

## Poland's Reimbursement System: Strengths & Weaknesses

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## 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

## “Disclaimer”

- All health care and pharmaceutical system have their strengths and weaknesses.
- Historical developments, traditions and culture have a large influence on how the reimbursement is set up.
- Nonetheless: There is always room for improvement.
- Human rights approach is applied to assess the right to access to essential medicines.

## Outline

- An overview of the Polish reimbursement system - key characteristics in a European comparison
- Criteria for assessing a reimbursement system
- Assessing the reimbursement system
- Recommendations & the way forward

## Health care - characteristics

- Social Health Insurance system, financed through employees' contributions collected by the Social Insurance Institution (Zakład Ubezpieczeń Społecznych, ZUS)
- Strong regionalisation with 6 sickness funds in each voivodaship and one for the military services
- The right to receive health services (Polish Constitution) and coverage of all Polish population
- In 1998, the common Health Insurance Law (Ustawa o Powszechnym Ubezpieczeniu Zdrowotnym), based on the rule of societal solidarity, was implemented.

## Health system and status

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

-n.a. = not available, no = number

Data as of 31 December

<sup>1</sup> Year 2007

<sup>2</sup> Year 2006

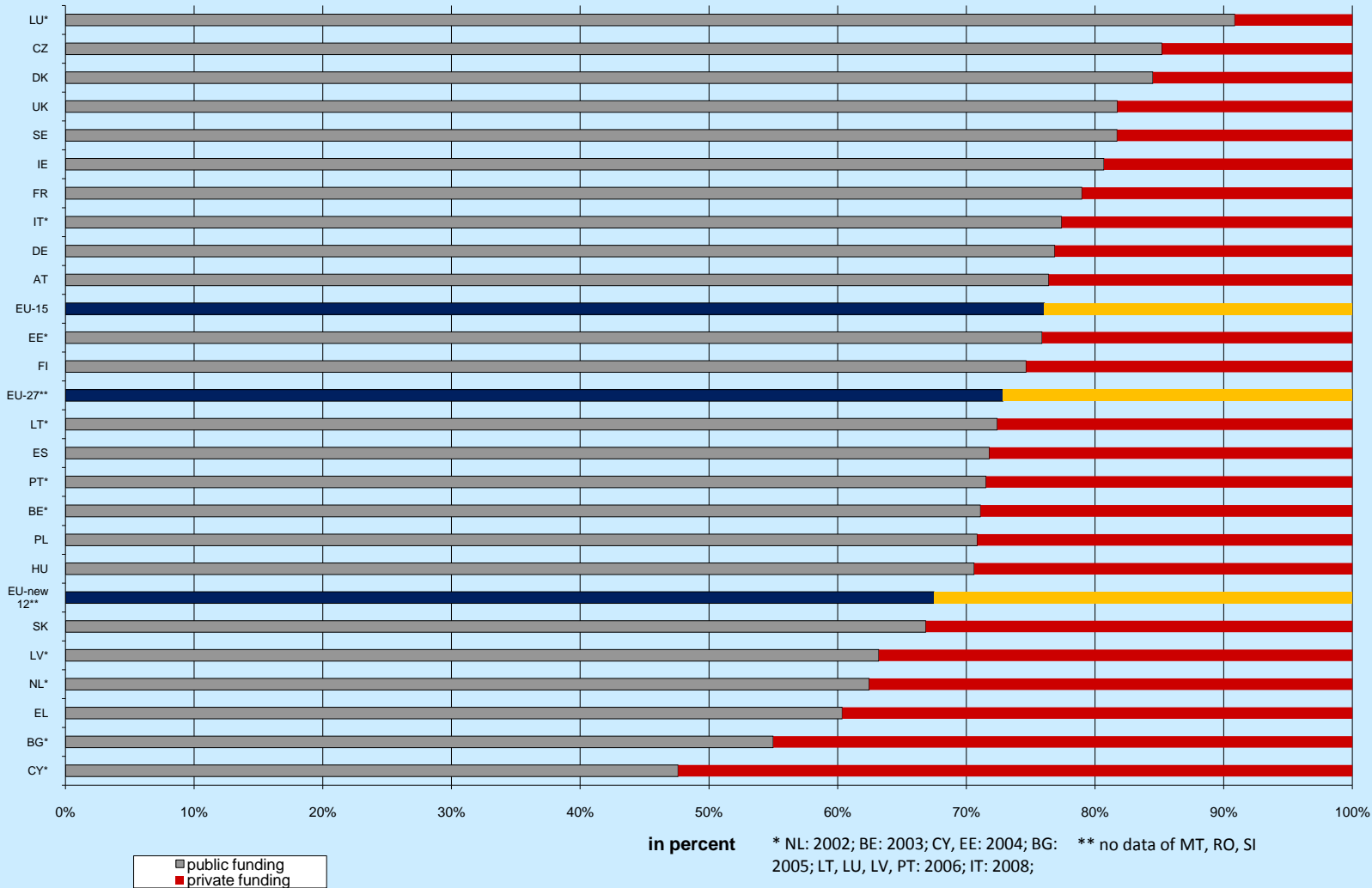
Source: EUROSTAT, OECD 2009, information from Polish Ministry of Health

