Presentation by the Pricing Committee

PUBLIC HEARINGS: PORTFOLIO COMMITTEE ON HEALTH

MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL

31st October 2014 : 10h30-11h00

Chair: Prof. Fatima Suleman
Associate Professor, University of KwaZulu-Natal

Context

- What is the Pricing Committee?
  - Minister appoints members
    - Membership – DTI, Finance, Competition Commission, Pharmacists, Law, Consumer, Academics. No industry representation.
  - Recommendations made to the Minister of Health
  - Secretariat – Pharmaco-economic Evaluation (PEE) Unit in the Department of Health
  - Provides for a transparent pricing system in the private sector
    - Ability to track prices from manufacturer to patient – know how much each step in the system charges

A Transparent Pricing System

- The "transparent pricing system" was to be based on *"a single exit price"*, defined as *"the only price at which manufacturers shall sell medicines and Scheduled substances to any person other than the State"*.
- In effect from 2006
- Single Exit Price is the sum of the ex-manufacturer price and the logistics fee of a medicine
- Prior to the introduction of the SEP volume discounts were retained by the value chain and not passed onto consumers
  - Discontinuation of rebates, discounts and sampling - protection of consumers in rural areas – lower socioeconomic status – will pay more if discounts persist

Extent of Price Reductions

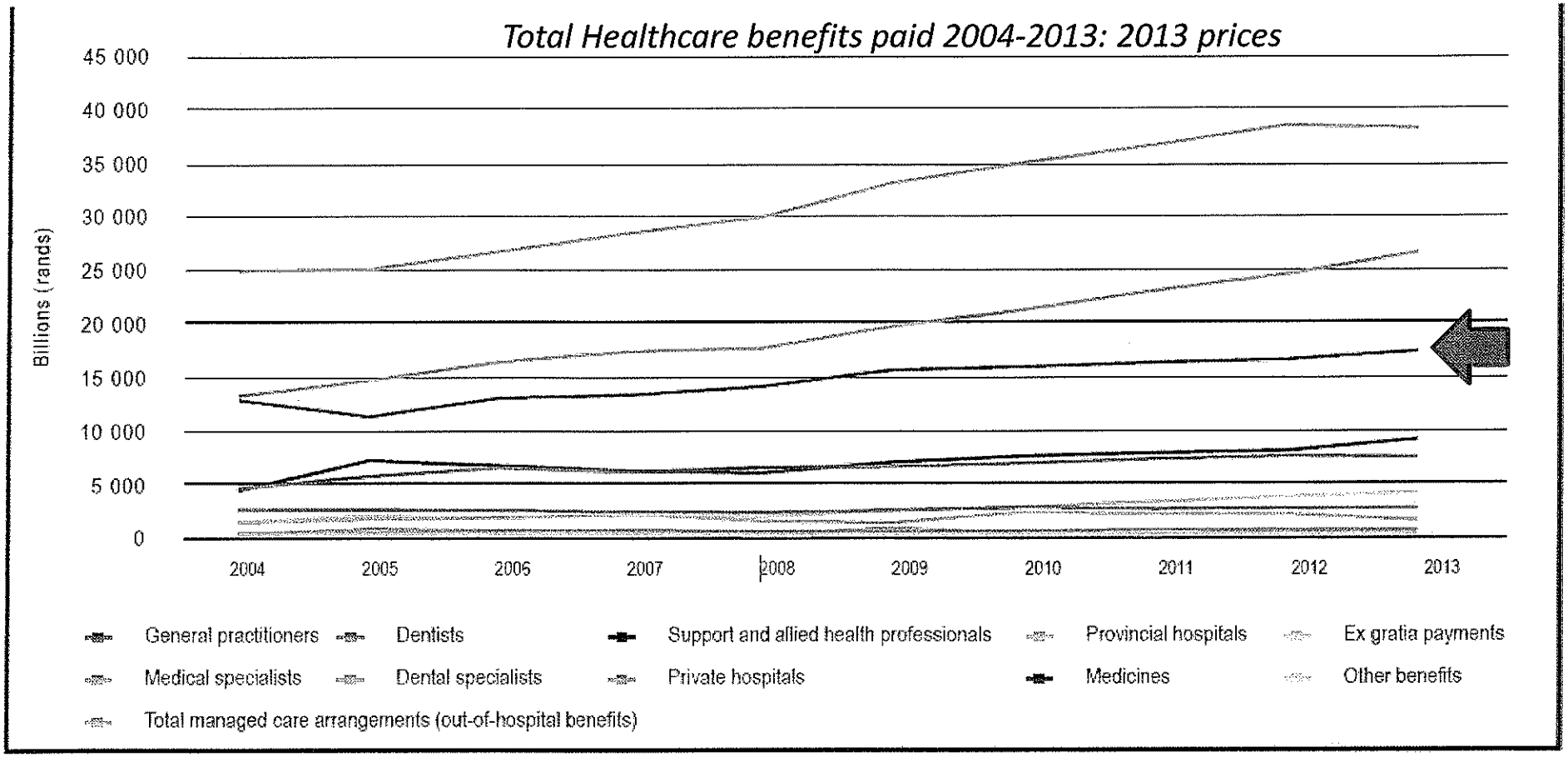
Emsley R, Booysen F.Cost-effectiveness of an atypical conventional antipsychotic in South Africa - An economic evaluation of quetiapine versus haloperidol in the treatment of patients partially responsive to previous antipsychotics. SAJP, Volume 10 No. 3 October 2004

