DEPARTMENT OF HEALTH

NO. 748 **28 JULY 2017**

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

The Minister of Health has, in terms of section 22A(2) of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), on the recommendation of the Medicines Control Council, made and updated the Schedules in the Schedule.

This Schedule amends the Schedules as inserted by Government Notice R.509 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 24727, 10 April 2003; substituted by Government Notice R.935 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 31387, 5 September 2008; and amended by Government Notice R.1230 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 32838, 31 December 2009; Government Notice R.227 (Medicines and Related Substances Act: Schedules)in Government *Gazette* 35149, 15 March 2012; Government Notice R.674 (Medicines and Related Substances Act, 1965: Schedules) in Government Gazette 36827, 13 September 2013, Government Notice R.690 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 36850, 20 September 2013,Government Notice R.104 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 37318, 11 February 2014; Government Notice R.352 (Medicines and Related Substances Act, 1965: Schedules) in, Government *Gazette* 37622, 8 May 2014; Government Notice R.234 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 38586, 20 March 2015; Government Notice R.254 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 39815, 15 March 2016; and Government Notice R.254 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 40041, 03 June 2016 using the following convention:

- Words in bold and in square brackets (e.g. **[Gamma benzene hexachloride]** in Schedule 1), indicate omission from a Schedule

- Words underlined with a solid line (e.g. Gamma benzene hexachloride), indicate insertions in a Schedule.

SCHEDULE

In these Schedules, "the Act" means the Medicines and Related Substances Act, 1965 (Act No.101 of 1965)

Note: Where an alternative schedule(s) is included in natural parentheses at any point of an inscription, this is provided to indicate one or more alternative scheduling designation/s. This is for information only and shall not be used in the interpretation of such inscription.

SCHEDULE 1

a. All substances referred to in this Schedule are excluded when specifically packed, labelled, sold and used for –
   (i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and
   (ii) analytical laboratory purposes.

b. All preparations of substances or mixtures of such substances containing or purporting to contain any substance referred to in this Schedule and includes the following:
   (i) The salts and esters of such substances, where the existence of such salts and esters is possible; and
   (ii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.

c. In terms of section 22A(4)*(a)*(v) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act No. 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care, the Schedule 1 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.

(i)	Annexure 1A:	Emergency Care Provider (Paramedic);
(ii)	Annexure 1B:	Emergency Care Provider (Emergency Care Practitioner);
(iii)	Annexure 2:	Dental Therapist;
(iv)	Annexure 3:	Optometrist.

Acetylcysteine,

a. when used as a mucolytic in acute respiratory conditions for a maximum treatment period of 5 days;

b. except when intended for injection or for the management of paracetamol overdosage. (S3)

Bifidobacterium adolescentis,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);

b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

c. [except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.]

Bifidobacterium animalis *subsp*. Animalis,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);

b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

c. [except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.]

Bifidobacterium animalis *subsp*. Lactis,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);

Schedule 1

b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

c. **[except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.]**

Bifidobacterium bifidum,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);

b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

c. **[except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.]**

Bifidobacterium breve,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);

b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

c. **[except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.]**

Bifidobacterium lactis,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);

b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

c. **[except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.]**

Bifidobacterium longum *subsp.* Infantis,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);

b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

c. **[except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.]**

Bifidobacterium longum *subsp.* Longum,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);

b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

c. **[except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.]**

Chromium, in oral preparations or mixtures containing more than 200 **[50]** µg of Chromium per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S0)

Ciclopirox.

Diclofenac,

a. when intended for application to the skin and containing more than 1 % m/m of diclofenac; (S3)

Schedule 1

b. except when intended for application to the skin and containing 1 % m/m or less of diclofenac subject to a maximum pack size of 50 grams; (S0)

c. except when intended for the emergency treatment of acute gout attacks, subject to a maximum daily dose of 150 mg for a maximum treatment period of 3 days; (S2)

d. except when intended for the treatment of fever or mild to moderate pain of inflammatory origin, subject to a maximum daily dose of 75 mg for a maximum treatment period of 5 days.(S2)

Ephedra alkaloids (natural or synthetic), **[unless listed separately in the Schedules],**

a. when intended for application to skin, eyes, ears and nares and containing 1 percent or less of ephedra alkaloids, and not intended for export; (S6)

b. except oral preparations and mixtures, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedrine per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of 360 milligrams and limited to one pack per customer. (S2)

Ephedrine,

a. preparations and mixtures intended for application to the skin, eyes, ears and nares and containing 1 percent or less of ephedrine, and not intended for export; (S6)

b. except products registered in terms of the Act, not intended for export, and being oral preparations and mixtures, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedrine per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of 360 milligrams and limited to one pack per customer. (S2)

Iodine,

a. in oral preparations or mixtures containing more than 150 µg of Selenium per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S0)

Lactobacillus acidophilus,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);

b. except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

c. **[except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972)**

containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.]

