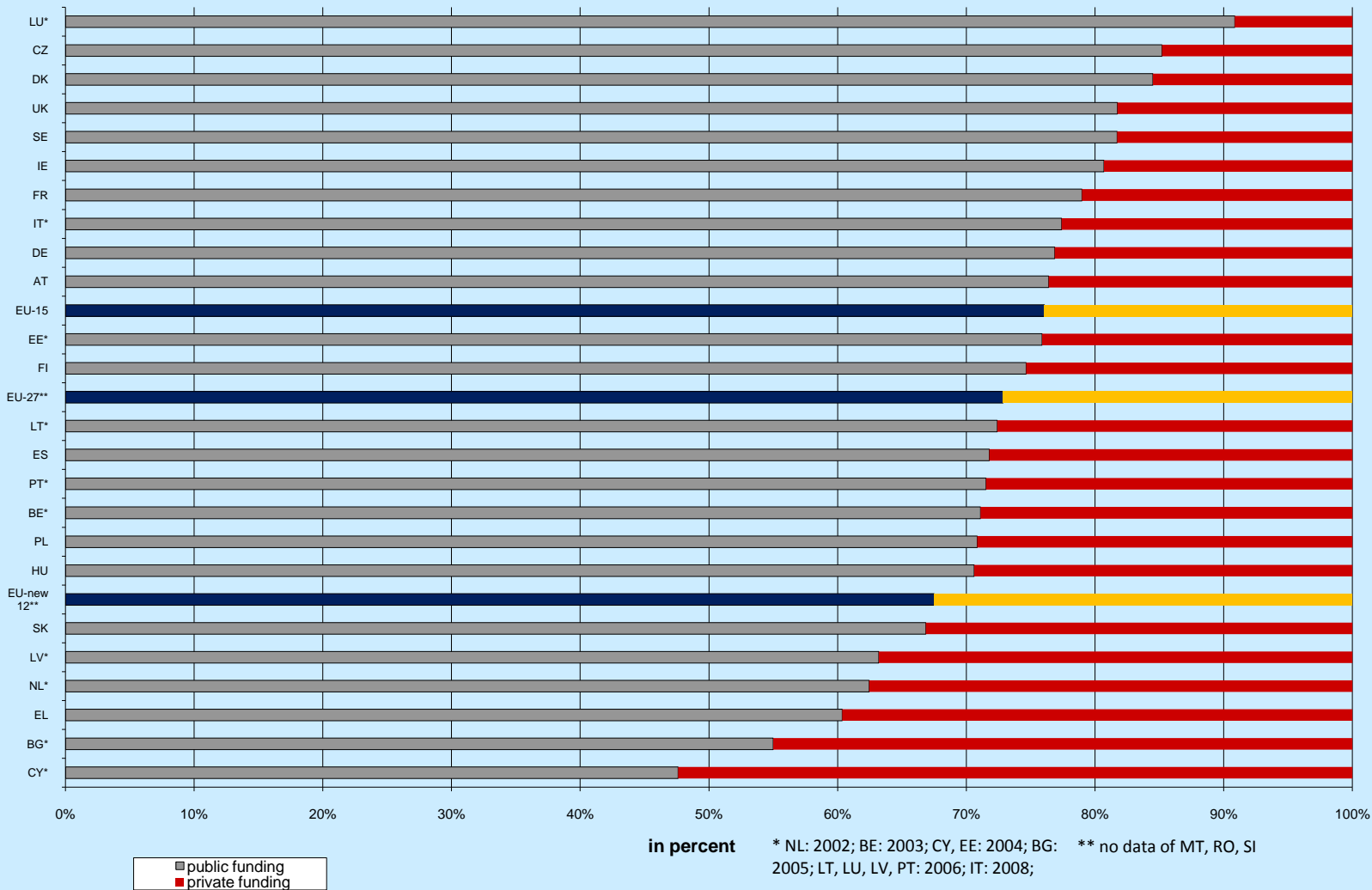
Source: EUROSTAT, OECD 2009, INFARMED/PPRI 2008, INFARMED information at ÖBIG request

Health and pharmaceutical expenditure

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%	28.5%
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%

