No. R. 1211 **1 December *2006***

MEDICINES AND RELATED SUBSTNACES ACT, 1965

REGULATIONS RELATING TO A TRANSPARENT PRICING SYSTEM FOR MEDICINES AND SCHEDULED SUBSTANCES

METHODOLOGY FOR INTERNATIONAL BENCHMARKING OF THE PRICES OF MEDICINES AND SCHEDULED SUBSTANCES IN SOUTH AFRICA

The Minister of Health intends in terms of regulation 5(2)(e) of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances as published in Government Gazette Number 28214 of 11 November 2005, to publish the Methodology for International Benchmarking of the Prices of Medicines and Scheduled Substances in South Africa reflected in the Schedule.

Interested persons are invited to make written comments by no later than 19 February 2007 to:

The Director-General: Health (Attention: Dr A Pillay)
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0001

SCHEDULE

Draft Methodology for International Benchmarking of Medicine Prices in South Africa

BACKGROUND

The Government of South Africa wishes to ensure that citizens obtain value for money when purchasing pharmaceutical products, whether this is in the public or private health sector. Modem drugs are expensive to develop and it is accepted that countries should contribute to the costs of research and development, so long as these costs are accurately estimated and according to their ability to pay. The principle of differential pricing of essential medicines is accepted by the World Health Organization and World Trade Organization, and is practised by some pharmaceutical manufacturers.

The Pricing Committee's view is that the purchase prices of medicines in the private sector should relate to their therapeutic performance and take account of national socio-economic factors. In the last decade several countries have instituted programs that involve evaluation of the cost-effectiveness of pharmaceutical products, and these countries have negotiated drug prices using a range of techniques that involve evidence-based comparisons with standard treatments. The Pricing Committee and Department of Health wish to establish such a program in South Africa. As a first step the Committee wishes to ensure that South African citizens do not pay higher prices than their counterparts in other countries. To achieve this initial aim the Pricing Committee has recommended the introduction of international price benchmarking. This document outlines the methodology proposed by the Pricing Committee.

DEFINITIONS

"originator medicine"

means a medicine, registered in South Africa, where such medicine is currently protected by a patent or had been protected by a patent previously. Such medicine may be marketed either by the original patent holder or another entity.

"independent multisource medicines (generics)"
means medicines, registered in South Africa, where such a medicine has never been protected by patent legislation. Such medicines are being manufactured by companies other than the company that originally held the patent.

"benchmark product for originator medicines"
means an originator medicine in the benchmark countries, with the same International Non-proprietary Name (INN), strength and dosage form. Where the pack size varies, a unit price comparator for the closest pack size will be used (e.g. price per tablet, millilitre or capsule). If there is no identical strength available then the lowest available common denominator e.g. mg/mg price comparisons of the active ingredients will be used.

"benchmark product for generic medicines"
means generic medicine/s with the same INN, route of administration and strength. Where the pack size varies, a unit price comparator for the closest pack size will be used (e.g. price per tablet, millilitre or capsule). If there is no identical strength available then the lowest available common denominator e.g. mg/mg price comparisons of the active ingredients will be used.

"benchmark price"
In South Africa: means the Rand equivalent of the ex-manufacturer price, i.e. the SEP less (or nett of) the Logistics Fee and VAT, for the same branded or generic product.
In Australia, Canada, New Zealand and Spain: means the Rand equivalent of the ex-manufacturer price, i.e. the list price less the Logistics Fee (or wholesaler fee), taxes, discounts and/or rebates, for the same originator product. There may be several selling prices in benchmark countries, in which case the price used in the largest ambulatory sector will be used.

"benchmark country"
means any of the countries from the basket of comparator countries selected below (i.e. Australia, Canada, New Zealand, South Africa or Spain).

"INN"
means International Non-proprietary Name.

"SEP" means Single Exit Price as defined in the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances made in terms of the Medicines and Related Substances Act No 101 of 1965

METHODOLOGY

Benchmarking will be applied at the level of the smallest dosage unit (e.g. a single tablet, capsule, ml of a liquid, etc) of the identical INN in the same dosage form. In circumstances where there are differences in the quantity of the active ingredient then the comparison should be conducted on a milligram per milligram basis. Where the unit price differs for different pack sizes the price of the closest pack size will be used for the comparison.

In benchmarking for originator medicines, where the identical INN is not available in Australia, Canada, New Zealand, or Spain then the Pricing Committee would consider:

- Other countries in which the medicine manufacturers sell the product
- Burden of disease
- Therapeutic class comparisons
- For multi-ingredient products, the sum of the cost of the individual ingredients

These criteria will be used to make a product-by-product determination.

There are two main classes of medicines in South Africa, i.e. originator and generic medicines (as defined above). The benchmarking methodology will differ for originator and generic medicines as described below.

Originator Medicines

As per the definitions above, the price of originator medicines in each of the five benchmark countries will be obtained and converted into rands. The lowest price from amongst the five benchmark countries will be used to obtain the benchmarked price (if the South African benchmark price is the lowest then the price will remain the same).

Generic Medicines

The benchmarking will be done one month after the SEP has been published for the originator medicines. The South African ex-manufacturer price shall be used as a basis for benchmarking. The benchmark price (ex-manufacturer) for generic

medicines shall be at least 40% lower than the ex-manufacturer of the originator medicine. The benchmark price will become the new maximum manufacturer price.

Combination Medicines

Combination medicines are made up of two or more active ingredients in the same dosage form. Benchmarking for combination products will based on each of the active ingredients (International Non-proprietary Name) in the dosage form. The methodology applicable to each active ingredient (INN) could be either the "originator medicine methodology" or "generic medicine methodology". If the manufacturer of the active ingredient is the original patent holder then the originator medicine methodology shall apply to such an active ingredient. If the manufacturer of the active ingredient is not the original patent holder then the generic medicine methodology shall apply to such an active ingredient. The manufacturer price of a combination product is the sum of the individual active ingredients.

In circumstances where the active ingredients in the combination are made up of both originator medicines and generic medicines then the manufacturer price of such medicines can only be finalised after the benchmarking of the originator medicines.

Products With Identical Ingredients But Different Trade Names

In circumstances where the same manufacturer produces medicine/s with the identical active ingredient/s but uses different trade names for each product then the single exit price of each product must be the same. In circumstances where identical products have different prices, the benchmark price will be set at the lowest priced trade name.

If the benchmarking methodology results in a company having to sell a product at an unviable price then the company may apply to the committee (with supporting evidence) for relief from the methodology.

Process

The sponsoring company will conduct the initial benchmarking using a standardised template as determined by the National Department of Health. The processes and procedures used in the benchmarking exercise should be audited to ensure the accuracy of the exercise. The National Department of Health will then check the accuracy of the calculated benchmark prices. It is assumed that international

companies will be able to access the ex-manufacturer price of the relevant products in the benchmark countries from their country or head offices.

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MINISTER OF HEALTH