## 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%

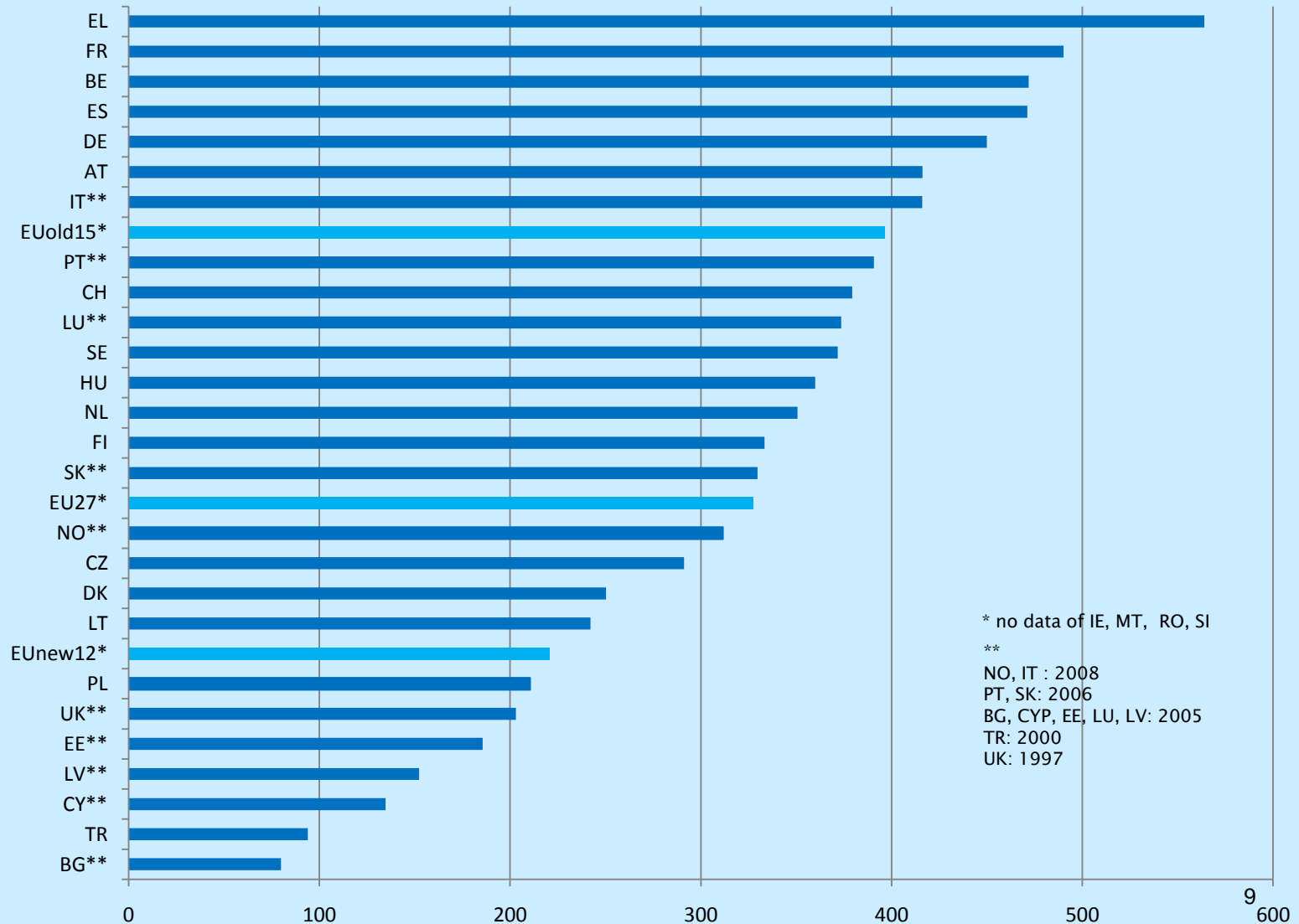
Source: EUROSTAT, OECD 2008/9, national statistics provided in INFARMED/ PPRI 2008