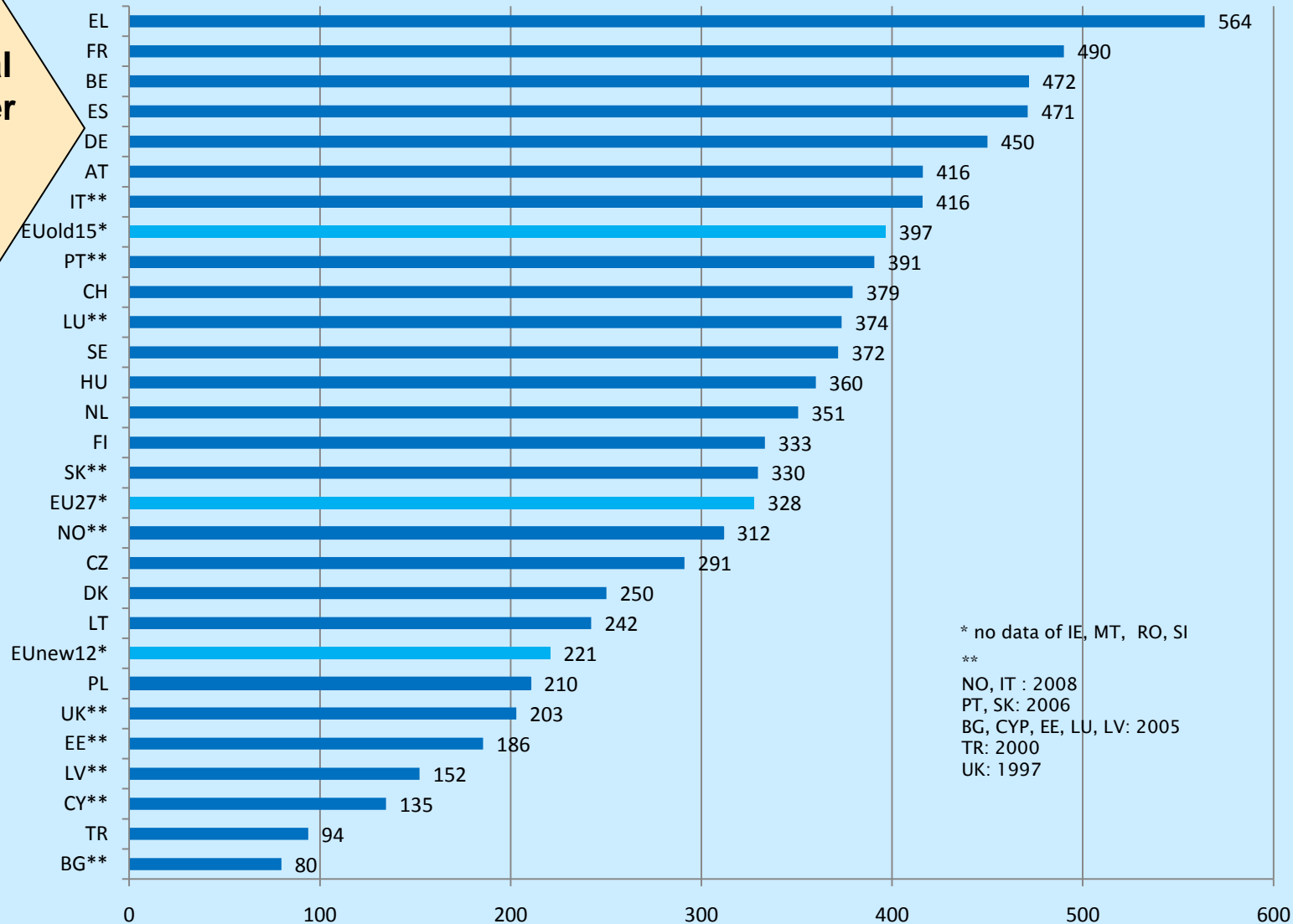
Source: EUROSTAT, OECD 2008/09, national statistics provided in INFARMED/ PPRI 2008

