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DEPARTMENT OF HEALTH

NO. 438 **19 MAY 2017**

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965) AS AMENDED

REGULATIONS RELATING TO A TRANSPARENT PRICING SYSTEM FOR MEDICINES AND SCHEDULED SUBSTANCES: (DRAFT DISPENSING FEE TO BE CHARGED BY PERSONS LICENSED IN TERMS OF SECTION 22C (1) (a))

I, DR A MOTSOALEDI, the Minister of Health have, on the recommendation of the Pricing Committee, in terms of Section 22G (2) (b) of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) as amended, made the regulations in the schedule.

Interested persons are requested to submit comments in writing, both on a compact disc and hard copy, on the proposed regulations within 3 months of publication of this notice to the following address:

The Director-General: National Department of Health
Attention to the Director: Pharmaceutical Economic Evaluations Directorate Room 419, South Tower Civitas Building, Corner: Thabo Sehume &Bloed Streets Pretoria 0001

SCHEDULE

Definitions

1. In these regulations any word or expression to which a meaning has been assigned in the Act shall have such meaning and, unless the context indicates otherwise-

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"**the Regulations**" means the Regulations Relating to the Transparent Pricing System for Medicines and Scheduled Substances published under Government Notice No. R1102 of November 2005 as amended.

Substitution of Regulation 12

2. The following regulation is hereby substituted for Regulation 12 of the Regulations:

"12. The appropriate dispensing fee as contemplated in section 22G (2) (b) of the Act to be charged by persons licensed in terms of section 22C (1) (a) of the Act must be calculated, exclusive of VAT, as follows:

(a) Where the single exit price of a medicine or scheduled substance is less than one hundred and twenty rand (R120.00), the dispensing fee must not exceed 30% of the single exit price in respect of that medicine or scheduled substance;

(b) Where the single exit price of a medicine or scheduled substance is equal to or greater than one hundred and twenty rand (R120.00), the dispensing fee must not exceed thirty six rand (R36.00) in respect of that medicine or scheduled substance;

3. The provisions of Regulation 12 must be reviewed annually by the Minister after taking into account-

(a) the need to ensure the availability and affordability of quality medicines and scheduled substances in the Republic;

(b) annual inflation rates published periodically by Statistics South Africa;

(c) information supplied by persons licensed to dispense in terms of section 22C (1)(a) in accordance with guidelines determined by the Director-General from time to time by Notice in the Gazette; and

(d) any other information the Minister may deem necessary to consider.

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4. Persons Licensed to dispensing in terms of section 22C (1) (a) must-

(a) by means of a clearly displayed notice in the dispensing practice, inform members of the public of the maximum fee structure used by such dispensing practice to determine the dispensing fee; and

(b) provide an invoice in respect of each medicine that clearly indicates the-

(i) dispensing fee charged; and

(ii) the single exit price;

DR A MOTSOALEDI, MP

MINISTER OF HEALTH

DATE 23/3/2017.