Pricing and reimbursement of pharmaceuticals in Central-Eastern European countries

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Pricing and Reimbursement of Medicines – European Practices
UNDER THE PATRONAGE OF THE PARLIAMENTARY HEALTHCARE COMMITEE TO THE 41ST NATIONAL ASSEMBLY
Sofia, 7 June 2012

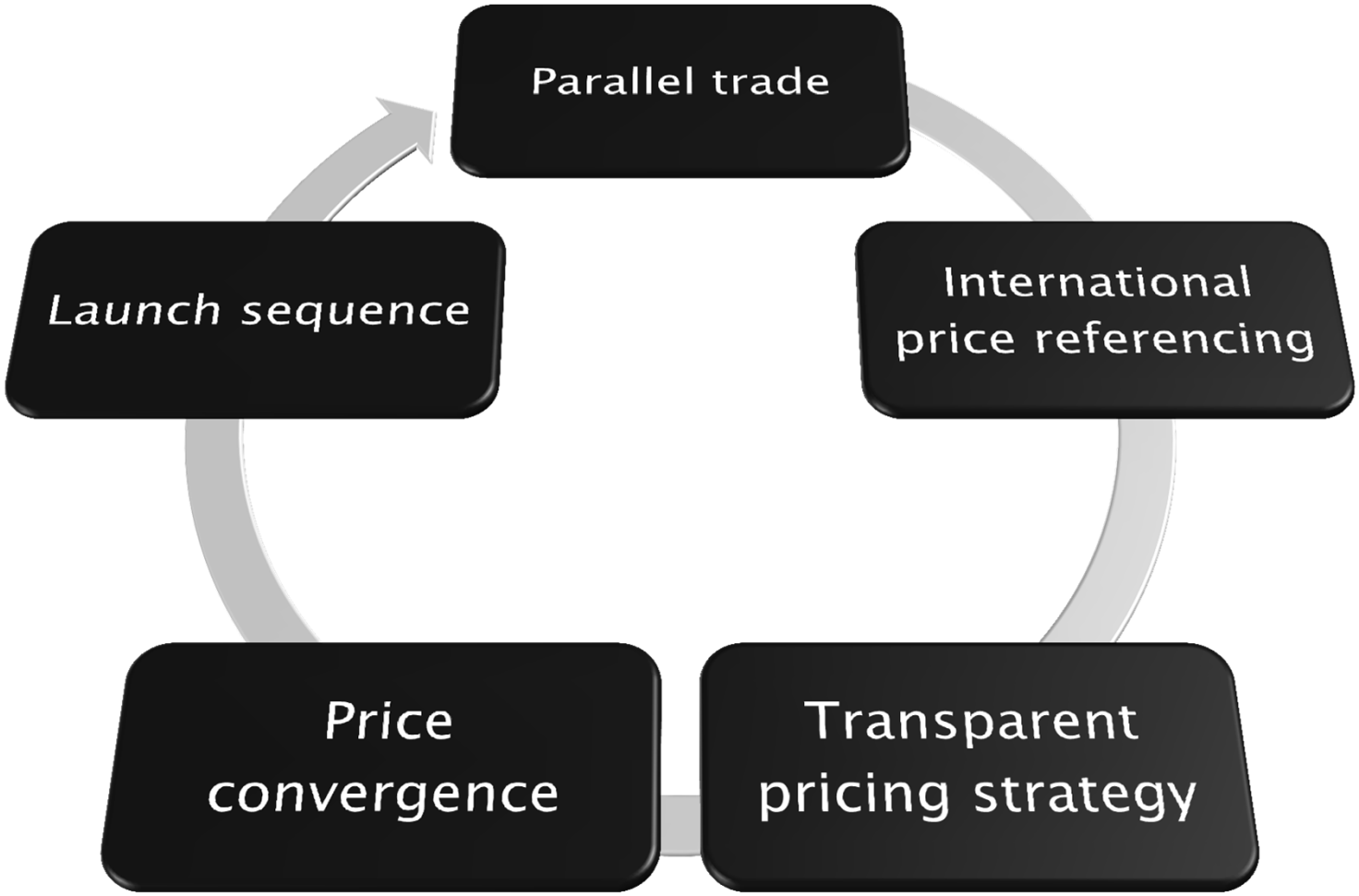
Economic environment in Central-Eastern Europe (CEE)