Public/private funding of health expenditure



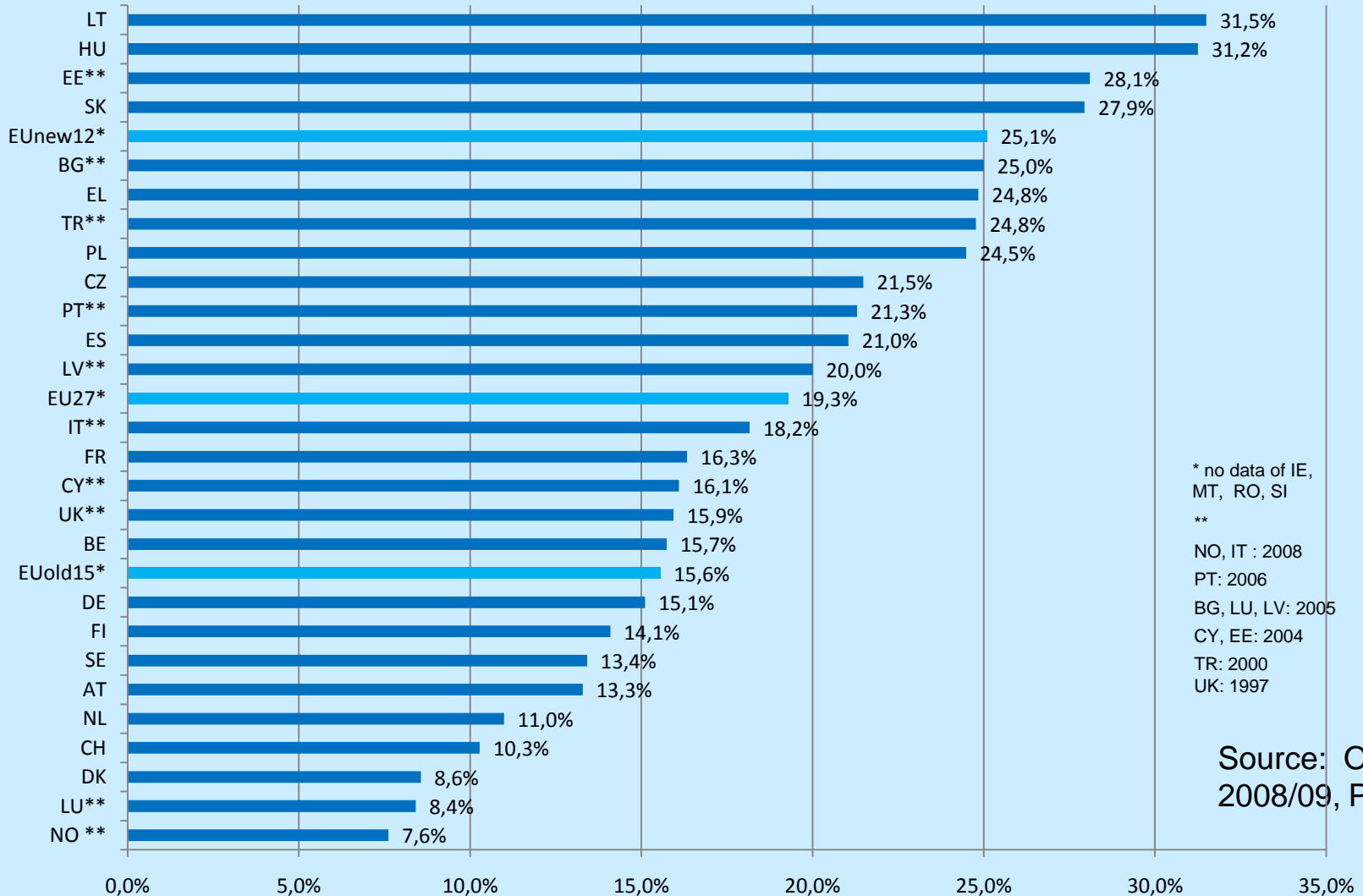
Source: OECD 2009, PPRI

**Pharmaceutical
expenditure per
capita 2007
in € PPPa**



