

## DEPARTMENT OF HEALTH

NO. 5361

4 October 2024

**MEDICINES AND RELATED SUBSTANCES ACT, 1965****EXCLUSION OF MEDICINES FROM THE APPLICATION OF CERTAIN PROVISIONS OF REGULATION 12 OF THE GENERAL REGULATIONS MADE IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES ACT, (ACT 101 OF 1965)**

The Minister of Health, in terms of section 36(1) of the Medicines and Related Substances Act, 1965 (Act No.101 of 1965) (the Act), and on the recommendation of the South African Health Products Regulatory Authority, hereby excludes medicines from the application of certain provisions of regulation 12(2) of the General Regulations made in terms of the Act, in that all medicines are excluded with respect only to the requirement that the patient information leaflet required in terms of regulation 12(1), also be in one other official language in addition to English: Provided that—

- (a) when the patient information leaflet accompanying the medicine contains the required information only in English, such information must be provided in an electronic format in any one of the other official languages; and
- (b) the manner in which such information in another language may be accessed is indicated on the patient information leaflet supplied with the medicine.

This exclusion shall be effective from the date it is published in the *Gazette* until regulation 12 is amended, or until otherwise communicated by means of a notice in the *Gazette*.



DR PAKISHE AARON MOTSOLEDI, MP  
MINISTER OF HEALTH

DATE: 21/10/2024