## Public/private funding of health expenditure



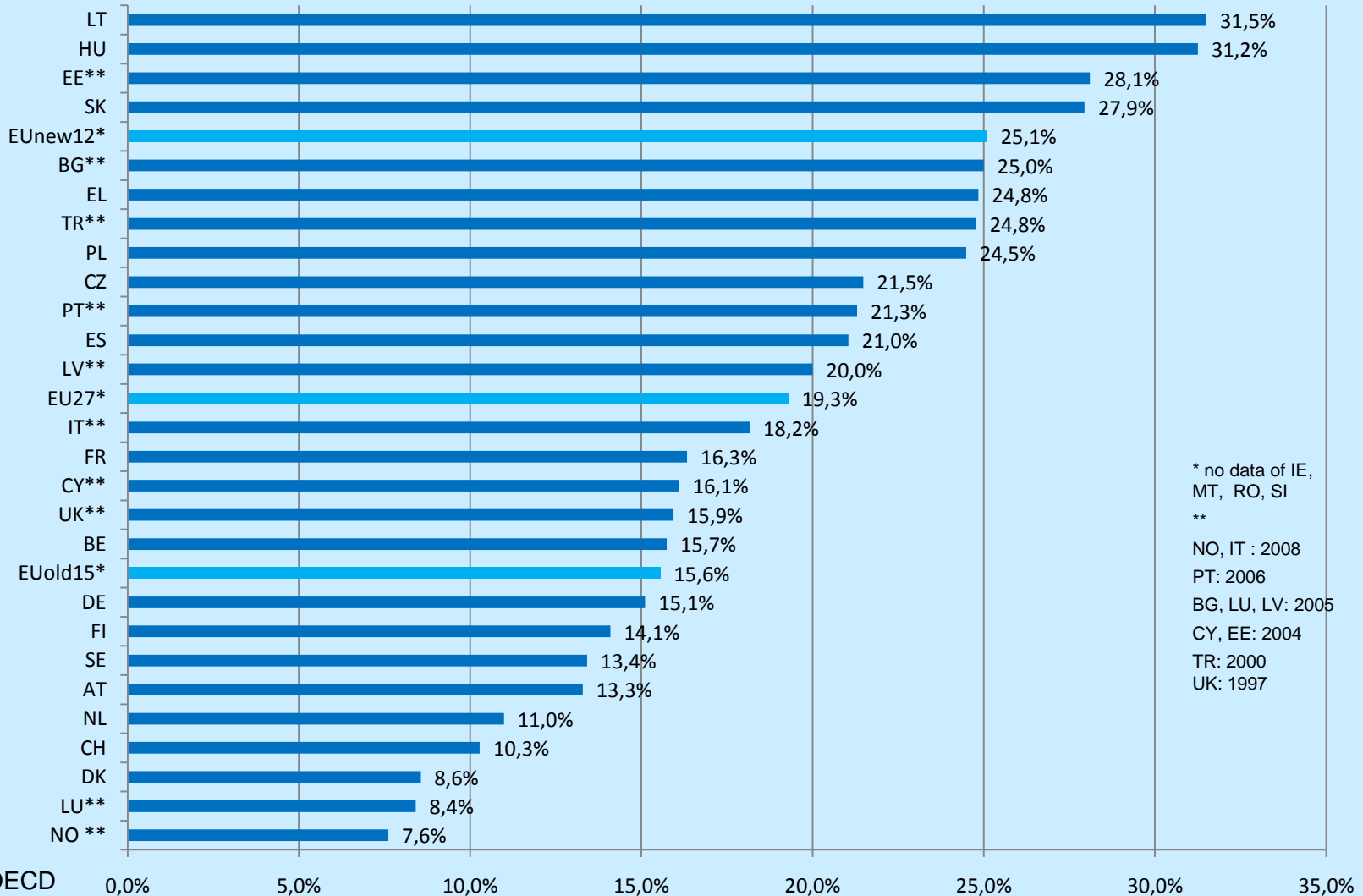


## Pharmaceutical expenditure per inhabitant 2007 in € PPPa

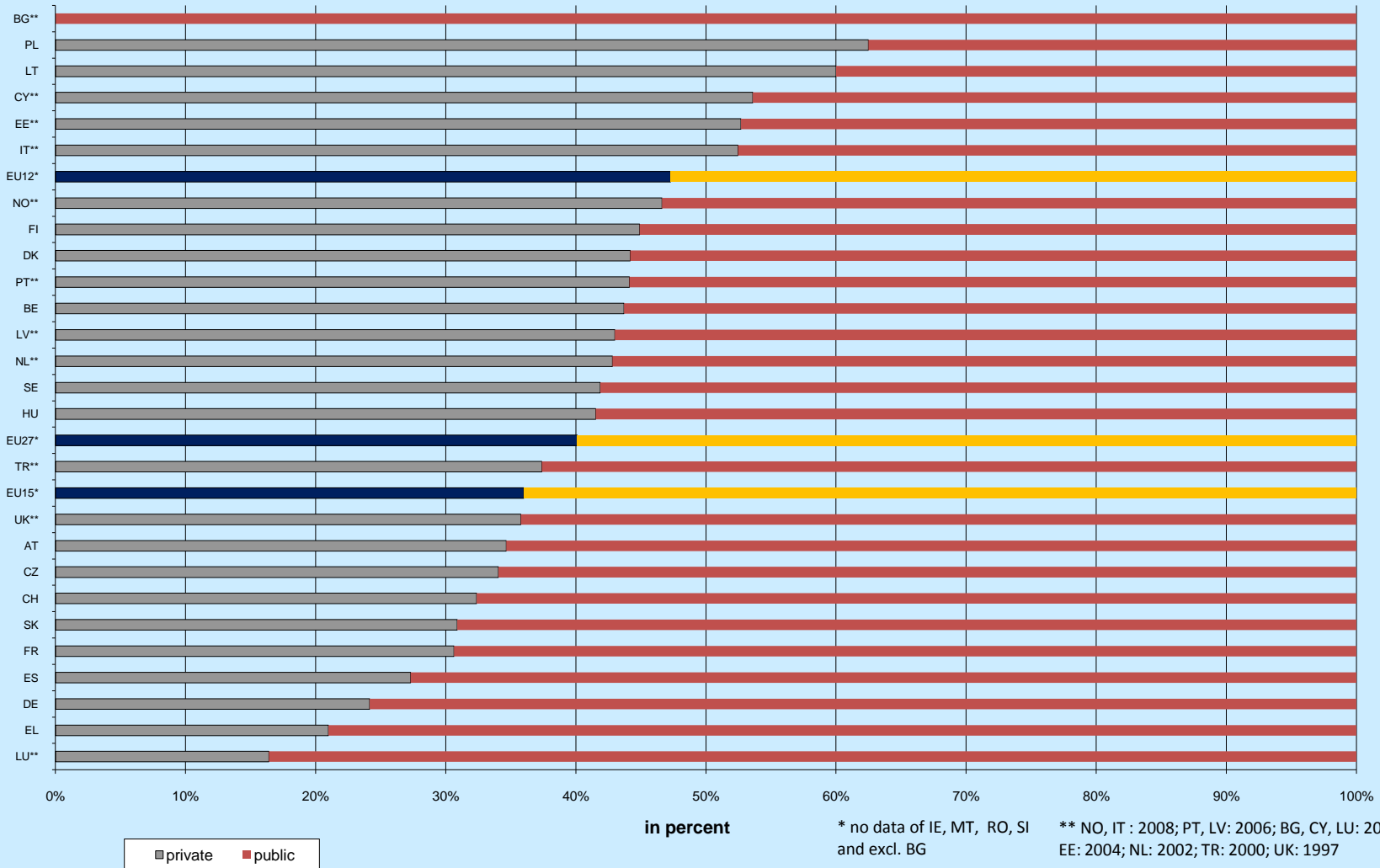


Source: OECD  
2009, Eurostat  
2009, PPRI

## Share of pharmaceutical expenditure in % of total health expenditure 2007



## Public/private funding of pharmaceutical expenditure



## Pharmaceutical system – responsible authorities

### Market authorisation

National Office for Registration of Medicinal  
Products, Medical Devices and Biocides

