
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

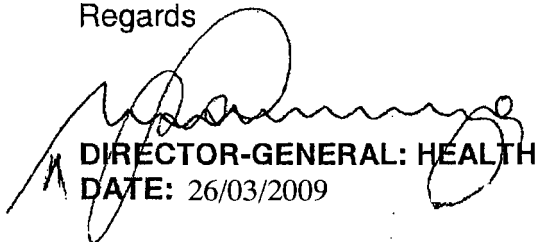
All telephonic enquiries relating to SEP updates will be strictly between 13h00 and 16h00 (Monday to Friday).

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).