Government Gazette
Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Regulation Gazette **No. 10189** *Regulasiekoerant*

Vol. 587 **Pretoria, 12 May / Mei 2014** **No. 37625**

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GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 354 **12 May 2014**

MEDICINES AND RELATED SUBSTANCES ACT (ACT NO. 101 OF 1965)

REGULATIONS RELATING TO A TRANSPARENT PRICING SYSTEM FOR MEDICINES AND SCHEDULED SUBSTANCES: (BENCHMARK METHODOLOGY)

The Minister of Health, in terms of Regulation 5(2)(e) of the Regulations relating to a Transparent Pricing System for Medicines and Scheduled Substances ("the Regulations"), as amended, and after recommendation from the Pricing Committee, intends to publish the methodology for medicines and scheduled substances prices to conform with international benchmarks.

Interested persons are requested to submit comments on the proposed methodology within 3 months of publication of this notice to the following address:

The Director-General: National Department of Health
For attention: Director: Pharmaceutical Economic Evaluations
Room 2610, South Tower
Civitas Building
Corner Thabo Sehume Street and Struben Street

A. BENCHMARKING METHODOLOGY

The proposed methodology covers originator medicines and scheduled substances and does not apply to generic medicines at this stage.

B. SCHEDULE

Proposed Methodology for International Benchmarking of Medicine Prices in South Africa.

C. 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. Modern medicines 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, factoring the cost of research and development and not making medicines unaffordable. 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 National Department of Health (NDoH) 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 by the Pricing Committee.

D. DEFINITIONS

1) "originator medicine"

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

2) **"independent multi-source medicines (generics)"**

Medicines or scheduled substances, registered in South Africa, where such a medicine or scheduled substance has never been protected by patent legislation. Such medicines or scheduled substances are being manufactured by companies other than the company that originally held the patent.

3) **"benchmark product for originator medicines"**

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.

4) **"benchmark product for generic medicines"**

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.

5) "benchmark price"

In South Africa: means the Rand equivalent of the ex-manufacturer price, i.e. the SEP less (or net 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.

6) "benchmark country"

Any of the countries from the basket of comparator countries selected below (i.e. Australia, Canada, New Zealand, South Africa or Spain). There may be a supplementary list published by NDoH from time to time.

7) "INN"

International Non-proprietary Name.

8) "SEP"

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.

E. METHODOLOGY

This section provides the methodology for international benchmarking of medicines and scheduled substances. 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 inappropriately reduced, the recommended approach incorporates two protections for applicants:

i. A phased approach, which delays the implementation of the ultimate benchmark by two-years for originator products; and

ii. An exemption process, which permits applicants to challenge the ultimate benchmark price based on the process outlined (Guideline document to be published by NDoH).

The methodology is as follows:

1) A selection ("basket") of appropriate countries has been identified, the prices of which will be benchmarked against prevailing prices in South Africa. The two benchmark methodologies will be applied in sequence to existing medicines:

a. In **Phase 1**: The benchmark price will be the average of prices in the country 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 prices in the basket* ("interim benchmark 1").

b. In **Phase 2**: the *lowest price* in the country basket will apply ("final benchmark"). A medicine will be exempt from this phase if the lowest price in the basket of countries is higher than an interchangeable multi source product that is already on the South African market.

2) This IBM methodology will apply to all originator medicines for which there are less than 2 generic competitors (both of which are not from the originator companies and are from separate, independent manufacturers). However, applicants are not prevented from complying where the methodology is not applicable at this point. It is the intention of the Minister of Health to address the methodology for products that are not currently included. On completion of Phase 2, originator medicines with 2 or more generic competitors and generics medicines will be addressed next.

3) Price conversions into Rands will be performed in accordance with the methodology outlined below (see G 4).

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 (Guidelines to be published by NDoH).

5) The final benchmark will apply automatically two years after the introduction of the interim benchmark except for those exempt as described under phase 2 under Clause (a) above.

6) Both the *Phase 1* and the *Phase 2* benchmark price values must be annually calculated by all the pharmaceutical companies and provided to NDoH in the prescribed format. This information must be submitted whether or not the methodology is deemed to be applicable or not, i.e. for all medicines.

7) An exemption from the final benchmark will be permissible, on application, where an affected company can demonstrate that the affected medicine could negatively affect patient access based on the final benchmark being applied or the resulting price is distorted and prejudicial to the applicant.

8) Applications for exemption from the final benchmarking must be submitted on a form and in the manner to be prescribed to the *Directorate of Pharmaceutical Economic Evaluations* of NDoH twelve months before the date for implementation of the Final benchmark.

9) A Review Panel will be established for the purpose of assessing exemption applications.

10) The Review Panel will assess the case according to the information before them.

11) An Applicant that trades in the private and public sector may appeal on the basis of a weighted average price in both sectors.

12) Any new medicine coming onto the market after the publication of the final international benchmarking methodology for implementation 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.