### Pricing

Ministry of Health advised by the Drug  
Management team

### Reimbursement

## Reimbursement - Procedure

- Application for reimbursement by pharmaceutical company (proposed price, the manufacturing costs and pharmaco-economic analyses)
- Pharmaceutical needs to have a price
- Reimbursement applications are evaluated by the Drug Management Team
- Decision within 90 days
  - Fast-track procedure for generics
  - Infringement procedures
- Appeal procedure

## Reimbursement: Eligibility criteria

- EU overview of 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)
- Poland has a product-specific eligibility scheme, supplemented by
  - Population-group-specific eligibility e.g. war veteran have no co-payments
  - Disease-specific eligibility e.g. cancer patients have no co-payments

## Reimbursement: Positive list

- European comparison
  - Positive lists in 23 of the EU Member States (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
  
- Poland
  - If considered eligible for reimbursement, the pharmaceutical is included on the positive list (one for the out-patient and one for the in-patient sector)
  - Quarterly updates
  - The positive list for the out-patient sector is publicly available on the website of the Ministry of Health: <http://www.mz.gov.pl>

## Reimbursement: Reimbursement rates/1

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

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

Source: Ministry of Health/PPRI Poland 2007<sup>α</sup>



## Reimbursement: Exemptions for vulnerable groups

- Exemptions from the general reimbursement scheme  
Patients receive 100% reimbursement in case of:
  - Cancer
  - Epilepsy
  - War veterans

## 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.*

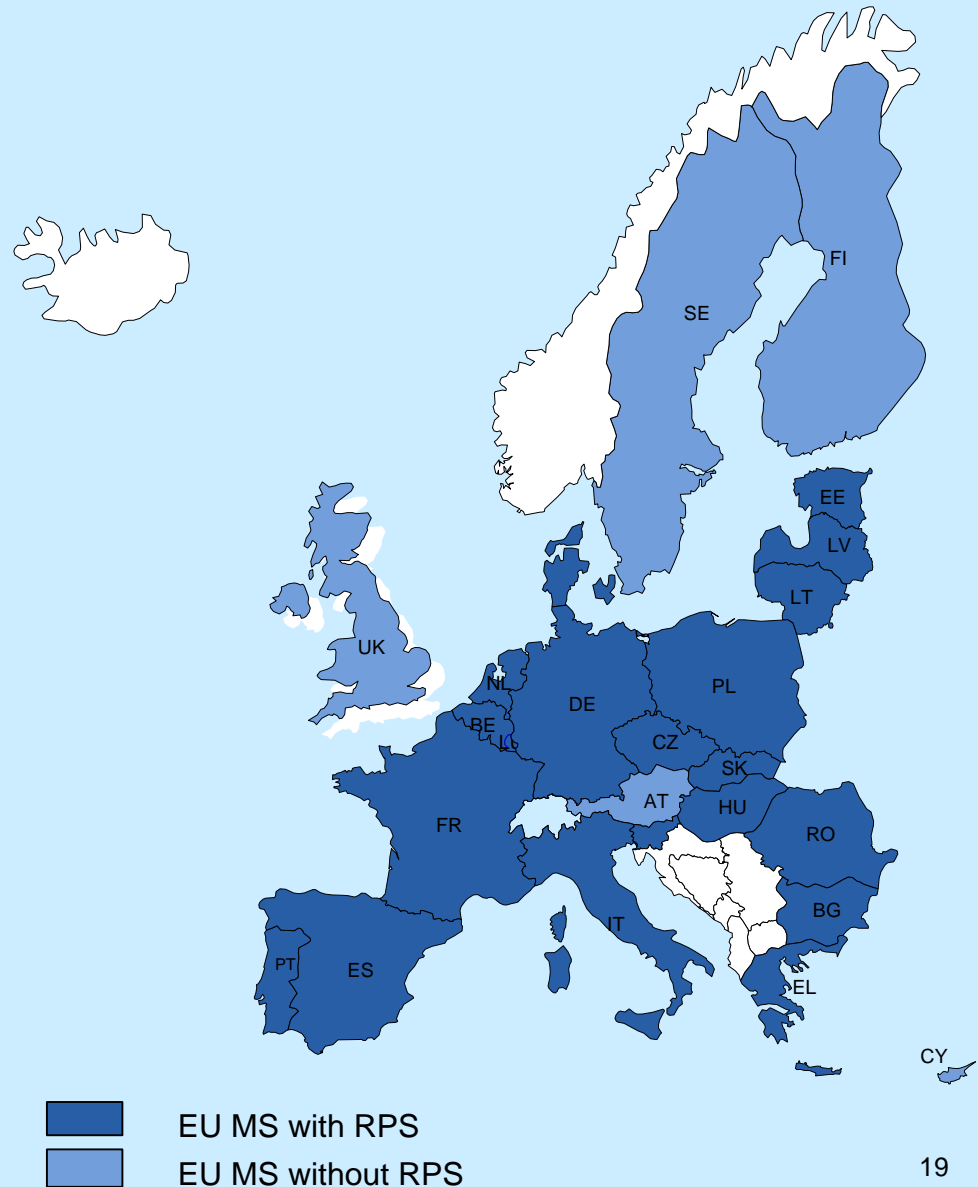
Source: PPRI Glossary, <http://ppri.goeg.at>