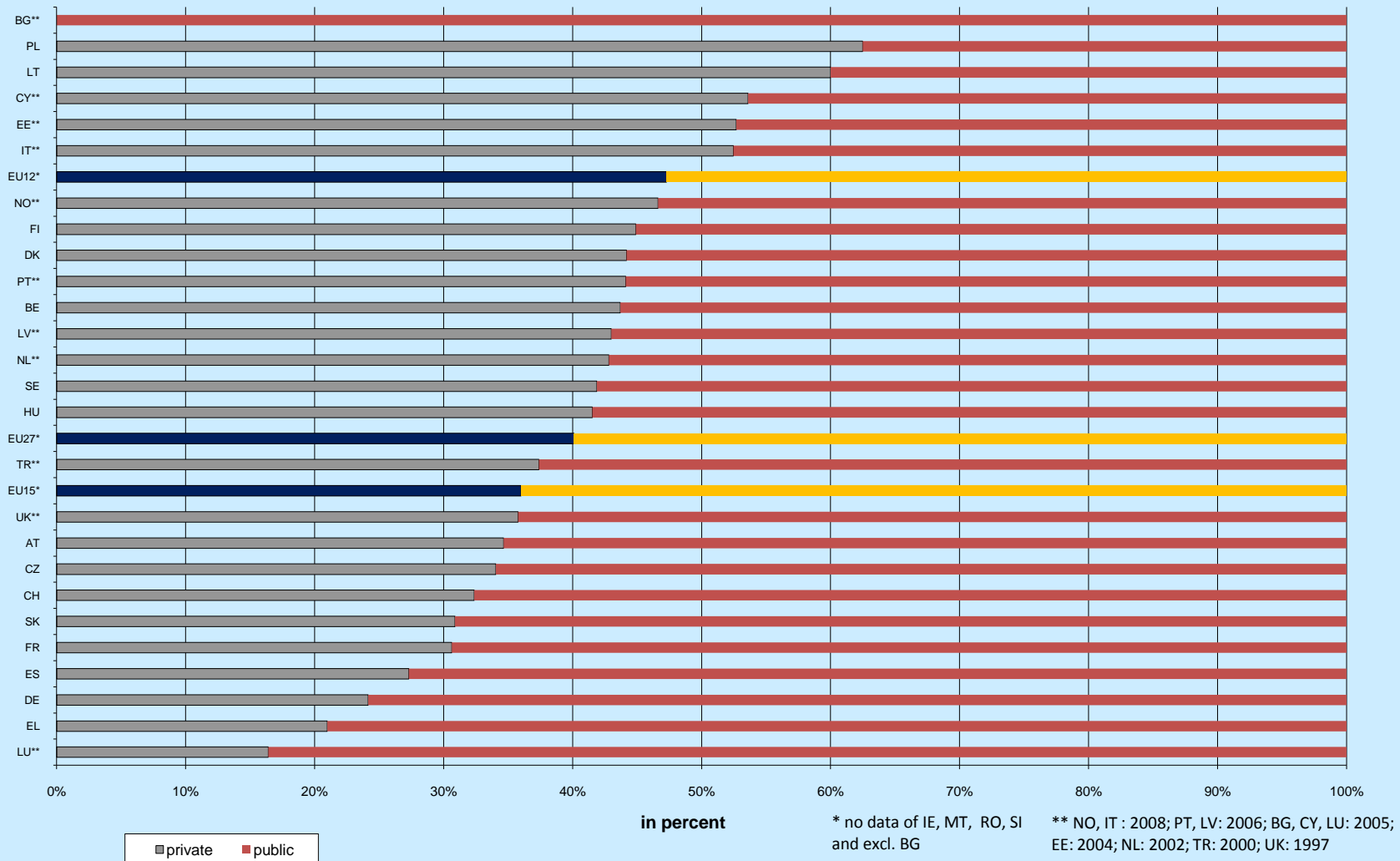
Source: OECD
2009, Eurostat
2009, PPRI

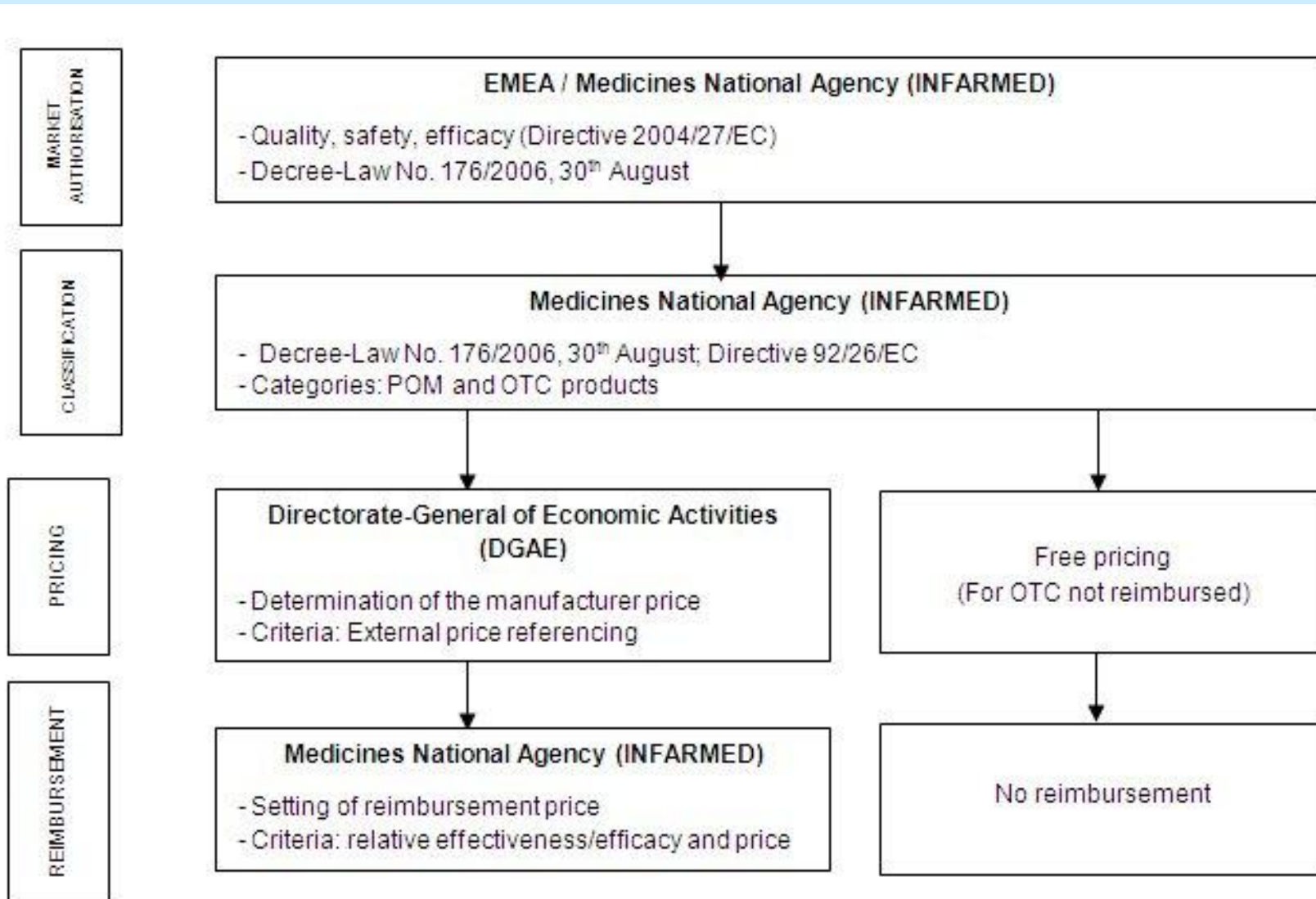
Share of pharmaceutical expenditure in % of total health expenditure 2007



