# South Africa – Clinical guidelines and health technology assessment in pharmaceutical pricing

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# Background

**Public Sector**

- Serves 38 million people
- Mainly essential drugs supplied
- 70% (volume) of medicine sales
- Medicine budget – R3billion
- Income based user fees – free to special groups
- < 50% of pharmacists work in the public sector serving 80% of population
- GDP spend on health: R122.4-billion (49.2%) in the public sector (2011 National Treasury Fiscal Review)

**Private Sector**

- Essentially insured population – 7 million
- All registered drugs available
- 30% (volume) of medicine sales
- Medicine budget – R13billion
- High premiums – unaffordable
- Most pharmacists work in the private sector serving 20% of population
- GDP spend on health: R120.8-billion (48.5%) in the private sector (2011 National Treasury Fiscal Review)

# Public Sector

- A three-tier system involving national, provincial and local government;
- Based on EMLs and STGs

- PHC (4) Paediatric (3) Adult (3)
- 1996/1998/2003/2008 1998/2006/2013 1998/2006/2012
- Available from: http://www.health.gov.za/edp.php
- Web App: http://www.health.gov.za/appfront/#/

# Selection

- Medicines are included based on quality, safety, effectiveness and cost.
- Process.
  - Request for submissions – Provinces.
  - Conditions are reviewed against available ABC analyses.
  - STGs are reviewed.
  - New medicines report is compiled.
  - Chapters are sent out for comment.
  - Editorial process.

