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DEPARTMENT OF HEALTH

NO. 6464 **1 August 2025**

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 intends, in terms of section 35 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) (the Act), and on the recommendation of the South African Health Products Regulatory Authority, to make 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 the attention of the Director: Public Entities and Relations Management, mihloti.mushwana@health.gov.za and paul.tsebe@health.gov.za), within three months of the date of publication of this Notice.

DR PAKISHE AARON MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 28/6/2025

SCHEDULE

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:-

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

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

Amendment of Regulation 40 of the General Regulations

2. Regulation 40 of the Regulations is hereby amended by the substitution for the following: -

"Vigilance

40. (1) A holder of a certificate of registration in respect of a medicine or Scheduled substance, in terms of section 15 of the Act, must –

(a) establish and maintain a Pharmacovigilance System Master File and accompanying quality system, in accordance with the guidelines stipulated by the Authority;

(b) appoint a qualified person responsible for pharmacovigilance; and

(c) comply with the requirements, as set out in guidelines issued by the Authority, for the submission of risk management plans, periodic safety update reports and periodic benefit-risk evaluation reports;

(d) submit to pharmacovigilance inspection of such systems, on a routine or *ad hoc* basis;

(f) ensure that appropriate and timely corrective and preventive action plans are implemented to address findings observed during an

inspection, with appropriate prioritization of critical and/or major findings; and

(g) conduct post-authorisation safety and efficacy studies were deemed necessary.

(2) Any person referred to in sub-regulation (1) must, whenever requested by the Authority–

(a) conduct a concise critical analysis of the safety, quality or effectiveness of a medicine or Scheduled substance;

(b) submit the results thereof to the Authority within a specified time frame;

(c) in the case where, after receipt of the results referred to in paragraph (a), the Authority determines that the medicine or Scheduled substance may not be safe to use, submit to the Authority, if required to do so-

(i) case reports of all adverse events or suspected or actual adverse drug reactions in respect of the medicine or Scheduled substance;

(ii) where applicable, details of the volumes of such medicines or Scheduled substance sold; and

(iii) any other data as requested by the Authority.

(3) Notwithstanding the requirements of sub-regulations (1) and (2), a holder of a certificate of registration must –

(a) keep and maintain or have access to records of the adverse event data in respect of the medicines or Scheduled substances for which it holds a certificate of registration;

(b) inform the Authority, in the manner and within the time frame as determined by the Authority, of any -

(i) new or existing quality, safety or effectiveness concerns related to any medicine or scheduled substance, including but not limited to adverse drug reactions; and

(ii) risk management activities associated with that medicine.

(4) A health care provider, veterinarian or any other person should inform the Authority, in the manner as determined by the Authority, of any-

(a) suspected adverse drug reactions; or

(b) new or existing safety, quality, or effectiveness concerns, occurring as a result of the use of any medicine or scheduled substance.

(5) Sub-regulations (1), (2) (3) and (4) also apply in the case of all categories of unregistered medicines sold or used which are not subject to registration or in terms of sections 14(3), 14(4), 15C, 21 and 36 of the Act.

(6) Nothing in this regulation shall be interpreted as prohibiting any person from reporting any adverse drug reaction, safety, quality or effectiveness concern related to any medicine or Scheduled substance to the Authority.

Title

3. These Regulations are called the General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965); Amendment, 2025.