- Major proportion of health care financing is from public resources
- Global economic recession → initiatives to reduce public spending
- Focus on pharmaceutical expenditure (i.e. promotion of generic drugs; controlled reimbursement of innovative medicines)
- Pressure by payers on pharma companies to justify prices of their drugs:
  1. reference pricing (international price referencing + therapeutic reference pricing)
  2. value based pricing

Value based price

- What is value based price?
  - the drug is cost-effective at a given price
  - the price increase can be justified by additional health gain or savings in the health care budget
- The appropriate value based price in a country may not be the optimal price in other countries

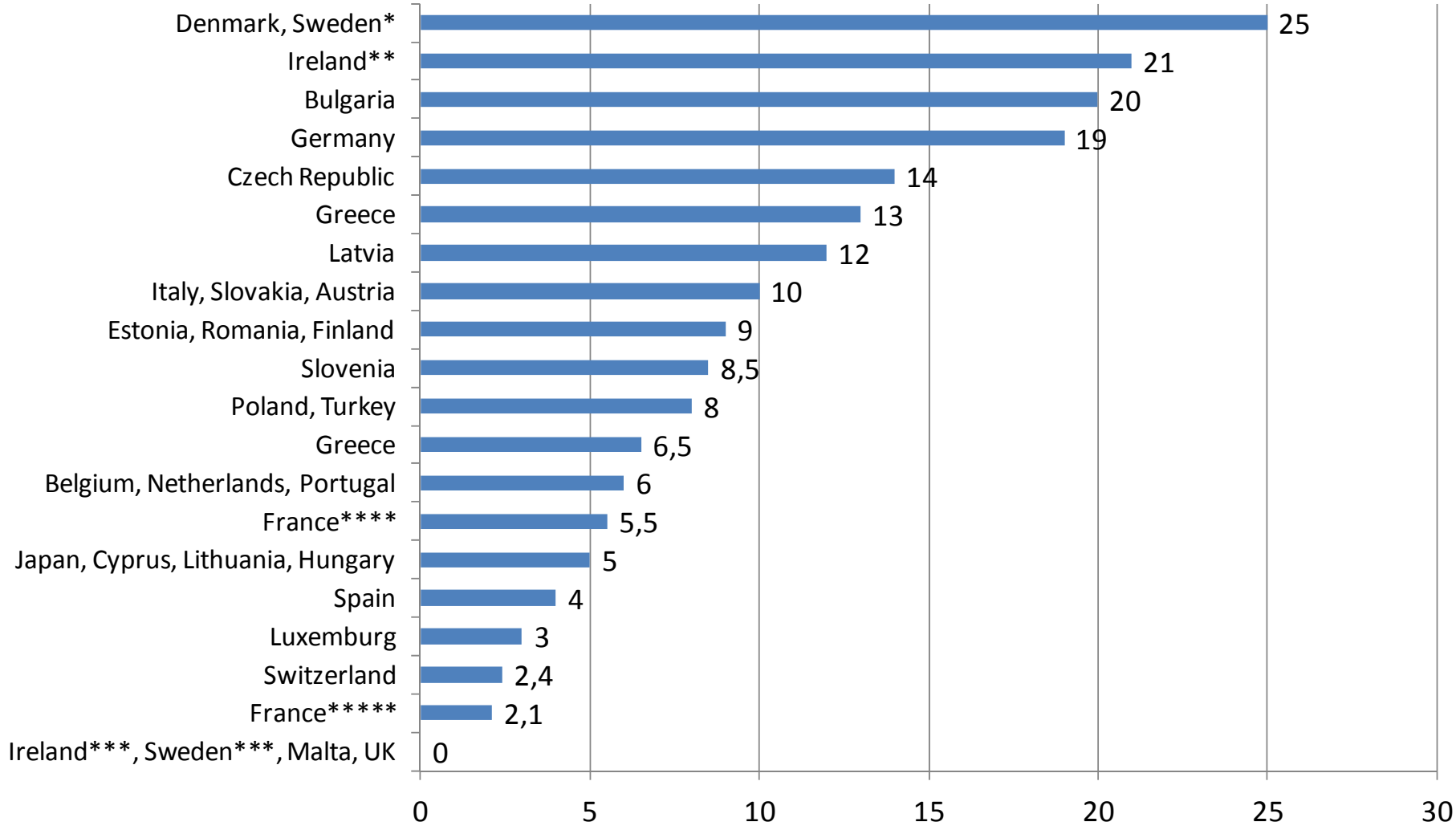
Implication of European Union (and European Monetary Union) on pharmaceutical pricing



International price referencing – which price?

