

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, mihloti.mushwana@health.gov.za), within three months of the date of publication of this Notice.



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DR AARON MOTSOLEDI

MINISTER OF HEALTH

DATE:

11/3/2019

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 genetically 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 sub-regulation (2) under the headings as determined by the Authority."

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

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