DEPARTMENT OF HEALTH

NO. 5180 **6 September 2024**

MEDICINES AND RELATED SUBSTANCES ACT, 1965

GENERAL REGULATIONS MADE IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965): AMENDMENT

The Minister of Health hereby, in terms of section 35 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, makes regulations in the Schedule.

Interested persons are invited to submit any substantiated comments or representations on the proposed regulations to the Director-General of Health, Private Bag X828, Pretoria, 0001 (for attention of the Director: Public Entities Governance; mihloti.mushwana@health.gov.za and paul.tsebe@health.gov.za), within three months of publication of this Notice.

DR PAKISHE AARON MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 15/8/2024

SCHEDULES

Definitions

1. In these regulations, any word or expression to which a meaning has been assigned in the Act shall have the meaning so assigned, unless the context indicates otherwise: -
"Regulations" means the General Regulations as published under Government Notice 859 in Government Gazette 41064 of 25 August 2017; and
"the Act" means the Medicines and Related Substances Act, 1965 (Act 101 of 1965).

Amendment of Regulation 12(2) of the regulations

2. Regulation 12 of the Regulation is hereby amended by the substitution for subregulation (2) for the following:

"(2) The patient information leaflet shall contain the following information with regard to the medicine in at least English ***[only and one other official language]***—

Amendment of regulation 12(3) of the regulations

3. Regulation 12 of the Regulations is hereby amended by substitution for subregulation (3) the following:

"(3) Information contemplated in subregulation (2) **[may]** shall also be provided in electronic format accessible in any of the other official languages and in any other format to enable its accessibility for persons living with disabilities.".

Short Title

4. These Regulations are called the General Regulations made in terms of section 35 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965): Amendment, 2024.