DEPARTMENT OF HEALTH

NO. 6880 **28 November 2025**

MEDICINES AND RELATED SUBSTANCES ACT, (101 OF 1965 AS AMENDED)

REGULATIONS RELATING TO A TRANSPARENT PRICING SYSTEM FOR MEDICINES AND SCHEDULED SUBSTANCES: 2026 DRAFT DISPENSING FEE FOR PERSONS LICENSED IN TERMS OF SECTION 22C (1) (a)

The Minister of Health, on the recommendation of the Pricing Committee and in terms of Section 22G(2)(b) of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965, as amended), hereby intends to amend Regulation 12, as set out in the Schedule below, to provide for the timeous publication of the appropriate dispensing fees to be charged by persons licensed in terms of Section 22C (1) (a).

The Minister intends to recalibrate the timelines for the publication of the dispensing fees to align with actual market determinants of the fees and with stakeholder requests that such fees be published at the beginning of each calendar year. Accordingly, the draft fee for 2026 will be based on the prevailing dispensing fees published by Notice in Government Gazette No. 53426, dated 26 September 2025, as reflected in the Schedule below. In accordance with regulation 12 of the Transparent Pricing Regulations, the period January 2025 to December 2025 will be considered in determining the key inflationary inputs for recalibrating the dispensing fee for 2026.

Interested persons are invited to submit written comments on the proposed regulations within three months of the date of publication of this Notice. Submissions must be made both electronically and in hard copy, and delivered to: The Director-General: National Department of Health **(Attention to the Director: Pharmaceutical Economic Evaluations Directorate, Dr AB Xuma Building, Office D -16A, 1112 Voortrekker Rd, Pretoria Townlands 351-JR, Pretoria, 0187)); e-mail:** SEPUpdates@health.gov.za and Ntobeko.Mpanza@health.gov.za.

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 (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 or equal to one hundred and sixty rand (R160.00), 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 greater than one hundred and sixty rand (R160.00), the dispensing fee must not exceed forty-eight rand (R48.00) 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.

4. Not less than three months before the review contemplated in regulation 12 (2), the Minister must publish a notice in the Gazette declaring his or her intention to make that review and inviting interested persons to furnish him or her in writing with any comments thereon or any representation they may wish to make in regard thereto.

5. 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.
(iii) VAT component

DR A MOTSOALEDI, MP

MINISTER OF HEALTH

DATE 9/11/2025