
GOVERNMENT COMMENT NOTICE

DEPARTMENT OF HEALTH

NO. R.

..... 2024

MEDICINES AND RELATED SUBSTANCES ACT NO. 101 OF 1965

(ANNUAL SINGLE EXIT PRICE ADJUSTMENT (SEPA) OF MEDICINES AND SCHEDULED SUBSTANCES FOR THE YEAR 2025)

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, (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.

Based on the comments received from previous annual reviews on the adjustment methodology, stakeholders have recommended weightings in the review of the annual Single Exit Price Adjustment (SEPA) expressed as follows:

- I. 70% CPI + 30% forex
- II. 50% CPI + 50% Forex
- III. 100% CPI
- IV. 50% PPI + 50% CPI

Stakeholders are encouraged to propose alternative formula proposals, supported by evidence, for consideration and acceptance in the SEPA determination, with a new comment Notice published if accepted.

The Minister, in making his determination for the next annual adjustment cycle may consider the weighting(s) as a guide *in addition* to the provisions of Regulation 8(1) as listed above.

The official published data to be used in the determination of SEPA with respect to regulation 8(1) would be obtained from official publications by Statistics South Africa at www.statssa.gov.za and the South African Reserve Bank at www.resbank.co.za. The review period is from August 2023 to July 2024, commencing at the end of the previous cycle.

Interested persons are invited to submit any substantiated comments demonstrating their rational and supporting evidence with regard to the factors considered when determining 2025 SEPA in terms of the provisions in regulation 8(1) as listed above. Submissions should be sent via e-mail to sepupdates@health.gov.za, within three months from the date of publication of this Notice to:

The Director-General: Health
For Attention: Ms Ntobeko M. Mpanza
Director (Pharmaceutical Economic Evaluations Directorate)
Room D16-14A
Dr Xuma Building
1112 Voortrekker Road, Pretoria Townlands 351 – JR
PRETORIA

For any further enquiries please contact Ms NM Mpanza at the Directorate: Pharmaceutical Economic Evaluations: telephone: 012 395 8209/8181/4/5; e-mail: sepupdates@health.gov.za or Ntobeko.Mpanza@health.gov.za


DR MJ PHAAHLA, MP
MINISTER OF HEALTH

DATE: 19/04/2024