Lactobacillus brevis,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);

b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

c. [except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.]

Lactobacillus caucasicus,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);

b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

c. [except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.]

Lactobacillus casei,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);

b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

c. [except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.]

Schedule 1

Lactobacillus fermentum,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);
b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

c. [except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.]

Lactobacillus gasseri,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);
b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

c. [except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.]

Lactobacillus helveticus,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);
b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

c. [except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.]

Lactobacillus johnsonii,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);

b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

c. [except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.]

[Lactobacillus] Lactococcus lactis,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);

b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

c. [except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.]

Lactobacillus paracasei,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);

b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

c. [except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.]

Lactobacillus plantarum,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);

b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

Schedule 1

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

c. **[except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.]**

Lactobacillus reuteri,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);

b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

c. **[except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.]**

Lactobacillus rhamnosus,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);

b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

c. **[except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.]**

Lactobacillus salivarius,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);

b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

c. **[except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.]**

Methionine,

a. in oral preparations containing more than the maximum daily dose of 210 mg of methionine alone or in combination with other active pharmaceutical ingredients.(S0)

Racecadotril.

Selenium,

a. in oral preparations or mixtures containing more than 200 **[60]** µg of Selenium per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)

b. except in preparations thereof for injection when intended for veterinary use. (S4)

p-Synephrine,

a. *oral preparations and mixtures registered in terms of the Act and intended for the symptomatic relief of nasal and sinus congestion, where the recommended daily dose for adults is 50 milligrams or less and for children 6 to 12 years is 25 milligrams or less, with a maximum pack size of 5 days; (S6)*

b. *except preparations and mixtures registered in terms of the Act and intended for application to the skin, ears and nares containing 1 percent or less of p-synephrine and containing 0.2 percent or less for application to the eyes; (S0)*

c. *except oral preparations and mixtures registered in terms of the Act and intended for the symptomatic relief of nasal and sinus congestion, where the recommended daily dose for adults is more than 50 milligrams and for children 6 to 12 years is more than 25 milligrams. (S2)*

5-Hydroxy Tryptophan,

a. in oral preparations with a maximum daily dose not exceeding 220 mg of L-tryptophan, alone or in combination with other active pharmaceutical ingredients; (S5) **[when intended for medicinal use in dosages of less than 5 milligrams/kg/day or]**

b. except in oral preparation with a maximum daily dose not exceeding 220 mg of L-tryptophan alone or in combination with other active pharmaceutical ingredients, with general health claims as a health supplement. (S0) **[intended as supplementation for nutritional purposes]**.

L-tryptophan,

Schedule 1

a. in oral preparations with a maximum daily dose not exceeding 220 mg of L-tryptophan, alone or in combination with other active pharmaceutical ingredients; (S5) **[when intended for medicinal use in dosages of less than 5 milligrams/kg/day or]**

b. except in oral preparation with a maximum daily dose not exceeding 220 mg of L-tryptophan alone or in combination with other active pharmaceutical ingredients, with general health claims as a health supplement. (S0) **[intended as supplementation for nutritional purposes]**.

Vanadium,

a. in oral preparations or mixtures containing more than 182 µg of Selenium per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S0)

ANNEXURE 3: OPTOMETRIST

OPTOMETRIST (Bachelors degree in Optometry – B OPTOM) registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974) and in possession of a Section 22A(15) permit as provided for by the Medicines and Related Substances Act, 1965 (Act 101 of 1965)

- END SCHEDULE 1 -

SCHEDULE 2

a. All substances referred to in this Schedule are excluded when specifically packed, labeled, sold and used for –

(i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and

(ii) analytical laboratory purposes.

b. All preparations of substances or mixtures of such substances containing or purporting to contain any substance referred to in this Schedule and includes the following:

(i) The salts and esters of such substances, where the existence of such salts and esters is possible; and

(ii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.

c. In terms of section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within their scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care, the Schedule 2 substances and medicines provided for in the Annexures to this Schedule published in the Gazette in terms of the Act.

(i) Annexure 1A: Emergency Care Provider (Paramedic);

(ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner);

(iii) Annexure 2: Dental Therapist;

(iv) Annexure 3: Optometrist.

