The Health Technology Assessment journey in South Africa - lessons for countries in transition to universal coverage

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Disclaimer

This presentation reflects my own views and does not reflect the views of the SA government or any other organization or committee that I have been affiliated with.

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Outline

- Background to HTA in South Africa
- SA Pharmacoeconomic guidelines
  - Key components
  - Lessons learnt
  - Challenges / debates
- Interrelationship between pharmacoeconomics and access to medicines
- Key recommendations

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Definition: HTA

It is a **process** that examines the available **evidence** to form a **conclusion** as to the **merits or role** of a particular **technology** in relation to its possible use and **reimbursement** in current medical practice.

ISPOR, 2007

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Pharmacoeconomics

- Development of guidelines for pharmaco-economic submission by pharma to government started in 2008
- Guidelines published on 1 Feb 2013
- PE guidelines apply to private sector
- No guidelines for medical devices

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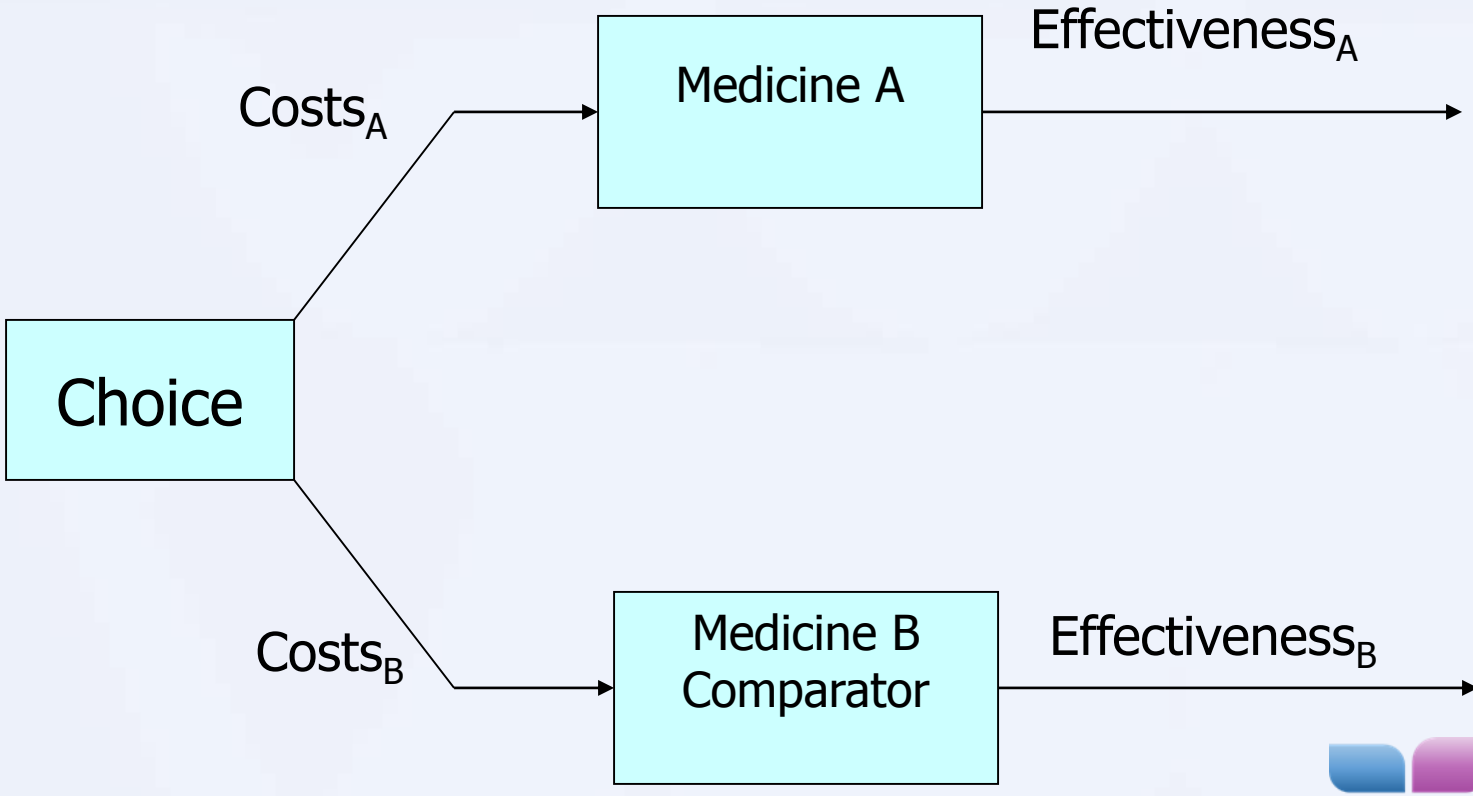
Pharmacoeconomic Evaluation



