GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 234 **20 March 2015**

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

SCHEDULES

The Minister of Health has, in terms of section 22A (2) of the Medicines and Related Substances Act, 1965 (Act 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 published in Government Notice R.509 (Medicines and Related Substances Act, 1965 (Act 101 of 1965): Schedules), Government Gazette 24727, 10 April 2003; Government Notice R.935 (Medicines and Related Substances Act, 1965 (Act 101 of 1965): Schedules), Government Gazette 31387, 5 September 2009; Government Notice R.1230 (Medicines and Related Substances Act, 1965 (Act 101 of 1965): Schedules), Government Gazette 32838, 31 December 2009; Government Notice R.227 (Medicines and Related Substances Act, 1965 (Act 101 of 1965): Schedules), Government Gazette 32838, 15 March 2012; Government Notice R.690 (Medicines and Related Substances Act, 1965 (Act 101 of 1965): Schedules), Government Gazette 36850, 20 September 2013 and Government Notice R.104 (Medicines and Related Substances Act, 1965 (Act 101 of 1965): Schedules), Government Gazette 37318, 11 February 2014 and Government Notice R.227 (Medicines and Related Substances Act, 1965 (Act 101 of 1965): Schedules), Government Gazette 37622, 8 May 2012 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 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.

Bifidobacterium adolescentis,

a. in pharmaceutical preparations and mixtures **[containing ≥1 x 10^9 cfu probiotics per dosage unit]** with medicinal claim(s);

b. except in pharmaceutical preparations and mixtures <u>for one or more strains</u> 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 No.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 **[containing ≥1 x 10^9 cfu probiotics per dosage unit]** 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 No.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 **[containing ≥1 x 10^9 cfu probiotics per dosage unit]** 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 No.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 **[containing ≥1 x 10^9 cfu probiotics per dosage unit]** 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 (Ac No. 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 **[containing ≥1 x 10^9 cfu probiotics per dosage unit]** 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 No. 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 **[containing ≥1 x 10^9 cfu probiotics per dosage unit]** 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 No. 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 **[containing ≥1 x 10^9 cfu probiotics per dosage unit]** 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 No. 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 **[containing ≥1 x 10^9 cfu probiotics per dosage unit]** 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 No. 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.

Ketoprofen,

a. when intended for application to the skin; (S3) **[(S2)]**

b. **except** when intended for the short term management of headache, toothache, muscular ache, backache, minor pain associated with arthritis, pain associated with menstrual cramps (dysmenorrhoea), minor aches and pains associated with the common cold and fever, at a maximum dose of 75 milligrams of ketoprofen in 24 hours; (S2)

c. **except** when intended for the emergency treatment of acute gout attacks; (S2)

d. **except** when intended for the treatment of post-traumatic conditions, subject to a maximum dose of 100 milligrams of ketoprofen per day, for a maximum treatment period of 5 days; (S2)

e. **except** in the form of lozenges indicated and intended for the relief of pain associated with sore throats in patients 18 years and older subject to-

(i) a maximum of 12,5 milligrams per lozenge;

(ii) a maximum of 5 lozenges in any 24 hour period;

(iii) a maximum treatment period of 3 days; and

(iv) a maximum pack size of 15 lozenges. (S2)

Lactobacillus acidophilus,

a. in pharmaceutical preparations and mixtures **[containing ≥1 x 10^9 cfu probiotics per dosage unit]** 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 No. 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 **[containing ≥1 x 10^9 cfu probiotics per dosage unit]** 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 No. 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 **[containing ≥1 x 10^9 cfu probiotics per dosage unit]** 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 No. 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 **[containing ≥1 x 10^9 cfu probiotics per dosage unit]** 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, 1974 (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 fermentum,

a. in pharmaceutical preparations and mixtures **[containing ≥1 x 10^9 cfu probiotics per dosage unit]** 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, 1974 (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 **[containing ≥1 x 10^9 cfu probiotics per dosage unit]** 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, 1974 (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 **[containing ≥1 x 10^9 cfu probiotics per dosage unit]** 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 No. 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 **[containing ≥1 x 10^9 cfu probiotics per dosage unit]** 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 No. 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 lactis,

a. in pharmaceutical preparations and mixtures **[containing ≥1 x 10^9 cfu probiotics per dosage unit]** 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 No. 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 **[containing ≥1 x 10^9 cfu probiotics per dosage unit]** 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 No. 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 **[containing ≥1 x 10^9 cfu probiotics per dosage unit]** 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 No. 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 **[containing ≥1 x 10^9 cfu probiotics per dosage unit]** 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 No. 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 **[containing ≥1 x 10^9 cfu probiotics per dosage unit]** 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 No. 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 **[containing ≥1 x 10^9 cfu probiotics per dosage unit]** 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 No. 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.

- END SCHEDULE 1 -

SCHEDULE 2

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 No. 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.

