

Interrelationships between cost, patient access and ethics for medicines

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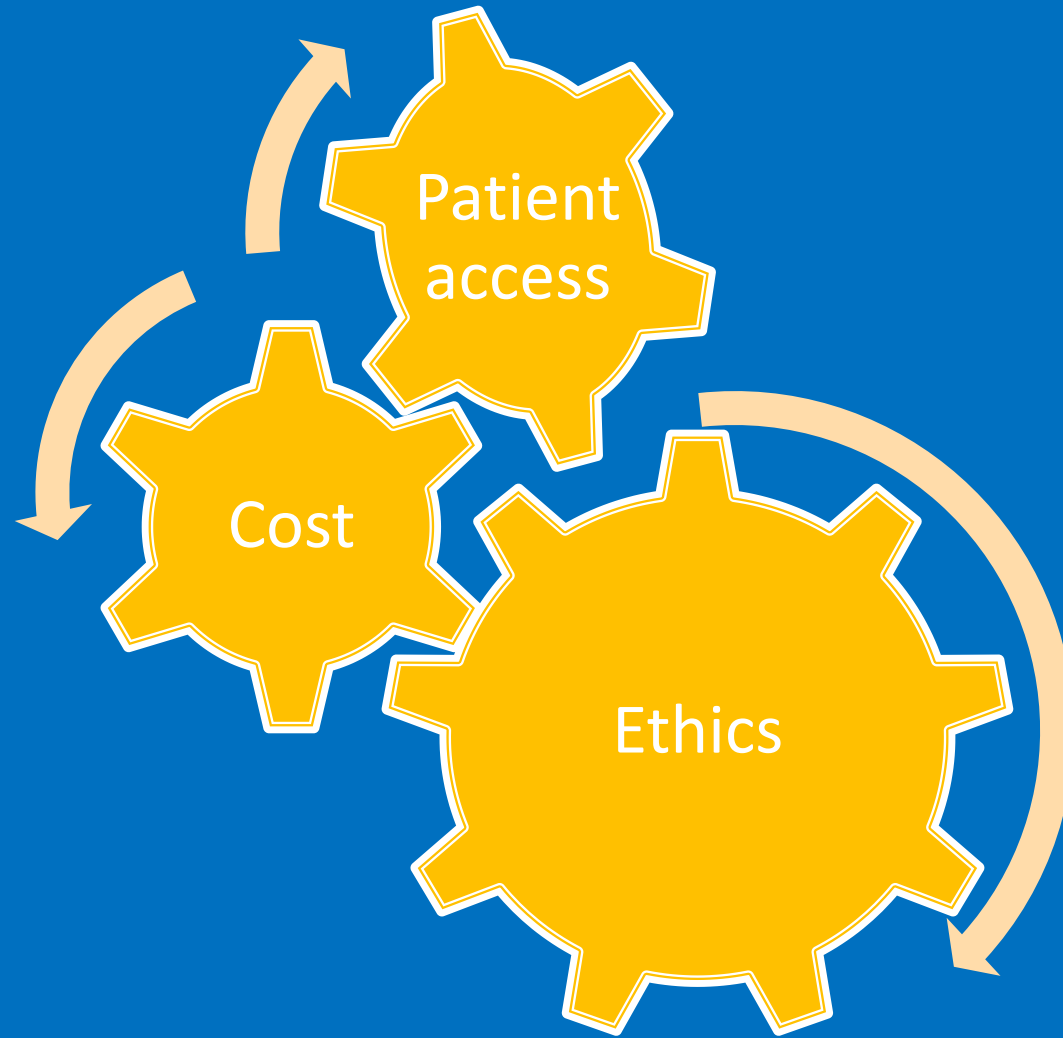
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Focus