13) The timeline for implementation is as follows:

a. Regulation 5(2)(e) of the Regulations requires that the SEP be set in compliance with the international benchmarking methodology "*within 3 months of publication of such methodology*".

b. If, for example, the Committee recommendations are approved by the Minister and published by the end of August 2014, SEPs must comply with the interim Phase 1 benchmark by the beginning of December 2014. In order to stagger the process, NDoH may develop a time schedule, notifying each applicant the date by which they are expected to comply.

c. Applicants must therefore submit full data for each of their medicines when applying the interim benchmark methodology, within one month of publication of the benchmarking methodology (e.g. by the end of September 2014 using the above illustrative timeline) or in accordance with the time schedule mentioned in E 13, b above.

d. For new medicines, the process starts when information is submitted as is required by regulation 19 of the Pricing Regulations of 2005, as amended and must comply as per Clause 12 above.

14) Verification of benchmarking as implemented by applicants

a. The correct application of the methodology shall be audited by independent auditors appointed by each applicant who shall make a declaration as to the correct application of the methodology.

b. The Department of Health will also conduct an internal audit process.

F. BENCHMARK COUNTRIES

Selected benchmark countries (the "basket")

1) Australia;
2) Canada;
3) New Zealand;
4) Spain; and
5) South Africa.

The country basket may be reviewed every two years. A possible complementary list of countries for inclusion may be provided by the Department of Health on their website from time to time.

G. IDENTIFICATION OF COMPARATOR PRODUCT AND PRICE

1) Overview

This section outlines the recommended approach for identifying comparator products and their prices.

a. Originator products with the same INN, strength, dosage form and exact or closest pack size will be used for the comparison;

b. The comparator price will be the Rand equivalent of the ex-manufacturer price;

c. The responsibility will be placed on the applicant to identify and supply the relevant information on the products and their associated prices as they occur in the benchmark countries;

d. 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:

i. Other countries, from the complementary list in which the medicine manufacturers sell the product

ii. Burden of disease

iii. Therapeutic class comparisons

2) **Product Identification**

a. The license holder that received approval for the registration of a particular medicine (the "applicant") needs to identify the INN name(s) of all the products being sold in South Africa in accordance with the regulatory authority's requirements.

b. Thereafter, the identical product must be identified in each of the benchmark countries. In circumstances where there is no identical INN, the product will be placed on a list of 'no comparator' items.

c. After matching the INNs, the strength and dosage form must also be identical. If there is no identical strength available in a benchmark country, then the lowest common strength should be used (e.g. a milligram for milligram price comparison of the active ingredients).

d. This process should be applied in each benchmark country. So, for example if the identical strength and dosage form is available in two of the benchmark countries, but different strengths are available in the remaining benchmark countries, a milligram for milligram comparison must be done in these countries. This will ensure that the product is benchmarked for the full basket of countries wherever possible.

e. In circumstances where there is no identical dosage form, products with the same route of administration may be considered. If there is still no available product in the basket of countries, it will be placed on the "no comparator" list.

f. The pack size must be identical for every product in the basket. Where the pack size varies then a unit price comparator for the closest pack size will be used (e.g. price per tablet, millilitre, or capsule, etc.).

g. Following this benchmarking process, the products that are on the "no comparator" list may be subjected to an audit process to verify this status. This list may then be subjected to a different methodology that may need to be prescribed, particularly if the list contains products that are essential medicines or products that consume a large proportion of budgets, e.g. medicines prices may be compared to those in countries in the complementary list (see F above).

3) **Price Identification**

Where more than one selling price occurs in a benchmark country, *the price used in the largest ambulatory sector must be used.*

To determine the comparator ex-manufacturer price, the Rand equivalent of the ex-manufacturer price needs to be determined. The comparator price should be determined as follows:

a. Ex-manufacturer price = Pharmacy purchase price less all add on charges (wholesale fee, logistics fee, taxes, rebates and all discounts). This will provide the ex-manufacturer price in the foreign currency.

b. The ex-manufacturer price in South Africa is determined as follows:

- Ex-manufacturer = (SEP – Logistic fee) – VAT

Where the unit price differs for different pack sizes, *it is recommended that the price of the closest pack size be used for the comparison*.

4) **Exchange Rate Conversion**

All exchange rate and inflation data must be sourced from the South African Reserve Bank.

The prices of pharmaceutical products in the basket of countries are denominated in their various currencies. To benchmark the prices, the currencies must be appropriately converted to South African Rands (ZAR). A

12-month historical average will be specified to convert all prices to ZAR.

DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 14/5/2014

NOTICE – CHANGE OF TELEPHONE NUMBERS: GOVERNMENT PRINTING WORKS

As the mandated government security printer, providing world class security products and services, Government Printing Works has adopted some of the highly innovative technologies to best serve its customers and stakeholders. In line with this task, Government Printing Works has implemented a new telephony system to ensure most effective communication and accessibility. As a result of this development, our telephone numbers will change with effect from 3 February 2014, starting with the Pretoria offices.

The new numbers are as follows:

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