# EML Process

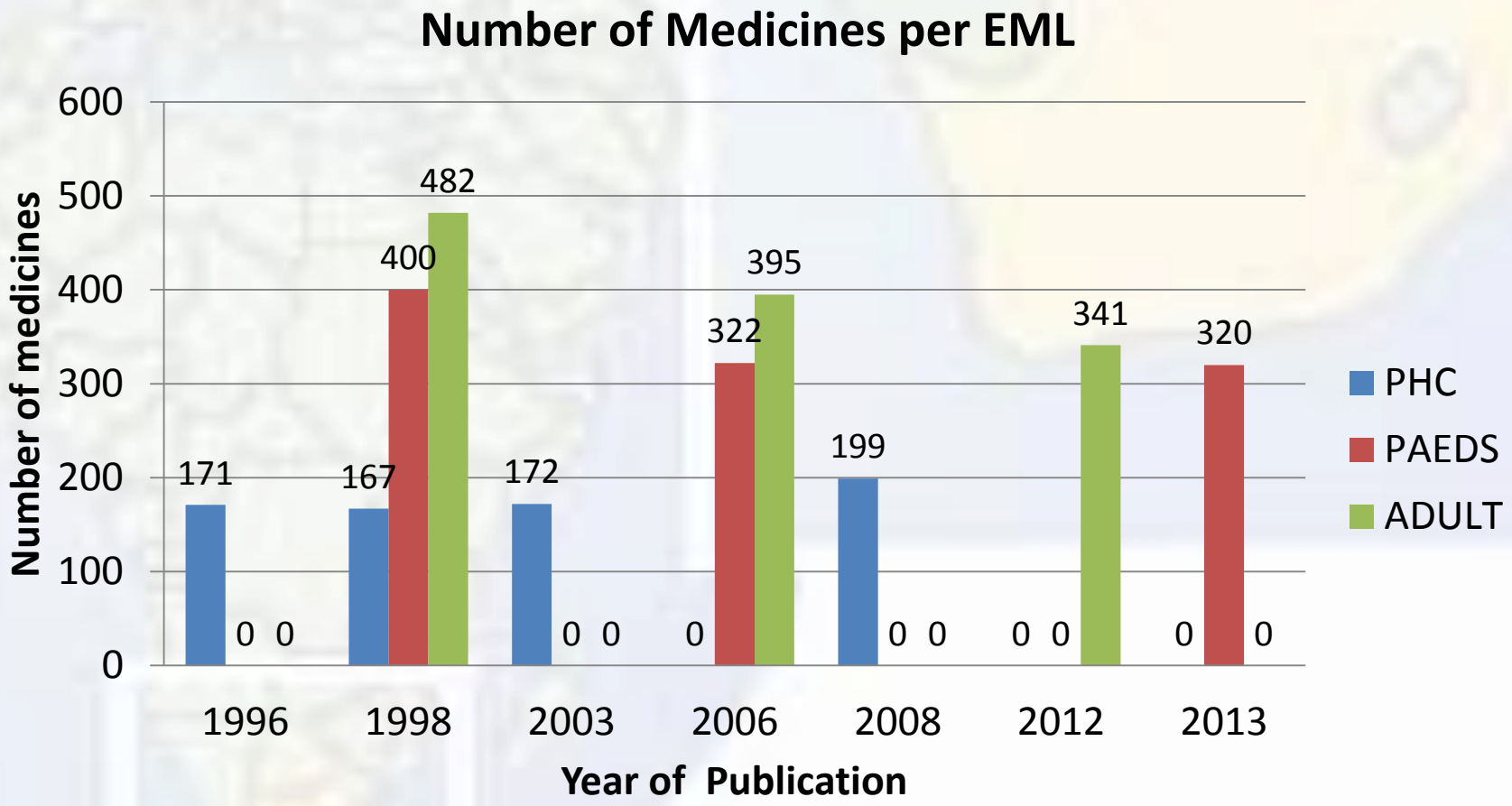
**1996 to 1999**

- Primary focus was:
  - equity
  - the establishment of a universal package of care and
  - removal of irrational medicines.
- Evidence based medicine (EBM) was introduced.
- Cost
  - Introduction of therapeutic class – increased competition.
  - Multi source pharmaceutical products or generics
  - Prices were published in formularies and “code lists”.
  - ARVs.

**2000 onward**

- Peer review by academia, societies, provinces and institutions.
- Standardised format for medicines review.
- EBM approach strengthened.
- Governance systems.
- Cost
  - Price.
  - Greater use of pharmacoeconomics.
  - Improved alignment between the tender and the EDL

# Constantly Reviewing….




1279 medicines as of Feb 2014

# Pricing: Tender negotiation

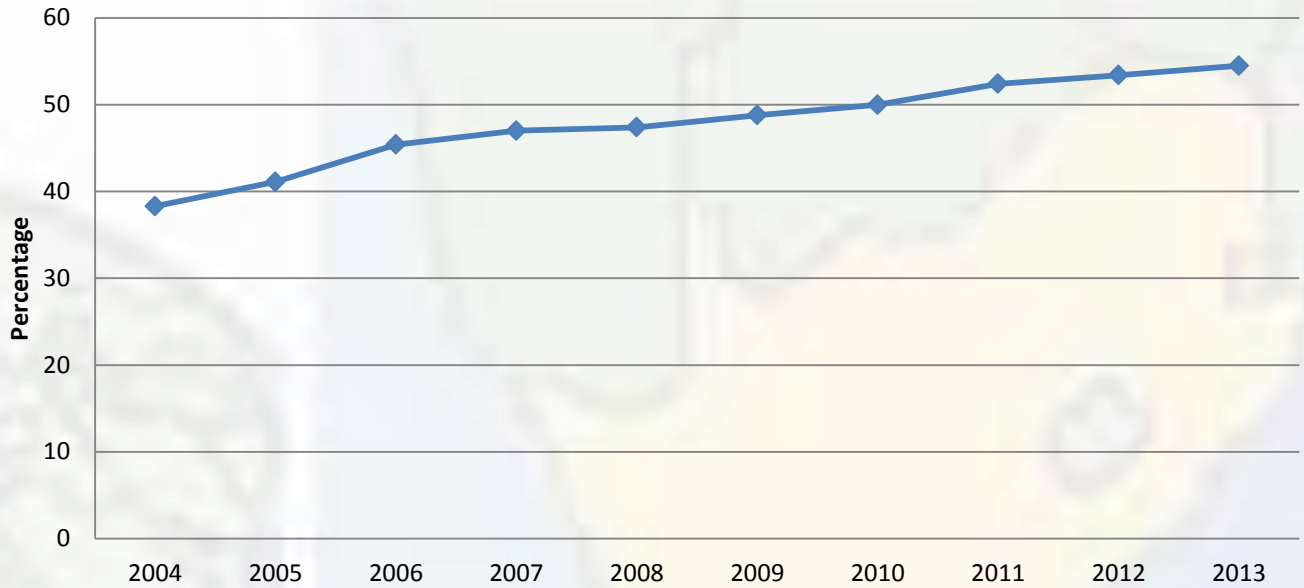
- Pooled procurement – All 9 Provinces
- Good prices are driven by
  - Economies of scale – volume.
  - Competition – generic specifications & recently therapeutic classes
- Tenders are split into dosage forms
- Split tenders found to work better