Source: OECD
2008/09, PPRI

Public/private funding of pharmaceutical expenditure





Source: PPRI Pharma Profile Portugal, 2008

Reimbursement: Eligibility criteria / 1

- Possible reimbursement eligibility schemes
 - Product-specific eligibility (key scheme in 19 EU Member States)
 - Disease-specific eligibility (key scheme in the Baltic states)
 - Population-group-specific eligibility (CY, MT; IE)
 - Consumption-based-specific eligibility (DK, SE)

- Portugal has a product-specific eligibility scheme, supplemented by
 - Population-group-specific eligibility: “Special regime” for low-income pensioners
 - Disease-specific eligibility (100% reimbursement for specific diseases)

Reimbursement: Eligibility criteria / 2

➤ Eligibility to reimbursement (acc. to DL 129/2005)

- 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.

→ Included in the positive list

Reimbursement: Eligibility criteria / 3

- De-listing (i.e. exclusion from reimbursement)
 - 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
- OTC products are normally not reimbursable, except in exceptional circumstances
in fact, there are some OTC products on the positive list

Reimbursement - Procedure

- Application for reimbursement by pharmaceutical company
- A medicine needs to have a price
- Applications are validated by INFARMED – two steps:
 - Pharmaco-therapeutic evaluation
 - Pharmaco-economic evaluation
- Decision within 90 days
 - Fast-track procedure for generics
- Appeal procedure

Reimbursement: Positive list

➤ Portugal

- If considered eligible for reimbursement, the medicine is included on the positive list (**Prontuário Terapêutico**)
- No negative list
- Monthly updates
- Prontuário is publicly available on the website www.infarmed.pt
- Hospital sector: a national Hospital Pharmaceutical Formulary (Formulário Hospitalar Nacional de Medicamentos) - www.infarmed.pt/formulrio/index.html, plus hospital formularies (“addendums”) in the hospitals

➤ European comparison

- Positive lists in 23 of the 27 EU MS (all but DE, ES, EL, UK)
- Negative lists are less common (DE, HU, UK; legal basis in EL and FI)
- Hospital sector: usually no nation-wide list, formularies in hospitals

Reimbursement: Reimbursement rates / 1

➤ Portugal

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).

➤ European comparison

- Only in a few European countries (AT, DE, IT, NL, UK) all reimbursable medicines are 100% reimbursed

