

GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH**NO. R. 3343****28 April 2023****MEDICINES AND RELATED SUBSTANCES ACT, 1965****GENERAL REGULATIONS MADE IN TERMS OF THE MEDICINES AND RELATED
SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965) AMENDMENT, 2023**

The Minister of Health has, 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, made regulations in the Schedule.



DR M.J. PHAAHLA, MP
MINISTER OF HEALTH
DATE: 16/03/2023

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 sub-paragraph (1)(cc) (iv) of the following sub-paragraph: -

**"(iv) containing at least 5 percent of the 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 of 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"

Short Title

6. These Regulations are called the General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965); Amendment 2023.