DEPARTMENT OF HEALTH

NO. 6465 **1 August 2025**

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

GENERAL REGULATIONS MADE IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965): AMENDMENT

The Minister of Health intends to make, in terms of section 35 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), and in consultation with the South African Health Products Regulatory Authority (SAHPRA), amendments to the 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 month of the date of publication of this notice.

DR PA MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 26/6/2025

SCHEDULE

Definitions

1. In these regulations — any expression to which a meaning has been assigned in the Act, shall bear such meaning, unless the context indicates otherwise

"the Act" means the Medicines and Related Substances Act, 1965 (Act 101 of 1965); and

"the Regulations" means the General Regulations as published under Government Notice 859 in *Government Gazette* 41064 of 25 August 2017.

Amendment of regulation 1

2. Regulation 1 is hereby amended —

(*a*) by the deletion of the definition of "counterfeit medicine";

(*b*) by the insertion after the definition of "Site Master File" of the following definition:

" "substandard medicine" means a medicine that fails to meet either its quality standards or specifications or both."

(*c*) by the insertion after the definition of "expiry date" of the following definition:

" "falsified medicine" means a medicine for which the identity, composition or source is deliberately or fraudulently misrepresented";

Amendment of regulation 6

3. Regulation 6 is hereby amended —

(*a*) by the substitution in sub-regulation (1) of the following paragraph:

"(1) No person shall import any medicine or scheduled substance, including medicines imported in terms of section 15C of the Act, into the Republic except through one of the following ports of entry, in a manner as determined by the Authority:

(*a*) Cape Town International Airport or Cape Town harbour;

(*b*) Chief Dawid Stuurman International Airport, Port Elizabeth harbour or Ngqura harbour;

(*c*) King Shaka International Airport or Durban harbour; or

(*d*) O.R. Tambo International Airport." and

(*b*) by the insertion after sub-regulation (1) of sub-regulation (1a):

"(1a) Despite sub-regulation (1), a person may import any medicine or scheduled substance in a manner as determined by the Authority through:

(a) Beit Bridge border post (Zimbabwe border);

(b) Vioolsdrift border post (Namibia border);

(c) Kopfontein border post (Botswana border);

(d) Maseru Bridge border post (Lesotho border);

(e) Lebombo border post (Mozambique border);

(f) Oshoek border post (Eswatini border),

provided that the Authority is notified of and approves the intended importation."

Amendment of Regulation 51

4. Regulation 51 is hereby amended —

(a) by the substitution in sub-regulation (1) for paragraph (b) of the following:

"(*b*) is suspected of being falsified";

Short Title

5. The Regulations are called General Regulations made in terms of section 35 of the Medicines and Related Substances Act, Amendment, 2025.