

## Pricing and reimbursement of medicines A European overview

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### Objective and outline

- » Why is Europe different?
- » Funding health and pharmaceutical expenditure
- » Elements of pharmaceutical systems
- » Pricing policies and procedures
  - Pricing policies and procedures
  - Distribution remuneration
  - Taxes
- » Reimbursement
  - Reimbursement lists and rates
  - Eligibility
  - Reference price systems
- » Generic policies
- » Challenges

*Pharmaceutical policy surveys and  
analyses often are focused on the  
out-patient sector → in-patient  
policies are considered*

## Disclaimer and acknowledgements

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Credits go to:

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- The members of the PPRI network

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Is Europe different?  
Is the European Union different?

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## Pharmaceutical system

### Globally

- A rather small public pharmaceutical sector in many countries
- Medicines in the public sector are distributed / dispensed to the patients (free-of-charge / co-payments)
- Essential medicines list
- Medicines are purchased by the state (public procurement) and sometimes also distributed by the state (central/regional warehouses)
- Patients need to buy medicines in the private sector out-of-pocket.
- No price control on medicines in the private sector.

### Europe / European Union

- The distinction between public and private sectors is not always clear
- Medicines are often supplied through private channels, but largely publicly funded
- Reimbursement list (positive list)
- Medicines on the reimbursement list are (partially) reimbursed by the payers (= NHS / SHI). There is some co-funding.
- Prices of many medicines are regulated (= price control), at the manufacturer and at the distribution levels.

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## Health insurance coverage

*"Millennium Development Goal (MDG) 8-E expresses a global commitment to ensure that access to essential affordable medicines is achieved by 2015. To achieve this goal an increase in spending on medicines in low- and middle-income countries may be required. This could be achieved by an increase in health insurance coverage or increased public expenditure."*  
(WHO, The World Medicines Situation 2011, chapter on Medicines Expenditure)

### National Health Service (NHS) and Social Health Insurance Systems (SHI) in the EU Member States

System	EU Member States
NHS	CY <sup>1</sup> , DK, ES, EL, FI, IE, IT, LV, MT, PT, SE, UK = 12
SHI	AT, BE, BG, CZ, DE, EE, FR, HU, LT, LU, NL, PL, RO, SI, SK = 15

<sup>1</sup> Cyprus, currently a kind of NHS, is being transformed to a SHI

Please note that mixed systems are possible.

Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Vienna

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## Pharmaceutical expenditure / globally vs. Europe

**TABLE A1.2 Total pharmaceutical expenditure in absolute and per capita level by region of country group, 2005/2006 (million US\$)**

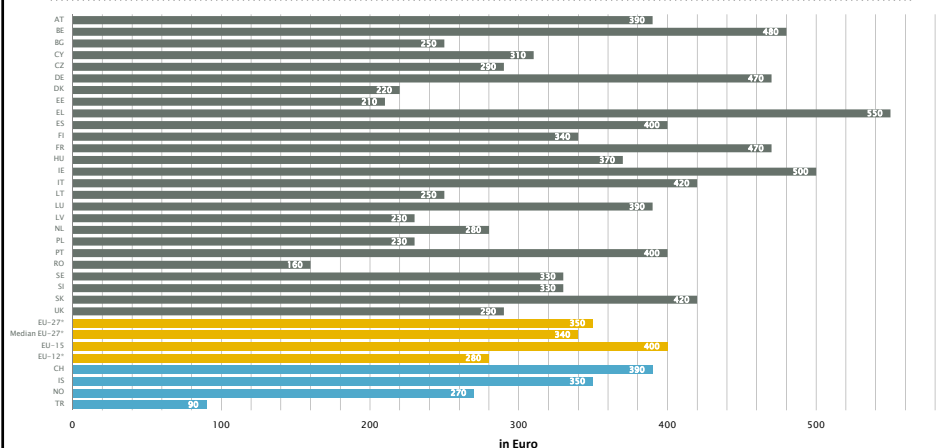
Region	N	Population (000s)	Absolute amount (million US\$)	Per capita (US\$)
AFRO	31/46	629913 (9.97%)	\$8 101.1 (0.9%)	\$21.1
AMRO	35/35	890 361 (14.1%)	\$356 882.1 (41.5%)	\$117.8
EMRO	16/21	481 711 (7.6%)	\$12580.5 (1.5%)	\$59.8
<b>EURO</b>	<b>50/53</b>	<b>871 998 (13.8%)</b>	<b>\$293 187.9 (34.1%)</b>	<b>\$325.8</b>
SEARO	9/11	1 696 228 (26.8%)	\$25 575.7 (3.0%)	\$16.0
WPRO	20/27	1 749 000 (27.7%)	\$162 886.8 (19.0%)	\$142.8
<b>TOTAL</b>	<b>161/193</b>	<b>6 319 211 (100.0%)</b>	<b>\$859214.1 (100.0%)</b>	<b>\$155.4</b>