- The structure of distribution chain of pharmaceuticals is reasonably different in countries (e.g. pharmacies, wholesalers, direct sales to large providers, etc)
- Value added tax (VAT) also varies
- Consequently public price of pharmaceuticals cannot be compared, as it is influenced by wholesaler margin, pharmacy margin and VAT
- Multinational pharma companies are responsible only for the manufacturer (or ex-factory) price, distribution margins and VAT depend on how the system of pharmaceutical provision is designed by local policy-makers
- As the intention of international price referencing is to put pressure on pharmaceutical companies to reduce their drug prices in certain countries, ex-factory price is used for comparison

Pharmaceutical VAT in Europe (%)



** OTC; ** non-oral medicines; ***oral medicines; **** non-reimbursed; *****reimbursed;*

Source: VAT Rates Applied in the Member States of the European Union; European Commission Taxation and Customs Union; 2012

Implications of international price referencing in lower income European countries

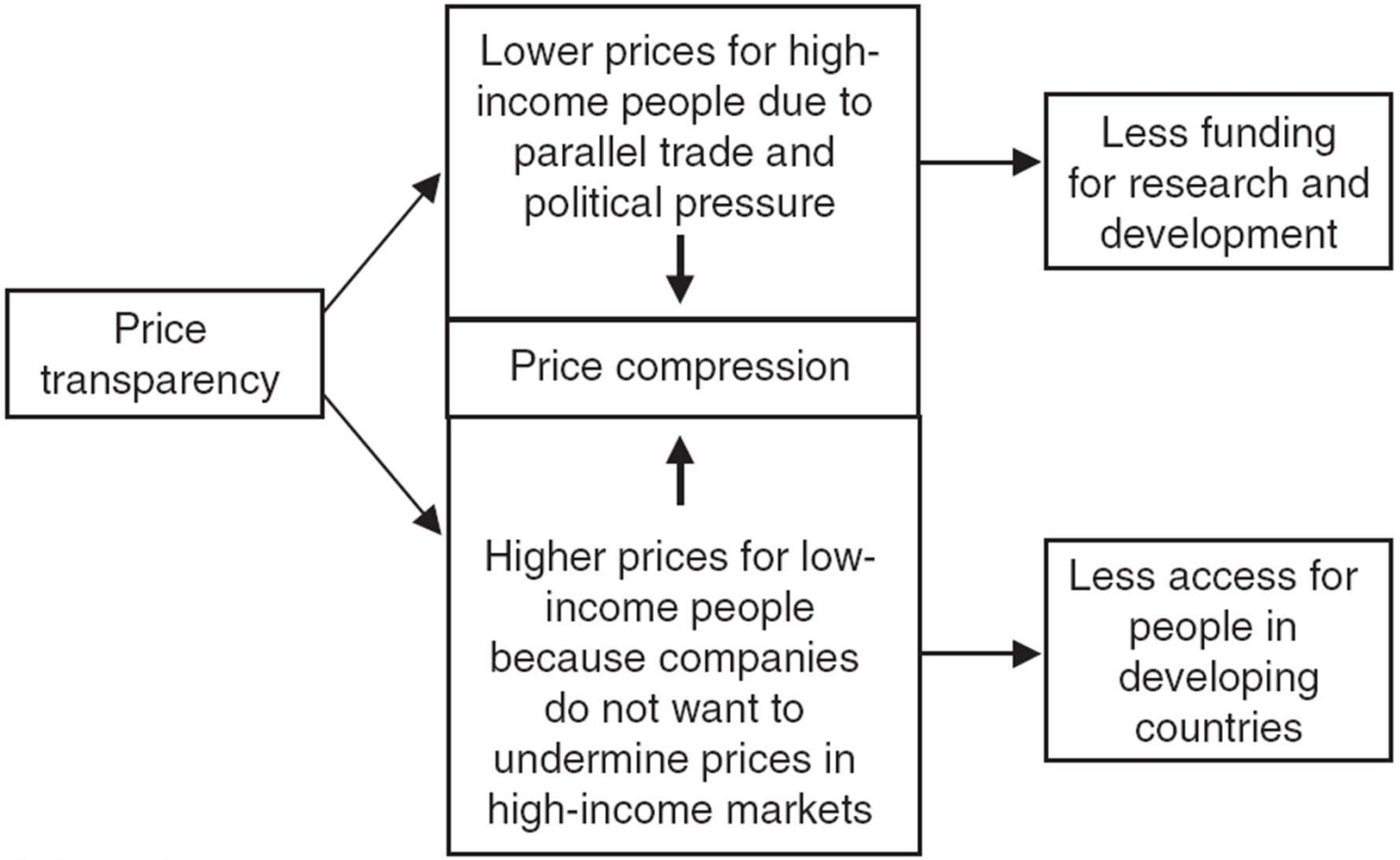
- Ex-factory price of drugs established in high income countries is often not justifiable in lower income CEE countries
- Payers in almost all European lower income countries would like to have the European floor price for reimbursed medicines
- Only one country can have the lowest European price