[Acetylcysteine, except when intended for injection or for the management of paracetamol overdosage. (S3)]

Alcaftadine.

Diclofenac,

a. when intended for the emergency treatment of acute gout attacks, subject to a maximum daily dose of 150 mg for a maximum treatment period of 3 days; (S3)

b. when intended for the treatment of **[post traumatic conditions]** fever or mild to moderate pain of inflammatory origin, subject to a maximum daily dose of 75 mg for a maximum treatment period of 5 days;

c. except when intended for application to the skin and containing 1 % m/m or less of diclofenac subject to a maximum pack size of 50 grams; (S0)

d. except when intended for application to the skin and containing more than 1 % m/m of diclofenac. (S1)

Doxycycline,

a. when intended and labelled for the chemoprophylaxis of malaria in those aged 8 years and older, for periods not exceeding 4 months of continuous use. (S4)

b. **[except in preparations thereof for the treatment of animals and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947), excluding when intended for administration in animal feed.]**

Ephedra alkaloids (natural or synthetic), contained in products registered in terms of the Act, and not intended for export, unless listed separately in the Schedules,

a. oral preparations and mixtures, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedra alkaloids per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of **[720]** 360 milligrams and limited to one pack per customer; (S6)

b. except when intended for application to skin, eyes, ears and nares and containing 1 percent or less of ephedra alkaloids. (S1)

Ephedrine, contained in products registered in terms of the Act, and not intended for export,

a. oral preparations and mixtures, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedrine per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of **[720]** 360 milligrams and limited to one pack per customer; (S6)

b. except preparations and mixtures intended for application to the skin, eyes, ears and nares and containing 1 percent or less of ephedrine. (S1)

Insulin glargine.

Levodropropizine.

Phenylpropanolamine (norephedrine), contained in products registered in terms of the Act, and not intended for export, unless listed separately in the Schedules,

Schedule 2

a. oral preparations and mixtures where the recommended daily dose for adults does not exceed 100 milligrams and for children 6 to 12 years does not exceed 50 milligrams, when in combination with another pharmacologically active substance and intended for the symptomatic relief of nasal and sinus congestion, subject to a maximum pack size of 300 milligrams for adults and 150 milligrams for children, limited to one pack per customer. (S6)

Potassium,

a. in oral preparations or mixtures containing more than 20 millimoles (1500mg) of potassium per 24 hours; **[(S0)]**

b. except when intended for intravenous infusion or for injection; (S3)

c. except when contained in oral rehydration preparations. (S0)

Pseudoephedrine, contained in products registered in terms of the Act, and not intended for export,

a. Immediate-release oral preparations and mixtures containing not more than 60 milligrams of pseudoephedrine per dose or controlled-release oral preparations and mixtures containing not more than 120 milligrams of pseudoephedrine per dose, and not more than 240 milligrams per day, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer. (S6)

p-Synephrine,

a. oral preparations and mixtures registered in terms of the Act and intended for the symptomatic relief of nasal and sinus congestion, where the recommended daily dose for adults is more than 50 milligrams and for children 6 to 12 years is more than 25 milligrams; (S6)

b. except preparations and mixtures registered in terms of the Act and intended for application to the skin, ears and nares containing 1 percent or less of p-synephrine and containing 0,2 percent or less for application to the eyes; (S0)

c. except oral preparations and mixtures registered in terms of the Act and intended for the symptomatic relief of nasal and sinus congestion, where the recommended daily dose for adults is 50 milligrams or less and for children 6 to 12 years is 25 milligrams or less, with a maximum pack size of 5 days. (S1)

Schedule 2

ANNEXURE 3: OPTOMETRIST

OPTOMETRIST (Bachelors degree in Optometry – B OPTOM) registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974) and in possession of a Section 22A(15) permit as provided for by the Medicines and Related Substances Act, 1965 (Act 101 of 1965)

- END SCHEDULE 2 -

SCHEDULE 3

a. All substances referred to in this Schedule are excluded when specifically packed, labelled, sold and used for –

(i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and

(ii) analytical laboratory purposes.

b. All preparations of substances or mixtures of such substances containing or purporting to contain any substance referred to in this Schedule and includes the following:

(i) The salts and esters of such substances, where the existence of such salts and esters is possible; and

(ii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.

c. In terms of section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care, the Schedule 3 substances and medicines provided for in the Annexures to this Schedule published in the Gazette in terms of the Act.