Note: N is number of countries

Source: WHO, The World Medicines Situation 2011, chapter on Medicines Expenditure

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## Pharmaceutical expenditure per capita 2009 in € PPPa



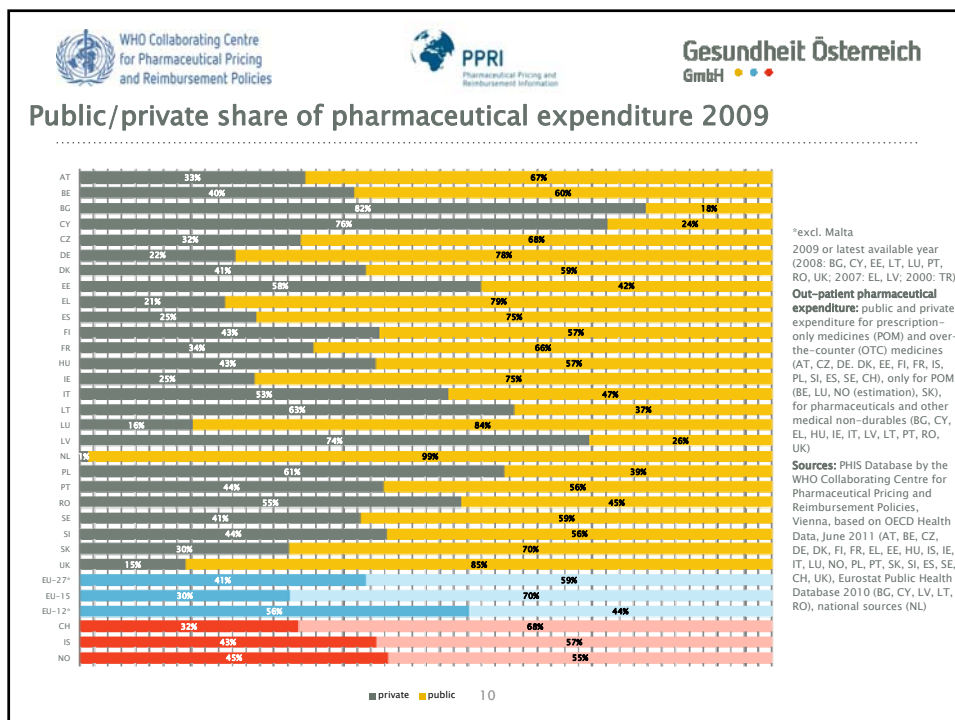
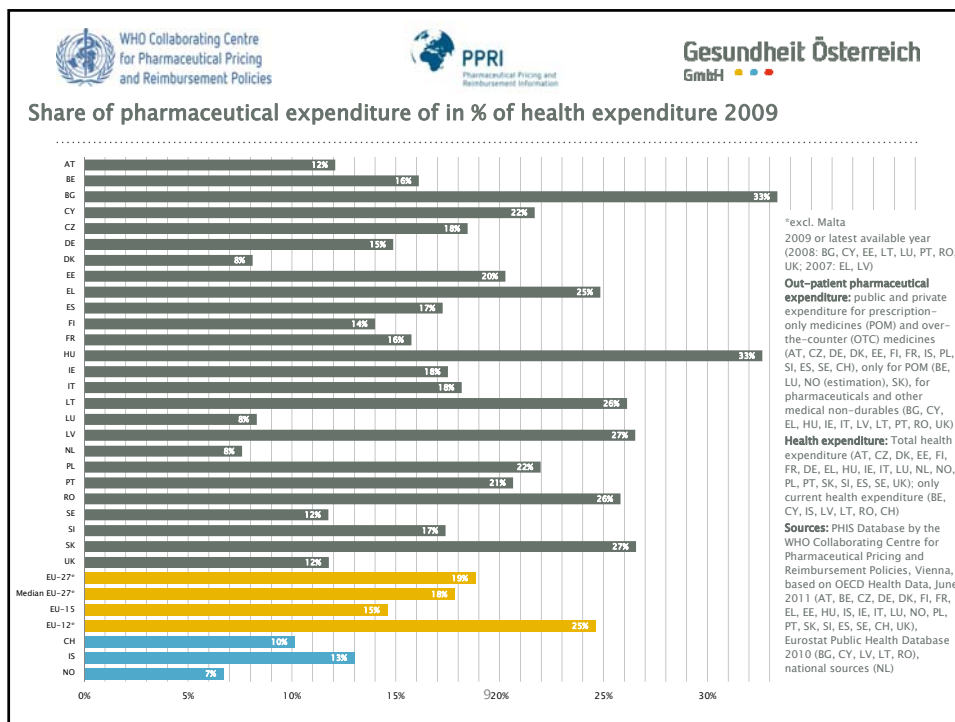
\*excl. Malta