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Key components

- Submissions are voluntary
- New chemical entities and new indications for existing medicines
- SEP is reasonable or not
- PE conducted after medicine is registered with MCC
- Pre-approval of the PE model
- Simple vs complex models
- PE evaluation and re-imbursement decisions are separated
- 3rd party payer (funder) perspective
- Direct costs
- Applicant have option to comment on findings

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Lessons learnt (personal view)

- Voluntary submissions were unsuccessful
- Ensure adequate financial resources
- Transparent process is essential – process for selection of reviewers
- Require a source for data
- Plan an effective communication strategy

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Challenges / Debates

- Develop technical capacity
- Independent appeals process
- Absence of CE thresholds
- Utility values – not available nor validated
- What is standard of care?

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PE evaluation and re-imbursement

- Can government decide how medical schemes should spend their money?
- Budget impact analyses not part of PE guidelines.

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Simple models vs complex modelling

Section 8 : Modelled Evaluation

‘The Pricing Committee discourages the use of complex models where a simple model will adequately support the economic argument. Only models that are transparent, as determined by the Pricing Committee will be considered’.

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Regulations relating to a transparent pricing system for medicines and scheduled substances (30 April 2004)

Section 14 (5):

DG may request in writing:

Details as to the comparative efficacy, safety and **cost effectiveness** of the medicine or Scheduled substance relative to that of other medicines or Scheduled substances in the same therapeutic class compiled in a manner consistent with guidelines published by the Director-General in the Gazette from time to time.

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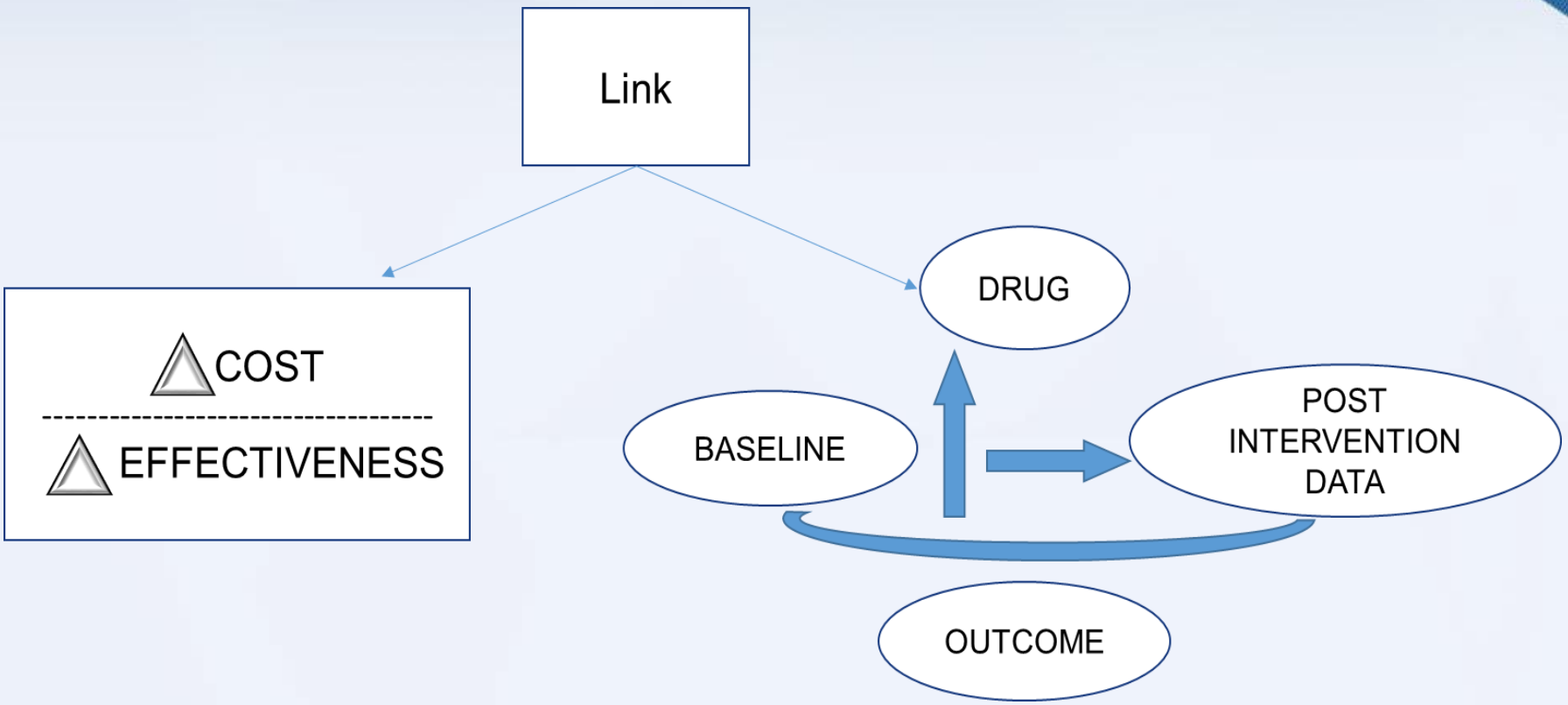