## Reimbursement: Reference price systems in the EU MS 2009

FI: RPS from 4/2009 on

→ 22 EU Member  
States with a  
reference price system

Source: PPRI 2008, updated  
information



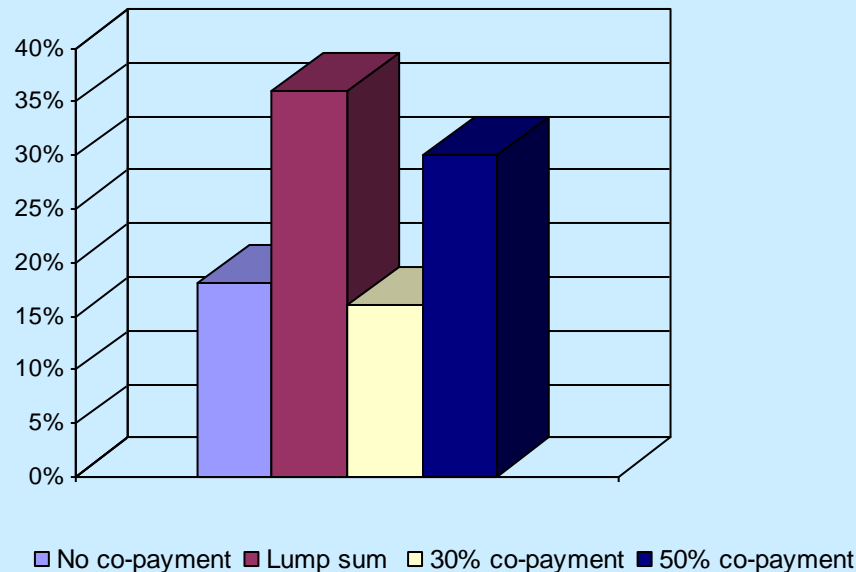
## Reference price system

- Introduced in 1998, scope
- Methodology
  - Reference groups: ATC 5 and 4 (sometimes even at ATC 3 level)
  - Reference price: lowest price per unit (based on daily defined doses)
- Updated biannually
- Publication on the Ministry of Health website:  
<http://www.mz.gov.pl>
- Exemption for cancer patients, patients with epilepsy and war veterans

## Co-payments

- Percentage co-payment: 0%, 30% and 50%
- Co-payment due to the reference price system
- No prescription fee, however for certain pharmaceutical a lump sum of PLN 3.20 / € 0.77 is charged

## Division of reimbursable medicines according to co-payment rates, 2005



Source: Błaszczuk, P; 2006

## ➤ **Pharmaceutical budgets for doctors**

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

*Pharmaceutical budgets are a cost-containment measure of third party payers. The maximum amount of money to be spent on pharmaceuticals in a specific region or period of time is fixed ex-ante.*

- European comparison

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

- Poland

- No pharmaceutical budgets for doctors

## Generics promotion

- 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
  
- Poland
  - INN prescribing: allowed
  - Generic substitution: allowed, doctor & patients may oppose it
  - Fast-track reimbursement procedure for generics

## 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

### Government commitment

Access to health	Yes	Access to equitable health care is recognized in several laws, decrees and legal provisions and implemented by the Social health insurance.
Access to essential medicines	Yes	The right to receive medical treatment including medicines is ensured in several laws, acts and legal provisions covering the whole population.
Essential medicines policy	No	Poland has no explicit essential medicines policy.