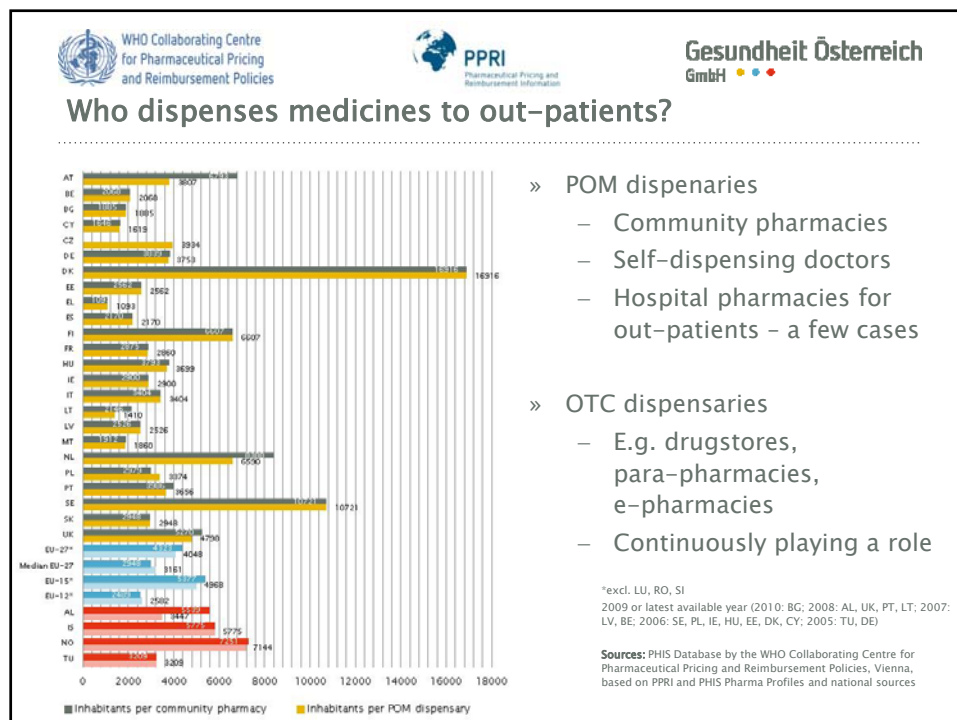
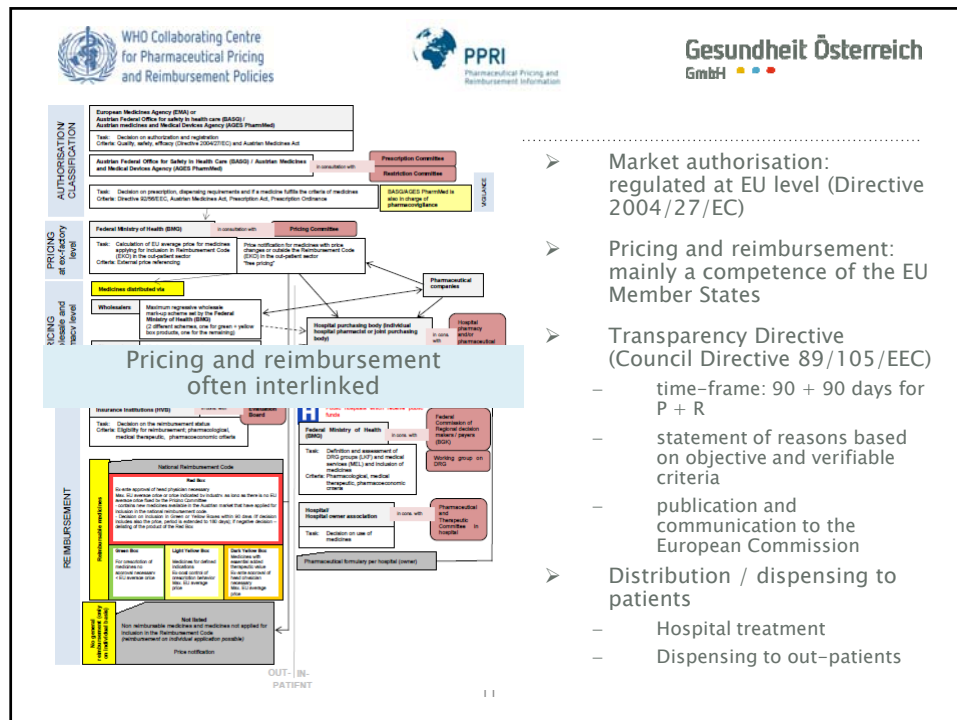
2009 or latest available year (2008: BG, CY, EE, LT, LU, PT, RO, UK; 2007: EL, LV; 2000: TR)