Reimbursement: Reimbursement rates / 2

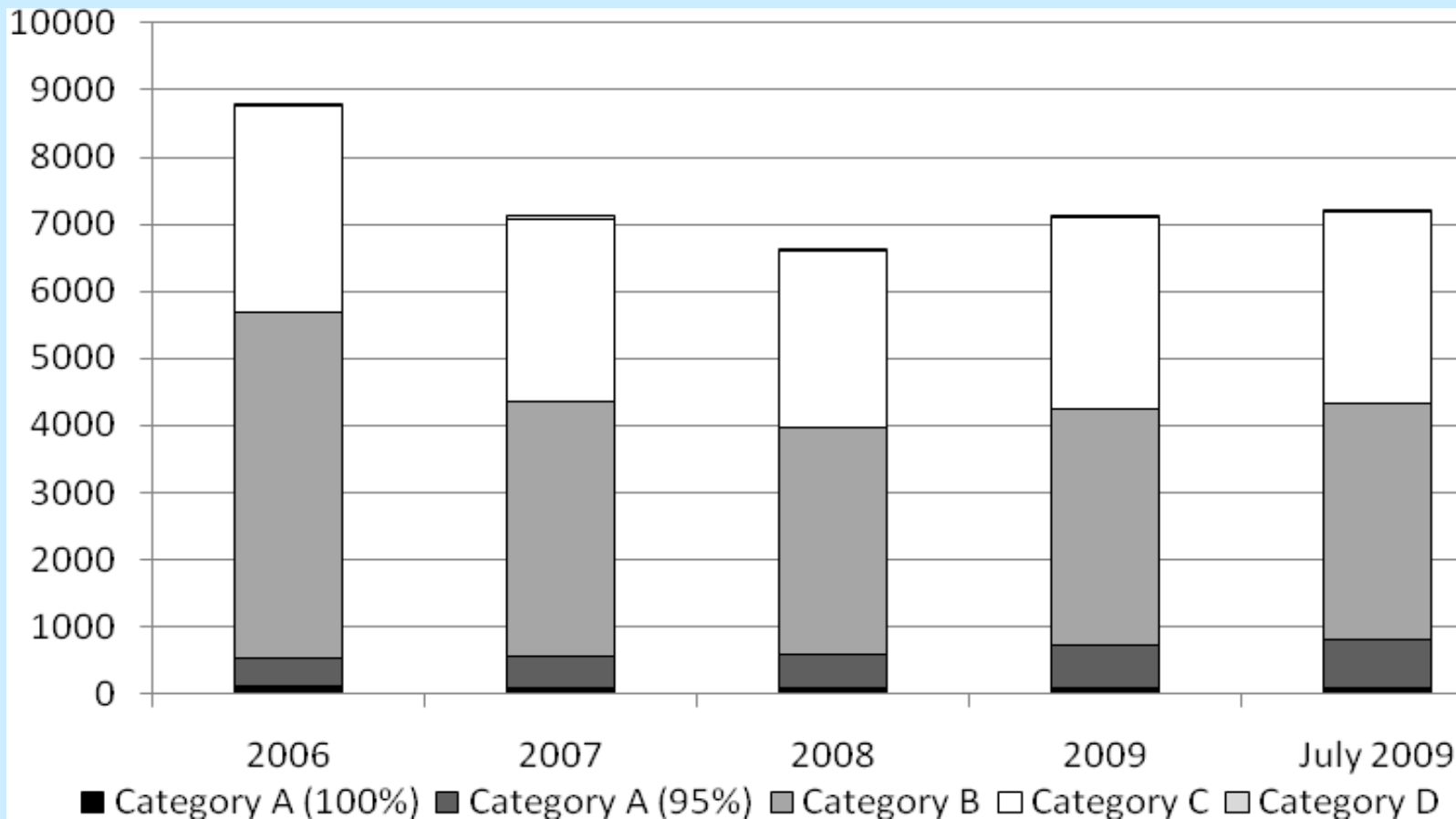
➤ General Regime

- Reimbursement rates of 100% and 95% (Category A), 69% (B), 37% and 15%
- Decrease in reimbursement rates in Feb. 2007 (70% → 69%, 40% → 37%) and in Oct. 2005 (100% → 95%)
- 2000 – 2005: 10% higher reimbursement rates for generics (100%, 80%, 50%, 30%)

➤ Special Regime

- Pensioners with incomes below the national minimum wage
- 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).
- Since June 2009: 100% reimbursement on all generics under the special regime

Number of medicines in the Prontuário



As of 1 January, incl. different pharmaceutical forms, strengths and pack sizes

Source: INFARMED

Reference Price System

Definition:

The social health insurance / national health service determines a maximum price (= reference price) to be reimbursed for certain pharmaceuticals. On buying a pharmaceutical for which a fixed price / amount (= reimbursement price) has been determined, the insured person must pay the difference between the fixed price / amount and the actual pharmacy retail price of the pharmaceutical in question, in addition to any fixed co-payment or percentage co-payment rates. Usually the reference price is the same for all pharmaceuticals in a given ATC 4 and/or ATC 5 level group.