## Assessment of the reimbursement system

Coverage of the population		
Health care	Yes	The Social health insurance system covers the whole population of Poland. In addition, migrants have also the right to receive medical treatment.
Medicines	Yes	The right of health care treatment also includes access to (essential) medicines.

## Assessment of the reimbursement system

### List of essential medicines

Positive list	Yes	Poland has a positive list in the out-patient sector and a national Hospital Pharmaceutical Formulary in the in-patient sector.
Scope	~ 3.380 medicines	The Polish reimbursement list for the out-patient sector includes around 3.380 medicines. Additionally, there is a list with maximum prices of 28 active substances for the in-patient sector as well as special budgets for therapeutic programs for the in-patient sector.
Updates	quarterly	In reality, the reimbursement list is not updated quarterly.

## Assessment of the reimbursement system

Transparency		
Publication of lists	Yes	The reimbursement list for the out-patient sector is published and freely accessible on the internet. In the out-patient sector the budgets for some therapeutic programs such as for chemotherapy (which are similar to reimbursement lists) are published in orders of the National Health Fund.
Publication of prices	Yes	Prices of medicines used in the out-patient sector are published and freely accessible on the internet.

## Assessment of the reimbursement system

Rational selection of medicines		
Positive list	Point of criticism	In theory, there should be transparent criteria for selecting medicines, but in recent years, this has been, among others, a reason why Poland received an infringement procedure from the EC.
Reference price system	Yes	There are clear criteria and rules; however, pharmaceutical companies have not always observed the rules.

## Assessment of the reimbursement system

<b>Mechanisms for enforcement</b>		
Appeal procedure in reimbursement	Yes	Pharmaceutical companies which have received a negative decision on the inclusion into reimbursement may appeal to the supreme administrative court.
Fines and sanctions	No	There are no possibilities for the National Health Fund to fine contracted physicians in case they do not adhere to prescription guidelines.



## Assessment of the reimbursement system

<b>Beneficiaries and stakeholders</b>		
Involvement and consultation	Low	In general, the Polish reimbursement system is based on rather technical criteria than on committees involving stakeholders.
Role of stakeholders	Physicians	Especially the role of physicians is crucial, since they decide which medicines to prescribe. This has an impact on the level of co-payment for the patient.
Patients understanding the system	Low	The reimbursement system is complex thus patients need to be very well informed to ask for the right medicine e.g. with lower co-payment. However patients do not seem to fully understand the system.
Vulnerable groups	Special groups	There is free treatment for certain population groups: cancer patients, epileptic patients and war veterans.

## Assessment of the reimbursement system

<b>Availability</b>		
Medicines launched	8,089 authorised (2005) 4.198 on the market (2005)	Poland has a high number of medicines authorised; however only half of the number is actually on the market.
Pharmacies	Depending on the region	In general, the number of inhabitants per pharmacy differs between regions. In 2007, there were 10,632 pharmacies in Poland.

## Assessment of the reimbursement system

<b>Affordability</b>		
Price level	Rather low	Polish prices of medicines compared at ex-factory price level are amongst the lowest in Europe (IPF 2008).
Co-payments	% co-payments	Co-payments are rather high in Poland. Only for 18% of the reimbursable medicines, patients do not have to co-pay.
Private funding of pharmaceutical expenditure	Rather high	The share of private funding in pharmaceutical expenditure (62%) is very high compared to the EU average (36%).
Promotion of less expensive medicines	Yes	Through the introduction of the reference price system there has been a consistent policy of promoting generic alternatives.

## 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**
- **5 minutes presentation per rapporteur**

## Conclusions

- 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
  - Strengthening the valuable assessment of new molecules for the inclusion into the reimbursement system through Health Technology Assessment
  - Affordability might be restricted, as co-payments are rather high
  - Enforcement of certain cost-containment measures such as generic substitution
  - More public information campaigns so that patients better understand the system and know what their rights are!

## Thank you for your attention!



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