**Out-patient pharmaceutical expenditure** (in Euro, adjusted for purchasing power): public and private expenditure for prescription-only medicines (POM) and over-the-counter (OTC) medicines (AT, CZ, DE, DK, EE, FI, FR, IS, PL, SI, ES, SE, CH, TR), only for POM (BE, LU, NO (estimation), SK), for pharmaceuticals and other medical non-durables (BG, CY, EL, HU, IE, IT, LV, LT, PT, RO, UK)

EU-12 are the "new" EU Member States which acceded on / after May 2004 to the EU

**Sources:** PHIS Database by the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Vienna, based on OECD Health Data, June 2011 (AT, BE, CZ, DE, DK, FI, FR, EL, EE, HU, IS, IE, IT, LU, NO, PL, PT, SK, SI, ES, SE, CH, UK, TR), Eurostat Public Health Database 2010 (BG, CY, LV, LT, RO), national sources (NL)





## Price control

### Definition:

*Pricing policies where government authorities set the price of a pharmaceutical and/or indirectly influence it (e.g. statutory pricing, price negotiations, public procurement). Contrary to free pricing.*

Source: PPRI/PHIS Glossary (<http://phis.goeg.at>)

### Practice in the EU

- » Price control in nearly all EU Member States
- » In the majority of the EU Member States, price control is limited to reimbursable medicines
  - E.g. AT, CZ, EE, FR, HU, IT, LT, SK, SI
  - For all medicines (e.g. BE, EL, LU) or for POM (e.g. BG, RO)
- » “Free pricing countries”: DK and DE
- » PPRS in UK

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Sources: PHIS Database by the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Vienna, based on PPRI and PHIS Pharma Profiles and national sources

## Pricing policies at manufacturer level

### » Statutory pricing

- Definition: Pricing system, where pharmaceutical prices are set on a regulatory basis (e.g. law, enactment, decree).
- Practice: Most common price control policy in the EU (e.g. BE, BG, CY, CZ, EL, ES, LT, LU, PT, SE)

