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GENERAL NOTICE

NOTICE 1474 OF 2009

NOTICE: ANNUAL REVIEW OF THE SINGLE EXIT PRICES OF MEDICINES AND SCHEDULED SUBSTANCES

In terms of regulation 8(1) of the Regulations relating to Transparent Pricing System for Medicines and Scheduled Substances published under the Medicines and Related Substances Act, 1965 (Act No. 11 of 1965) the Minister of Health intends to review the Single Exit Prices of medicines.

Interested persons are invited to submit any substantiated representations on the review of the Single Exit Price to the Director-General of Health, Private Bag X828, Pretoria, 0001, (for the attention of the Director: Pharmaceutical Economic Evaluations) within three months of the date of the publication of this notice.

DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 28/10/2009

GOVERNMENT NOTICE

No. X. XXXX **DD Month 2009**

MEDICINES AND RELATED SUBSTANCES ACT, 1965

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

INFORMATION TO BE PUBLISHED BY MANUFACTURERS AND IMPORTERS OF MEDICINES AND SCHEDULED SUBSTANCES BEFORE TAKING AN INCREASE IN THE SINGLE EXIT PRICE

I, Karmani Saravana Chetty, have determined in accordance with Regulation 21 of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances published in Government Notice 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 both 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 approved package insert for the product
7. Product Proprietary Name as per the MCC registration certificate

8. Active Ingredients 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. Logistic 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 Logistic 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 TAKE A PRICE INCREASE

1) In terms of Section 15 of the Act 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 labeled compact disc) and hard copy. Information must be arranged according to the schedule specified (see Excel template attached). Note - Due to previous problems with email submissions this mode of communication will no longer be accepted.
3) All notifications should be accompanied by a covering letter on the applicant's company letterhead that must be signed by the responsible person. This covering letter should specify the contact person for future communications relating to the submission.
4) Any information that does not comply with the prescribed format will be rejected.
5) All notifications should be delivered to:

The Director
Pharmaceutical Economic Evaluations
Room 937
Hallmark Building
Department of Health
Pretoria
0001

6) Upon receipt of the proposed new SEP from the applicant, the Directorate: Pharmaceutical Economic Evaluations (PEE) will acknowledge receipt of the submission in writing.

7) A maximum of 15 submission will be accepted per week on a first come first serve basis.

8) The new increased SEP will only come into effect 30 working days after receipt of the notification of intention to take a price increase. In circumstances where the proposed new SEP by the applicant is deemed to be inaccurate by the Directorate: PEE then the applicant may not implement such an increase until such errors are corrected.

9) 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.*

10) Any discrepancies to the Single Exit Prices supplied by the applicant will be returned to the applicant to be rectified.

11) Resubmission of rectified submissions should follow the same procedure as delineated above.

12) Rectified discrepancies returned to the Directorate: PEE will be verified for correctness and the new Single Exit Prices of 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 specified date.

13) 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 specified date will be rejected.

14) The increase request must be equally distributed across the components of the SEP. An applicant may not apply for a higher percentage increase on the manufacturer price than on the logistics fees and vice versa.

15) 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.

16) Any applicant not in compliance with the Medicine Pricing Regulations for any of the products in their portfolio will not be entitled to apply for the 2010 annual price increase for their portfolio pending resolution of the transgression.

17) All applicants must demonstrate and describe how the logistics fee of each product is calculated. In support of this calculation and explanation a certified copy of the logistics fee contracts with the logistics service provider must be provided. The portfolio of products of applicants failing to comply with this requirement will be rejected.

18) 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.

19) In the event that any discrepancy in the SEP has not resolved before the specified date, the Single Exit as per the Directorate Pharmaceutical Economic Evaluations' records on that date will be communicated to all relevant parties.

20) The last date for communication of Single Exit Price increases to stakeholders, by the Directorate: PEE, will be in accordance with the date specified in the gazette.

21) Regulation 9 applications will not be considered for any product until a Regulation 8 increase is completed.

DR KS CHETTY
ACTING DIRECTOR-GENERAL: HEALTH
27/10/2009