
GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. 290

13 April 2010

MEDICINES AND RELATED SUBSTANCES ACT, 1965

INFORMATION TO BE FURNISHED BY MANUFACTURERS AND IMPORTERS OF MEDICINES AND SCHEDULED SUBSTANCES BEFORE APPLYING AN INCREASE TO THE SINGLE EXIT PRICE

I, **YOGAPRAGASEN GOVINDSAMY PILLAY**, Acting Director-General, has determined in accordance with Regulation 21 of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances published in Government Gazette Number 28214 of 11 November 2005 that the following information must be submitted to the Directorate: Pharmaceutical Economic Evaluation (PEE) within the National Department of Health by a licensed manufacturer or importer of the medicine or scheduled substance.

Such information should be provided in electronic (Excel with an xls filename extension on a labelled compact disc) and hard copy. The submission should include information regarding the applicant's entire portfolio; this includes products for which the applicant is not applying for an increase:

1. 10 digit applicant MCC license number
2. Applicant Name as registered with MCC
3. Product MCC Registration Number
4. 9 digit NAPPI code in numerical format
5. ATC 4 code as per WHO classification
6. Schedule as per the MCC approval package insert for the product
7. Product Proprietary Name as per the MCC registration certificate
8. Active Ingredient in the product as per MCC registration. Each active ingredient should appear on a separate row
9. Strength of the product, i.e. the numerical or quantum portion of the strength of each active ingredient
10. Unit of the product, i.e. the unit in which the strength is measured
11. Pack size of the product

12. Dosage form
13. Ex-manufacturer price (VAT exclusive) as at the specified date
14. Logistics Fee (VAT exclusive) as at the specified date
15. Value Added Tax (VAT) on the sum of the ex-manufacturer price and Logistics fees as at the specified date
16. Single Exit Price as at the specified date, i.e. the sum of the ex-manufacturer price, Logistics fees and VAT.
17. Unit Price
18. Effective date in the format dd month yyyy
19. Requested ex-manufacturer price (VAT exclusive)
20. Requested Logistics fee (VAT exclusive)
21. VAT on the sum of the requested ex-manufacturer price and requested Logistics fees
22. New SEP requested
23. New Unit Price

The information should be submitted in the order outlined above.

PROCEDURE FOR NOTIFICATION OF INTENTION TO INCREASE THE SINGLE EXIT PRICE

1. In terms of Section 15 of the Medicines and Related Substance Act 101 of 1965, only the applicant is entitled to supply the notification of intention to increase the Single Exit Price (SEP). Any notification of intention to increase the SEP from a *marketing or distribution company* will be rejected.
2. Information requested in terms of Regulation 21 of the Regulations must be furnished both in electronic format (excel with an xls filename extension on a labelled compact disc) and hard copy. Information must be arranged according to the schedule specified (see templates published on the Department of Health website). Note due to previous problems with email submission this mode of communication will no longer be accepted.
3. All notifications should be accompanied by a covering letter on the applicant's company letterheads that must be signed by the responsible person for the application. This covering letter should specify the contact person for future communications relating to this submission.
4. Any information that does not comply with the prescribed format will result in the respective application being rejected.

5. All notifications should be delivered to:

The Director

Pharmaceutical Economic Evaluations

Room 932

Hallmark Building

231 Proes Street

Department of Health

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6. Upon receipt of the proposed new SEP from the applicant, the Directorate Pharmaceutical Economic Evaluations (PEE) will acknowledge receipt of such correspondence in writing.
7. The new increased Single Exit Prices will only be effective 30 working days after receipt of the notification of intention to take a price increase. In circumstances where the proposed new Single Exit Prices by the applicant is deemed to be inaccurate by the Directorate: PEE then applicant may not implement such an increase until such errors are corrected.
8. The Directorate: PEE will verify the correctness of the new Single Exit Prices as supplied by the applicant. Single Exit Prices confirmed to be accurate, will be communicated to all stakeholders by the Directorate: PEE, and will be published on the National Department of Health's website, specifying the effective date of the new Single Exit Prices of medicines.
- Note:** Notification of price increases to other stakeholders e.g. price file vendors, remains the responsibility of the Directorate Pharmaceutical Economic Evaluations.*
9. Any discrepancies to the Single Exit Prices supplied by the applicant will be returned to the applicant to be rectified.
10. Resubmission of rectified submissions should follow the same procedure as delineated above.
11. Rectified discrepancies returned to the Directorate: PEE will be verified for correctness and the new Single Exit Prices to such products will only be effective 30 working days after receipt of the rectified schedule. The increase is applicable to the SEP as of the 15th February 2010.
12. An applicant may only apply for an SEP increase up to the maximum allowable percentage as published by the Minister. Applicants applying for more than this percentage increase on the SEP as per the 15th February 2010 will be rejected.

13. Only one SEP increase is permitted on a product in an annual cycle. Thus for example an applicant would not be permitted to apply for a portion of the maximum increase permitted for 2010 and then later in the year apply for an increase for the balance.
14. The Directorate: PEE will communicate the new Single Exit Prices to all relevant parties. The Single Exit Prices published by the Directorate: PEE will be the prevailing prices as of the effective date and no other price will exist.
15. In the event that any discrepancy in the SEP has not been resolved before the specified effective date, the SEP as per the Directorate PEE records on that date will be communicated to all relevant parties.
16. The last date for communication of SEP increases to stakeholders, by the Directorate PEE, will be in accordance with the date specified in the gazette.
17. Regulation 9 applications will not be considered for any product until an increase in terms of Regulation 8 has been completed.