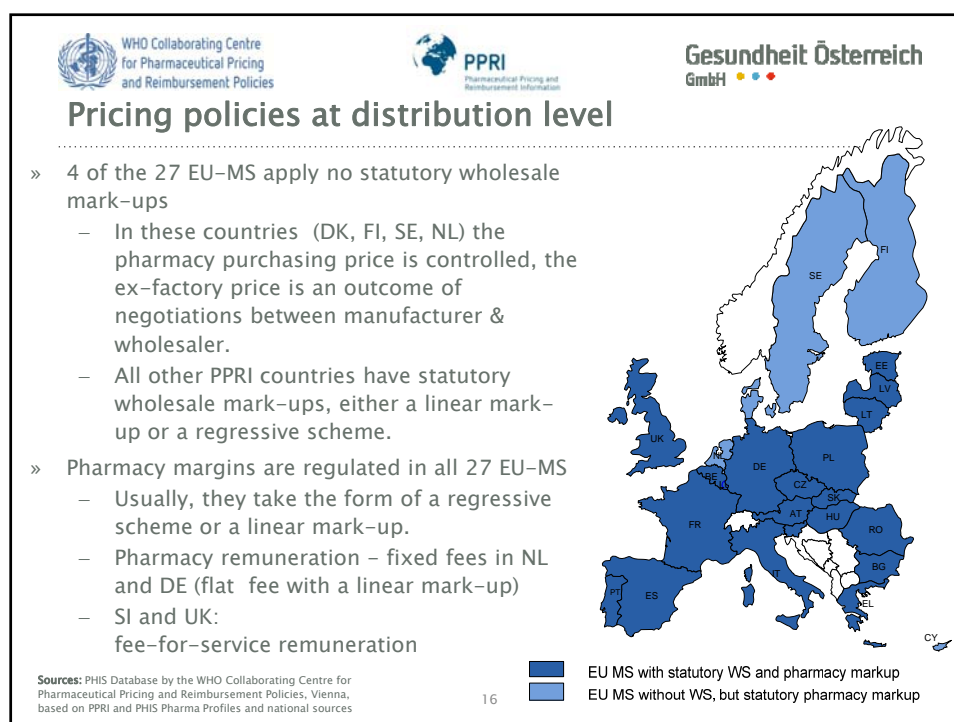
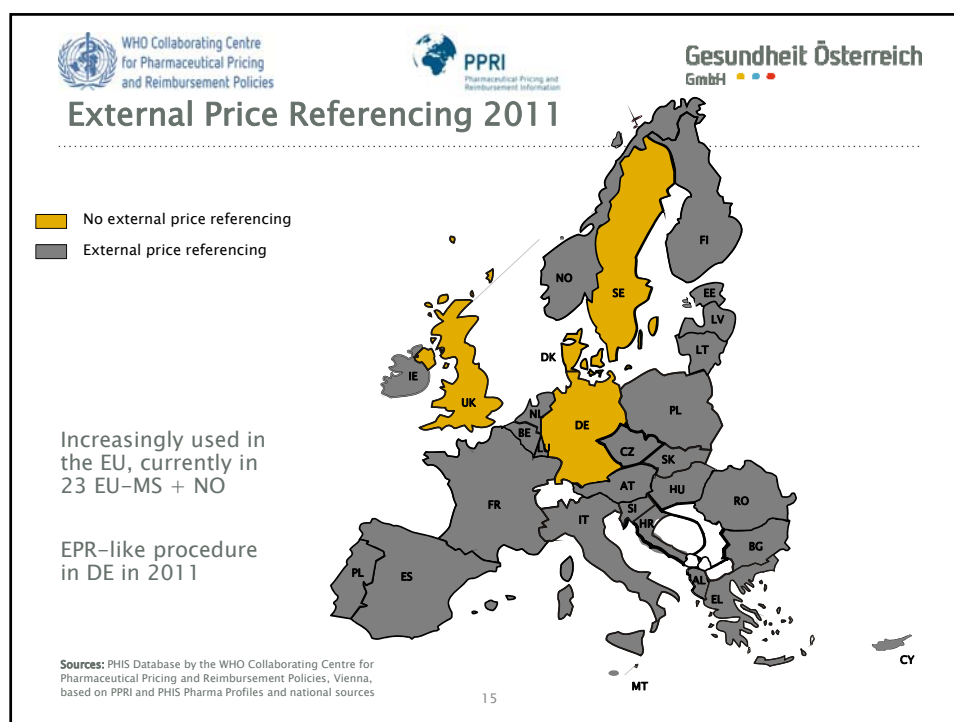
### » Price negotiations

- Definition: A form of pricing procedure, where pharmaceutical prices are discussed / negotiated (e.g. between manufacturer and social health insurance / national health service).
- Practice: Used in a few countries (ES, FR, IT)