- Awarded tenders can be viewed at: http://www.health.gov.za/mpc.php

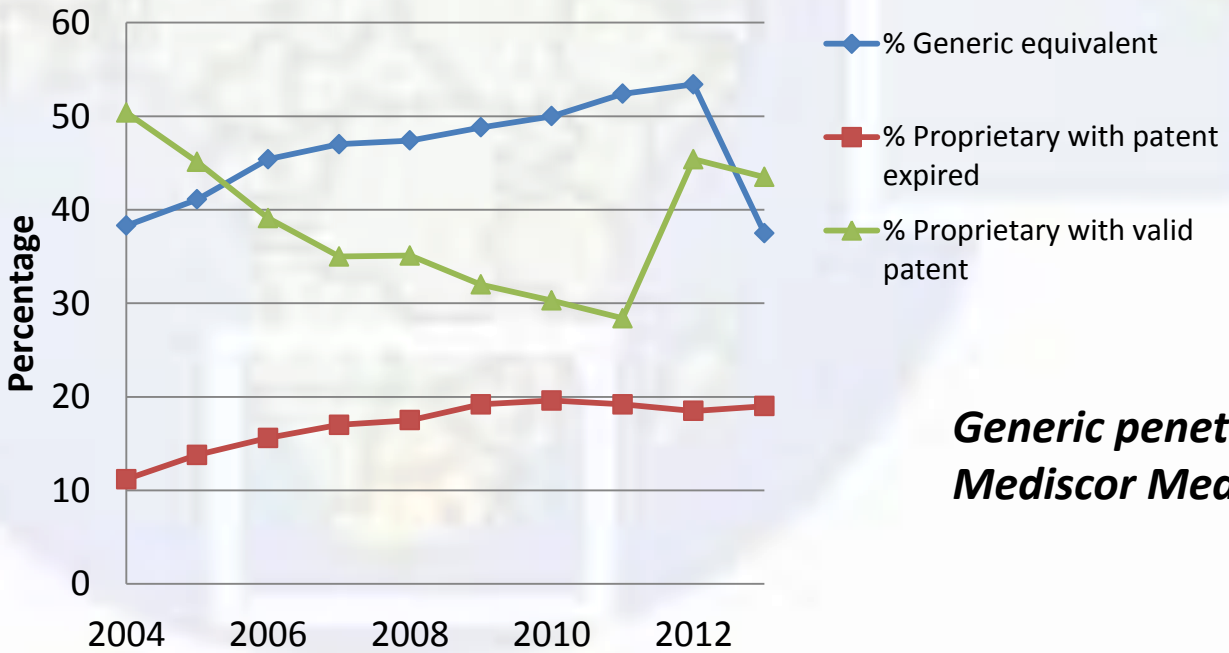
# National Drug Policy 1996 – Private Sector Pharmaceutical Policy Reforms

- Generic substitution policy – offer √
- Establishment of pricing committee √
- Single exit price for medicines √
- *Fixed fee for wholesalers – comments - complex*
- Fixed fee for pharmacists √
- Transparent pricing system √
- No volume discounts, rebates or bonuses (18A) √
- *International benchmarking – Comment notice*
- *Reference pricing*
- Pharmacoeconomics Guidelines √