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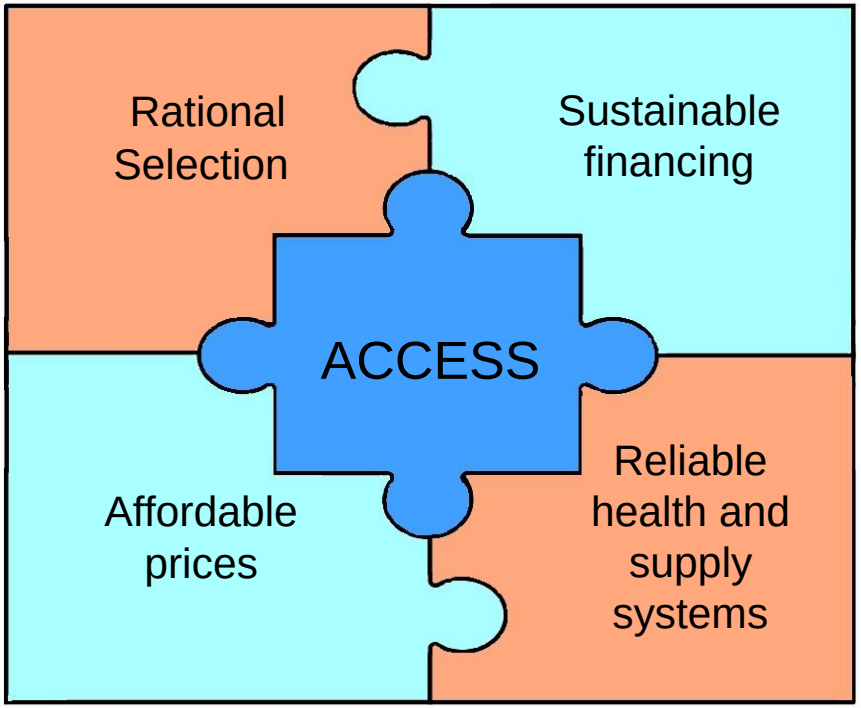
- National treatment guidelines
- National EML
- Rational use of EML



- Increased public funding
- Out-of-pocket spending
- Cost sharing with patients
- Donor assistance
- Donation of medicines

- Price information
- Price competition
- Bulk procurement
- Generic policies
- Equitable pricing
- Reduction or elimination of duties and taxes
- Local production of assured quality

- Health sector development
- Public-private-NGO mix
- Regulatory control
- Procurement co-operatives
- Traditional and complementary medicines

WHO framework for access to essential medicines

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Summary

- PE submissions should be mandatory
- The PE models and their workings should be clear
- Need to conduct more costing studies
- Conduct outcomes research
- Need establish sources for data
- Develop mechanism to share data
- Ensure proper interpretation of clinical trials

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