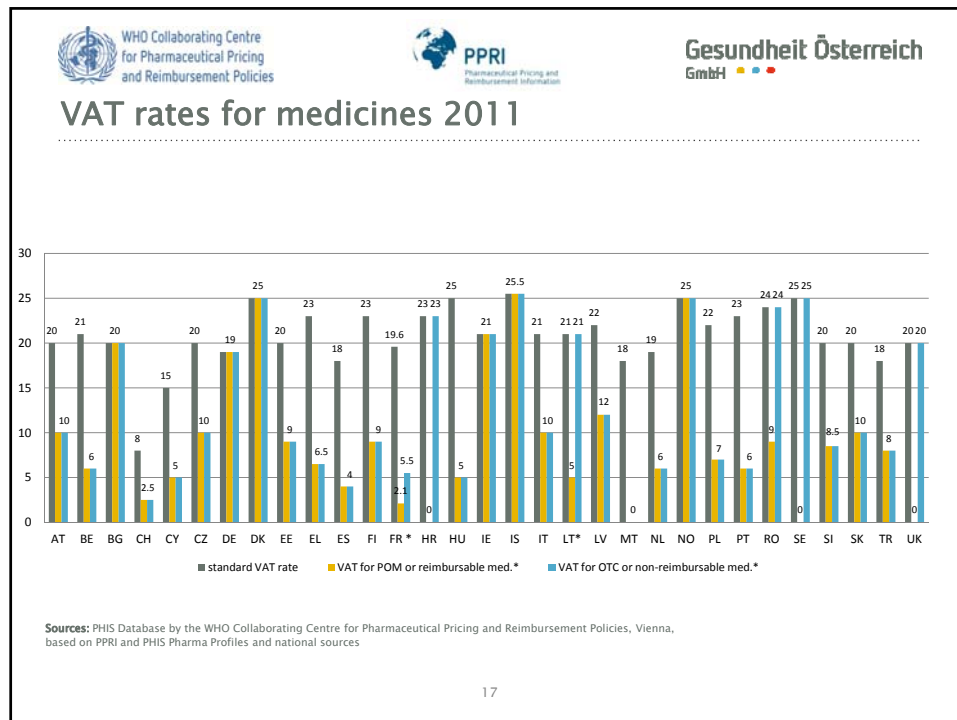
### » Procurement

- Definition: Buying medicines on the basis of a tendering procedure, granting the contract to the best tenderer (pharmaceutical company / importer). Often public procurement, i.e. done by the state (e.g. public hospitals)
- Practice: in the hospital sector and/or for public functions

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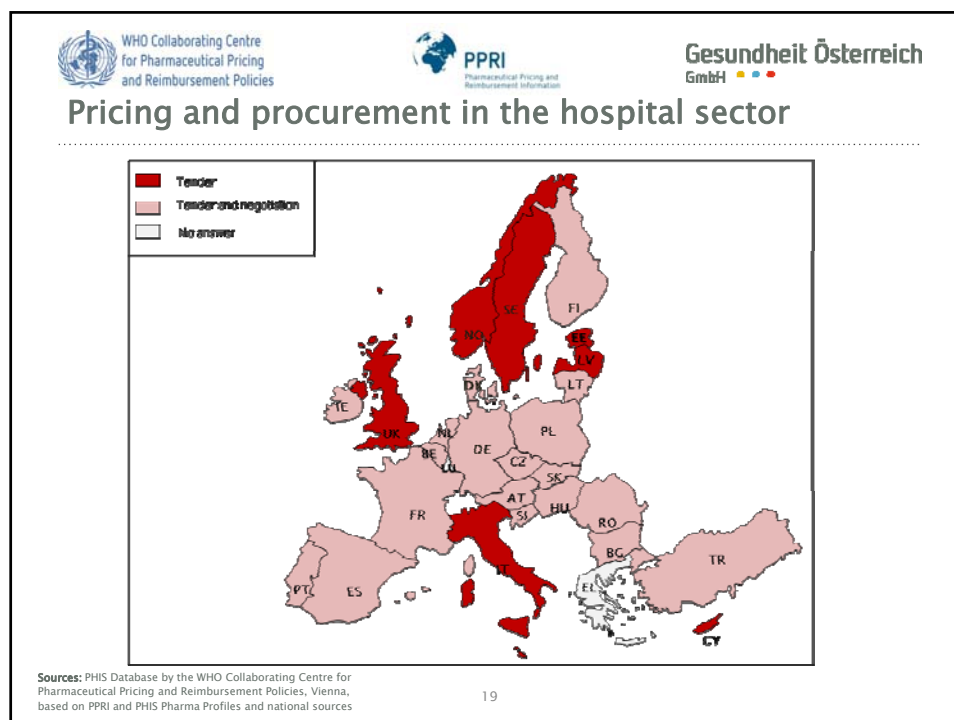
PPRI Pharmaceutical Pricing and Reimbursement Information