Fluticasone furoate,

a. when intended for nasal administration, as an aqueous spray, in the short-term (less than 6 months) prophylaxis and treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to-
   (i) a maximum daily dose of 55 micrograms per nostril; and
   (ii) a maximum pack size limit of 120 doses. (S3)
b. **except** when intended for administration other than by inhalation or nasal administration. (S4)

Fluticasone propionate,

a. when intended for nasal administration, as an aqueous spray, **[other than by aerosol]**, in the short-term (less than 6 months) prophylaxis and treatment of symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to-
   (i) a maximum daily dose of 100 micrograms per nostril;
   (ii) and a maximum pack size limit of 120 doses. (S3)
b. **except** when intended for administration other than by inhalation or nasal administration. (S4)

Ketoprofen,

a. when intended for the short term management of headache, toothache, muscular ache, backache, minor pain associated with arthritis, pain associated with menstrual cramps (dysmenorrhoea), minor aches and pains associated with the common cold and fever, at a maximum dose of 75 milligrams of ketoprofen in 24 hours;
b. when intended for the emergency treatment of acute gout attacks or for the treatment of post-traumatic conditions, subject to a maximum dose of 100 milligrams of ketoprofen per day, for a maximum treatment period of 5 days;
c. in the form of lozenges indicated and intended for the relief of pain associated with sore throats in patients 18 years and older subject to-
   (i) a maximum of 12,5 milligrams per lozenge;
   (ii) a maximum of 5 lozenges in any 24 hour period;
   (iii) a maximum treatment period of 3 days; and
   (iv) a maximum pack size of 15 lozenges. (S3)
d. **except** when intended for application to the skin. (S1)

- 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 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 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).

Caffeine, when intended for injection.

Imepitoin, when intended for veterinary use.

Insulin aspart.

Insulin degludec.

Fluticasone furoate,

a. when intended for inhalation or nasal administration;

b. **except** when intended for nasal administration, as an aqueous spray,[**other than by pressurised aerosol,**]in the short-term (less than 6 months) prophylaxis and treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to-

   (i) a maximum daily dose of 55 micrograms per nostril; and

   (ii) a maximum pack size limit of 120 doses. (S2)

c. **except** when intended for administration other than by inhalation or nasal administration. (S4)

Fluticasone propionate,

a. when intended for inhalation or nasal administration;

b. **except** when intended for nasal administration as an aqueous spray, **[other than by pressurised aerosol, and indicated for]** in the short-term (less than 6 months prophylaxis and treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to-

(i) a maximum daily dose of 100 micrograms per nostril; and

(ii) a maximum pack size of 120 doses. (S2)

c. **except** when intended for administration other than by inhalation or nasal administration. (S4)

Ketoprofen, **[except]**

a. **except** when intended for application to the skin; (S1)

b. **except** when intended for the short term management of headache, toothache, muscular ache, backache, minor pain associated with arthritis, pain associated with menstrual cramps (dysmenorrhoea), minor aches and pains associated with the common cold and fever, subject to a maximum dose of 75 milligrams of ketoprofen in 24 hours; (S2)

c. **except** when intended for the emergency treatment of acute gout attacks or for the treatment of post-traumatic conditions, subject to a maximum dose of 75 milligrams of ketoprofen per day and a maximum treatment period of 5 days; (S2)

d. **except** in the form of lozenges indicated and intended for the relief of pain associated with sore throats in patients 18 years and older subject to-

(v) a maximum of 12,5 milligrams per lozenge;

(vi) a maximum of 5 lozenges in any 24 hour period;

(vii) a maximum treatment period of 3 days; and

(viii) a maximum pack size of 15 lozenges. (S2)

- 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:

   (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 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 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.

Agalsidase beta.

[Alginatic] Alginic Acid, its salts and complexes thereof, when intended for use in gastric regurgitation, gastro-oesophageal reflux and reflux associated with hiatus hernia in infants and young children under the age of 6 years. (S0)

Apixaban.

Boceprevir.

Capsaicin, when intended for transdermal application.

Ceftaroline.

Cloprostenol, when intended for veterinary use.

Copper,

a. in preparations thereof for injection; (S0)

b. except in oral preparations or mixtures containing more than 4 mg of Copper per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S1)

Decitabine.

Empagliflozin.

Enzalutamide.

Fluticasone furoate, **except -**

a. when intended for nasal administration, as an aqueous spray, in the short-term (less than 6 months) prophylaxis and treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to-

(i) a maximum daily dose of 55 micrograms per nostril; and

(ii) a maximum pack size limit of 120 doses. (S2)

b. when intended for inhalation or nasal administration. (S3)

Fluticasone propionate, **except -**

a. when intended for nasal administration as an aqueous spray, in the short-term (less than 6 months prophylaxis and treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to-

(i) a maximum daily dose of 100 micrograms per nostril; and

(ii) a maximum pack size of 120 doses. (S2)

c. when intended for inhalation or nasal administration. (S3)

Ganirelix.

Gonadorelin.

Lixisenatide.

Ocriplasmin.

Pradofloxacin, when intended for veterinary use.

Prucalopride.

Teriflunomide.

Vilanterol.

Zotarolimus.

– 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 (Act No, 56 of 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 **

Vortioxetine.

– END SCHEDULE 5 –

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 (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 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).

Tapentadol.

– 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.

[Phenylbutazone]

– 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: 9/3/2015