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GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 31

18 January 2012

MEDICINES AND RELATED SUBSTANCES ACT, 1965

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) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 101 OF 1965

The Minister of Health, on the recommendation of the Pricing Committee, in terms of section 22G of the Medicine and Related Substances Act, 1965 (Act No. 101 of 1965) ("the Act"), intends to make the following changes to the regulations in the Schedule pertaining to the dispensing fee to be charged by persons licensed in terms of Section 22C (1) (a) of the Act.

In 2011, the Pricing Committee undertook to collect data from involved stakeholders to inform a structured review of the dispensing fee for the current year. By the 28th September 2011, despite all reasonable attempts to collect completed data sets, insufficient data had been received in order to proceed with the analysis. The Pricing Committee therefore elected to recommend an inflator adjusted fee to be implemented.

Interested persons are requested to submit comments on the proposed regulations within four weeks of publication of this notice to the Director-General: Health for the attention of the Director: Pharmaceutical Economic Evaluations; Room S 2610 South Tower; Civitas Building; Corner Andries and 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-

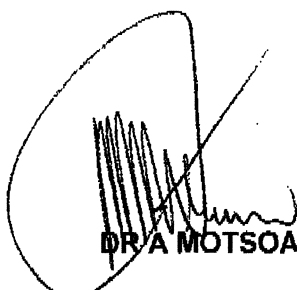
"the Regulations" means the Regulations Relating to the Transparent Pricing System for Medicines and Scheduled Substances published under government Notice No. R1102 of November 2005 as amended.

Substitution of Regulation 12

2. The following regulation is hereby intended to be substituted for regulation 12 of the regulations:

"12. The appropriate dispensing fee as contemplated in section 22G 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:

1. Where the Single Exit Price of a medicine or Scheduled substance is less than or equal to eighty eight rands, the dispensing fee must not exceed 30% of the Single Exit Price in respect of that medicine or Scheduled substance.
2. Where the Single Exit Price of a medicine or Scheduled substance is greater than eighty eight rands, the dispensing fee must not exceed twenty six rands and forty cents of the Single Exit Price in respect of that medicine or Scheduled substance.
3. The provisions of this regulation may be reviewed annually by the Minister with regard to CPI, the PPI and the need to ensure the availability, affordability of quality medicines and scheduled substances in the Republic".



DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 11/1/2012