Implications of international price referencing in lower income European countries

- Consequently payers need to have better information on ex-factory prices in other European reference countries. They
  - usually mandate the submission of ex-factory prices in other countries,
  - often meet and exchange information on successful pharmaceutical cost-containment strategies.
- There are initiatives in some European countries (some are even funded by EU) to increase price transparency by building databases to support pricing decisions of payers
- Currency fluctuations drive price erosion for lower income CEE countries outside the Euro zone → opportunity for payers in other countries to induce price erosion through domino effect

Who benefits more from price transparency (i.e. pricing databases): higher or lower income countries?

Impact of transparent pharmaceutical pricing



Ridley DB: Pharmacoeconomics 2005; 23 (7): 651-658

Western Europe vs Central Eastern Europe

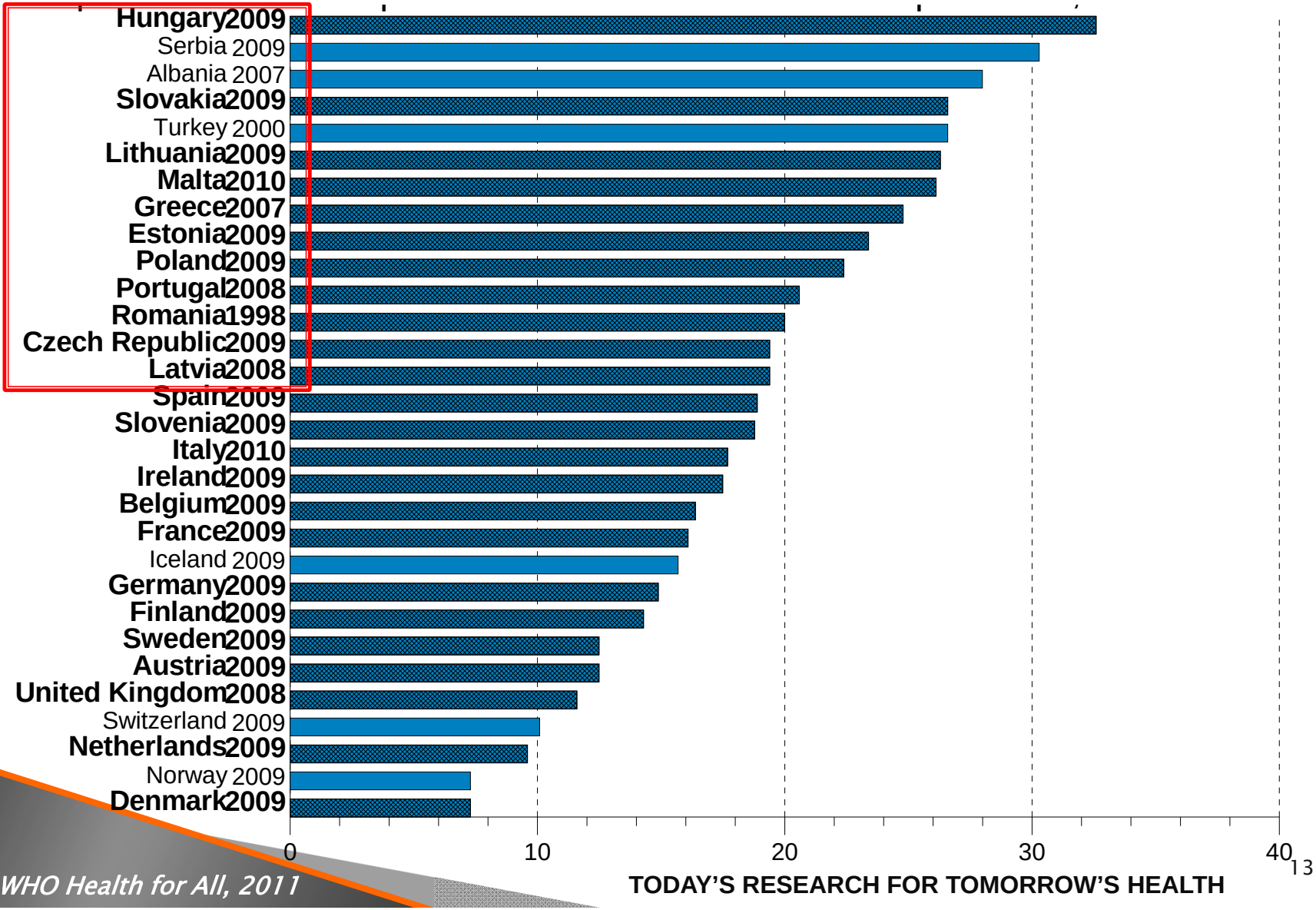
- Life expectancy and health status: WE > CEE
- Demand for health care (lives to be saved): CEE > WE
- GDP: WE > CEE
- Health care spending: WE > CEE

