GENERAL NOTICE

NOTICE 1053 OF 2008

DEPARTMENT OF HEALTH

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (Act No. 101 of 1965)

CALL FOR COMMENT ON A METHODOLOGY FOR INTERNATIONAL BENCHMARKING OF ORIGINATOR MEDICINE PRICES

The Minister of Health intends, on the recommendation of the Pricing Committee under section 22 G of the Medicines and Related Substances Act, 1965(Act No. 101 of 1965) to implement the methodology in the Schedule. Interested persons are invited to submit any substantiated comments or representations in writing on the proposed methodology to the Director-General: Health, Private Bag X828, Pretoria, 0001 (for the attention of the Cluster Manager: Financial Planning and Health Economics - Dr A Pillay) within thirty days from date of publication of this notice.

SCHEDULE

METHODOLOGY FOR INTERNATIONAL BENCHMARKING OF ORIGINATOR MEDICINE PRICES

1. METHODOLOGY

The proposed framework for international benchmarking adopts the position that the *lowest price in a selected basket of countries should be used as the ultimate price for the purposes of benchmarking.*

However, to cater for the possibility that some prices may be drastically reduced unfairly, the recommended approach incorporates two protections for pharmaceutical manufacturer:

1. A phased approach, which delays the implementation of the ultimate benchmark by two-years; and
2. An exemption process, which permits pharmaceutical companies to challenge the ultimate benchmark price based on the full disclosure of all aspects of the pricing of a product.

The method to be followed is:

1. A selection ("basket") of appropriate countries has been identified, the prices of which will be benchmarked against prevailing prices in South Africa. Countries selected are:

   Australia, Canada, New Zealand, South Africa and Spain.

2. Two benchmark methodologies will be applied in sequence to existing medicines:

a. In **Phase 1**: The average of the lowest three prices in the basket, if this is lower than the South African ex-manufacturer price, or remain at the existing South African price if this is lower than the *average of the lowest three prices* ("interim benchmark 1").

b. In **Phase 2**: the *lowest price* in the basket will apply if this is lower than the South African ex-manufacturer price or remain at the existing South African price if this is lower than the lowest price in the benchmark ("final benchmark").

3. Price conversions into Rands will be performed in accordance with the methodology outlined in the **Exchange Rate** section (Section 2) below.

4. In exceptional circumstances, an applicant may apply for exemption from the interim benchmark, but will be required to provide complete disclosure on all factors relevant to the matter.

5. The final benchmark will apply automatically two years after the introduction of the interim benchmark. However, applicants will be required to submit full data on the application of the final benchmark methodology to each of their products within nine months of publication of the benchmarking methodology.

6. Both the *interim* and the *final* benchmark price values will be calculated annually by the affected companies and provided to the *Department of Health*. The Committee will review the benchmarked prices on a regular basis.

7. An exemption from the final benchmark will be permissible, on application, only where an affected company can demonstrate to the satisfaction of the Committee and the Minister that the resulting price is distorted and prejudicial to the manufacturer.

8. Applications for exemption from the final benchmark must be submitted on a form and in the manner to be prescribed, to the *Directorate of Pharmaceutical Economic Evaluations* (Department of

Health) one year before the date for implementation of the final benchmark.

9. A review panel will be established for the purpose of assessing exemption applications.

10. Any new medicine entering the South African market after the publication of the international benchmarking methodology must comply immediately with the *final benchmark*, i.e. must set their ex-manufacturer price at the lowest price in the basket of benchmark countries.

11. New medicines coming onto the market after the initiation of the reform (i.e. within 3 months from the gazetting of the regulations) for which an exemption from the benchmarking methodology is sought, must submit its application concurrently with their application to the Medicines Control Council ("MCC") to register a new medicine.

12. A medicine that has been registered by the MCC without any exemption application having been submitted, will not be permitted an exemption.

13. The decisions of the review panel will be made public and will include a non-confidential set of reasons. However, the information submitted to motivate for the exemption, and the full decision, will be kept confidential.

14. The review panel will be permitted to require full disclosure of all information relevant to reach a final determination. Any failure to provide this information will prejudice an application.

2. EXCHANGE RATE[1]

1. **Three-year linear regression**: A 3-year linear regression, using monthly exchange rate averages, will be used to produce a projection

[1] All exchange rate and inflation data was sourced from the South African Reserve Bank.

of the monthly nominal exchange rates in the benchmark year. The average of the monthly rates is used as the conversion rate for benchmarking. This approach essentially applies the formula produced by the regression analysis to project forward the nominal exchange rate monthly averages for the benchmark year (2008 in this instance). (See **Table 2.1** for the equations used and **Figure 2.1**).

Table 2.1: Equations

Australian Dollar ("AUD"):	$Y = 0.0457X + 4.4415$
European Euro ("Euro"):	$Y = 0.0733X + 7.3358$
New Zealand Dollar ("NZD"):	$Y = 0.0302X + 4.1366$
Canadian Dollar ("CAN"):	$Y = 0.0605X + 4.8233$