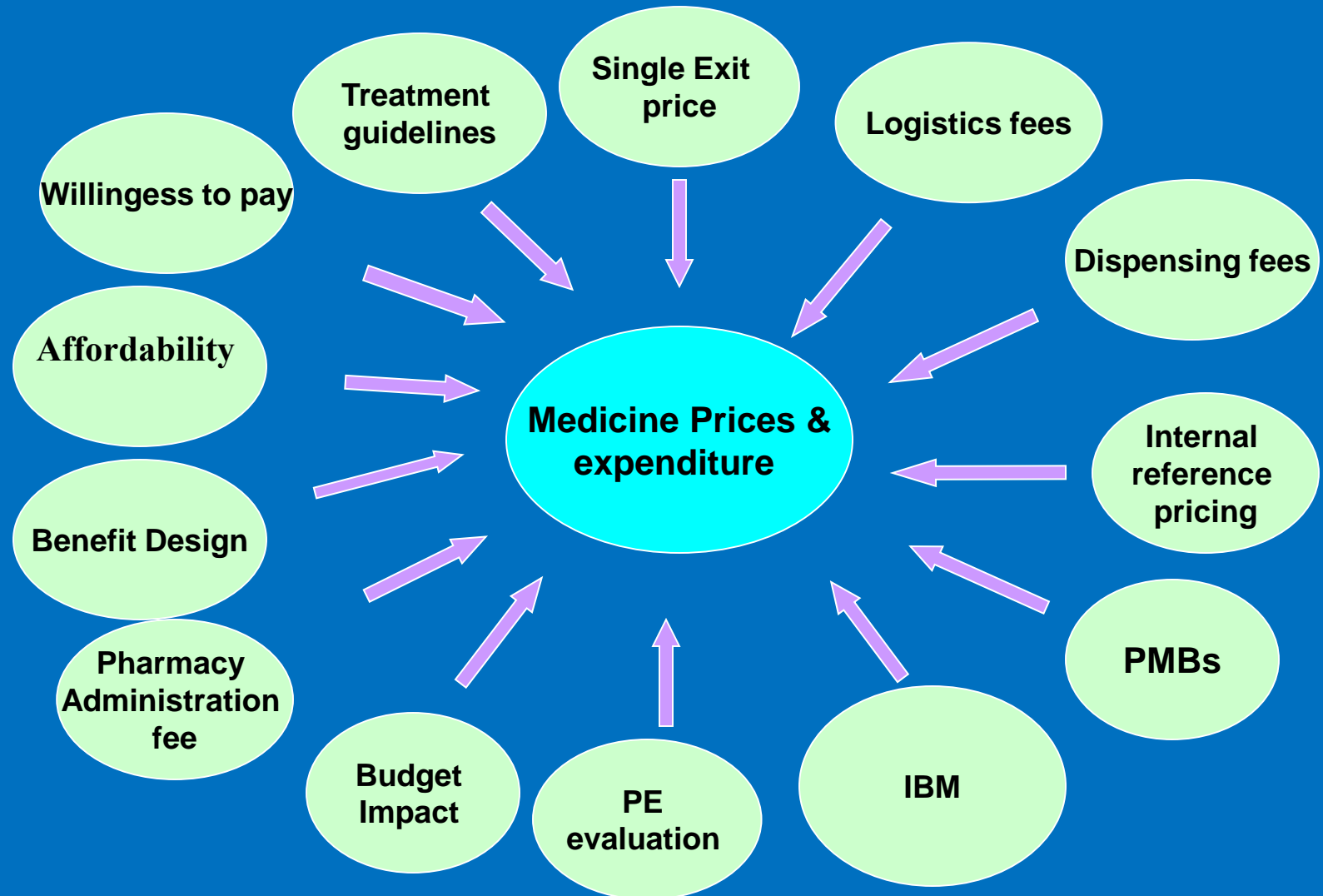
- Factors influencing access to medicines
- International approach to medicines pricing policies and interventions
- Funding models for medicines
- Role of pharmacoeconomics
- Rational use of medicines
- Ethics considerations
- Concluding remarks





WHO framework for access to essential medicines

Factors Influencing Medicine Prices and Expenditure



International approach to medicine pricing policies and intervention

- External reference pricing
- The role of health insurance in the cost-effective use of medicines
- The regulation of mark-ups in the pharmaceutical supply chain
- Competition policy
- Sales tax on medicines
- Promoting use of generic medicines
- Pharmacoeconomic analysis

Differential pricing

Adapting drug prices to the purchasing power of consumers in different geographical or socio-economic segments could potentially be a very effective way to improve access to medicines for people living in low and middle-income countries.

State of Differential Pricing

Observed prices may be inversely correlated with the per capita income (GDP), implying poor countries pay higher prices.

(Scherer and Watal 2002, Maskus and Ganslandt 2002, Hellerstein 2004, Lai and Yadav 2007, Waning et al 2009).

Funding models

- Price volume arrangements
- Patient access programmes (free drugs)
- Risk sharing schemes

Patient access programme

- Price /utilization capping:
 - Free initiation of therapy
 - Costs covered by pharma if an accumulated dose is exceeded
 - costs covered by pharma if certain number of cycles are exceeded
- additional medicines at no costs or a large discount is provided by pharma if a payer's budget is exceeded