(i) Annexure 1A: Emergency Care Provider (Paramedic);

(ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner);

(iii) Annexure 2: Dental Therapist;

(iv) Annexure 3: Optometrist.

Acetylcysteine,

a. when intended for injection or for the management of paracetamol overdosage;

b. except when used as a mucolytic in acute respiratory conditions for a maximum treatment period of 5 days. (S1)

Diclofenac,

a. except when intended for application to the skin and containing 1 % m/m or less of diclofenac subject to a maximum pack size of 50 grams; (S0) **[and]**

b. except when intended for application to the skin and containing more than 1 % m/m of diclofenac; (S1)

c. except when intended for the emergency treatment of acute gout attacks, subject to a maximum daily dose of 150 mg for a maximum treatment period of 3 days; (S2)

d. except when intended for the treatment of **[post traumatic conditions]** fever or mild to moderate pain of inflammatory origin, subject to a maximum daily dose of 75 mg for a maximum treatment period of 5 days.(S2)

Alogliptin.

Digitalis, its glycosides and other active principles thereof, unless diluted below one unit (BP) in each 2,0 grams.(S0)

Meloxicam, except when intended for veterinary use. (S4)

Potassium **[chloride]**,

a. when intended for intravenous infusion or for injection;
b. except when contained in oral rehydration preparations; (S0)
c. except in oral preparations or mixtures containing more than 20 millimoles (1500mg) of potassium per 24 hours. (S2)

Protamine.

Sacubitril.

[Silymarin]

Schedule 3

ANNEXURE 3: OPTOMETRIST

OPTOMETRIST (Bachelors degree in Optometry – B OPTOM) registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974) and in possession of a Section 22A(15) permit as provided for by the Medicines and Related Substances Act, 1965 (Act 101 of 1965)

- END SCHEDULE 3 -

SCHEDULE 4

a. All substances referred to in this Schedule are excluded when specifically packed, labelled, sold and used for –

(i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and

(ii) analytical laboratory purposes.

b. All preparations of substances or mixtures of such substances containing or purporting to contain any substance referred to in this Schedule and includes the following:

(ii) The salts and esters of such substances, where the existence of such salts and esters is possible; and

(iii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.

c. In terms of section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care, the Schedule 4 substances and medicines provided for in the Annexures to this Schedule published in the Gazette in terms of the Act.

(i) Annexure 1A: Emergency Care Provider (Paramedic);

(ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner);

(iii) Annexure 2: Dental Therapist;

(iv) Annexure 3: Optometrist.

Alirocumab.

Axitinib.

Bazedoxifene

Bee venom, except preparations intended for application to the skin. (S1)

Carfilzomib.

Catridecacog.

Schedule 4

Chlortetracycline, except when listed elsewhere in the Schedules and except injections thereof intended for the treatment of animals **[anaplasmosis, footrot, heartwater, navel ill and pneumonia in sheep and cattle and capsules thereof intended for the use in pigeons and derivatives when intended for topical use in the management of wounds in animals]** and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Colistimethate.

Colistin,

a. when presented as a finished pharmaceutical product; and

b. except when compounded by a pharmacist in terms of Section 14(4) of the Act, by a veterinarian, or by a holder of a Section 22C(1)(a) licence, or presented as the raw material. (S6)

Dichlorophen, **[except]**

a. except in preparations and mixtures when intended for application to the skin; (S0)

b. except in preparations containing 0,5 percent or less of dichlorophen when intended for use in terms of the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972);

c. except when intended for use and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Deslorelin.

Doxycycline, except

a. when intended and labelled for the chemoprophylaxis of malaria in those aged 8 years and older, for periods not exceeding 4 months of continuous use; (S2)

b. in preparations thereof for the treatment of animals and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947). **[excluding when intended for administration in animal feed.]**

Evolocumab.

Fidaxomicin.

Ibrutinib.

Ingenol mebutate.

Ixekizumab.

Lipegfilgrastim.

Meloxicam, when intended for veterinary use. (S3)

Schedule 4

Mifamurtide.

Nivolumab.

Obinutuzumab.

Octogog alfa.

Olodaterol.

Orbifloxacin.

Oxytetracycline, except when listed elsewhere in the Schedules and except preparations thereof for the treatment of animals and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947) **[excluding when intended for administration in animal feed.]**

Pasireotide.

Pembrolizumab.

Pertuzumab.

Pirfenidone.

Rolitetracycline except when listed elsewhere in the Schedules and except injections thereof intended for the treatment of animals **[anaplasmosis, footrot, heartwater, navel ill and pneumonia in sheep and cattle]** and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Secukinumab.

