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GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH

NO. 750 20 August 2021

MEDICINES AND RELATED SUBSTANCES ACT, (ACT NO. 101 OF 1965)

(ANNUAL SINGLE EXIT PRICE ADJUSTMENT (SEPA) OF MEDICINES AND SCHEDULED SUBSTANCES FOR THE YEAR 2022)

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.

Based on the comments received from previous annual reviews on the adjustment methodology, stakeholders have recommended a CPI weighting and a foreign exchange weighting in the review of the annual SEP adjustment expressed as follows:

- (a) 70% (South African CPI) + 30% (foreign exchange rate) = % adjustment Or
- (b) 50% (South African CPI) + 50% (foreign exchange rate) = % adjustment Or
- (c) 100%_Foreign exchange rate = % adjustment Or
- (d) 100% South African CPI = % adjustment.

The Pricing Committee in its recommendation for the next annual adjustment cycle may consider the weighting(s) *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.

Individual companies may be required to provide profit margins for each line item in their product portfolio. The exchange rate for each company's weightings may be considered from import and export information obtained from the Department of Trade and Industry.

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: Ms Ntobeko M. Mpanza e-mail: Ntobeko.Mpanza@health.gov.za

Director (Pharmaceutical Economic Evaluations Directorate)

Room 2611 South Tower

Civitas Building

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PRETORIA, 0001

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 ZL MKHIZE, MP

MINISTER OF HEALTH

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