Government Gazette
Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Vol. 527 Pretoria, 22 May Mei 2009 No. 32245

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GENERAL NOTICE

NOTICE 575 OF 2009

To all pharmaceutical manufacturers/Importers

REVISED PROCEDURE FOR UPDATING SINGLE EXIT PRICES WITH THE DEPARTMENT OF HEALTH

In order to promote the transparency in the pricing of medicines and scheduled substances in the Republic, and to ensure that provision of price updates are in line with the spirit of the legislation, the Department of Health (DoH) has developed the following process for implementation with immediate effect.

1. Submission of applications

Only the applicant holder is entitled to supply the single exit price (SEP) update. Any notification to update an SEP from a marketing company or distribution company will not be accepted.

All applications with respect to SEP updates must be furnished both in electronic format (excel) on a compact disc and in a document format, and delivered to DoH at the address provided below. Applications sent by e-mail will not be accepted. The notification of price updates to all stakeholders e.g. price file vendors, remains the responsibility of DoH.

Timelines for notifying DoH regarding price updates remains the same i.e. 48 working hours prior to implementation for permanent SEP reductions, SEP reductions (non permanent) SEP increase after a non-permanent reduction. Launching of a new product, new line extensions, discontinuation of a product and change of product details will require a 30 days prior notification period.

2. Templates for SEP updates

DoH has developed specific templates (A – G) that must be used by all applicants for each price update notification, as elaborated in the narrative (Annexure A) attached.

All applicants are required to furnish the Directorate Pharmaceutical Economic Evaluations (PEE) with information as specified in Annexure A when an update is requested. Failure to comply will result in the single exit prices that prevail on the existing Department of Health's records remaining as official.

3. Manufacturer/Importer Details

The Directorate: PEE is in the process of updating all the manufacturer and importer contact details. Applicants are advised to complete the attached spreadsheet, see Annexure B, titled "Manufacturer Contact Details". Should the responsible person within the organization change; the responsibility lies with the manufacturer/importer to update their records with the Directorate: PEE.

4. Telephonic enquiries

All telephonic enquiries relating to SEP updates will be strictly between 13h00 and 16h00 (Monday to Friday).

All correspondence should be addressed to:

The Director:
Pharmaceutical Economic Evaluations
Room 937
Hallmark Building
231 Proes Street
Department of Health
Pretoria
0001

Contact person:
Mr E Slivo
Tel: 012 312 3387
Fax: 012 312 3313/0051
E-mail: sepupdates@health.gov.za

Regards

DIRECTOR-GENERAL: HEALTH
DATE: 26/03/2009

ANNEXURE A:

INFORMATION AND INSTRUCTIONS FOR USING THE Single Exit Price (SEP) UPDATE TEMPLATES

1. Department of Health (DoH) has developed seven different excel templates and one word document template (specific to product launch) that must be used by all applicants for each price update notification. It is mandatory to fill in all the fields in the templates. If a template is incomplete it will be returned to the applicant for completion and resubmission.

   Timelines for notifying DoH regarding price updates are 48 working hours prior to implementation date for Templates A, B and C:

   - permanent SEP reductions
   - SEP reductions (non permanent)
   - SEP increase after a non permanent SEP reduction

   Timeline for notifying DoH regarding price update is 30 days prior to commencement of sale for Templates D, E, F and G:

   - launching of a new product
   - new line extension
   - discontinuation of a product
   - product detail amendments

   An incomplete submission will be returned to the applicant. The timelines will only commence on receipt of a correct and complete submission.

2. **The templates require that the following details be provided:**

   - Date of the submission
   - Detailed description of a price update.
   - Contact details of the person responsible for a price update. It is the responsibility of the applicant to ensure that these contact details are up-to-date on the records of the Directorate: PEE.
   - Effective date of the price update (taking note of the time limitations).

