

DEPARTMENT OF HEALTH

NO. 1480

29 DECEMBER 2017

MEDICINES AND RELATED SUBSTANCES ACT, (ACT NO. 101 OF 1965, AS AMENDED)**ANNUAL ADJUSTMENT OF THE SINGLE EXIT PRICE OF MEDICINES AND SCHEDULED SUBSTANCES [SEPA] FOR THE YEAR 2018**

I, DR A MOTSOALEDI, the Minister of Health, have determined on recommendation of the Pricing Committee, in terms of Regulation 8(1) of the Regulations relating to a Transparent Pricing System for Medicines and Scheduled Substances published in terms of the Medicines and Related Substances Act, (Act 101 of 1965), that the Single Exit Price (SEP) of Medicines and Scheduled Substances may only be submitted for the first time in 2018 from 02nd January 2018 and by no later than 19th February 2018 to a maximum of 1.26% of the SEP of medicines and their related pack sizes that was available as at 22nd December 2017; regardless of how that SEP was arrived at for the 2018 cycle. The final date for resubmissions will be 01st March 2018.

All medicines and their related pack sizes with SEP approved with an effective date no later than 22nd December 2017 are not eligible for SEPA 2018. An applicant may only submit once in the 2018 cycle unless a resubmission is made for not approved medicines.

An adjustment in the Single Exit Price in terms of this Notice may only be implemented by the manufacturer or importer of the relevant medicine or scheduled substance, no later than 32 working days after the date that the manufacturer or importer has communicated the information requested by the Director-General in terms of the Notice published in terms of Regulation 21 of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled substances.



DR A MOTSOALEDI, MP

MINISTER OF HEALTH

DATE: 14/12/2017