Selenium **[salts]**,

a. in preparations thereof for injection when intended for veterinary use;
b. except in oral preparations or mixtures containing more than 200 µg of Selenium per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)

Semuloparin.

Tetracycline, except when listed elsewhere in the Schedules and except injections thereof intended for the treatment of animals **[anaplasmosis, footrot, heartwater, navel ill and pneumonia in sheep and cattle and derivatives when intended for topical use in the management of wounds in animals]** and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Trastuzumab emtansine.

Ustekinumab.

Schedule 4

ANNEXURE 3: OPTOMETRIST

OPTOMETRIST (Bachelors degree in Optometry – B OPTOM) registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974) and in possession of a Section 22A(15) permit as provided for by the Medicines and Related Substances Act, 1965 (Act 101 of 1965)

– END SCHEDULE 4 –

SCHEDULE 5 AND SPECIFIED SCHEDULE 5

a. All preparations or mixtures of such substances containing or purporting to contain substances that is chemically related and incorporates a structural fragment into its structure that is similar to the structure of a listed substance and /or exhibits pharmacodynamic properties similar to the listed substance referred to in this Schedule include the following:

   (i) The salts and esters of such substances, where the existence of such salts and esters is possible; and

   (ii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.

   (iii) all homologues of listed substances (being any chemically related substances that incorporate a structural fragment into their structures that is similar to the structure of a listed substance and/or exhibit pharmacodynamic properties similar to the listed substance in the schedules), unless listed separately in the Schedules.

b. In terms of Section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe and apply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care, the Schedule 5 and Specified Schedule 5 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.

   (i) Annexure 1A: Emergency Care Provider (Paramedic);

   (ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner).

c. Specified Schedule 5 substances listed in this schedule are subject to additional control in terms of section 22A of the Act as required under the provisions of the 1971 Convention on Psychotropic Substances and are denoted by **

5-Hydroxy Tryptophan,

a. except in oral preparations with a maximum daily dose not exceeding 220 mg of L-tryptophan, alone or in combination with other active pharmaceutical ingredients; (S1) **[when intended for medicinal use in dosages of less than 5 milligrams/kg/day or]**

Schedule 4

b. except in oral preparation with a maximum daily dose not exceeding 220 mg of L-tryptophan alone or in combination with other active pharmaceutical ingredients, with general health claims as a health supplement. (S0) **[intended as supplementation for nutritional purposes]**.

Phenazepam.

L-tryptophan,

a. except in oral preparations with a maximum daily dose not exceeding 220 mg of L-tryptophan, alone or in combination with other active pharmaceutical ingredients; (S1) **[when intended for medicinal use in dosages of less than 5 milligrams/kg/day or]**

b. except in oral preparation with a maximum daily dose not exceeding 220 mg of L-tryptophan alone or in combination with other active pharmaceutical ingredients, with general health claims as a health supplement;(S0) **[intended as supplementation for nutritional purposes]**.

SCHEDULE 6

a. All preparations or mixtures of such substances containing or purporting to contain substances that is chemically related and incorporates a structural fragment into its structure that is similar to the structure of a listed substance and /or exhibits pharmacodynamic properties similar to the listed substance referred to in this Schedule include the following (unless expressly excluded or unless listed in another Schedule):

(i) the isomers of such substances, where the existence of such isomers is possible within the chemical designation;

(ii) the esters and ethers of such substances and of the isomers referred to in (i) as well as the isomers of such esters and ethers, where the existence of isomers of such esters or ethers is possible;

(iii) the salts of such substances and of the isomers referred to in (i), as well as the salts of the esters, ethers and isomers referred to in (ii), where the existence of such salts is possible;

(iv) the isomers of any of the salts referred to in (iii), where the existence of such isomers is possible;

(v) all preparations and mixtures of any of the above.

(vi) all homologues of listed substances (being any chemically related substances that incorporate a structural fragment into their structures that is similar to the structure of a listed substance and/or exhibit pharmacodynamic properties similar to the listed substance in the schedules), unless listed separately in the Schedules.

b. In terms of Section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care, the Schedule 6 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.

(i) Annexure 1A: Emergency Care Provider (Paramedic);

(ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner).

Cannabidiol, when intended for therapeutic purposes.

