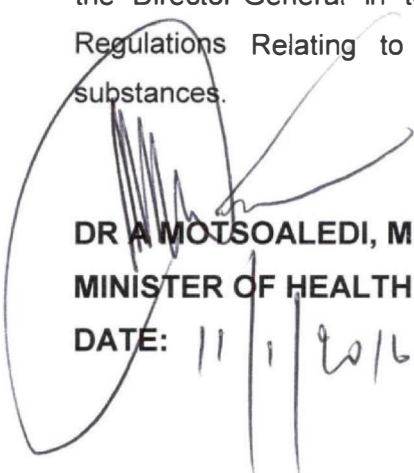

GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH**NO. 24****13 JANUARY 2016****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 2016)**

I, DR A MOTSOLEDI, 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 2016 from 11 January 2016 and by no later than 11 March 2016 to a maximum of **4.80 %** of the Single Exit Price that was available as at 22 December 2015; regardless of how that SEP was arrived at for the 2016 cycle. The final date for resubmissions will be 28 April 2016.

All medicines and their related pack sizes approved with an effective date after 22 December 2015 are not eligible for SEPA 2016. An applicant may only submit once in the 2016 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, 30 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 MOTSOLEDI, MP
MINISTER OF HEALTH

DATE: 11/1/2016