GOVERNMENT NOTICES

DEPARTMENT OF HEALTH

No. R. 1388 **24 December 2008**

MEDICINES AND RELATED SUBSTANCES ACT, 1965

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

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

I, TD MSELEKU, the Director-General of Health, have 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 in both electronic (Excel format) and document format must be communicated to the Directorate: Pharmaceutical Economic Evaluation at the National Department of Health by a manufacturer or importer of the medicine or scheduled substance in respect of which it intends to take a price increase:

1. MCC registration number per chemical entity
2. 9- digit NAPPI Code
3. Brand name;
4. Active ingredient/s;
5. Strength and dosage form;
6. pack size;
7. ex-manufacturer price as at 01 December 2008;
8. new increased ex-manufacturer price;
9. logistic fee as at 01 December 2008;
10. new increased logistic fee;
11. Value Added Tax;
12. New single exit price after the increase

PROCEDURE FOR NOTIFICATION OF INTENTION TO INCREASE THE SINGLE EXIT PRICE

1) In terms of Section 15 of the Medicines and Related Substance Act 1965, only the applicant is entitled to supply the notification of intention to increase the single exit price. Any notification of intention to increase the single exit price received from a marketing or distribution company will not be accepted.

2) Information requested in terms of Regulation 21 of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances must be furnished both in electronic format (excel) on a compact disc and in document format in the exact order as outlined above. Due to previous problems with email notifications this method of communication cannot be accepted.

3) Any information that is not supplied in the prescribed format as outlined will be regarded as incomplete and returned to the applicant.

4) All notifications should be delivered to:

The Director

Pharmaceutical Economic Evaluations

Room 937

Hallmark Building

231 Proes Street

Department of Health

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5) Upon receipt of the proposed new single exit price from a manufacturer /importer the Directorate Pharmaceutical Economic Evaluations will acknowledge receipt of such correspondence in writing.

6) The new increased Single Exit Prices will only be effective 30 days after receipt of the notification of intention to take a price increase. In circumstances where the proposed new Single Exit Prices by the manufacturer/importer is determined to be inaccurate by the Directorate Pharmaceutical Economic Evaluations then manufacturer/importer may not implement such an increase until such errors are corrected.

7) The Directorate Pharmaceutical Economic Evaluations 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 Pharmaceutical

Economic Evaluations, and will be published on the National Department of Health 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.*

8) Any discrepancies to the single exit prices supplied by the applicant will be returned to the applicant to rectify.

9) Rectified discrepancies returned to the Directorate Pharmaceutical Economic Evaluations will be verified for correctness and the new Single Exit Prices to these products will only be effective 30 days after receipt of the rectified schedule.

10) The Directorate Pharmaceutical Evaluations will communicate the new Single Exit Prices to all relevant parties. The Single Exit Prices communicated by the Directorate will be the prevailing prices as of the effective date and no other price will exist.

11) In the case where any discrepancy in the single exit price is not resolved before 30 September 2009, the Single Exit as per the Directorate Pharmaceutical Economic Evaluations' records will be regarded as the official Single Exit Price, and will be communicated to all relevant parties.

12) The last date for communication of Single Exit Price increases to stakeholders, by the Directorate Pharmaceutical Economic Evaluations, will be 30 September 2009.

MR TD MSELEKU
DIRECTOR-GENERAL: HEALTH
DATE: 2008-12-11