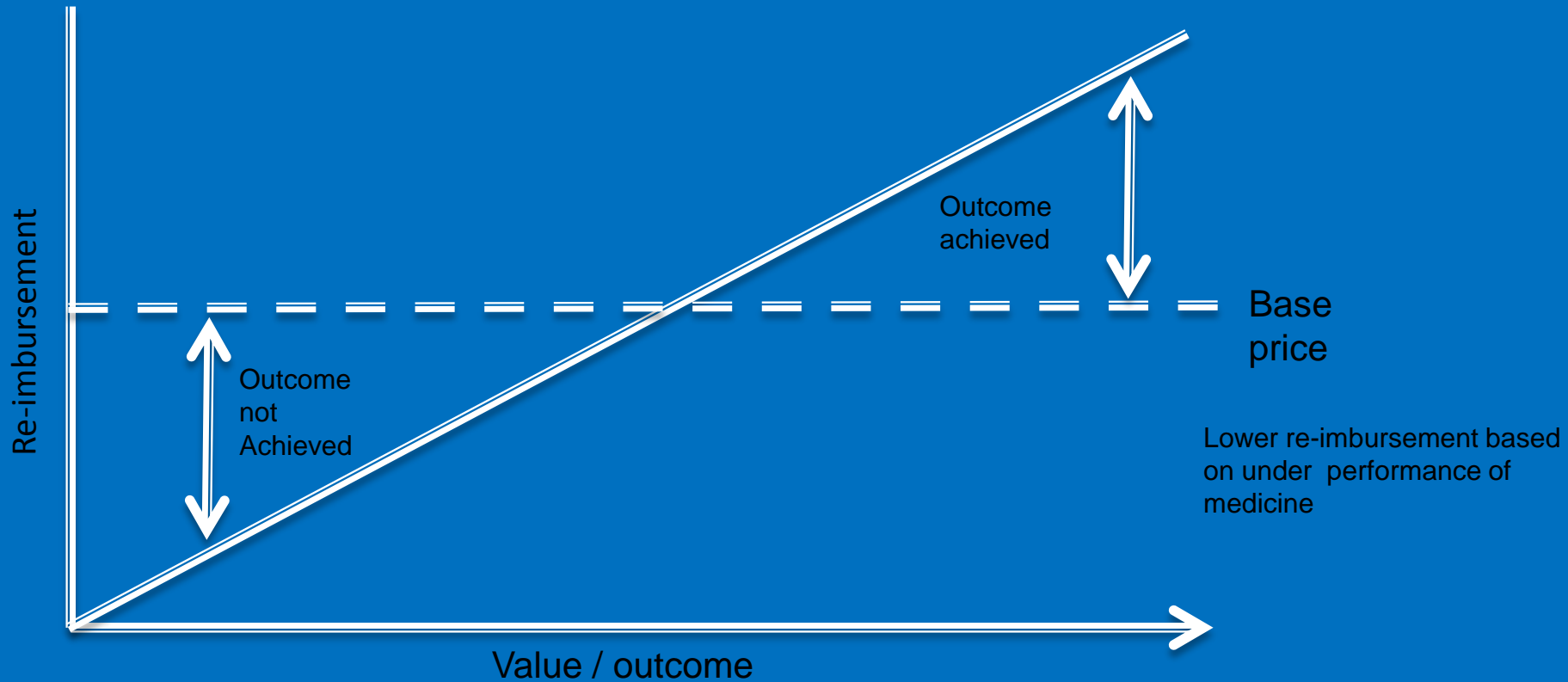
Risk sharing schemes

- Process by which two parties or more agree to share the risks associated with achieving a certain outcome.
- Risk-sharing agreements are particularly useful for costly drugs that have some degree of uncertainty associated with their clinical outcomes, and spread the risk between pharma and the payer.
- A risk-sharing agreement is a tool for manufacturers of biological medicines and payers to manage the risk of introducing clinically effective and very expensive medicines into the healthcare market.

Risk sharing schemes

- Financial based
 - price-volume arrangements
 - Based on payback mechanism
- Outcomes/performance-based

Outcome-based re-imburement



Rational use of medicines

Cost-effective medicines become
cost-ineffective is used irrationally

Rational use of medicines

Some approaches to improve the rational use of medicines:

- Evidence-based medicine
- Formularies
- Cost-effectiveness
- Clinical pathways
- Multidisciplinary teams
- Centre of excellence

Pharmacoeconomics

- A scientific discipline that assesses the overall value of pharmaceutical health care products. It relates the cost of the product to the value it delivers.
- Pharmacoeconomics provides information critical to the optimal allocation of health care resources.

Pharmacoeconomics

- Whether the price of a medicine is reasonable or not.
- Provides for detailed evidence-based analyses examining cost and effectiveness.
- Cost-effectiveness does not always mean affordable.

Pharmacoeconomic guidelines

- Published in the Government Gazette No 36118 on the 1st of February 2013
- Objectives
 - Create a standard for conducting economic evaluation;
 - Describe a process of compiling a submission;
 - Describe the process to be followed when submitting an application;
 - Provide an overview of the principles and methods to be applied;
 - Promote transparency regarding the value of medicines;
 - Create a forum which provides an objective review of the value of medicines;
 - Ensure a common understanding of the criteria and information that is required.

Key trends

- Move towards value-based pricing or reimbursement
- Information-driven approach to improve efficiency of health care
- Comparative effectiveness evaluations
- Real-world evidence in value demonstration
- Personalized medicines

Cost, patient access and ethics

- Funder or societal perspective
- Pay for cost-effective medicines that are not affordable
- Patient access programme that do not benefit everyone
- Is it ethical to use medicines in patients if one does not know whether it offers value for money in a resource constrained environment?

Concluding remarks

Cost and access – closely interrelated:

- Regulatory
 - International benchmarking
 - Pharmacoeconomic evaluation
 - Price control / transparency in pricing
- Patient access programmes - strictly controlled environment
- Risk sharing – access to innovator medicines
- Affordability – best measure of access

Ethics – related to cost and patient access