Schedule 6

Coca leaf and any salt, compound, derivative or preparation of coca leaf and any salt, compound, derivative or preparation thereof that is chemically equivalent or identical to any of these substances, whether obtained directly or indirectly by extraction from material or substances obtained from plants, or obtained independently by chemical synthesis, or by a combination of extraction and chemical synthesis, except decocainized coca leaf and extractions of coca leaf where such extractions contain no cocaine or ecgonine (S0)

Colistin,

a. when compounded by a pharmacist in terms of Section 14(4) of the Act, by a veterinarian, or by a holder of a Section 22C(1)(a) licence, or presented as the raw material; and

b. except when presented as a finished pharmaceutical product. (S4)

Ephedra alkaloids (natural or synthetic), unless listed separately in the Schedules,

a. except products registered in terms of the Act, not intended for export, and being oral preparations and mixtures, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedra alkaloids per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of **[720]** 360 milligrams and limited to one pack per customer; (S2)

b. except when intended for application to skin, eyes, ears and nares and containing 1 percent or less of ephedra alkaloids. (S1)

Ephedrine,

a. except products registered in terms of the Act, not intended for export, and being oral preparations and mixtures, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedrine per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of **[720]** 360 milligrams and limited to one pack per customer; (S2)

b. except preparations and mixtures intended for application to the skin, eyes, ears and nares and containing 1 percent or less of ephedrine. (S1)

Phenylpropanolamine (norephedrine),

a. except products registered in terms of the Act, not intended for export and oral preparations and mixtures where the recommended daily dose for adults does not exceed 100 milligrams and for children 6 to 12 years does not exceed 50 milligrams, when in combination with another pharmacologically active substance and intended for the symptomatic relief of nasal and sinus congestion, subject to a maximum pack size of 300 milligrams for adults and 150 milligrams for children, limited to one pack per customer (S2)

Schedule 6

Pseudoephedrine, except contained in products registered in terms of the Act, and not intended for export, being oral preparations and mixtures containing not more than 60 milligrams or controlled-release oral preparations and mixtures containing not more than 120 milligrams of pseudoephedrine per dose, and not more than 240 milligrams per day, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer. (S2)

p-Synephrine,

a. *except preparations and mixtures registered in terms of the Act and intended for application to the skin, ears and nares containing 1 percent or less of p-synephrine and containing 0,2 percent or less for application to the eyes; (S0)*

b. *except oral preparations and mixtures registered in terms of the Act and intended for the symptomatic relief of nasal and sinus congestion, where the recommended daily dose for adults is 50 milligrams or less and for children 6 to 12 years is 25 milligrams or less, with a maximum pack size of 5 days; (S1)*

c. *except oral preparations and mixtures registered in terms of the Act and intended for the symptomatic relief of nasal and sinus congestion, where the recommended daily dose for adults is more than 50 milligrams and for children 6 to 12 years is more than 25 milligrams. (S2)*

– END SCHEDULE 6 –

SCHEDULE 7

All preparations or mixture of such substances containing or purporting to contain substances referred to in this Schedule include the following (unless expressly excluded or unless listed in another Schedule):

(i) the isomers of such substances, where the existence of such isomers is possible within the chemical designation;

(ii) the esters and ethers of such substances and of the isomers referred to in (i), as well as the isomers of such esters and ethers, where the existence of isomers of such esters, or ethers is possible;

(iii) the salts of such substances and of the isomers referred to in (i), as well as the salts of the esters, ethers and isomers referred to in (ii), where the existence of such salts is possible;

(iv) the isomers of any of the salts referred to in (iii), where the existence of such isomers is possible;

(v) all preparations and mixtures of any of the above.

(vi) all homologues of listed substances (being any chemically related substances that incorporate a structural fragment into their structures that is similar to the structure of a listed substance and/or exhibit pharmacodynamic properties similar to the listed substance in the schedules), unless listed separately in the Schedules.

5F – APINACA (5F AKB-48).
Acetylfentanyl.
Butyrfentanyl.
Ethylone.
Ethylphenidate.

Fentanyl-analogues (unless listed in another Schedule) including:

(xii) 4-anilino-*N*-phenethylpiperidine (ANPP);

(xiii) N-phenethyl-4-piperidone (NPP).

MDMB – CHMICA.

4- MEC.

Methiopropamine (MPA).

Methoxetamine (MXE).

MT-45.

Para-methoxymethylamphetamine (PMMA).

Para-methyl-4-methylaminorex (4,4-DMAR).

Pentedrone.

α-pyrrolidinovalerophenone (α-PVP).

U47700.

XLR-11.

– END SCHEDULE 7 –

These Schedules as amended come into operation on the date of publication in the Government *Gazette*.

DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 6/7/2017