



Leveraging Affordability in Drug Pricing

BHF Southern African Conference

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SEP Legislation – The next steps

- Intention is to achieve market predictability.
 - Set annual cycle.
 - NDoH DB is the official source of the SEP.
 - Market place should not accept prices that are communicated unilaterally.
 - The prevailing price in the market place is used as the base for the annual increase.

- The fundamental tenant of the SEP
 - Transparent pricing
 - Eliminates any gaming that may occur in the supply chain
 - Potential savings accrue to the end user of the medicine.
 - Bonus & discount systems were removed.
 - Market has adapted.
- Logistics fee
 - Narrative reports.
 - Service providers with dual SAPC registration.
 - Advent of the so called “virtual” wholesalers.

SEP Legislation – The next steps (3)

- A draft logistics fee has been published in the government gazette for comment.
- Intention is to manage the gaming that may occur.
- Speaks to the fundamentals of a transparent pricing system.
- Early Indications are that some role players oppose such a system.
- Sets a maximum with competition below.

- Anticipated outcomes of improved transparency:
 - Management of the contribution the distribution system makes on the overall cost of medicines.
 - Removal of the potential for perversities that prevailed in the bonus and discount system to shift to this legitimate cost.
 - Equal access to markets by all manufacturers.
 - Manage dispensing fee system confounders.

Pharmacoeconomic Guidelines

- Original draft was prepared in 2007 however publication was held in abeyance whilst the international benchmarking system was under review.
- In 2009 - 2010 extensive revision.
- Draft guidelines have been finalized by the pricing committee and are currently in the administrative phase.
- Guidelines will be published for comment prior to finalization.

- Objectives of the guideline
 - Describe the
 - Process
 - Which medicines require submission
 - Provide an overview of the principles and methods
 - Promote access to information regarding the value of medicines
 - Create a independent and objective forum for review
 - Expedite the review through common understanding

■ Contents

Part A: Process for Submission

1. Introduction
2. Role and responsibilities of the Pricing Committee
3. General guidelines followed by the Pricing Committee
4. Criteria for medicines requiring Pharmacoeconomic Submissions
5. Recommendations of Cost-Effectiveness
6. Procedures for Submissions
7. General Recommendations on Preparing a Submission

- **Contents - *continued***
- **Part B: Content of Submission**
 2. Description of Disease/Clinical Condition
 3. Details of Medicine
 - i. Pharmacological class and action
 - ii. Clinical Indication/s
 - iii. Treatment Details
 - iv. Co-administered Therapies
 - v. Choice of Comparator Treatment
 - vi. Expert Opinion

Pharmacoeconomic Guidelines (3)

■ Contents Part B: Content of Submission - *continued*

4. Clinical Outcomes (Effectiveness)

- i. Description of search strategies for relevant data
- ii. Listing of all Comparative Trials
- iii. Selection of Comparative Trials used in the Submission
- iv. Exclusion of Clinical Trials
- v. Evaluation of Clinical Trials For Inclusion in the Submission
- vi. Assessment of measures taken to minimise bias in RCTs
- vii. Characteristics of the comparative randomised trials
- viii. Analysis of the comparative randomised trials
- ix. Indirect comparison of outcomes from randomised trials
- x. Evaluation of non randomised clinical trials

5. Perspective

6. Time Horizon

7. Type of Pharmacoeconomic Analysis

8. Modelled Evaluations

- i. Pre-approval of a model
- ii. Modelling Options
 - a. Decision Analysis Inputs
 - b. Markov Model Inputs
- iii. Population used in the modelled evaluation
- iv. Presenting Clinical Inputs
- v. Quality of Life Measures and Utilities
- vi. Resource Use and Costing Inputs
 - a. Indirect Costs
- vii. Discounting
- viii. Dealing with Uncertainty and Sensitivity Analyses
- ix. Presenting the Results of the Modelled Evaluation

International Benchmarking:

- The need:
- Rheumatoid arthritis case study
 - Disease-modifying antirheumatic drugs (DMARDs)
 - Sulphasalazine
 - Registered over 70 years ago but only recognized as a DMARD 30 yrs later.
 - Leflunomide
 - Registered 1998

International Benchmarking (2)

Medicine	Dose		Source	Cost pa
<i>Leflunomide</i>	10	mg	SEP	R 8,664.13
	20	mg	SEP	R 8,854.41
	10	mg	Australia -PBS	R 2,466.19
	10	mg	New Zealand	R 3,429.87
	10	mg	Canada	R 3,871.53
Sulphasalazine	2000	mg	RT289-2010	R 3,269.09
	2000	mg	SEP	R 4 327.44
	2000	mg	Australia -PBS	R 3,127.85
	2000	mg	New Zealand	R 964.60
	2000	mg	Canada	R 2,005.10

International Benchmarking (3)

- Draft document in the administrative process.
- 1st phase will focus on patented medicines.
- Need to consider generics.
 - What is the rationale for market segmentation?
 - Variance can be as much as 300%.
 - Market access of the mnf is not uniform.
 - Often contributes toward copayments by the clients.