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## Relevant price types

Out-patient	In-patient
✓ Ex-factory price	✓ Ex-factory price <b>Official hospital price</b>
✓ Pharmacy purchase price (wholesale price)	✓ Pharmacy purchase price (wholesale price)
✓ Pharmacy retail price net	✓ Pharmacy retail price <b>Actual hospital price</b>
✓ Pharmacy retail price gross	✗ Pharmacy retail price

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## Reimbursement lists

- Positive lists (synonym: formulary)
  - Definition: List of medicines that may be prescribed at the expense of the third party payer.
  - Practice – out-patient: In 24 EU Member States (in all but DE, ES, UK) – in the out-patient sector
  - Practice – in-patient: hospital pharmaceutical formularies (at hospital level; additionally national formularies in FR, LV, PT & regional formulary in DK + NO)
- Negative lists
  - Definition: List of medicines which cannot be prescribed at the expense of the third party payer
  - Practice – out-patient: Negative lists are less common (DE, HU, UK; legal basis in FI and in EL)
- Positive / negative lists have to be seen in consideration with the reimbursement eligibility schemes!

Sources: PHIS Database by the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Vienna, based on PPRI and PHIS Pharma Profiles and national sources

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## Reimbursement eligibility schemes – key schemes

- **Product-specific eligibility**
  - Definition: Eligibility for reimbursement depends on the medicine in question (either a medicine is considered as reimbursable or as non-reimbursable).
  - Practice: In most EU Member States
- **Disease-specific eligibility**
  - Definition: Eligibility for reimbursement is linked to the underlying disease which shall be treated.
  - Practice: Key scheme in the Baltic States
- **Population-group-specific eligibility**
  - Definition: Specific population groups (e.g. children, old-age pensioners) are eligible for medicines, while others are not.
  - Practice: Key scheme in CY, MT, IE; elements on many countries
- **Consumption-based eligibility**
  - Definition: The level of reimbursement depends on the expenses for medicines of a patient within a certain period of time (increasing reimbursement with rising consumption).
  - Practice: DK, SE

**Sources:** PHIS Database by the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Vienna, based on PPRI and PHIS Pharma Profiles and national sources

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## Reimbursement rates

- **Definition**

The percentage share of the price of a medicine or medicinal service, which is reimbursed/subsidized by a third party payer. The difference to the full price of the medicine or medicinal service is paid by the patients.
- **Practice in EU – out-patient**
  - Defined percentages such as 100% for essential medicines, 80% for chronic medicines, 60% for medicines that have moderate improved therapeutic effect
  - Only AT, DE, IT, NL and UK have 100% reimbursement (additional co-payments such as prescription fees are common)
- **Practice in EU – in-patient**
  - 100% coverage/reimbursement for medicines in in-patient care

**Sources:** PHIS Database by the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Vienna, based on PPRI and PHIS Pharma Profiles and national sources

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## Reference price systems

### 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://phis.goeg.at>

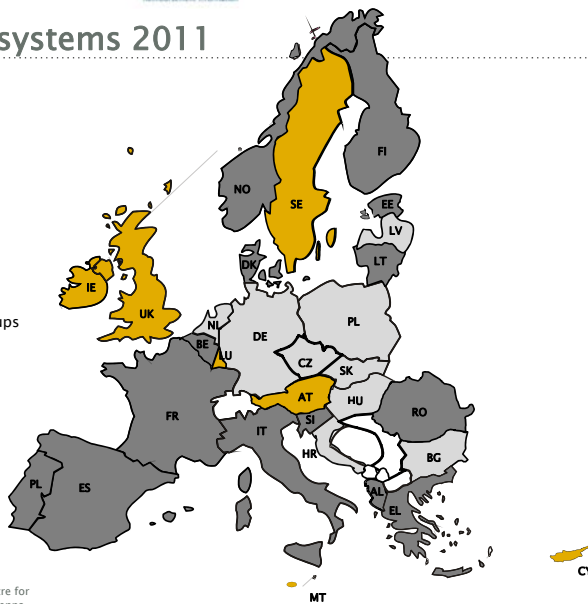
Sources: Glossary, WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Vienna,

