

DEPARTMENT OF HEALTH

NO. 304

08 MARCH 2019

MEDICINES AND RELATED SUBSTANCES ACT, (ACT NO. 101 OF 1965)
(ANNUAL SINGLE EXIT PRICE ADJUSTMENT (SEPA) OF MEDICINES AND SCHEDULED
SUBSTANCES FOR THE YEAR 2020)

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% (South African CPI) + 30% (foreign exchange rate) = % 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.

The Pricing Committee (PC) notes stakeholder feedback relating to the consistency and timeliness of the approach for calculation of the annual SEPA, challenges relating to fluctuations in the SEPA quantum from year to year, and differing stakeholder views on the relative weights on the CPI and exchange-rate parameters to be applied.

Therefore, the PC is considering a review for the methodology to calculate the SEPA that will be applied consistently for the years **2020**, **2021**, and **2022** in line with its legislated mandate under the following fields: Time period, Parameter Weighting, Sources of Parameter and Differentiation of SEPA. In addition, the PC is seeking comment on potential quantitative approaches and relevant research relating to the consideration of availability, affordability and quality of medicines and scheduled substances in South Africa when calculating the SEPA.

In terms of Time Period:

Option 1: Parameter values drawn from the previous 12 months, using a mean value over the months July-June in the year preceding the year that the SEPA is to be applied. For example, parameter values used to calculate the SEPA in 2020 would be drawn from the period July 2018 to June 2019.

Option 2: Parameter values drawn the previous 36 months, using a mean value over the months July-June in the years preceding the year that the SEPA is to be applied. For example, parameter values used to calculate the SEPA in 2020 would be drawn from the period July 2016 to June 2019.

Option 3: Parameter values drawn the previous 6 months, using a mean value over the months January-June in the year preceding the year that the SEPA is to be applied. For example, parameter values used to calculate the SEPA in 2020 would be drawn from the period January 2019 to June 2019.

In terms of calculation for Parameter Weighting:

Option 1: Formula: 70% (CPI) + 15% (USD:ZAR exchange rate) + 15% (EURO:ZAR exchange rate) = % SEP Adjustment

Option 2: Formula: 70% (CPI) + 10% (USD:ZAR exchange rate) + 10% (EURO:ZAR exchange rate) + 10% (INR:ZAR exchange rate) = % SEP Adjustment

Option 3: Formula: 60% (CPI) + 10% (USD:ZAR exchange rate) + 10% (EURO:ZAR exchange rate) + 10% (INR:ZAR exchange rate) + 10% (CNY:ZAR exchange rate) = % SEP Adjustment

Option 4: Formula: 80% (CPI) + 10% (USD:ZAR exchange rate) + 10% (EURO:ZAR exchange rate) = % SEP Adjustment

Option 5: Formula: 100% (CPI) = % SEP Adjustment

In terms of Source of Parameter:

It is proposed that values for the Consumer Price Index is drawn from Statistics South Africa [www.statssa.gov.za] and values for exchange rates are drawn from South African Reserve Bank [www.resbank.co.za]. Alternative sources for parameter values are invited.

In terms of Differentiation of SEPA:

The PC acknowledges that the impact of CPI and exchange rates have differing effects on the pricing structure for different types of medicine in South Africa. The PC is seeking stakeholder feedback on Differentiated SEPA Application in line with the following options:

Option 1: Differentiation by proportion of local manufacture. For example, a SEPA formula that contains a greater weight for CPI could be applied to medicines that have a larger proportion of the costs of production within South Africa.

Option 2: Differentiation by proprietary status. For example, the SEPA formula as applied to proprietary medicines could have further parameter(s) to reflect the differences in market dynamics between proprietary medicines and generic medicines.

Option 3: Differentiation by classification of "high-cost". For example, the SEPA formula as applied to medicines classified as "high cost" (as determined by a stated Average Daily Cost or similar) may have further parameter(s) to reflect the differences in affordability between high cost and other medicines in South Africa.

Consideration of Affordability:

The PC invites proposals for how the SEPA formula can quantitatively incorporate considerations of affordability. In addition, the PC invites relevant research related to affordability of medicines in South Africa, including but not limited to prices of proprietary and generic medicines relative to international averages and the impact of SEPA on out of pocket expenditure and medicine utilization.

Alternative configurations of the calculation for weighting of parameter values are also welcome.

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)

Room0419 South Tower

Civitas Building

Corner Thabo Sehume & Struben Streets

PRETORIA, 0001

For any further enquires please contact the Directorate: Pharmaceutical Economic Evaluations:
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Dr A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 12/2/2019