

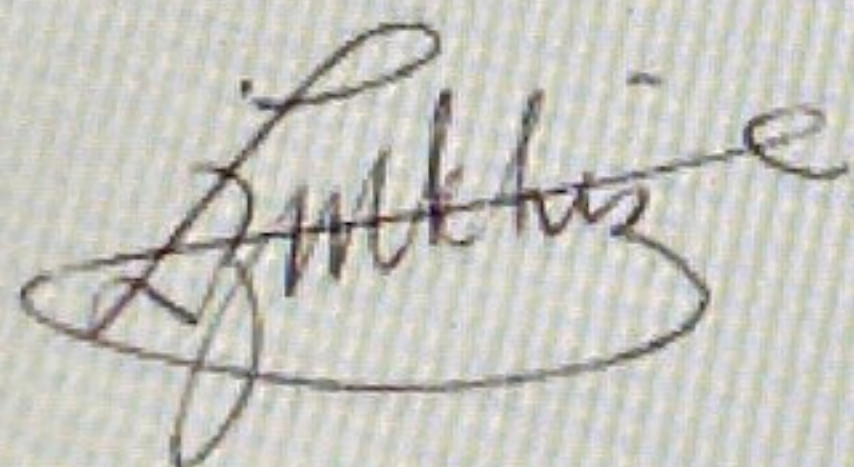
**MEDICINES AND RELATED SUBSTANCES ACT, (ACT NO. 101 OF 1965)**

**ANNUAL SINGLE EXIT PRICE ADJUSTMENT [SEPA] OF MEDICINES AND SCHEDULED SUBSTANCES FOR THE YEAR 2021**

I, DR ZL MKHIZE, the Minister of Health, has 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 be adjusted to a maximum of 3.68% of the SEP of medicines and their related pack sizes that was available as at 21<sup>st</sup> December 2020 regardless of how that SEP was arrived at for the 2020 cycle. Applications for adjustments of the SEP may only be submitted for the first time in 2021 from 11<sup>th</sup> January 2021 and by no later than 22<sup>nd</sup> February 2021.

All medicines and their related pack sizes with SEP approved with an effective date later than 21<sup>st</sup> December 2020 are not eligible for SEPA 2021. An applicant may only submit once in the 2021 cycle unless a resubmission is made for eligible medicines that have not been previously approved for an adjustment in 2021 period in which an application was made. The final date for resubmissions will be 08<sup>th</sup> March 2021.

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 ZL MKHIZE, MP**

**MINISTER OF HEALTH**