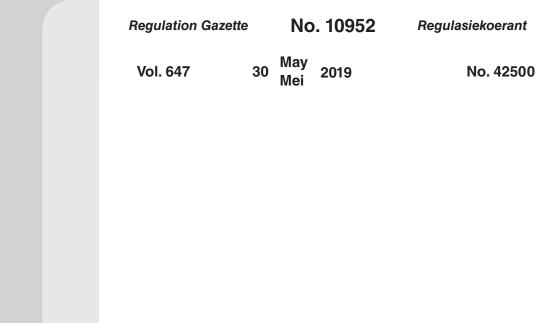


Government Gazette Staatskoerant REPUBLIC OF SOUTH AFRICA REPUBLIEK VAN SUID AFRIKA



N.B. The Government Printing Works will not be held responsible for the quality of "Hard Copies" or "Electronic Files" submitted for publication purposes



AIDS HELPLINE: 0800-0123-22 Prevention is the cure

This gazette is also available free online at www.gpwonline.co.za

IMPORTANT NOTICE:

THE GOVERNMENT PRINTING WORKS WILL NOT BE HELD RESPONSIBLE FOR ANY ERRORS THAT MIGHT OCCUR DUE TO THE SUBMISSION OF INCOMPLETE / INCORRECT / ILLEGIBLE COPY.

NO FUTURE QUERIES WILL BE HANDLED IN CONNECTION WITH THE ABOVE.

Contents

No.		Gazette No.	Page No.
	Government Notices • Goewermentskennisgewings		

Health, Department of/ Gesondheid, Departement van

R. 846 Medicines and Related Substances Act (101/1965): General regulations made in terms of the Act: Amendment... 42500 4

GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH

NO. R. 846

30 MAY 2019

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, 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), 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 Governance, <u>mibloti.nushwana@health.gov.za</u>), within three months of the date of publication of this Notice.

DR AARON MOTSOALEDI MINISTER OF HEALTH DATE: 11 3 815

SCHEDULE

Definitions

1. In these regulations-

"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 10 of the Regulations

- **2.** Regulation 10 of the Regulations is hereby amended by the substitution for subparagraph (1)(cc)(iv) of the following sub-paragraph:
 - "(iv) containing at least 5 percent of <u>genetically</u> modified organisms the following warning "contains genetically modified organisms"."

Amendment of Regulation 11 of the Regulations

- **3.** Regulation 11 of the Regulations is hereby amended by the substitution for paragraph (1)(d) of the following paragraph:
 - "(d) **[under the headings and]** shall contain the particulars specified in subregulation (2) <u>under the headings as determined by the Authority</u>."

Amendment of Annexure 1 of the regulations

4. Annexure 1 of the Regulations is hereby amended by the substitution for Class 33.3 of the following Class:

"33.3 [Phytotherapy] Ayurveda"

Amendment of Annexure 2 of the regulations

5. Annexure 2 of the Regulations is hereby amended by the substitution for Class 28.3 of the following Class:

"28.3 [Phytotherapy] Ayurveda"

Title

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

This gazette is also available free online at www.gpwonline.co.za

Printed by and obtainable from the Government Printer, Bosman Street, Private Bag X85, Pretoria, 0001 Contact Centre Tel: 012-748 6200. eMail: info.egazette@gpw.gov.za Publications: Tel: (012) 748 6053, 748 6061, 748 6065