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GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH

NO. 702

09 JULY 2018

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

"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 twenty four rand (R124.00), 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 four rand (R124.00), the dispensing fee must not exceed thirty seven rand and twenty cents (R37.20) 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.

(e)

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

11/6/2018

DEPARTMENT OF HEALTH

NO. 703

09 JULY 2018

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965)**REGULATIONS RELATING TO A TRANSPARENT PRICING SYSTEM FOR MEDICINES AND SCHEDULED SUBSTANCES: (DRAFT DISPENSING FEE FOR PHARMACISTS)**

I, DR A MOTSOALEDI, the Minister of Health have, on recommendation of the Pricing Committee, in terms of section 22G 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 three months of publication of this notice to 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-

"dispense" means the supply of medicines based on a prescription to a patient or someone on behalf of the patient by a health professional authorized by law to supply medicines and includes-

- (a) the interpretation and evaluation of the prescription;
- (b) the selection, reconstitution, dilution, labelling, recording and the actual supply of the medicine;
- (c) the provision of information and instructions to ensure safe and effective use of a medicine by a patient; or
- (d) the provision of information as contemplated in section 22F (1) (a) of the Act.

"dispensing fee" means a fee determined in terms of these regulations, exclusive of Value Added Tax, that may be charged to dispense a medicine; and

"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.

Amendment of Regulation 10

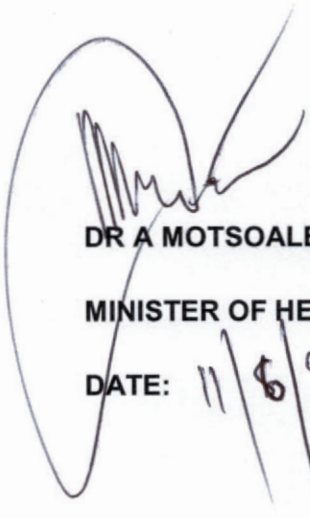
2. The following regulation is hereby substituted for regulation 10 of the regulations:

- "10. (1) The appropriate dispensing fee, exclusive of VAT, as contemplated in section 22G of the Act to be charged by pharmacists, must:
- (a) Where the single exit price of a medicine or scheduled substance is less than one hundred and nine rand and fifty seven cents (R109.57), the dispensing fee shall not exceed R13.15 plus 46% 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 greater than or equal to one hundred and nine rand and fifty seven cents (R109.57) but less

than two hundred and ninety two rand and twenty six cents (R292.26), the dispensing fee shall not exceed R25.20 plus 33% of the single exit price in respect of that medicine or scheduled substance;

- (c) where the single exit price of a medicine or scheduled substance is greater than or equal to two hundred and ninety two rand and twenty six cents (R292.26) but less than one thousand and twenty two rand ninety four cents (R1022.94), the dispensing fee shall not exceed R77.00 plus 15% of the Single Exit Price in respect of that medicine or scheduled substance;
 - (d) where the single exit price of a medicine or scheduled substance is greater than or equal to one thousand and twenty two rand ninety four cents (R1022.94), the dispensing fee shall not exceed R178.00 plus 5% of the Single Exit Price in respect of that medicine or scheduled substance.
- (2) The provisions of regulation 10 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 pharmacists 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.
- (3) A pharmacist dispensing a medicine must-
- (a) by means of a clearly displayed notice in the pharmacy, inform members of the public of the maximum fee structure used by such pharmacist to determine the dispensing fee; and

- (b) provide an invoice in respect of the sale 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: 11/8/2018

DEPARTMENT OF HEALTH

NO. 704

09 JULY 2018

MEDICINES AND RELATED SUBSTANCES ACT, (ACT NO. 101 OF 1965)
(ANNUAL SINGLE EXIT PRICE ADJUSTMENT (SEPA) OF MEDICINES AND SCHEDULED
SUBSTANCES FOR THE YEAR 2019)

In terms of Regulation 8 (1) of the Regulations Relating to the Transparent Pricing System for Medicines and Scheduled Substances of the Medicines and Related Substances Act, 1965 (No. 101 of 1965) as amended, the Minister of Health is required to determine on an annual basis, the extent to which medicine prices may be adjusted. In making this determination the Minister considers the following provisions of Regulation 8 (1)-

- (a) the average CPI for the preceding year;
- (b) the average PPI for the preceding year;
- (c) changes in the rates of foreign exchange and purchasing power parity;
- (d) international pricing information relating to medicines and scheduled substances;
- (e) comments received from interested persons in terms of regulation 8(2); and
- (f) the need to ensure the availability, affordability and quality of medicines and scheduled substances in the Republic.

Comments received from previous annual reviews on the adjustment methodology have indicated that stakeholders would like to have a CPI weighting and a foreign exchange weighting in the review of the SEP adjustment as follows:

$$70\% \text{ (South African CPI)} + 30\% \text{ (foreign exchange rate)} = \% \text{ adjustment}$$

The Pricing Committee in its recommendation for the next annual adjustment cycle may consider this weighting *in addition* to the provisions of Regulation 8(1) as listed above.

The official data to be used with respect to the Consumer Price Index (CPI) for South Africa and the foreign exchange rates would be obtained from official publications by the Statistics South Africa at www.statssa.gov.za and the South African Reserve Bank at www.resbank.co.za respectively.

Interested persons are invited to submit any substantiated comments in writing, both on a compact disc and a hard copy within three months from the date of publication of this Notice to:

The Director-General: Health

For Attention: Director (Pharmaceutical Economic Evaluations)

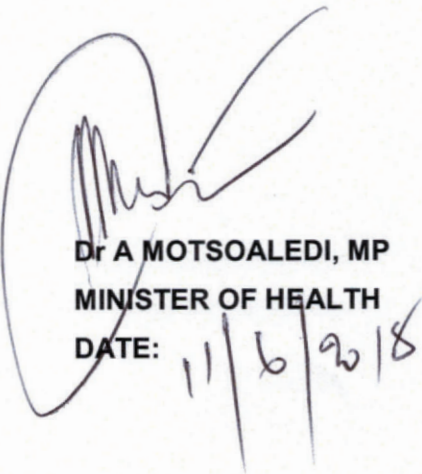
Room 0419 South Tower

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Corner Thabo Sehume & Struben Streets

PRETORIA, 0001

For any further enquires please contact the Directorate: Pharmaceutical Economic Evaluations: telephone: 012 395 8181/4/5; e-mail: sepupdates@health.gov.za



Dr A MOTSOLEDI, MP

MINISTER OF HEALTH

DATE: 11/6/2018

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