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.