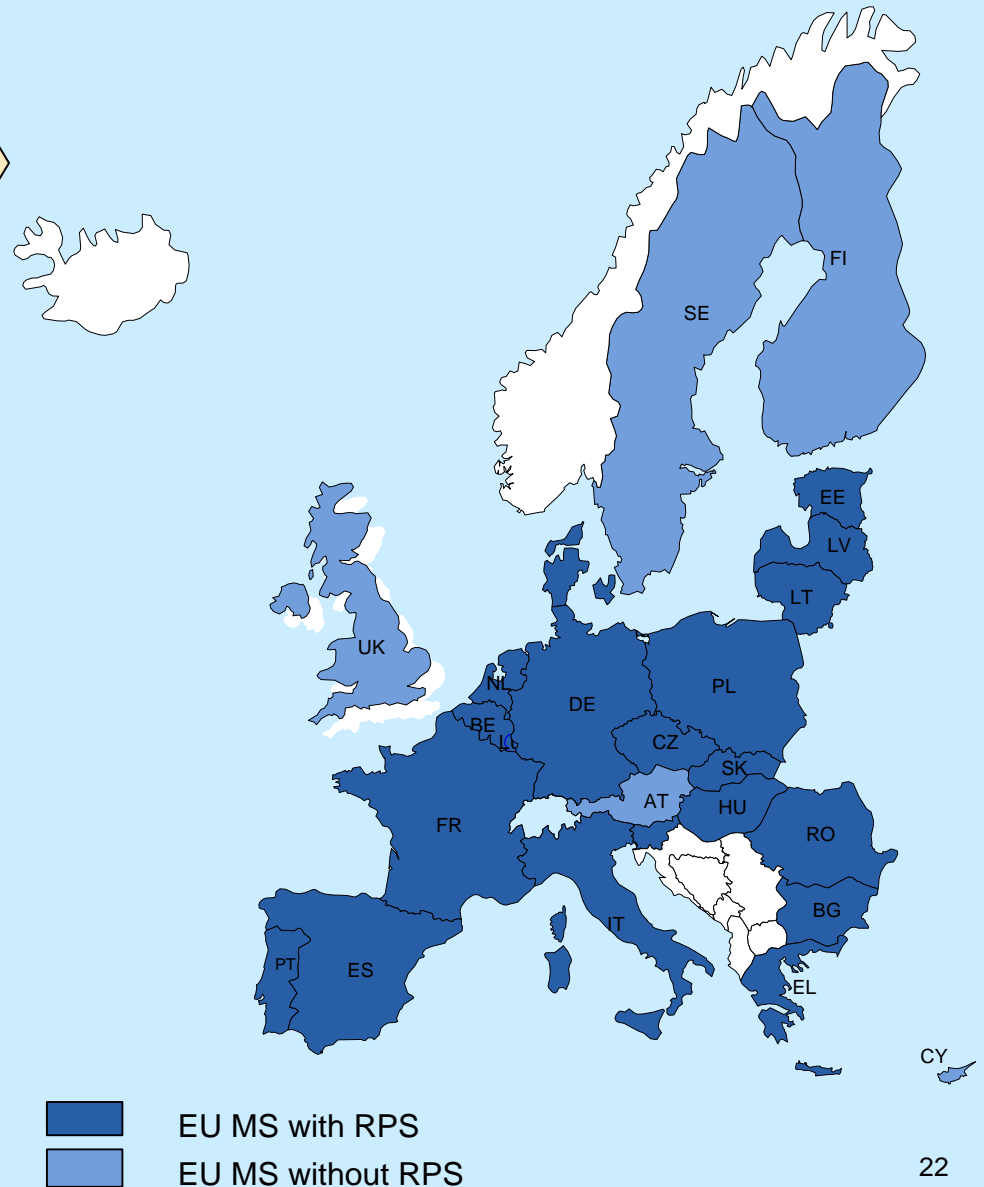
Source: PPRI/PHIS Glossary, <http://ppri.goeg.at>

Reimbursement: Reference price systems in the EU MS 2009

FI: RPS from 4/2009 on

→ 20 EU Member
States with a
reference price system

Source: PPRI 2008, updated
information



Reference price system

- Introduced in 2002, scope
 - July 2009: 158 active substances (5,200 medicines) in 595 reference groups
 - 2003: 35 active ingredients in 143 reference groups
- Methodology
 - Reference groups: ATC 5
 - Reference price: price of the most expensive price in the cluster
- Exemption for people under the “Special regime”
 - Reference price is increased by 20%
- Updated on a monthly basis
- Publication
 - Available on the INFARMED website
 - Paper version sent to all physicians and pharmacists 4 times / year

Co-payments

➤ Percentage co-payment

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%

➤ Co-payment due to the reference price system

➤ No prescription fee

➤ No deductible

➤ No co-payments in the hospital sector

Pharmaceutical budgets for doctors

➤ Portugal

- No pharmaceutical budgets for doctors
- At overall level, limits on public pharmaceutical expenditure - framework agreements between the pharmaceutical industry (through the Portuguese Pharmaceutical Industry Association, APIFARMA) and the Ministry of Health from 2006 - 2009