Comparison pharmaceutical expenditure in high and middle income countries in 2009

Parameters		Average of middle income countries (<30'000 USD GDP/capita)	Average of high income countries (>30'000 USD GDP/capita)	P-value
Total health care expenditure per capita (USD)		1659	5181	<0.001
Total pharmaceutical & medical device exp. per capita (USD)		380	658	0.001
Total health care expenditure	% of GDP	**8.52%**	**10.64%**	**0.003**
Total pharm & med device exp		**1.99%**	**1.42%**	**0.004**
Total pharm & med device exp.	% of total health care expenditure	**23.6%**	**13.4%**	**<0.001**

Source: OECD Health Data 2011

Share of pharmaceutical expenditure in total health spending *(last available year)*



Source: WHO Health for All, 2011

Consequences of international price referencing in lower income countries

1. lower income countries spend higher proportion on drugs than high income countries *(as drug prices are similar to international prices, but salary of physicians and cost of hospitalisation is adjusted to local purchasing power)*

2. despite their greater health care need, patients have more limited access to innovative pharmaceuticals

Solutions to facilitate differential pricing (1)

- Ramsey (differential) pricing – adjustment of ex-factory prices to local purchasing power – the old method. May not be realistic expectation…
- EU restrictions on international price referencing (e.g. referencing according to the GDP) and parallel trade – against the EU framework

Solutions to facilitate differential pricing (2)

- confidential rebate mechanism in lower income countries (e.g. discount, rebate, claw-back): successful approach only if
  - confidentiality remains
  - confidential rebate is not implemented in high income countries
- risk-sharing in lower income countries (i.e. patient access schemes)
  - financial risk sharing: easy to implement even is small lower income countries
  - outcome based risk-sharing: experience mainly in higher income countries, but already started in Poland and Hungary

Conclusion

- Stakeholders, especially in middle income countries should
  1. understand the implications of increased transparency of pharmaceutical pricing,
  2. and develop solutions to prevent the limited accessibility of new medicines in lower income countries.
- Differential pricing (both internationally and within a country) can improve the accessibility of vulnerable patients to new technologies

Options to sustain the public financing pharmaceuticals

1. Volume restrictions
   - more new technology are reimbursed → more positive political messages, more honorarium for experts and lobbists
   - restricted accessibility of patients → inequity, corruption, under the table payment for physicians by patients
   - no verifiable criteria for decisions → poor allocative efficiency, opportunity costs, moral crisis
2. Evidence based health policy
   - less technology are reimbursed → more politically difficult decisions and less honorarium for experts and advocacy
   - equal access of patients to reimbursed technologies → decreased corruption and gratuity, improved equity
   - justfiable decisons → reduced opportunity costs; alleviation of moral crisis

Implementation of HTA/HE in lower income countries: necessary steps

- methodological guidelines – how to conduct economic evaluations
- decision rules – willingness to pay for a quality adjusted life years gain
- legislation: incorporation of cost-effectiveness evidence into the reimbursement process
- **public budget and organisation for health technology assessment**
- single HTA
- **training**
  - final decision-makers
  - appraisal committee / Public HTA office
  - future trainers
- **gradual implementation**: 20-30 top cases ⇨ iteration and correction
- standardization of HTA appraisal methodology

Conclusion (2)

- In difficult economic period the most critical question for the policy-makers is whether
  - they really want to improve the rationale of health care decision making
  - or they should just concentrate on reducing the public health care spending (as in recent years).
- Implementation of evidence based health policy is more complicated route in the short-term, but it may pay off in the long-term