

## DEPARTMENT OF HEALTH

NO. 1589

23 DECEMBER 2016

**MEDICINES AND RELATED SUBSTANCES ACT, (ACT NO. 101 OF 1965)****REGULATIONS RELATING TO A TRANSPARENT PRICING SYSTEM FOR  
MEDICINES AND SCHEDULED SUBSTANCES: AMENDMENT****(DISPENSING FEE TO BE CHARGED BY PERSONS LICENSED IN TERMS OF  
SECTION 22C (1) (a))**

The Minister of Health has, 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) as amended, made the regulations in the schedule.

**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.

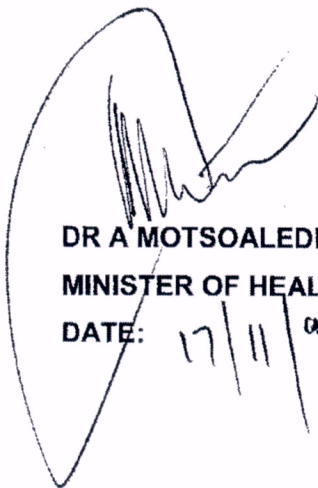
### Substitution of Regulation 12

2. The following regulation is hereby 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:

- (a) Where the single exit price of a medicine or scheduled substance is less than one hundred and seventeen rand (R117.00), 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 seventeen rand (R117.00), the dispensing fee must not exceed thirty five rand and ten cents (R35.10) in respect of that medicine or scheduled substance;
3. The provisions of sub-regulation (2) 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 Minister from time to time by Notice in the Gazette; and
  - (d) any other information the Minister may deem necessary to consider.

4. Persons Licensed to dispense 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 using the dispensing practice of the maximum fee structure used by such dispensing practice to determine the dispensing fee; and
  - (b) provide an invoice that in respect of each medicine clearly indicates the-
    - (i) dispensing fee charged; and
    - (ii) the single exit price;



**DR A MOTSOLEDI, MP**  
**MINISTER OF HEALTH**  
DATE: 17/11/2016