➤ European comparision

- Quite rare
- Budgets are in: DE, CZ, ES in some regions, IE (with incentives), LV (sanctions against doctors), SE in some regions, UK

Monitoring and reviews

➤ Portugal

- Reviews of the reimbursement status within three years
- Since 2006, also reviews for medicines in the hospital sector
- Market monitoring by INFARMED, monthly reports on the website
- Prescription guidelines: indicative, National Prescribing Formulary, National Hospital Pharmaceutical Formulary
- Prescription monitoring: done by the Regional Health Authorities

➤ European comparison

- Reviews and market monitoring: not so commonly done
- Prescription guidelines: all EU MS, mostly indicative
- Prescription monitoring: all EU MS, referring to the reimbursement market

Generics promotion

➤ Portugal

- INN prescribing: mandatory, but no sanctions
- Generic substitution: indicative, doctor & patients may oppose it
- Higher rates for generics (2000-2005), from June 2009 on: exemption from any co-payment on reimbursed generics for people under the Special Regime
- Incentives to convert „copies“ into genericss
- Simplification of the reimbursement process (2006)
- Information policies (e.g. „Guia dos Génericos“, quarterly updated, available on the website

➤ European comparison

- INN prescribing: 4 EU MS mandatory, 18 EU MS indicative, 5 EU MS not allowed
- Generic substitution: 6 EU MS mandatory, 13 EU MS indicative, 8 EU MS not allowed

Assessment of the reimbursement system

**To have an equitable (fair),
effective and sustainable
pharmaceutical reimbursement
system,
what would be important for
you?**

Assessment of the reimbursement system

- Rights to essential medicines is a human rights
 - ICESCR specified availability, accessibility, acceptability and quality as interrelated and essential components for the fulfillment of the right to health in all its forms
- Definition of essential medicines
 - “Medicines that satisfy the priority health care needs of the population”(WHO)
 - WHO list of essential medicines = a model product & a model process, as the implementation of the EM concept is intended to be flexible
 - National responsibility
- Assessment from a human rights based perspective incl. public health

Assessment of the reimbursement system

- I. Government commitment
- II. Coverage of the population
- III. List of essential medicines
- IV. Transparency
- V. Rational selection of medicines
- VI. Mechanism for enforcement
- VII. Beneficiaries and stakeholders
- VIII. Availability
- IX. Affordability

Assessment of the reimbursement system

I. 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.

Assessment of the reimbursement system

II. 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.

Assessment of the reimbursement system

III. 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.

Assessment of the reimbursement system

IV. 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.

Assessment of the reimbursement system

V. 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.

Assessment of the reimbursement system

VI. 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.

Assessment of the reimbursement system

VII. 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.

Assessment of the reimbursement system

VII. 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.

Assessment of the reimbursement system

IX. 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.

Group work

- **Do you share the views expressed in the assessment?**
 - **Group 1:**
 - I. Government commitment
 - II. Coverage
 - III. List of essential medicines
 - **Group 2:**
 - IV. Transparency
 - V. Rational selection of medicines
 - VII. Mechanisms for enforcement
 - **Group 3:**
 - VII. Beneficiaries and stakeholders
 - VIII. Availability
 - IX. Affordability

- **Is there anything missing (not mentioned in the report and/or presentation)?**

Group work / Procedure

- Building the groups
- Select a speaker, who will present your conclusions to the plenary
- Select a rapporteur, who will take notes

- **25 minutes for group work**
- **5 minutes presentation per rapporteur**

Conclusions / 1

- We (= authors of the report) consider the Portuguese reimbursement system as 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.
 - Regular updates 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.

Conclusions / 2

- Room for improvement:
 - Rather **high out-of pocket payments**: -->Affordability might be restricted. Policy-makers should, at least, protect vulnerable groups.
 - Rather **high generic prices**: Good generics promotion policies --> to be continued. Mechanisms (e.g. sanctions or financial incentives) for better enforcement of the rules should be considered.
 - Improve **knowledge transfer** and **awareness-raising**: In spite of good publication policies by INFARMED, patients do not fully understand the system. A task for civil society, acting as “translators”.

Thank you for your attention!



Dr. Sabine Vogler
Head of Pharma Team

GÖG / ÖBIG (Austrian Health Institute)
Stubenring 6, 1010 Vienna. AUSTRIA
Tel. +43 1 51561/147

e-mail: sabine.vogler@goeg.at

<http://www.goeg.at> → Health Economics
<http://ppri.oebig.at>, <http://phis.goeg.at>