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## Reference price systems 2011

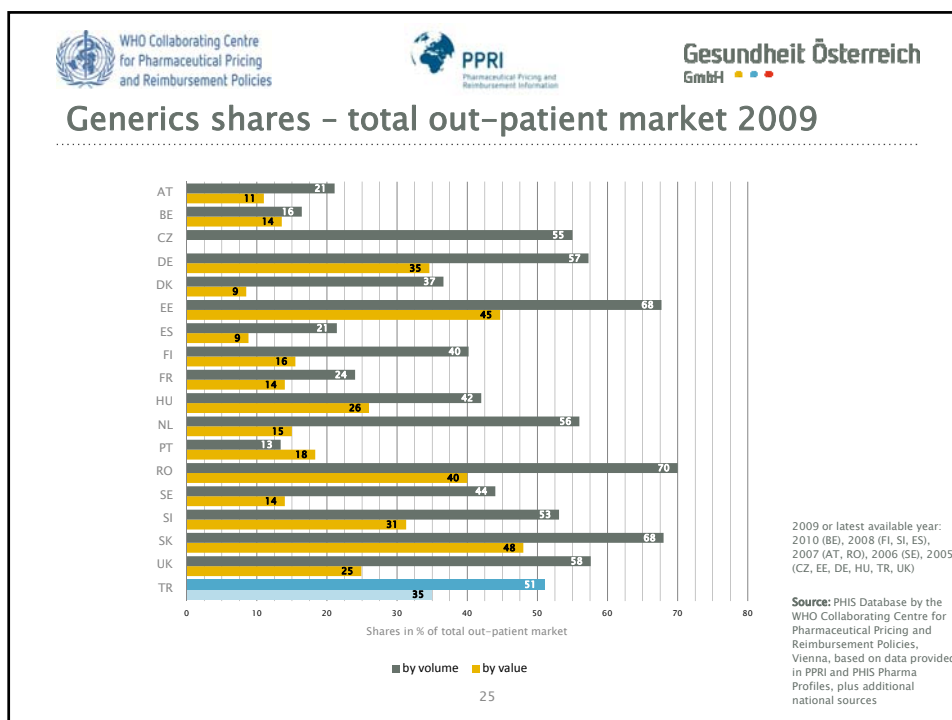
- No Reference Price System
- Reference Price System, reference groups at ATC 5 level
- Reference Price System, broader definition of reference groups

20 EU Member States with a reference price system



Sources: PHIS Database by the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Vienna, based on PPRI and PHIS Pharma Profiles and national sources

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## Generic substitution and INN prescribing

**Generic substitution:** Practice of substituting a pharmaceutical, whether marketed under a trade name or generic name (branded or unbranded generic), by a pharmaceutical, often a cheaper one, containing the same active ingredient(s). Source: PPRI/PHIS Glossary, <http://phis.goeg.at>

Practice of generic substitution in the EU

- Not allowed in seven countries
- Allowed in 22 countries,
  - thereof indicative in 14 and
  - mandatory in eight

**INN (International non-proprietary name) prescribing** refers to physicians prescribing medicines by its INN, i.e. the active ingredient name instead of the brand name. INN prescribing may be allowed (indicative INN prescribing) or required (mandatory INN prescribing). Source: PPRI/PHIS Glossary

Practice of INN prescribing in the EU

- Not allowed in five countries
- Allowed in 23 countries,
  - thereof indicative in 18 and
  - mandatory in 5
- Supported by electronic prescribing system in the Netherlands

Sources: PHIS Database by the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Vienna, based on PPRI and PHIS Pharma Profiles and national sources

## Challenges & outlook

- Pharmaceutical policies should ensure the access to essential / needed medicines in spite of tight budgets
- Make decisions based on best practice, evidence and experiences from other countries
- Not only pricing and reimbursement, but other elements of a rational use of medicines
- Not only focusing on the out-patient sector, but considering also the hospital sector & good-practice examples of interface management
- Benchlearning is important, but each country needs to formulate its policies in according to the country-specific framework impacted by culture and historic developments
- Need for common understanding, databases, information systems

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## For further reading & data sources



http://whocc.goeg.at

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