# Use of Generics




**Generic Utilization Rate increase**

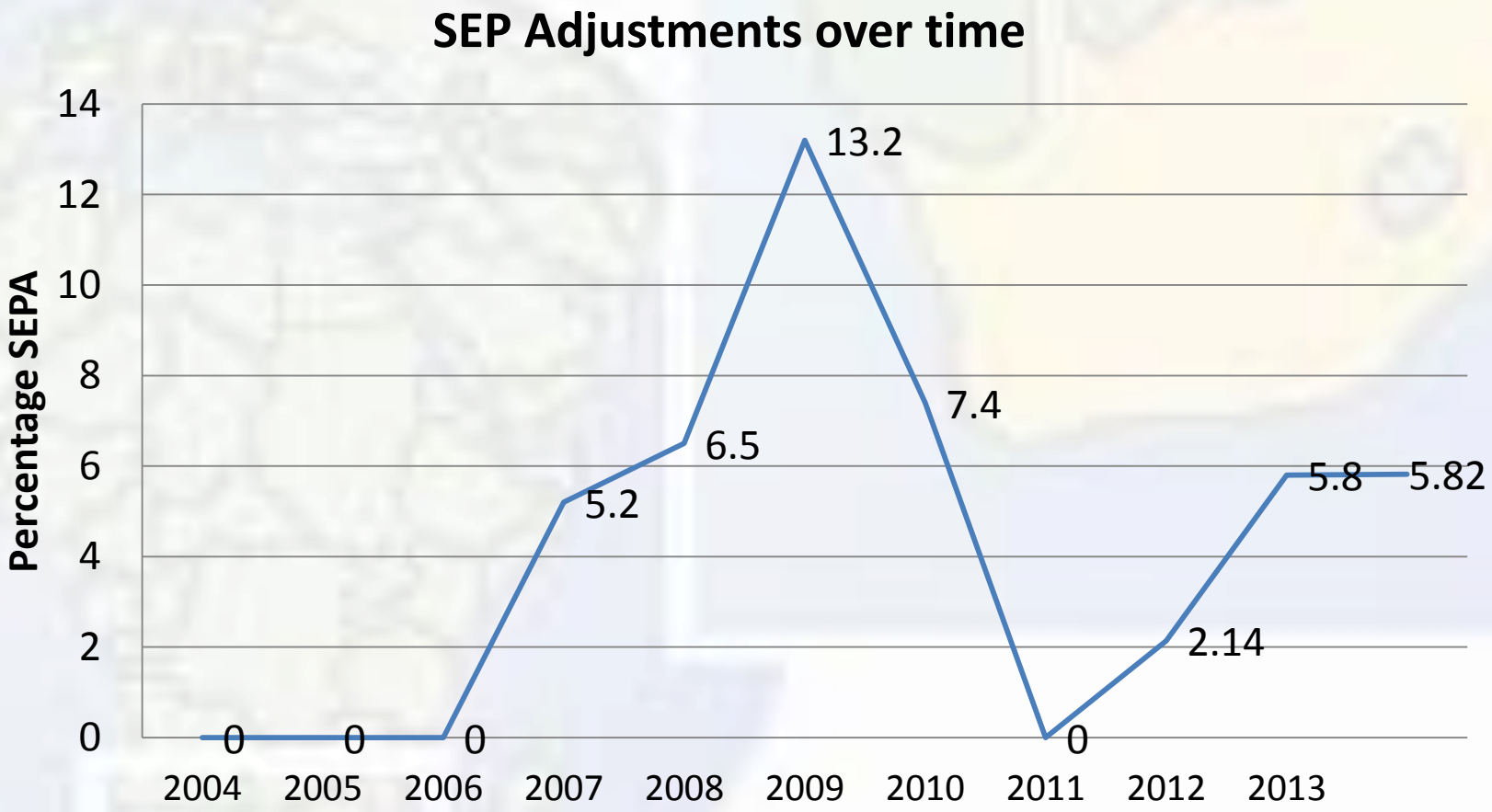



***Generic penetration (as reported in the Mediscor Medicines Reviews 2004-2013)***

# Establishment of a Pricing Committee

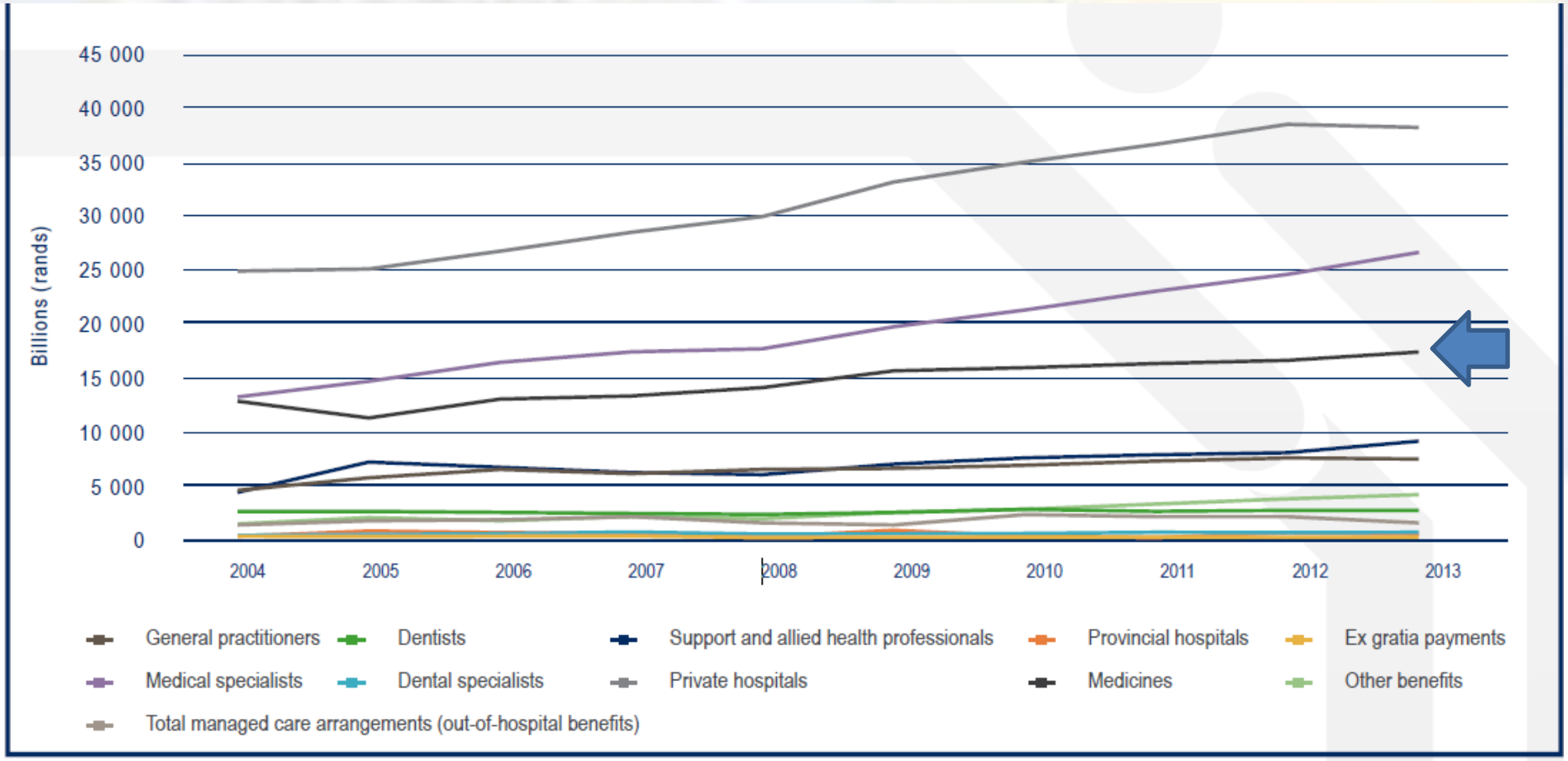
- Minister appoints members
  - Membership – DTI, Finance, Competition Commission, Pharmacists, Law, Consumer, Academics. No industry representation.
- Recommendations to Minister
- Secretariat - Pricing Unit in the Department of Health
- Provide for a transparent pricing system in the private sector

# Policy: Single exit price for medicines




***SEP Database Available at:***
***http://www.mpr.gov.za/PublishedDocuments.aspx#DocCatId=21***

# Total Healthcare benefits paid 2004-2013: 2013 prices



# Other Policies

- Dispensing Fee - implemented in 2007
  - Some constitutional challenges
  - Negotiation with stakeholders
  - Four tier fee structure implemented – based on model that defines cost and expenditure input for pharmacists – systematic review of model required or move to facilitating negotiation forum?
- Transparency to patient

- Guideline for Pharmacoeconomic Evaluations

- Evidence based approach
  - Comparative effectiveness
  - Comparative safety
  - Direct and indirect costs

- This method rewards true innovation – widely used in many countries.
- Guideline implemented – in voluntary phase for private sector – used as guide for public sector too