- Manufacture's MCC registration numbers, i.e. a full ten digits number per applicant as appearing in the MCC certificate.
- The applicant's full name as registered with MCC.
- A full MCC registration number per chemical entity per product line must be furnished.
- A nine-digit product specific nappi code as issued by Medikredit.
- ATC4 code as prescribed by World Health Organization (WHO).
- Medicine schedule as registered with MCC.
- A full product proprietary name as registered with MCC.
- A full description of a generic/active ingredient [International non proprietary name (INN)] per product. Where a product contains more than one active ingredient each active ingredient must be provided separately on a new line.
- The quantity of each active ingredient per product shall be furnished as a unit on each line.
- The character describing the quantum of the active ingredient per product must be furnished per active ingredient e.g. mg, g, IU, ml, %, etc. This character should not be combined in a single cell with the quantum mentioned above.
- The pack size, which is a number of units in a pack as linked to a nappi code and a price.
- The dosage form in an abbreviated format as prescribed by WHO.
- The VAT exclusive ex-Manufacturer price as defined in the Regulations relating to a transparent system in the pricing of Medicines and Scheduled substances (section 22G of the Medicines and Related Substances Act).
- The VAT exclusive logistics fee as described in the Regulations relating to a transparent system in the pricing of Medicines and Scheduled substances (section 22G of the Medicines and Related Substances Act).
- Value Added Tax (VAT)
- SEP as described in the Regulations relating to a transparent system in the pricing of Medicines and Scheduled substances (section 22G of the Medicines and Related Substances Act), i.e. the sum of the manufacturer price (VAT excl) + logistics fee (VAT

excl) + VAT.

- Unit price as described in the Regulations relating to a transparent system in the pricing of Medicines and Scheduled substances (section 22G of the Medicines and Related Substances Act), must always be displayed next to the SEP per product.
- Columns relating to status and price change type will be for official use, by DoH only.

Attached, see templates A-G that must be used to communicate all SEP updates notifications to the Directorate: PEE. All templates are to be completed in full in order for a submission to be considered.

3. Template Details

A. **Template A: Permanent price reduction**

The existing SEP and the new SEP request must be furnished at all times. All pack sizes and the corresponding details that are in the market are to be provided for each product on a new line.

B. **Template B: SEP reduction (non permanent) template**

The existing single exit prices and the requested single exit prices must be furnished. The batch number, expiry date, and number of units to be sold per product must be supplied. All pack sizes in the market and their corresponding details are to be provided, with each product on a new line.

NB! Non-permanent price reductions are allowed for a **minimum** period of six weeks.

The expected duration of the new SEP, based on historical sales, must be provided. If this period is less than 6 weeks, it must be noted that the minimum period for which an SEP reduction will be applicable will be 6 weeks.

C. **Template C: SEP Increase post non permanent SEP reduction**

The SEP prior to the increase request and the requested increased single exit price must be furnished. Where deemed necessary the DoH may request further details of the units sold. All pack sizes in the

market and their corresponding details are to be provided, with each product on a new line.

NB! SEP reductions are allowed for a **minimum** period of six weeks.

D. **Template D: Product launch**

This is an application that requires the applicant to fill in both the excel spreadsheet and the word document form (see Regulation 19 from attached).

The details on the calculations of the SEP for which the company is applying should be described in the **Regulation 19 form** (word document). The new single exit prices must also be furnished in **Template D** (the excel document).

It is mandatory that a **certified copy of the product's MCC registration certificate** must be included with every application. Failure to provide this implies an incomplete application. This template should not be used for product re-introduction or line extensions for products that already exist. It is for a completely new product.

All pack sizes being introduced into the market and their corresponding details are to be provided, with each product on a new line.

The effective date should be filled in a far right column per product. The earliest possible launch date is 30 days from the date of the submission.

E. **Template E: Line Extension**

The details of the new line extension should be on the 1st line followed by the details for products already in the market on subsequent lines in order for this application to be considered. Failure to provide all pack sizes that currently exist implies an incomplete submission. The official prices must be furnished per product. **A certified copy of the product's MCC registration certificate must be included in every application.**

The effective date should be filled in a far right column per product, for all line extension applications. The earliest possible launch date is 30 days from the date of the application.

F. **Template F: Discontinuation of a product**

The notification of discontinuation should be at least 30 days before the effective date. The last SEP at which the product is to be traded must be furnished at all times. All pack sizes remaining in the market must be provided for each product discontinued. A reason for the discontinuation and the effective date of the discontinuation of a product must be supplied.

The effective date should be filled in a far right column per product, for all line extension applications. The earliest possible effective date of discontinuation is 30 days from the date of the submission.

G. **Template G: Amendments to the Details of an Existing Product**

It is compulsory to notify the Directorate: PEE of every change to details of medicines and scheduled substances with a registered SEP. Template G will be used to furnish DoH with the original details and the specific amendments of a product already in the market. Depending on the type of amendment, there are instances where relevant evidence of the change must be attached, e.g. new MCC registration certificate for change of proprietary name.