- "We conducted our initial analysis using medication prices that were in effect before the recently introduced legislation that has resulted in significant cost cuts. In this analysis treatment with quetiapine did not result in cost savings compared with haloperidol. However, in view of the fact that recent legislation to introduce single exit prices has significantly cut costs of medication in South Africa, we decided to re-analyse the data using the prices introduced in August 2004. **The new prices resulted in a reduction of 36.7% in the cost of quetiapine and 13% for haloperidol**."

Government to curb private healthcare costs - Mail and Guardian – 26 Feb 2008

- "The introduction of medicine pricing regulations a few years ago resulted in a **20% drop in prices, and savings of over R2,3-billion on medicines**"

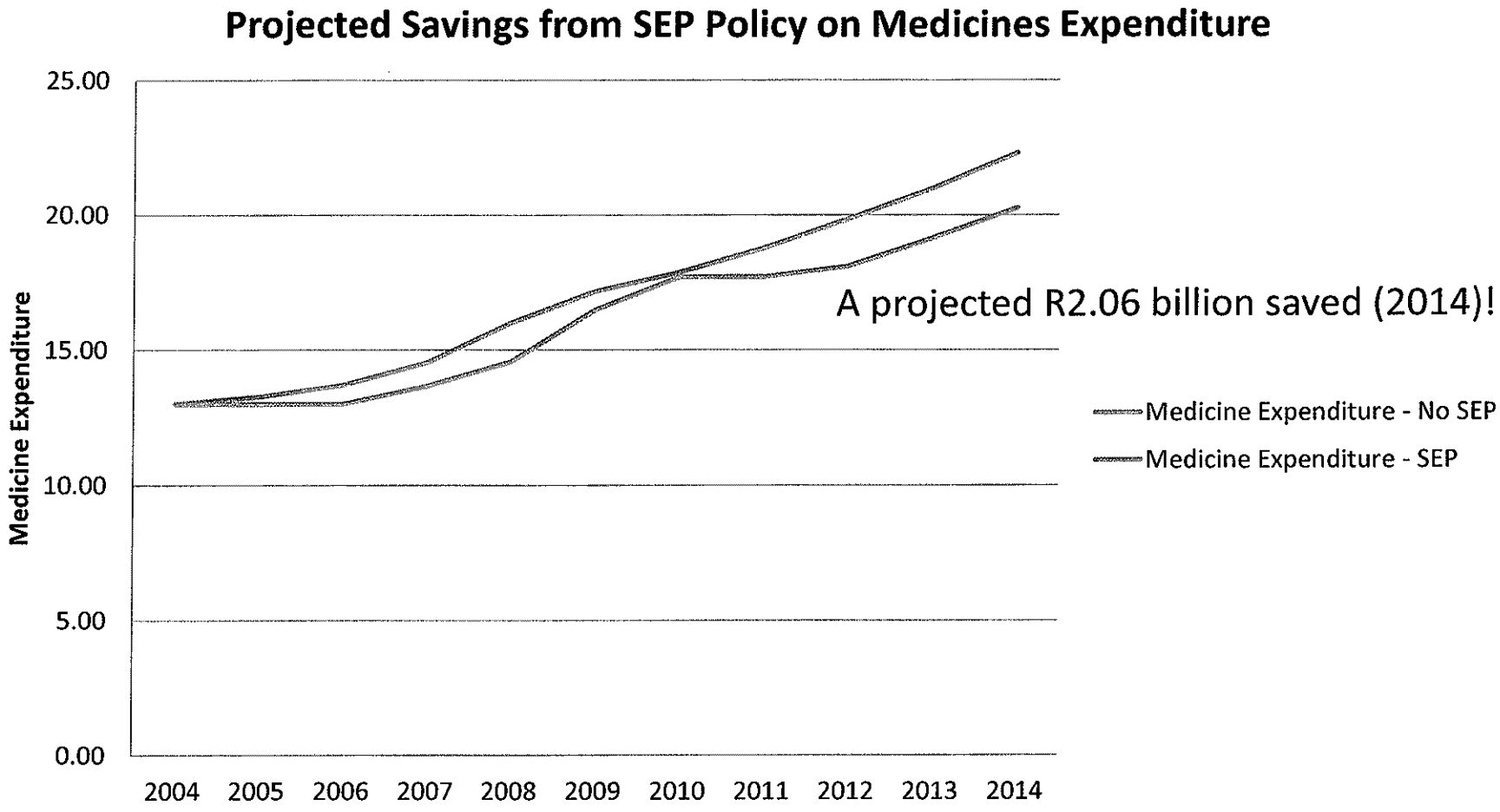
Savings Achieved:



Discovery Health Medical Scheme Integrated Annual Report 2012:

"Because of Single Exit Price (SEP) legislation, these drug price reductions benefit all users in the private healthcare system. Conservative estimates suggest total annual savings of about R319 million per year are achieved for the Scheme in medicine expenditure."

The changes



However, Schemes spent only R17 billion – savings of about R4 billion (2013)

Other Policies

- Dispensing Fee for Pharmacists - implemented in 2007
  - Four tier fee structure implemented – based on model that defines cost and expenditure input for pharmacists
- Transparency to patient
- Dispensing Fee for persons licensed under section 22C(1)(a)
  - 2 tier system

- 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

How does this affect the Bill?

- The Pricing Committee is provided for in the Act – and deals with the issue of sales and pricing of medicines in the private sector
  - Section 18A – Bonusing, sampling and other perverse incentives
  - Section 22G – Pricing regulations such as Single Exit Price, Dispensing Fee, Pharmaco-economic guidelines; methodology for Benchmarking medicine prices

Details of requested changes

22. The following section is hereby substituted for section 36 of the principal Act:

"Exclusion of any [product] medicine, Scheduled substance, medical device or IVD from operation of Act

36. (2) Notwithstanding subsection (1), the exclusion ***or exemption*** *of any [product] medicine or Scheduled substance from the operation of section**s*** ***18A and*** *22G shall be on the recommendation of the Pricing Committee* ***to the Minister****."*

Rationale

- The proposed South African Health Products Regulatory Authority deals with safety, efficacy, and quality of medicines
- The PC has been constituted with the relevant expertise for the regulation of medicines pricing.
  - It therefore follows that authorisation by the South African Health Products Regulatory Authority would introduce unnecessary administrative barriers without adding any additional technical benefits.
  - Can cause harm to companies – delays – resulting in medicines being made unviable and unavailable – affect consumers

In addition

Bill 6, s18A, as amended by s15 of Act 72 of 2008 - section 18A reads as follows:

Substitution of section 18A of Act 101 of 1965

15. The following section is hereby substituted for section 18A of the principal Act:

"Bonusing

18A. (1) No person shall supply any product, medical device or IVD according to a bonus system, rebate system or any other incentive scheme.

(2) Notwithstanding subsection (1), the Minister may prescribe acceptable and prohibited acts in relation to subsection (1)."

This has not been corrected in the Bill and needs to be corrected by replacing ***'product"*** with ***"medicines and scheduled substances"*** and, the end of (2) needs to have ***"in consultation with the Pricing Committee"*** added to it once Act 72 is promulgated.

Inspections and Appeals

- In order to facilitate the effective regulation of medicines pricing, the Pricing Committee requires access to an Inspectorate to enforce regulations as well as a dedicated Appeal Committee process.
- These sections need to cover all aspects of the Act and not just the registration of medicines aspect

Finally

2B.(2) The Authority may—

(a) liaise with any other regulatory authority or institution and may, without limiting the generality of this power, require the necessary information from, ***exchange information with*** *and receive information from any such authority or institution in respect of—*

(i) matters of common interest; or

(ii) a specific investigation; and

(b) enter into agreements to co-operate with any regulatory authority in order to achieve the objects of this Act.

Why?

Few reasons

- SEP
  - Harmonization of the regulatory processing pertaining to registration and pricing approvals to ensure efficient market entry without undue delays.
- Pharmaco-economic Evaluations
  - Synergies between the clinical review for registration approval and pharmacoeconomic evaluation thereby reducing the administrative burden on the applicant.
  - NHI – will use more of this evaluation
- *IBM (in process)*
  - *Identification of medicines that were reviewed as innovator medicines is important to ensure that the correct medicines are targeted*

Thank you!