# Guidelines for Pharmacoeconomic Evaluations in South Africa

**Published PE Recommendations Key Features:**

| Key Features: | |
|---|---|
| Title and year of the document | Guidelines for Pharmacoeconomic Submissions (December 2012) |
| Affiliation of authors | National Department of Health |
| Purpose of the document | To describe the process to be followed for PE applications and the criteria for medicines which require submissions; To create a forum which provides independent and objective review of the value of medicines |
| Standard reporting format included | Yes |
| Disclosure | Nothing required |
| Target audience of funding/ author's interests | Pharmaceutical companies, researchers, decision makers |
| Perspective | Default perspective: third-party payer. Option to use a broader perspective where justified according to specific considerations. |
| Indication | Approved indication |
| Target population | If submission pertains to a specific sub-group, within the registered indication, this must be clearly defined |
| Subgroup analysis | Yes (only if the group has been defined a priori in the clinical trial protocol and the study was sufficiently powered to analyse specified strata. |
| Choice of comparator | The main comparator is deemed to be the standard of care for local practice. All possible comparators need to be listed and justified. |
| Time horizon | Time Horizon is based on the natural course of the condition and the likely impact of the treatment. Depending on the type of intervention, it may be necessary to present a short term analysis based on the primary clinical data. |
| Assumptions required | Yes |
| Preferred analytical technique | Any of CMA, CEA, CUA and CBA considered but choice of analysis must be clearly justified. The modelled evaluation should be based on the outcomes measures which most closely validly estimate the final outcome. |
| Costs to be included | Direct costs. Indirect costs should generally be excluded. |
| Source of costs | No prefered source specified, although table needs to be provided clearly identifying the source of the reference for unit costs. |
| Modeling | Yes - where randomised trials available do not provide sufficient information. Modelling options include spreadsheet analysis, decision analysis, Markov models and Monte Carlo simulations. |
| Systematic review of evidences | Yes, including criteria for inclusion and exclusion of sources of evidence, evaluation of clinical trials for inclusion, assessment of measures taken to minimize bias, meta-analysis and indirect comparison. Search strategy to be clearly defined and be reproducible. |
| Preference for effectiveness over efficacy | Yes |
| Preferred outcome measure | Life Years Gained, deaths prevented or QALYs gained |
| Preferred method to derive utility | No preference stated for measurement of utilities |
| Equity issues stated | No differentiation between QALYs accruing to different groups |
| Discounting costs | Future costs should be discounted at an annual rate of 5% (range 0% to 10% for sensitivity analysis) |
| Discounting outcomes | Future benefits should be discounted at an annual rate of 5% (range 0% to 10% for sensitivity analysis) |
| Sensitivity analysis-parameters and range | Sensitivity analysis must be conducted on all variables using an appropriate range, as justified and referenced. Results to be presented in tabular form and tornado diagrams. |
| Sensitivity analysis-methods | One way sensitivity analysis must be conducted on all variables using an appropriate range, as justified and referenced. Two-way sensitivity analysis should be conducted on variables shown to be sensitive in the one-way analysis. |
| Presenting results | Results to be presented in a disaggregated form, and then increasingly aggregated. Present appropriately aggregated and discounted costs results separately for outcomes and resources and separtely for proposed medicine and its comparator. The final outcome should be presented as an ICER. |
| Incremental analysis | Yes |
| Total costs vs effectiveness (costeffectiveness ratio) | Yes |
| Portability of results (Generalizability) | The patient population to which the pharmaco-economic evaluation applies should be consistent with the patient population defined in the clinical part of the reimbursement request submission. |
| Financial impact analysis | Not specified |
| Mandatory or recommended or voluntary | Currently, the submission for pharmacoeconomic assessment is essentially voluntary, however, key figures in the Department of Health have to power to "call a product up" for economic assessment. |

# Towards Universal Health Care

- Progress: Medical Schemes looking at EMLs as guide and trying to the same evidence based approach
- IRP (ERP) – an option for assessing medicine prices in country (affordability)
- Pharmacoeconomic evaluations – new medicines – value for money
- Chronic Patients – managed by non-state actors – strict guidelines for referral and management

# Thank you!

Department of Health South Africa: http://www.health.gov.za/

South African Medicine Price Registry: http://www.mpr.gov.za/